

MONASH UNIVERSITY

FACULTY OF LAW

**A COMPARATIVE LEGAL ANALYSIS OF THE
REGULATION OF ADVERTISING OF MEDICINAL
PRODUCTS: A MALAYSIAN PERSPECTIVE**

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TABLE OF CONTENTS

CHAPTER 1	1
THE INTRODUCTORY CHAPTER	1
1.1 BACKGROUND TO THE THESIS INQUIRY	1
1.2 THESIS INQUIRY	4
1.2.1 Research Objectives	4
1.2.2 Research Question	5
1.3 RESEARCH METHODOLOGY AND STRUCTURE	6
1.3.1 Research Methodology	6
1.3.1.1 The Rationale for Comparison with the United States and Australia	7
1.3.1.2 The Rationale for Comparing the Key Aspects of Regulation	9
1.3.1.3 The Rationale for an Economic Analysis	12
1.3.2 Structure of the Thesis	12
1.4 SCOPE OF THE THESIS	14
1.5 TERMINOLOGY	16
 CHAPTER 2	 18
THE REGULATION OF ADVERTISING MEDICINAL PRODUCTS	18
2.1 INTRODUCTION	18
2.2 REGULATION	21
2.2.1 What is Regulation?	21
2.3 Best Practice Regulation	26
2.4 Identifying the Problem	29
2.4.1 Market Failures and Economic Regulation	29
2.4.1.1 Monopoly	30
2.4.1.2 Externalities	31

2.4.1.3	Information Failures	32
2.4.1.4	Scarce Goods and Public Goods	32
2.4.1.5	Anti-Competitive Behaviour	33
2.4.1.6	Unequal Bargaining Strength.....	33
2.4.1.7	Conclusion	33
2.4.2	Rationales for Social Regulation	34
2.4.3	Main Criticisms of Economic and Social Regulation	34
2.4.4	Conclusions.....	36
2.5	REGULATING DECEPTIVE ADVERTISING	38
2.5.1	Deceptive Advertising	38
2.5.2	Rationale for Regulating Deceptive Advertising	38
2.5.2.1	The Harms Caused by Deceptive Advertising	39
2.5.2.2	Market Failure and Information Asymmetry	39
2.5.3	Means of Addressing the Information Failure	41
2.6	REGULATING THE ADVERTISING OF MEDICINAL PRODUCTS	43
2.6.1	Medicinal Products and the Justification for Regulating Advertising	43
2.7	MODES OF REGULATION.....	47
2.7.1	Government ('Command and Control') Regulation	47
2.7.2	Alternative Modes of Regulation	49
2.7.2.1	Self-Regulation	50
2.7.2.2	Co-Regulation.....	53
2.7.2.3	Enforced Self-Regulation	56
2.7.3	Conclusion.....	59
2.8	Rules and Enforcement of Rules	62
2.8.1	Types of Rules	62
2.8.2	Ensuring Compliance with Rules.....	64
2.8.3	Addressing the Imprecision of Rules.....	65
2.8.4	Enforcement of Rules	67
2.8.4.1	Ex-ante review.....	67
2.8.4.2	Ex-Post Enforcement	68
2.8.5	Conclusion.....	70

2.9	ASSESSING EFFICIENCY AND EFFECTIVENESS OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS.....	71
2.9.1	Economic Analyses of Regulation.....	72
2.9.2	Cost-Benefit Analysis and Cost-Effectiveness Analysis of Advertising Regulation	72
2.9.3	Economic Analyses for the Regulation of the Advertising of Medicinal Products	76
2.10	CONCLUSION	83

CHAPTER 3 85

AN OVERVIEW OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS IN MALAYSIA.....85

3.1	INTRODUCTION	85
3.2	CLASSIFICATION OF MEDICINAL PRODUCTS IN MALAYSIA	87
3.2.1	Range of Products Classified as Medicinal Products.....	87
3.2.1.1	Prescription Drugs and Non-Prescription Drugs	88
3.2.1.2	Food.....	90
3.2.1.3	Nutrient Supplements.....	95
3.2.1.4	Cosmetics	95
3.2.1.5	Traditional Medicines	97
3.2.2	Implication of Classification of Products as Medicinal Products... ..	98
3.3	THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS. .	101
3.3.1	Laws that Govern the Advertising of Medicinal Products in Malaysia.	102
3.3.1.1	<i>The Medicines (Advertisement and Sale) Act 1956</i> (Malaysia)	102
3.3.1.2	<i>The Trade Descriptions Act 1972</i> (Malaysia).....	109
3.3.1.3	<i>The Consumer Protection Act 1999</i> (Malaysia).....	110
3.3.1.4	<i>Indecent Advertisement Act 1953</i> (Malaysia)	110
3.3.1.5	Conclusion	111

3.3.2	Codes of Practice and Industry Guidelines that Govern the Advertising of Medicinal Products	111
3.3.2.1	The <i>Pharmaceutical Association of Malaysia (PhAMA) Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010</i> (Malaysia)	112
3.3.2.2	The <i>Malaysian Code of Advertising Practice (Third Edition) 2008</i> (Malaysia)	113
3.3.2.3	The Communications and Multimedia Content Code 2004 (Malaysia)	115
3.3.2.4	Guidelines for Control of Cosmetic Products	116
3.3.3	Conclusion	117
3.4	REGULATORY CONTROL AND ENFORCEMENT OF ADVERTISING OF MEDICINAL PRODUCTS IN MALAYSIA	118
3.4.1	Pre-Approval of Advertisements	118
3.4.2	Monitoring Violation of Advertisements	120
3.4.3	Enforcement	121
3.4.3.1	Complaint Handling	121
3.4.3.2	Judicial Enforcement	122
3.4.3.3	Enforcement by Self Regulatory Organisations	123
3.4.4	Inadequacies in the System of Regulatory Controls	126
3.5	CONCLUSION	128

CHAPTER 4 130

THE REGULATION OF THE ADVERTISING OF MEDICINAL PRODUCTS IN AUSTRALIA130

4.1	INTRODUCTION	130
4.2	CLASSIFICATION OF THERAPEUTIC GOODS IN AUSTRALIA	133
4.2.1	Range of Products Classified as Therapeutic Goods	133

4.2.1.1	Prescription and Non-Prescription Drugs, Pharmacy-Only-Medicines and Complementary Medicines are Therapeutic Goods	133
4.2.1.2	Food.....	134
4.2.1.3	Dietary Supplements.....	140
4.2.1.4	Cosmetics	140
4.2.1.5	Implication of Classification as Therapeutic Goods	142
4.3	THE REGULATION OF THERAPEUTIC GOODS (MEDICINAL PRODUCTS) ADVERTISING IN AUSTRALIA	147
4.3.1	The Laws governing the Advertising of Therapeutic Goods in Australia.....	147
4.3.1.1	The Commonwealth Legislative Regime.....	147
4.3.1.2	States and Territory Legislative Regimes	156
4.3.1.3	Industry Codes of Practice.....	165
4.3.1.3	Conclusion	169
4.3.2	The Regulatory Control over the Advertising of Therapeutic Goods in Australia.....	169
4.3.2.1	Pre- Approval of Advertisements.....	170
4.3.2.2	Monitoring of Violation of Advertising Rules	174
4.3.2.3	Complaint-Handling Processes	175
4.3.2.4	Judicial Enforcement.....	180
4.4	REVIEWS OF THE REGULATORY SYSTEM IN AUSTRALIA	183
4.5	CONCLUSION	189

CHAPTER 5 192

AN OVERVIEW OF THE CURRENT REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS IN THE UNITED STATES192

5.1	INTRODUCTION	192
5.2	THE CLASSIFICATION OF MEDICINAL PRODUCTS IN THE UNITED STATES	195
5.2.1	Products that Qualify as Drugs in the United States.	197

5.2.1.1	Prescription Drugs and Non-Prescription Drugs, and Pharmacy-Only-Medicines.....	197
5.2.1.2	Food.....	199
5.2.1.3	Dietary Supplements.....	206
5.2.1.4	Cosmetics.....	209
5.2.1.5	Implication of Classification of Drugs in the United States.....	210
5.3	THE REGULATION OF THE ADVERTISING OF MEDICINAL PRODUCTS IN THE UNITED STATES	213
5.3.1	The Agencies that Regulate the Advertising of Medicinal Products in the United States	213
5.3.2	Shared responsibility between the FDA and the FTC	215
5.4	THE REGULATION OF ADVERTISING OF PRESCRIPTION DRUGS IN THE UNITED STATES	216
5.4.1	Laws Governing the Advertising of Prescription Drugs.....	216
5.4.1.1	<i>Federal Food Drug and Cosmetic Act 1938</i> (United States).....	217
5.4.2	The Regulatory Controls over the Advertising of Prescription Drugs	221
5.4.2.1	System of Pre-Approval of Advertisements	222
5.4.2.2	Monitoring of Violation of Laws.....	223
5.4.2.3	Enforcement of Violation of Laws	224
5.4.3	Conclusion.....	227
5.5	THE REGULATION OF THE ADVERTISING OF NON-PRESCRIPTION DRUGS AND FOOD, DIETARY SUPPLEMENTS AND COSMETICS – HEALTH RELATED PRODUCTS (HRP's).....	228
5.5.1	Law Governing the Advertising of Non-Prescription Drugs and HRP's	228
5.5.1.1	<i>Federal Trade Commission Act 1914</i> (United States).....	229
5.5.1.2	FTC Policy Statement on Deception	230
5.5.1.3	FTC Policy Statement Regarding Advertising Substantiation	231
5.5.1.4	Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction	232

5.5.1.5	The FTC Enforcement Policy Statement on Food Advertising	234
5.5.1.6	The Dietary Supplement: An Advertising Guide for Industry (the 'DSAGI').....	236
5.5.2	Regulatory Controls on Advertisements of NPD and HRP's	238
5.5.2.1	Monitoring of Violations and Review of Advertisements	238
5.5.2.2	Enforcement of Violation of Laws	239
5.6	CHALLENGES IN THE REGULATION OF MEDICINAL PRODUCTS IN THE UNITED STATES	242
5.6.1	First Amendment Protection	242
5.6.2	Learned Intermediary Rule	246
5.6.3	Rule on Federal Pre-exemption	247
5.6.4	Implication of Intermediary Rule, the Rule on Federal Pre-Exemption and First Amendment Protection	250
5.7	CONCLUSION	251

CHAPTER 6 253

A COMPARATIVE ANALYSIS OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS253

IN THE UNITED STATES, AUSTRALIA AND MALAYSIA.....253

6.1	INTRODUCTION	253
6.2.	THE REGULATION OF ADVERTISING OF PRESCRIPTION DRUGS	255
6.2.1	Classes of Drugs	255
6.2.2	Prescription Drugs: Prescribing Practices and Promotion	256
6.2.3	The Advertising of Prescription Drugs in the Three Jurisdictions	257
6.2.4	Regulating DTCA of Prescription Drugs	260
6.2.4.1	Arguments in Favour of DTCA of Prescription Drugs.....	262
6.2.4.2	Arguments against DTCA of Prescription Drugs	263
6.2.4.3	Analysis of the Competing Arguments	270
6.2.4.4.	Economic Analysis of DTCA of Prescription Drugs	275

6.2.4.5	Why a Continued Ban on DTCA of Prescription Drugs in Malaysia?.....	280
6.3	THE REGULATION OF THE ADVERTISING OF PRODUCTS CLASSIFIED AS MEDICINAL PRODUCTS.....	283
6.3.1	Classification of Products as Medicinal Products	283
6.3.1.1	Classification of Non-Prescription Drugs (NPD) as Medicinal Products	285
6.3.1.2	Food Classified as Medicinal Products	286
6.3.1.3	Dietary Supplements Classified as Therapeutic Goods	288
6.3.1.4	Cosmetic Products Classified as Medicinal Products	289
6.3.1.5	Analysis of the Implication of Classification As Medicinal Products.....	290
6.3.1.6	Recommendations for Malaysia	296
6.3.2	Use of Rules in the Regulation of Medicinal Products	296
6.3.2.1	Advertising Rules in the Three Jurisdictions	297
6.3.2.2	An Evaluation of Rules in the Three Jurisdictions	301
6.3.3	Regulatory Controls of Products Classified as Medicinal Products..	309
6.3.3.1	The Three Types of Regulatory Controls in the Three Jurisdictions	310
6.3.3.2	An Evaluation of the Regulatory Controls in the Three Jurisdictions	320
6.3.3.3	Recommendations for Malaysia	328
6.3.4	Comparative Analysis of the Regulation of Products Classified as Medicinal Products.....	332
6.3.4.1	The Regulation for Advertising of Medicinal Products in Malaysia.....	332
6.4	CONCLUSION	336
	CHAPTER 7	339
	THESIS FINDING	339
7.1	INTRODUCTION	339
7.2	THE METHODOLOGY	341
7.2.1	Comparative Study.....	341

7.2.2	Economic Analysis	342
7.3	THESIS FINDING	343
7.3.1	The Research Questions and Objectives	343
7.3.2	Thesis Findings	344
7.3.2.1	Recommendation 1	344
7.3.2.2	Recommendation 2	345
7.3.2.3	Recommendation 3	345
7.3.2.4	Recommendation 4	346
7.3.2.5	Recommendation 5	347
7.3.2.6	Recommendation 6	348
7.3.2.7	Recommendation 7	348
7.3.2.8	Recommendation 8	348
7.3.2.9	Recommendation 9	349
7.4	LIMITATIONS AND CHALLENGES IN THE STUDY.....	350
7.5	FUTURE STUDY	352

BIBLIOGRAPHY	353
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APPENDIX	385
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List of Diagrams, Tables and Appendix

Diagram 2.1	Flow Chart
Diagram 2.2	Costs & Benefits of Advertising of Medicinal Products
Diagram 3.2	Pyramid Structure for Healthy Consumption
Table 2.1	Advantages and Drawbacks of Alternative Modes of Regulation
Table 4.1	Status of the States and Territories in respect to Harmonization with the Therapeutic Goods Act 1989 (Cth)
Table 4.2	The Types of Advertisements and the Agency Responsible for their Approvals
Table 4.3	The Types of Goods and the Agencies that Handle the Complaints
Table 6.1	The Types of Permissible Claims on Advertisements (and labels) Which Will Not Result in the Products Being Classified as Medicinal Products
Appendix A	Official Website of Medicine Advertisement Board in 2007
Appendix B	Example of Advertisement found misleading by the Medicine Advertisement Board.
Appendix C	Compilation of Cases in breach of Medicines (Advertisement and Sale) Act 1956 (Malaysia) by the Pharmacy Enforcement Section of the Ministry of Health, Malaysia.
Appendix D	A Recent Internet Search of Websites on Types of Advertising Claims.

SELECTED ABBREVIATIONS

ACAC	Australian Cinema Advertising Council
ACCC	Australia Competition and Consumer Commission
ANZFS	Australia New Zealand Food Standards
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self-Medication Industry
ASAM	Advertising Standard Authority Malaysia
BCP	Bureaus of Consumer Protection
CBBB	Center of Better Business Bureaus Ins
CDER	Center for Drug Evaluation and Research
CCDR	Control of Drugs and Cosmetic Regulation 1984(Malaysia)
CHCA	Complementary Healthcare Council of Australia
CRP	Complaint Resolution Panel
CRN	Council for Responsible Nutrition
CTWG	Cosmetic Technical Working Group
CoPoNC	Code of Practice on Nutrient Claims in Food Labels and in Advertisements
DCA	Drug Control Authority (Malaysia)
DHHS	Department of Health and Human Services
DSAGI	Dietary Supplement Advertising Guide for Industry
DSHEA	Dietary Supplement Health and Education Act 1994 (U.S.A)
DPS	Director of Pharmaceutical Services
DCTA	Direct to Consumer Advertising
FACTS	Federation of Australia Commercial Television Stations
FARB	Federation of Australia Radio Broadcasters
FDA	Federal Drug Authority of the USA
FDAA	Food and Drug Administration (Amendment) Act 2007
FDAMA	Food and Drug Administration Modernization Act of 1997 (United States)
FDAADPROM	FDA Advertising and Promotional Manual
FFDCA	Federal Food Drug and Cosmetic Act 1914 (United States)
FSANZ	Food Standards Australia New Zealand
FQCD	Food Quality Control Division (Malaysia)
FTC	Federal Trade Commission
GAO	United States Government Accountability Office
GMA	Guideline on Medical Advertisement (Malaysia)
GMP	Good Manufacturing Practice
HRP	Health Related Products
LDL	Low-Density Lipoprotein
ICNA	Industrial Chemical (Notification and Assessment) Act 1989
MPA	Medicinal Products Advertising
MPS	Malaysian Pharmaceutical Society
NAD	National Advertising Division
NIH	National Institute of Health
PhAMA	Pharmaceutical Association of Malaysia
T/CM	National Traditional/Complementary Medicine

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ABSTRACT

Advertisements of medicinal products can empower consumers with information. Ideally, this information might enable them to make informed decisions, or lead to an early diagnosis or treatment of illnesses, or assist discussions with physicians regarding embarrassing conditions such as erectile dysfunction, weight loss and baldness. However, the content of advertisements is not always true and accurate. On many occasions, consumers have been misled by exaggerated claims or false claims of miracle cures. The increasing deceptive health claims in advertisements has resulted in an environment of confusion and mistrust amongst consumers and patients.

Medicinal products and these include prescription drugs and non-prescription drugs as well as products such as food, dietary supplements and cosmetics which are classified as medicinal products (the latter referred to as health-related products in the thesis), are at times promoted through the use of deceptive claims. In some instances, important information regarding the side effects of products and contraindications, where it is inadvisable to use the products, is omitted as this may have a negative impact on the purchase of the products. The consequence is that consumers are harmed by false and misleading advertising.

Countries adopt a variety of measures to address the problems posed by deceptive advertising. These include use of different types of rules and regulatory controls. In some instances varied advertising standards are used so as not to unduly restrict information. There are also differing levels of participation from industry in the regulation.

This thesis compares and assesses the regulation of the advertising of medicinal products in three jurisdictions, namely Malaysia, Australia and the United States. The study analyses significant reforms to the regulation of two types of advertising: (1) advertising of prescription drugs and (2) advertising of non prescription drugs and health related products. The issues therein analysed include: the classification of products as medicinal products in the respective regulatory regimes; the modes of regulation adopted in the regulation of advertising and the respective systems of regulatory controls, including pre-approvals of advertisements, monitoring of infringement and the respective enforcements.

The thesis argues that DTCA (direct-to-consumer advertising) of prescription drugs should not be allowed in Malaysia. It presents analysis that demonstrates why DTCA of prescription drugs may be appropriately regulated through its prohibition. With regard to advertising of non prescription drugs and health-related products, it argues that collaboration between regulatory agencies and industry associations would be beneficial in their regulation. The thesis considers the use of modes of regulation such as co-regulation and enforced self-regulation in the regulation of advertising of medicinal products, and uses economic analyses to gauge their effectiveness.

The thesis makes an original contribution to knowledge by exploring this under studied topic through the means of a comparative and economic analysis. It is hoped that the analysis drawn in this thesis will be of use to the regulator in Malaysia when considering an improvement to the regulation of advertising of medicinal products.

CANDIDATE'S STATEMENT

I affirm that this thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other institution. To the best of my knowledge this thesis contain no material previously published or written by any other person, except where due reference is made in the text of the thesis.

.....

Dedication

I dedicate this thesis to my sons, Yoganesh Manoharan and Dhavve Gaannish Manoharan. Without their sacrifices, understanding and support and most of all love, the completion of this work would not have been possible.

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CHAPTER 1

THE INTRODUCTORY CHAPTER

1.1 BACKGROUND TO THE THESIS INQUIRY

The thesis was motivated by concerns arising from prominent reports of serious adverse health effects suffered by people as a result of taking medicines that had been advertised as safe in Malaysia. A medicinal product known as Slim 10 was promoted as a purely herbal substance in a Singaporean television commercial, but it was later found to be adulterated with *Fenfluramine*, a substance that can cause heart-valve disease. The product was purchased and consumed by Andrea Heidi De Cruz, a Singaporean actress, who subsequently suffered liver failure. She purchased the pills falsely believing them to be safe.¹ Following the incident involving Andrea Heidi De Cruz, which caused a scare in Singapore, investigations commenced in Malaysia on the use of this product. The stories of two individuals who claimed to have taken the pill having seen similar advertisements and who suffered similar heart conditions, became widely known.² Concerns over the deceptive promotion and sale of slimming products increased with the press reporting more incidents and pressuring the government for a regulatory 'fix'.³

Whilst unsafe and ineffective medicinal products may be recalled, concerns have been raised about how to manage claims relating to the safety and efficacy of products which are made in advertisements. A recent Internet search of websites, for instance, revealed

¹ See *De Cruz Heidi v Guangzhou Yuzhing Health Products Co Ltd and Others* (2003) SGHC 229.

² K. Saithuruka 'Government Bans Bestrim' *The Star* (Malaysia) 5 June 2005; Also see *Nutriweb Online* (Malaysia) at <<http://www.nutriweb.org.my/article.php?sid=63>>.

³ See generally Dr Too 'Drug Control Authority Needs to Perk Up' *Malaysiakini Online* (Malaysia) 27 February 2006; How Safe Are The Herbal Option? *The Malay Mail* (Malaysia) 29 May 2002; Fong Celeste 'Stern Action Against Misleading Slimming Ads' *The Star* (Malaysia) 14 June 2002; Keeping a Watchful Eye on Slimming Products', *News Straits Times* (Malaysia) 29 July 2002; 'Banning Product is Not Good Enough', *The Star*, (Malaysia) 6 June 2002; Ensuring Slimming Pills are Really Safe', *New Straits Times*, (Malaysia) 3 July 2002; 'More Slimming Products Banned', *News Straits Times*, (Malaysia) 10 July 2002; Also see generally Poosparah Sujatani 'Ministry Orders Withdrawals of Slimming Product Bestrim' *New Straits Times* (Malaysia) 5 June 2002.

advertising claims such as that medicinal products are purely 'herbal and safe', '100% safe and effective', or '100% natural' are found.⁴ Also found were various testimonies; in one of which there was a claim of a cure for cervical cancer,⁵ while in another a product was promoted with the claim that it would address impotency in men.⁶ Advertisements also commonly show before and after photographs of patients who had taken the product and allegedly been cured.⁷ These sorts of claims are obviously very difficult for individual consumers to substantiate.

Concerns about incorrect or misleading information provided by pharmaceutical companies are supported by research studies. For examples, a recent study which focused on the quality of information provided by pharmaceutical companies in medical journals in three jurisdictions namely, Malaysia, Australia and the United States revealed that information on side effects, contraindications, warnings or precautions were given in less than half (41%) of the advertisements in medical journals in Malaysia.⁸ Important 'negative' information which is thought to discourage a physician from prescribing the product was omitted.⁹ It was also discovered that the minimum abbreviated prescribing information, as required by the *Pharmaceutical Association of Malaysia (PhAMA) Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia), which is the Malaysian guide governing the advertising of prescription drugs directed at health-care professionals was not provided in some advertisements.¹⁰ The study, in essence, found that low quality information is given to physicians in Malaysia when compared with

⁴ Rainforestherbs at <<http://www.rainforestherbs.com/products.html>>. The website was last visited on 9 November 2010.

⁵ <www.lengsian.com.my>. The website was last visited on 9 November 2010.

⁶ Rainforestherbs at <<http://www.rainforestherbs.com/products.html>>. The website was last visited on 9 November 2010.

⁷ See <www.healwell.com.my> Last visited on 9 November 2010.

⁸ Noordin Othman, Agnes Isabelle Vitry and Elizebeth Ellen Roughead, 'Medicines Information in Medical Journal Advertising in Australia, Malaysia and the United States: A Comparative Cross-Sectional Study' (2010) 3(1) *Southern Med Review* 11, 14.

⁹ Ibid.

¹⁰ Ibid.

Australia and the United States. Accordingly this study highlighted the need for effective regulation governing the advertising of prescription drugs to physicians in Malaysia.¹¹

A similar study is yet to be carried out with regard to the quality of information which is carried in print and broadcast advertisements, and on medicinal products other than prescription drugs. Nevertheless serious concerns over prohibited advertisement have been raised, and measures to address them are being actively considered.¹² Despite these concerns, there is an existing system in place for regulating advertising of medicinal products in Malaysia.

In Malaysia, claims about medicinal products may be permitted in advertisements if they are accurate and not misleading and do not pledge to prevent, treat, or cure serious illnesses without obtaining the necessary pre-approvals. The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) prohibits the making of deceptive advertisements, as well as advertising regarding the prevention or treatment of disease and conditions of human beings, such as diseases or defects of the kidney, heart, diabetes, epilepsy or fits, cancer, infertility, impairment of the sexual function or impotency.¹³ It also prohibits therapeutic claims in advertisements unless they are drugs and they have been subject to the requirement to prove safety and efficacy. The claims must also be pre-approved by the Medicine Advertisement Board (the MAB), which is the regulatory agency that oversees advertisements for medicines in Malaysia.¹⁴

This thesis aims to provide guidance to regulators in Malaysia by assessing the Malaysian regulatory regime, and making recommendations as to how the regulation of advertisements of medicinal products may be enhanced or improved so as to ensure that consumers are adequately protected from misleading claims in advertisements. The introductory chapter explains how the thesis will achieve this objective.

¹¹ Othman, Vitry and Roughead, above n 8.

¹² Interview with 3 officers namely; (1) Yogeswary a/p V Markandoo, the Deputy Director of Pharmacy Enforcement Division; (2) Nor Aza Binti Hassan, the Assistant Deputy Director of Pharmacy Enforcement Division; and (3) Azlinda Binti Abdul Samad, the Assistant Deputy Director of Pharmacy Enforcement Division, all from the Medicine Advertisement Board, Pharmacy Enforcement Division Ministry of Health Malaysia, (personal interview, 18 May 2007).

¹³ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (1) (a).

¹⁴ *Ibid* s 4B (1).

1.2 THESIS INQUIRY

The section of the chapter sets out the main research objectives of the thesis, before explaining the primary research question that will be addressed in the thesis. It also identifies the subsidiary research questions that must be dealt with in addressing the primary research question.

1.2.1 Research Objectives

The thesis essentially aims to evaluate the regulation of advertising of medicinal products in Malaysia and to suggest reforms so as to improve the existing Malaysian regulatory regime. In this thesis, medicinal products broadly include: prescription drugs; non-prescription drugs and products such as food, dietary supplements and cosmetic which, in this thesis, are referred to as health related products (the HRP). As will be seen, it is important to understand that HRP may be classified as medicinal products if it is found that therapeutic claims are made in the advertisements for these products.

The desired outcomes of this thesis are, by means of reasoned arguments and rigorous analysis, to enable Malaysia to make determinations on two questions, which the thesis identifies as central to an effective system for regulating advertising of medicinal products.

The questions are:

- First, should Malaysia permit direct-to-consumer advertising (DTCA) of prescription drugs or should Malaysia continue its ban on DTCA of prescription drugs?
- Second, what form of regulation should Malaysia adopt with regard to the regulation of advertising of non-prescription drugs and HRP both of which is permitted, so as to ensure that consumers are adequately protected from deceptive advertising?

As explained at [1.2.2] immediately below, the thesis aims to facilitate these determinations by answering one fundamental question, and addressing a number of subsidiary questions.

1.2.2 Research Question

The apparent proliferation of exaggerated or misleading claims in advertisements for medicinal products in Malaysia obviously raises many questions regarding the adequacy of regulation. In particular, questions arise in relation to: identifying the weaknesses in the regulatory regime which may result in inadequate regulation; the obstacles faced by regulators in addressing the problem of deceptive advertising; and the allocation of responsibility for failing to control deceptive advertising of medicinal products. These questions also raise much broader issues, such as the extent to which the failings in the Malaysian system of regulation might ultimately be a political issue. These are extremely complex questions and, consequentially, this thesis does not propose to address all of them; instead, it aims to focus on one primary concern: namely, how in certain respects, the existing system of regulation of advertising of medicinal products be improved so as to ensure that consumers are adequately protected against deceptive claims in advertisements? In dealing with this primary question, the thesis also addresses the following subsidiary questions:

- What are the strengths and weaknesses in the current system of regulation of advertising of medicinal products in Malaysia?
- What are the challenges faced in the regulation of advertising of medicinal products and how the challenges are addressed by Australia and the United States?
- Based on a comparative analysis between Australia, the United States and Malaysia, how can the regulation of the advertising of medicinal products in Malaysia be improved?
- How can the regulation of advertising of medicinal products be carried out cost-effectively?

1.3 RESEARCH METHODOLOGY AND STRUCTURE

This section of the chapter explains the research methodologies employed in answering the research questions, and the rationales for the methodologies employed in the thesis. It also sets out the structure of the thesis.

1.3.1 Research Methodology

The research undertaken in this thesis consists of two main types of analysis: first, a comparative analysis and second, an economic analysis. The comparative analysis undertaken in this thesis involves a comparison of the regulation of advertising of medicinal products in Australia and in the United States. The rationale for selecting Australian and the American regulatory regimes for comparison with Malaysian regime is explained at [1.3.1.1] immediately below. The comparative analysis focuses on the following key aspects of the respective regulatory regimes: the regulation of direct-to-consumer advertising (DTCA) of prescription drugs; the classification of products as medicinal products in the respective regulatory regimes; the modes of regulation adopted in the regulation of advertising; and the respective systems of regulatory controls, including pre-approvals of advertisements, monitoring of infringement and the respective enforcements.

The second type of analysis undertaken in this thesis is economic analyses. As the legal control of advertising of medicinal products takes the form of relatively complex regulatory regimes, economic analysis is considered essential to identifying the objectives of the respective regimes, as well as assessing the regimes. The application of economic analysis is considered essential in formulating recommendations to ensure that regulation in Malaysia is not only effective in preventing deceptive advertising, but is also cost effective. The economic analysis of regulation, and of the regulation of advertising of medicinal products, is explained in some detail in chapter 2 of the thesis. As explained at [2.9], the thesis employs forms of both cost-benefit and cost-effectiveness analyses. The rationale for employing an economic analysis is explained further at [1.3.1.3] below.

1.3.1.1 The Rationale for Comparison with the United States and Australia

There has been more accumulated experience in the regulation of advertising of medicinal products in Australia and the United States than in Malaysia. Therefore an analysis of the relatively complex regulatory regimes in those jurisdictions is likely to assist in evaluating the Malaysian regime. Moreover there have been significant studies and official reviews of the regulatory regimes in both Australia and the United States. For example, in Australia a number of studies have investigated whether consumers are adequately protected from misleading advertisements of medicinal products.¹⁵ Further, there is an extensive body of secondary literature concerning the regulation of advertising of medicinal products in Australia and United States. The extant Australian secondary literature ranges from discussions of the benefits of advertising prescription medicines,¹⁶ to the regulation of complementary medicines,¹⁷ the regulation of online pharmaceutical products¹⁸ the history of therapeutic goods regulation,¹⁹ and in relation to Australia, to the recent debate concerning the proposed Trans-Tasman Joint Regulatory Scheme.²⁰

¹⁵ Rhonda Galbally, *Review of Drugs, Poisons and Controlled Substances Legislation: Final Report Part A* (January 2001); Toogoolawa Consulting Pty Ltd, *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand*, (November 2002); Expert Committee on Complementary Medicines in Health System, *Complementary Medicine in Australian - Report to the Parliamentary Secretary to the Minister of Health and Ageing* (September 2003).

¹⁶ Peter R Mansfield, Do Advertisements in Clinical Software Influence Prescribing (2008)? 188(1) *Medical Journal of Australia* 13; Harvey, Ken J et al., Pharmaceutical Advertisements in Prescribing Software: An Analysis (2005) 183(2) *Medical Journal of Australia* 75; David A Newby and David A Henry, Drug Advertising; Truths, Half-Truths and Few Statistics (2002) 177(6) *Medical Journal of Australia* 285; Tim W Loke, Fong Chee Koh and Jeanette E Ward, Pharmaceutical Advertisement Claims in Australian Medical Publications (2002) 177 *Medical Journal of Australia* 291.

¹⁷ Ken, J. Harvey, et al., Commercialism, Choice and Consumer Protection: Regulation of Complementary Medicines in Australia (2008) 188(1) *Medical Journal of Australia* 21; Lorinda Hokin and Soraya Mir, Regulation and Enforcement of Advertising Requirements for Therapeutic Goods (2006) 14(10) *Australian Health Law Bulletin* 113; Graham Peachey, Regulation of Complementary Medicines: The Australian Experience (2000) 34 *Drug Information Journal* 311.

¹⁸ Paul Bernath, Regulation of Online Pharmacy: An Australian Perspective (2002-2003) 10 *Journal of Law and Medicine* 339.

¹⁹ John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Therapeutic Goods Administration, Canberra, 2007) 159.

²⁰ Frances H Miller, Consolidating Pharmaceutical Regulation Down Under : Policy Options and Practical Realities (2006) 25(1) *The University of Queensland Law Journal* 112; Thomas A Faunce, Kellie Johnston and Hilary Bambrick, The Trans-Tasman Therapeutic Product Authority: Potential AUSFTA Impacts on Safety and Cost-Effectiveness Regulation For Medicines and Medical Devices in New Zealand (2006) 37 *Victoria University Wellington Law Review* 365.

The United States, on the other hand, has a long and impressive history of regulating advertisements of medicinal products, but has taken quite a different approach to Australian. For instance, the United States regulatory regime gives greater prominence to consumer information, with advertisements being viewed as an important vehicle to convey information about medicines to consumers. The American secondary literature in the area is even more extensive than the Australian literature and includes the development of direct-to-consumer advertising regulation,²¹ the First Amendment Protection to advertising of prescriptions drugs,²² and an exploration of the advertising liabilities of direct-to-consumer-advertising.²³

As opposed to the wealth of research on the Australian and American regimes, there has not previously been a comprehensive study made into the regulation of advertising of medicinal products in Malaysia. In February 2010, a group of researchers conducted a comparative study on the provision of medicine information in widely circulated medical journals in Malaysia, Australia and the United States. This was the first comparative study

²¹ Francis B. Palumbo and C Daniel Mullins, The Development of Direct-to-Consumer Prescription Drugs Advertising Regulation (2002) 57 *Food and Drug Law* 423; John Shaeffer, Prescription Drug Advertising - Should States Regulate What Is False and Misleading? (2003) 58 *Food And Drug Law Journal* 630; Anthony D Cox and Dena Cox, 'A Defense of Direct-to-Consumer Prescription Drug Advertising' (2010) 53 *Business Horizon* 221; Isaac D. Montoya, Gwen Lee-Dukes and Dhvani Shah, 'Direct -To-Consumer Advertising: Its Effects on Stakeholders' (2008) 37(2) *Journal of Allied Health* 116; Jeffrey T Berger, et al., 'Direct-to-Consumer Drug Marketing: Public Service or Disservice?' (2001) 68(3) *The Mount Sinai Journal of Medicine* 197; Peter J. Neumann, et al., 'Drug Costs: Are Pharmaceuticals Cost-Effective? A Review Of The Evidence; Do Drug Treatments Give Value for the Money? Careful Analysis Can Yield Useful Information, This Study Finds' (2000) 19(2) *Health Affairs* 92; Kurt C Stange, 'Time To Ban Direct-To-Consumer Prescription Drug Marketing' (2007) 5(2) *Annals of Family Medicine* 101; Gary Humphreys 'Direct-to Consumer Advertising Under Fire *Bulletin of World Health Organisation*' (2009) 87(8), 576; Barbara Mintzes, et al., 'How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing? A Survey in Primary Care Environment With and Without Legal DTCA' (2003) 169(5) *Canadian Medical Association or its licensors* 405; Richard L Kravitz, et al., 'Influences of Patients' Request for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial' (2005) 293(16) *Journal of American Medical Association* 1995; Martin S. Lipsky and Christine A. Taylor., 'The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising' (1997) 45(6) *Journal of Family Practice* 495.

²² Miriam Shuchman, 'Drug Risks and Free Speech: Can Congress Ban Consumer Drug Ads? ' (2007) 356(22) *The New England Journal of Medicine* 2236; Brienne Taylor Greiner, 'A Though Pill to Swallow: Does the First Amendment Prohibit WV From Regulating Pharmaceutical Companies' Advertising Expenses to Lower the Cost of Prescription Drugs' (2007) 140 *West Virginia Law Review* 140.

²³ Heather Justin Lee, Liability for Direct-To-Consumer Advertising and Drug Information on the Internet (2001) 68(4) *Defense Counsel Journal* 412; Jaclyn Carole Hill, The Learned Intermediary Doctrine and Beyond: Exploring Direct-To-Consumer Drug Advertising Liability in The New Millennium (2005) *Defense Counsel Journal* 362.

on pharmaceutical product information in Malaysia, but the study was limited to information provided to physicians in medical journals.²⁴

Malaysia has limited experience in regulating the advertising of medicinal products, as well as a limited body of published research in this field. A comparative study of regulation involving countries which have both extensive regulatory experience and a substantial secondary literature should therefore assist in identifying inadequacies with the Malaysian regulatory system. Moreover, as Australia and the United States are both common law systems, albeit with quite different legal and political frameworks, comparison with the regulatory regimes in these jurisdictions is likely to be more relevant to Malaysia than comparisons with civil law jurisdictions.

Of course a degree of caution is required in undertaking any comparative analysis. Factors such as legislative history, economic and technological developments, and cultural issues, inevitably influence the manner in which a mode of regulation is established. Consequently studies which fail to consider these factors are generally criticised for lacking comprehensiveness.²⁵ However, a comparative analysis of key aspects of regulation of advertising of medicinal products must necessarily enhance the understanding of how regulation is carried out in a jurisdiction such as Malaysia, and thereby assist in identifying the alternatives available for improving regulation in Malaysia.

1.3.1.2 The Rationale for Comparing the Key Aspects of Regulation

An in-depth analysis of key aspects of regulation will enable an evaluation to be made regarding the regulation of advertising in the three jurisdictions. This is despite the fact that similar outcomes are reached by means of different rules, methods of implementation and institutions. The fundamental questions concern what contributions each of these aspects offer and how their relationship with one another informs the regulation of advertising of medicinal products.

²⁴ Othman, Vitry and Roughead, above n 8, 11.

²⁵ Stephen Breyer, 'Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives and Reform' (1979) 92(3) *Harvard Law Review* 549, 551.

First, the thesis examines the classification of medicinal products in the three jurisdictions. It attempts to solve the uncertainty posed by a lack of uniformity in terminology. It is noted that different terms such as 'drugs' and 'therapeutic goods' are used to refer to medicinal products or products which are intended for a medicinal purpose. Drugs, both prescription and the non-prescription types, and HRP's under certain circumstances, are classified as medicinal products. In other words, there are some instances when these products are exempt from classification as drugs and accordingly excluded from stringent regulations which governs drug safety and efficacy. The implication of declassification is profound, in the sense that it offers a lesser degree of protection to consumers. This comparative analysis uncovers a disparity in the types of products which qualify as medicinal products in the three jurisdictions, and as a result, varied degrees of controls and standards are applied. Consequently, a diverse level of protection is accorded to consumers, in the three jurisdictions.

Second, the thesis assesses the controls employed in the regulation of advertising of medicinal products. Two main controls, namely, use of varied types of rules and regulatory controls such as pre-approval of advertisements, monitoring of infringement and enforcement, are discussed under two separate sub-headings. Although they are inter-related, separate assessments are initially made so as to clarify what part each of the controls plays. A consideration of the impact of the controls working together follows.

Controls may be imposed through the rules. Rules include both those rules prescribed in legal instruments, such as the primary legislation, delegated legislation and codes of practices (hereafter referred to as formal rules) and rules which are not directly enforceable by law and which are found in industry guidelines (hereafter referred to as informal rules). These rules which form the basis for controls over advertising are analysed in terms of their comprehensiveness. Whilst rigid, poorly targeted, or difficult to 'implement and enforce' rules remain issues of concern in relation to formal rules, the informal rules are increasingly recognised as flexible and targeting the problem of deceptive advertising more effectively. These rules, which guarantee a minimum standard for advertising, are considered to be a part of the overall regulation. Hence, an analysis of how useful these rules are in shaping controls has been attempted. The aim is to enable a judgement to be made in respect of the sufficiency of the rules in achieving the objectives of preventing

deceptive advertising without ‘over-regulating’ the same to the detriment of the growth of industry.

The study of the regulation of advertising of medicinal products is incomplete or meaningless if one looks at the rules in isolation from their implementation. Unless a review of how the rules have been implemented is included, it is impossible to gain a comprehensive insight into the working of the system of regulation. Therefore regulatory controls employed in the regulation are reviewed.

A broad spectrum of regulatory controls may be used to prevent deceptive advertising, but the discussion in the thesis is confined to regulatory controls which include systems of pre-approval of advertisements, monitoring of violations of advertising laws and enforcement. Pre-approval of advertisements refers to a process where advertisements are checked for untrue, misleading or highly exaggerated medicinal claims before they are disseminated to the public. Monitoring refers to the process of identifying violations of regulations so as to enable appropriate measures to be taken to prevent violations from recurring. It is also to ensure that promotional activities conform to the standards established by law. Enforcement refers to a system where violations are detected and offenders are punished so as to prevent reoccurrence of prohibited activity or to encourage compliance with the law. Each of the three jurisdictions employs these three types of controls, but implements them quite differently. For example, a mandatory pre-approval of advertisements is not uniformly carried out in all the jurisdictions although the system of pre-approval is practiced. A system that places greater prominence on pre-approval seems to adopt a less vigorous enforcement. The thesis explains the possible rationale for their varied approaches and how a balance between varied controls is achieved.

The appropriate mode of regulation to be used for the regulation of advertising of medicinal products is also explored. The advantages and disadvantages of using an alternative mode of regulation such as co-regulation and enforced self-regulation in the regulation of advertising of medicinal products over the traditional form of command and control are explained. Cost-benefit analysis is used to support the recommendations of using a particular type of regulation over another type.

1.3.1.3 The Rationale for an Economic Analysis

Economic evaluations, including cost-benefit and cost-effectiveness analyses are used so as to enable the recommendation of a mode of regulation that is cost-effective. Diverse rules, methods of implementation and enforcement are necessarily, to a certain extent, influenced by cost factors. Consequently economic analyses are likely to provide all the appropriate stakeholders in Malaysia with a broader understating of key factors in their decisions with regard to the regulation of advertising of medicinal products. The techniques of economic analysis employed in this thesis are explained in some detail in chapter 2. While the thesis employs economic analysis, however, it is mindful that the objective is to provide viable, practical options for reforming the Malaysian regulatory regime, and not to provide 'perfect' solutions which may not be practical to implement in the Malaysian context.

1.3.2 Structure of the Thesis

The thesis is divided into three main parts. In the first part, this chapter, chapter 1, introduces what the thesis is about and the rationale for the thesis inquiry. It also introduces the methodology by which the inquiry is carried out. It presents the justifications for the comparative study with the United States and Australia, as well as for the aspects of regulation that are compared and analysed. The range of issues which the thesis covers is also highlighted in chapter 1. Chapter 2 then explains the concept of regulation in the context of regulating deceptive advertising. It also introduces and explains the economic analyses which can be employed to assess the effectiveness of regulation. The main objective of chapter 2 is to enhance the understanding regarding regulation, and the economic analyses of regulation, so as to facilitate the recommendation for an appropriate regulatory regime for Malaysia

The second part of the thesis consists of three chapters. Chapters 3, 4 and 5 review the regulation of the advertising of medicinal products in three jurisdictions, namely, Malaysia, Australia and the United States. These chapters explore key aspects, relevant to the regulation which includes: the classification of products as medicinal products in the respective regulatory regimes; the use of varied types of rules in the regulation of advertising of medicinal products, the modes of regulation adopted in the regulation of

advertising and the respective systems of regulatory controls, including pre-approvals of advertisements, monitoring of infringement and enforcements. The aim is to establish the foundation for a comparative analysis in Chapter 6. Accordingly, these three chapters examine the instances when products qualify for regulation as medicinal products, and then explain in some detail the regulations which govern the advertising of these products.

Chapters 6 and 7 comprise the third part of the thesis. Chapter 6 compares and analyses the regulation of the advertising of medicinal products in the three jurisdictions, and provides recommendations in relation to the proposed reforms of the Malaysian regulatory regime. It provides arguments to support the conclusions that DTCA of prescription drugs in Malaysia must continue to be prohibited and that the existing form of government regulation of the advertising of non-prescription drugs and HRP should be replaced by a system of co-regulation. Chapter 7 concludes the thesis by summarising the arguments made in the thesis and presenting the main conclusions and recommendations.

1.4 SCOPE OF THE THESIS

While the above sections of this chapter have explained the research problems addressed in this thesis, and how this thesis addresses these problems, it is important to also explain the areas that the thesis will not examine. There are many issues relating to the regulation of advertising of medicinal products that merit analysis. Nevertheless, it is essential for the thesis to focus on those issues which are most relevant to the central objective, which is to make recommendations for improving the Malaysian regulatory regime.

To begin with, the thesis is primarily concerned with claims carried in advertisements, and not on labels. While some reference is made to claims made on labels – as laws governing advertising are applicable to labels in certain jurisdictions – claims made on labels are outside the scope of the thesis.

Importantly, the thesis is confined to the regulation of advertisements of medicinal products which are directed at consumers, and does not address advertisements, and other literature, directed at physicians. The regulation of advertisements that are directed at physicians in medical journals is not explored as, given the expert knowledge possessed by physicians, this raises quite different issues to advertising directed at consumers.

Although there common issues arise in relation to the regulation of advertising of all products directed at consumers, this thesis focuses on the regulation of advertising of medicinal products. While deceptive advertising of consumer commodities, such as handbags or clothes, may clearly cause financial loss to consumers, medicinal products are in an entirely different category. This is because, unlike many other consumer products, misleading or deceptive advertising has the potential to cause not only financial harms, but potentially serious physical and psychological harms. As explained in chapter 2, the potential impact of medicinal products on the health and life of consumers raise quite distinct issues to those which arise in regulating advertising in general.

This thesis is also confined to an analysis of the regulation of advertising of medicinal products, and does not address issues relating to the manufacture or sale of such products. As explained in chapter 2, the regulation of advertising is concerned with the effects of communicating information to consumers and, in particular, minimising the harms

of communicating misleading or inaccurate information. These issues are quite different to those involved with controlling the manufacture of potentially harmful medicinal products, or that arise at the point of sale.

Finally, the thesis is not concerned with the regulation of traditional medicines, even though this is an important issue in Malaysia. For example, in Malaysia, there are established cultural beliefs that traditional medicines, especially products which are plant-based and natural foods, are inherently safe to consume. The particular ethnic composition of Malaysia means that the use of traditional herbs as medicines in Malaysia is especially widespread. Malaysia, which has a population of 28.25 million,²⁶ consists of four major ethnic groups, namely: the Malays - 53% of the population; the Chinese – 26%; indigenous -11.8%; the Indian – 7.7%; and others – 1.2%.²⁷ This ethnic composition naturally brings with it a diversity of culture and practices, including beliefs about the use of traditional medicines. While not dismissing the importance of the potentially harmful effects of advertising of traditional medicines, there are sensitive issues that must be taken into account in dealing with this issue in Malaysia that relate to culturally specific practices. The thesis therefore concentrates on the regulation of advertising of non-traditional medicinal products, leaving the advertising of traditional medicines to potential future research.

²⁶ The figures are as at 2nd of July 2010. See Source of Malaysia Official Websites, Department of Statistic Malaysia, < www.statistics.gov.my > at 13 September 2010.

²⁷ See www.geographia.com.my; Department of State, United States *Background Note: Malaysia* <<http://www.state.gov/r/pa/ei/bgn/2777.htm>> at 9 November 2010.

1.5 TERMINOLOGY

Research that involves a comparative study is ordinarily faced with the problem of lack of uniformity in terminology. This section of the chapter therefore provides an explanation of the key terms used in the thesis.

The term ‘medicinal products’ used in this thesis is borrowed from The International Comparative Legal Guide to Pharmaceutical Advertising.²⁸ In that publication, the term ‘medicinal products’ was used to refer to drugs or therapeutic products, however, explanation as to the types of products which would fall under the classification of medicinal products by virtue of therapeutic claims in advertisements were not given. In our analysis, the term ‘medicinal products’ is used to refer to group of products with medicinal value, or products which are intended to be used for medicinal, remedial or therapeutic purposes such as diagnosing, curing, mitigating, treating or preventing diseases. It is useful to appreciate that both the terms ‘drugs’ and ‘therapeutic goods’ are broadly defined in legislation in the United States, Malaysia and Australia, thereby allowing for a wide spectrum of products to fall within the classification. Key phrases in the definitions of these terms suggest that products which are capable of, or which are intended for a ‘medicinal or therapeutic purpose’ may be recognized as medicinal products.

The term ‘physician’ is used to refer to medical practitioners in the thesis. In Malaysia, the term ‘physician’ is generally associated with medical practitioners who are a specialist in a particular field of medicine. However, for the purposes of this thesis, the physician is to be understood to mean medical practitioners or doctors.

The terms ‘false and misleading advertisement’ and ‘deceptive advertising’ are used in the thesis. They essentially refer to advertisements which are untrue, inaccurate, unfair and lack appropriate information about risk, side effects and contraindications.

‘DTCA of prescription drugs’ refers to advertisements of prescription drugs that are directed at consumers in various media such as print and broadcast. The term is generally

²⁸ The International Comparative Legal Guide to Pharmaceutical Advertising 2008: *A Practical Insight to Cross-Boarder Pharmaceutical Advertising Work* (Global Legal Group, UK 2008) 1

used in the United States where the practice of advertising prescription drugs directly to consumer is allowed.

Therapeutic or medicinal claims refer to claims such as diagnosing, curing, mitigating, treating or preventing diseases which are carried on advertisements.

The term 'rules' is used broadly; it refers to provisions in the primary legislation as well as regulations, industry guidelines and codes.

CHAPTER 2

THE REGULATION OF ADVERTISING MEDICINAL PRODUCTS

2.1 INTRODUCTION

This chapter examines the meaning and rationale for regulation, the different modes of regulation and the advantages and disadvantages of employing them. It also examines the methods of assessing the effectiveness of regulation. The objective of this chapter is to enhance the understanding of the regulation of the advertising of medicinal products to facilitate the determination of the mode of regulation that is most suitable for Malaysia. This chapter has eight main sections.

Section [2.2] of the chapter examines the manner in which regulation has been viewed and described by scholars. It explores the various meanings assigned to the term 'regulation'. Noting that the term 'regulation' is defined broadly, the chapter proposes a precise definition for the term in order to facilitate the objective of the thesis. It proposes to use the definition given by Gunningham and Grabosky, namely, that regulation is not limited to the 'conventional forms of direct command and control...but also to include more flexible, imaginative and innovative forms of social control ...'.¹

Section [2.3] explains the principles of good regulatory processes or best practices which a government must consider before it decides on the choice of regulation for addressing a problem. It outlines the factors and considerations which it may take into account before a case for action is determined. In addition, it outlines the steps to be taken in arriving at the best form of regulation.

Section [2.4] explores the first step towards achieving the best form of regulation, which is precise identification of the problem to be addressed. It explains the various types of social and economic problems that warrant regulation and the rationale for regulating these problems. This section also examines the criticisms posed at that rationale.

¹ Neil Gunningham, Peter Grabosky and Darren Sinclair, *Smart Regulation: Designing Environmental Policy* (Clarendon Press, 1998), 4.

Section [2.5] examines the problems associated with deceptive advertising, in particular, information failure. It explores why deceptive advertising is regulated and how problems which arise from such advertising may be addressed. The objective in this section is to provide the basis for discussing the regulation of deceptive advertising of medicinal products in section [2.6].

Section [2.6] explores the rationales for regulating deceptive advertising of medicinal products, and in doing so it highlights the special characteristics of medicinal products which justify a more stringent regulation than those of most other types of products. In addition, it examines the informative value of advertising of medicinal products which is perceived to improve consumers' understanding of health care issues and which calls for a lesser form of control.

Section [2.7] explores the second step towards achieving the best form of regulation, namely, examining the range of feasible options to be considered in the regulation of advertising of medicinal products. It also examines the different modes of regulation which can be employed in the regulation. Additionally it explores both strengths and weaknesses in government regulation, as well as in self-regulation, co-regulation and enforced self-regulation.

The third step towards achieving best form of regulation is examining the effectiveness of the regulation. Section [2.8] examines two main factors which are important for determining that effectiveness, namely, how rules are drafted and how they are enforced. Subsequently the section of the chapter explores the types of rules which may be used in the regulation, and how imprecision in rules can be addressed so as to enhance compliances with the rules. It then investigates how these rules may be enforced.

An important step in the regulation is also examining the cost-effectiveness of the option selected. Section [2.9] explores the two types of economic analyses which can be carried out, namely, cost-benefit and cost-effectiveness. It applies these analyses to the regulation of advertising of medicinal products. Further, it highlights the differences in the opinions of scholars regarding the use of cost-benefit analysis in assessing the effectiveness of

regulation of advertising of medicinal products. It subsequently explores the use of cost-effectiveness in its analysis.

In section [2.10] of the chapter, the key arguments put forward in the chapter are summarised. The analysis is intended as a partial introduction to the analysis in Chapter 6. Chapter 6 compares and analyses, amongst other things, the mode of regulation for advertising of medicinal products in Malaysia (government regulation), with the mode in Australia (co-regulation) and the United States (government regulation).

2.2 REGULATION

This section of the chapter examines those issues concerning regulation which are central to the understanding of the regulation of the advertising of medicinal products. It examines the manner in which the understanding of regulation has changed and illustrates the many ways in which it has been analysed in contemporary scholarship. The objective is to propose a workable definition of the term 'regulation', so that this definition can be used in the discussion concerning appropriate forms for regulating the advertising of medicinal products.

2.2.1 What is Regulation?

Regulation is generally viewed as a form of control exercised by the state in order to govern activities which may potentially harm society.² It encompasses the idea of control imposed by the State to achieve desired outcomes by, for example, imposing sanctions, or the threat of sanctions, to compel compliance.³ Regulation is, however, increasingly being acknowledged as an activity which goes beyond purely state controls.⁴ In this respect, regulation is progressively being recognized as including controls which are formulated and enforced by self-regulatory agencies.⁵

Regulation may be broadly separated into two categories: (1) economic regulation; and (2) social regulation.⁶ Economic regulation is defined as 'taxes and subsidies of all sorts as well as explicit legislative and administrative controls over rates, entry and other facets of

² It is spoken of in terms of preventing many of 'society's ills' and protecting people from the 'inherent risk of daily life' in the Regulation Taskforce 2006 'Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business, Report to the Prime Minister and the Treasury, Canberra' (January 2006) (i). ('*Taskforce Report on Reducing Burden*').

³ See Anthony Ogus, *Regulation: Legal Form and Economic Theory* (Hart Publishing, 2004), 2.

⁴ See generally Julia Black, 'Critical Reflection on Regulation' (2002) 27 *Australian Journal of Legal Philosophy* 1; Gunningham, Grabosky and Sinclair, above n 1, 132; Judith Healy and John Braithwaite, 'Designing Safer Health Care Through Responsive Regulation' (2006) 184(10) *Medical Journal of Australia* 56.

⁵ See Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 3.

⁶ *Ibid* 4.

economic activities'.⁷ Social regulation, on the other hand, is the regulation of behaviour in order to enhance the broader public welfare, such as the improvement of health and safety of the people or the environment.⁸ Both forms of regulation may involve a range of regulatory instruments that address economic or social concerns.⁹

Regulation has been used, and its impact has been studied, in a broad spectrum of fields,¹⁰ ranging from water supply and sewerage disposal,¹¹ through to international business,¹² health and safety,¹³ genetically modified crops,¹⁴ accidents,¹⁵ and employment issues.¹⁶ It is used as not only a mechanism for preventing undesirable behaviour or activities, but also as an enabling or facilitating mechanism.¹⁷ As pointed out by Baldwin and Cave, regulation can be regarded as an enabling mechanism, in the sense that regulating a particular activity ensures that another activity is able to function in an orderly way.¹⁸

⁷ Richard A Posner, 'Theories of Economic Regulation' (1974) 5(2) *The Bell Journal of Economics and Management Science* 335, 335.

⁸ Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 4.

⁹ Johan den Hertog, 'General Theories of Regulation', (1999) 1 *Edward Elgar Encyclopaedia of Law and Economics*, 223, 223-225.

¹⁰ See Robert Baldwin and Martin Cave, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press, 1999) 1. As pointed out by Baldwin and Cave, regulation has 'stimulated interest in a host of disciplines; law, economics, political science, history, psychology, geography, management, and social administration'.

¹¹ David S. Saal and David Parker, 'The Impact of Privatization and Regulation of Water and Sewerage Industry in England and Wales: A Translog Cost Function Model' (2000) 21 *Managerial and Decision Economics* 253.

¹² A Vindelyn Smith Hillman and Maktoba Omar, 'FDI, International Business and Regulation: The Behaviour of UK Multinational Corporations' (2005) 17 (1) *European Business Review*, 69-82.

¹³ W. Kip Viscusi and Ted Gayer, 'Safety at Any Price?' (Fall 2002) 25 (3) *Regulation* 54.

¹⁴ Fern Wickson, 'Australia's Regulation of Genetically Modified Crops: Are We Risking Sustainability?' (2004) 2(1) *Australian Journal of Emerging Technologies and Society* 36.

¹⁵ Douglas J. Young and Thomas W. Likens, 'Alcohol Regulation and Auto Fatalities' (2000) 20 (1) *International Review of Law and Economics* 107.

¹⁶ Anthony Forsyth, 'Australian Regulation of Economic Dismissals: Before, During and After "Work Choices"' (2008) 30 *Sydney Law Review* 506.

¹⁷ See Baldwin and Cave, above n 10, 2.

¹⁸ *Ibid.*

However, despite its broad recognition as a set of control mechanisms, there is no single accepted definition of the term 'regulation'. Accordingly, the term has been defined in various ways, ranging from the authority which controls behaviour,¹⁹ through to the methods by which it is carried out²⁰ and the types of rules which are used to regulate.²¹ For example, Ogus describes regulation as 'cover[ing] a huge variety of industrial or non-industrial activities and involv[ing] a number of different legal forms'.²² His definition of the term is apparently based on the 'instruments' used to regulate activities. Meanwhile, Baldwin and Cave define the term 'regulation' broadly, as: (1) a specific set of commands; (2) deliberate state influence or (3) all forms of social control and influence.²³ Their definition of the term is clearly premised upon the fact that regulation is not limited to controls which emanate from governmental and non-governmental agencies, but extends to all forms of social control,²⁴ including influences such as culture,²⁵ technology²⁶ or market forces.²⁷

Healy and Braithwaite, on the other hand, define the term 'regulation' to mean governance in the 'broad sense of steering the flow of events rather than in the narrow sense of enforced compliance with rules'.²⁸ Their description of the term justifies the need for a flexible, participatory and devolved form of regulation to cater for matters including:

¹⁹ See Baldwin and Cave, above n 10, 2.

²⁰ See generally Baldwin and Cave, above n 10, 35-62; Healy and Braithwaite advocates responsive regulation (enforced self-regulation). See Healy and Braithwaite, above n 4; An array of regulatory strategies is recognized, such as the government regulation, self-regulation, co-regulation and responsive regulation. See Gunningham, Grabosky and Sinclair, above n 1, 38.

²¹ See *Taskforce Report on Reducing Burden* above n 2, 3.

²² Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 4.

²³ Baldwin and Cave, above n 10, 2.

²⁴ Ibid. This approach permits the inclusion of self regulators, market forces and courts as regulators.

²⁵ See Clare Hall, Collin Scott and Christopher Hood, *Telecommunications Regulation: Culture, Chaos and Interdependency Inside the Regulatory Process* (Routledge, 2000), 5-7; Also see generally Susan Wright, 'The Politicization of "Culture" (1998) 14(1) *Anthropology Today* 7-15.

²⁶ See Lawrence Lessig 'Code and Other Laws of Cyberspace (Basic Book, 1999). For example, the role of regulation is also discussed in areas of cyberspace.

²⁷ Len M. Nichols, et al., 'Are Market Forces Strong Enough To Deliver Efficient Health Care Systems? Confidence Is Waning' (2004) 23(2) *Health Affairs* 8, 10.

²⁸ Healy and Braithwaite, above n 4, 56.

changes in the environment, which are brought about by the introduction of new technologies; the increasing number and diversity of regulators (which exist at national, state government and industry levels); and changes resulting from privatization.²⁹ Finally, Gunningham and Grabosky consider that regulation should not be limited to the 'conventional forms of direct command and control...but also to include more flexible, imaginative and innovative forms of social control ...'.³⁰

The varied definitions of the term 'regulation' arise mainly because they were formulated to serve a particular purpose or address particular problems. For example, in Australia, when the Regulation Taskforce examined the extent to which government regulation inflicts unnecessary burdens and costs on industries,³¹ it defined 'regulation' as not limited to the use of legislation, delegated legislation and quasi-legislation by the government to regulate activities, expressly extending regulation to include industry codes or industry guidelines.³² Moreover, the Office of Regulation in Australia, in 1998, stated that the term 'regulation' can include 'any law or other government rules...and is not limited to primary or delegated legislation...[and] it includes quasi-regulation such as codes of conduct, advisory instruments and notes'.³³

Similarly, the definition of regulation in this thesis should be determined by reference to the purpose of regulating. The purpose of defining regulation in this thesis is essentially to determine best practices for the regulation of advertising of medicinal products. Given the breadth of this objective, the thesis therefore acknowledges 'regulation' as including 'controls' which emanate from both government and industry regulators, with the 'controls' including the use of government rules (which include primary and delegated legislation), as well as industry self-regulation (such as industry codes of conduct and industry guidelines). In short, the thesis adopts the definition given to the term 'regulation' by Gunningham and

²⁹ Ibid.

³⁰ Gunningham, Grabosky and Sinclair, above n 1, 4.

³¹ *Taskforce Report on Reducing Burden* above n 2, 3.

³² Ibid.

³³ See Office of Regulation Review, *A Guide to Regulation* (2nd ed, December 1998), A1. ('*Guide to Regulation 1998*').

Graboksy.³⁴ Gunningham and Graboksy described it in the broadest sense possible, 'to include not just conventional forms of direct ('command and control')... but also to include more flexible, imaginative and innovative forms of social control ...'.³⁵ This broad definition of regulation is used in this thesis as it permits an analysis of all alternative modes of regulation, from government regulation to industry self-regulation.

³⁴ Gunningham, Grabosky and Sinclair, above n 1, 4.

³⁵ Ibid.

2.3 Best Practice Regulation

The Australian government has endorsed principles of good regulatory process, which are outlined in the *Office of Best Practice Regulation Handbook*,³⁶ and which inform the choice of regulatory design and regulatory tools. The *Handbook* states that:

Determining whether regulation meets the dual goals of effectiveness and efficiency requires a structured approach to policy development that systematically evaluates costs and benefits.³⁷

An Occasional Paper produced by the Australian Communications and Media Authority (ACMA) has summarised the principles of best practice regulation as follows:

- Governments should not act to address problems until a case for action has been clearly established. This should include establishing the nature of the problem and why actions additional to existing measures are needed, recognising that not all problems will justify ... government action.
- A range of feasible policy options—including self-regulatory and co-regulatory approaches—need to be identified, and their benefits and costs, including compliance costs, assessed within an appropriate framework.
- Only the option that generates the greatest net benefit for the community, taking into account all the impacts, should be adopted.³⁸

This chapter of the thesis follows the principles of best practice regulation by firstly identifying the problem to be addressed by regulation. Secondly, the chapter explains the different modes of regulation, which range on a continuum from government regulation to self-regulation, and identifies the advantages and disadvantages of each the main different

³⁶ Department of Finance and Deregulation, *Best Practice Regulation Handbook*, June 2010. ('*Best Practice Regulation Handbook 2010*').

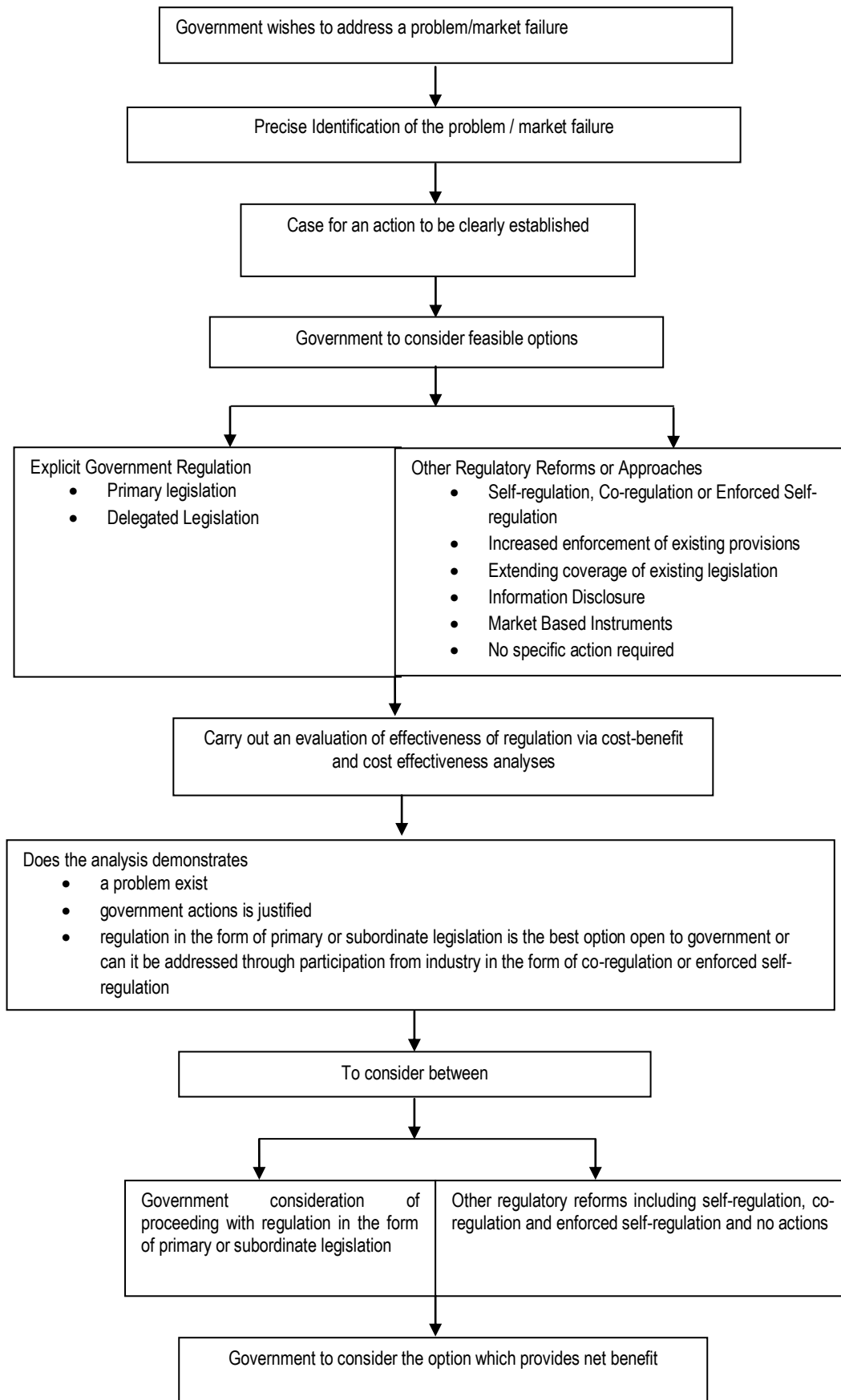
³⁷ Ibid 4.

³⁸ Australian Communications and Media Authority (ACMA), *Optimal Conditions for Effective Self- and Co-regulatory Arrangements*, Occasional Paper, June 2010. ('*Optimal Conditions for Effective Self- and Co-regulatory Arrangements 2010*').

modes. Thirdly, the chapter engages in a cost-benefit analysis of the regulation of advertising of medicinal products.

Diagram 2.1 below sets out the steps which the government must take towards achieving the best mode of regulation.

Diagram 2.1 - Flow Chart on How to Achieve Best Form of Regulation



2.4 Identifying the Problem

The Australian Government *Office of Best Practice Regulation Handbook* emphasises the importance of clearly defining the problem to be addressed by regulation. This problem may comprise the following economic or social problems:

- market failure (such as a lack of or misleading information, presence of externalities or public goods, or use of excessive market power)
- regulatory failure (such as a government-imposed restriction on competition that is not in the public interest)
- unacceptable hazard or risk (such as human health and safety hazards, or threat of damage to the physical environment), or
- social goals/equity issues (such as individuals or groups being unable to access available market information, goods or services).³⁹

The following sections of the chapter are aimed at identifying the problem to be addressed by the regulation of advertising of medicinal products. First, [2.4.1] examines the rationales for regulation, including the justifications for economic regulation, and [2.4.2] examines the justifications for social regulation. Secondly, [2.4.3] introduces the main criticisms of the accepted rationales for regulation, which are known as private theories of regulation.

2.4.1 Market Failures and Economic Regulation

The main rationale for economic regulation is that government intervention is necessary to deal with market failure.⁴⁰ To understand this rationale it is necessary to understand the operation of markets, and when they might fail.

The subject of economics is generally understood in terms of the allocation of scarce resources.⁴¹ It is assumed that, in perfect competition, scarce resources are efficiently

³⁹ *Best Practice Regulation Handbook 2010*, above n 36, 28.

⁴⁰ Ibid 29-30; Department of Treasury and Finance (Victoria), *Victorian Guide to Regulation*, 2nd ed, April 2007, 2-1– 2-2. ('*Victorian Guide to Regulation 2007*').

⁴¹ See generally Martin Shubik, 'On Different Methods for Allocating Resources' (1970) 23(2) *Kyklos* 332, 332; Francis M Bator, 'The Anatomy of Market Failure' (1958) 72(3) *The Quarterly Journal of Economics* 351;

allocated in a market for the benefit of individuals, or the population as a whole.⁴² In reality, however, a market may be impaired by circumstances such as a monopoly or abuses of market power, unequal bargaining power, information failures, externalities, scarcity or rationing, moral hazards or availability of public goods, or a combination these factors.⁴³ These circumstances, which are explained below, result in what is commonly known as a ‘market failure.’

A market failure is, by definition, a situation where a market is unable to rectify imperfections which arise in the market.⁴⁴ In other words, the market is incapable of allocating resources efficiently, without interference from the state or other sources.⁴⁵ In such a situation, there will be a need for regulation to rectify the damage caused.⁴⁶

It is generally believed that, in the event of market failure, economic regulation may improve the allocation of resources and rectify the failure.⁴⁷ As expressed by Hertog, ‘...government regulation is the instrument for overcoming the disadvantages of *imperfect competition, unbalanced market operation, missing markets and undesirable market results*’.⁴⁸ In order to determine when economic regulation may be justified, it is necessary to understand the main sources of market failure, which are as follows.

2.4.1.1 Monopoly

A monopoly held by a firm or industry is usually seen as undesirable, since it involves the imposition of high pricing and a restrictive supply of essential goods and services by a

Guide to Regulation 1998, above n 33, B11-12; Brett Frischmann M. ‘Evaluating the Demsetzian Trend in Copyright Law.(New Directions in Copyright Law and Economics) (2007) 3(3) *Review of Law & Economics* 1154.

⁴² Hertog above n 9, 225.

⁴³ Baldwin and Cave, above n 10, 9-16; See generally *Guide to Regulation 1998*, above n 33, E1-E5.

⁴⁴ Posner, above n 7, 335; Baldwin and Cave, above n 10, 9.

⁴⁵ Baldwin and Cave, above n 10, 9; *Best Practice Regulation Handbook 2010*, above n 36, 30-31.

⁴⁶ See generally W. Kip Viscusi, Joseph E. Harrington Jr and John M. Vernon, *Economics of Regulation And AntiTrust* (The MIT Press 4th ed, 2005) 3.

⁴⁷ Hertog above n 9, 225.

⁴⁸ *Ibid*.

single firm.⁴⁹ However, there are some circumstances where it is more efficient for a single large firm to 'monopolize'.⁵⁰ Generally known as 'natural monopoly', it is acknowledged that if a large firm's cost of producing more units decreases with increased outputs, it is cheaper for the company to supply those goods and services.⁵¹ It is cost efficient, in that case, for one firm to monopolize a market, but there may still be a need for government regulation to protect consumers from exploitation.⁵² It is thought that government is best placed to ensure that the public is protected from the financial abuse exercised by monopolistic firms.⁵³ The distinction between the circumstances where a monopoly is inefficient from those where it may be efficient is usually drawn by an analysis of barriers to entry.⁵⁴

2.4.1.2 Externalities

An externality impairs the market when the prices of products do not reflect the full social cost involved.⁵⁵ A common example of an externality is where a firm fails to internalize costs in the price of products, such as the cost of pollution caused by the firm during production processes and, as a consequence, the cost is born by the community as a whole.⁵⁶ It is possible that, in the example given, the polluter may be sued under private law (such as by means of an action for nuisance under tort law), but it is generally costly for individuals to bring such legal actions.⁵⁷ Therefore government regulation that, for example, imposes high taxes on polluters, or other forms of environmental control, may be justified.

⁴⁹ Baldwin and Cave, above n 10, 10.

⁵⁰ Ibid 10-11.

⁵¹ Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 30-31.

⁵² See generally Alfred E. Kahn, *The Economics of Regulation: Principles and Institutions* (MIT Press, 1988), 11; Baldwin and Cave, above n 10, 10.

⁵³ Baldwin and Cave, above n 10, 10-11.

⁵⁴ *Best Practice Regulation Handbook 2010*, above n 36, 30.

⁵⁵ See generally Baldwin and Cave, above n 10, 11.

⁵⁶ See generally Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 35.

⁵⁷ Ibid.

2.4.1.3 Information Failures

Consumers, in order to be able to make a rational decision, need to be adequately informed. However, a market may be unable to ensure the sustainability, availability and accessibility of information which enables consumers to make informed decisions. For example, a firm may fail to supply information due to its costliness, or due to a lack of incentive to do so. A company may lack incentives when it does not see any gains, financial or otherwise, from investing in the dissemination of information.⁵⁸ Alternatively, information may also be falsified or conveniently omitted in order to increase sales.⁵⁹

Information failure can be suitably addressed by regulation through, for example, imposing mandatory disclosure, or requiring warnings that are necessary to protect consumers from the consequences that flow from inadequate information.⁶⁰ As explained below, information failures may also be addressed by regulating the provision of inaccurate or deceptive information.

2.4.1.4 Scarce Goods and Public Goods

Government regulation is also understood to be necessary in order to ensure the availability of scarce goods.⁶¹ There is an argument that petrol, for example, should be made available to all at a minimum standard.⁶² Similarly, public goods, such as national security, whose benefits are shared by the public as a whole, are best controlled by government regulation, as it is impossible for private firms to selectively make the services available to those who have paid for the service and exclude those who have not.⁶³

⁵⁸ Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 40; Also, the seller may have incentive to provide information in a competitive market to distinguish their products from those of others. See Baldwin and Cave, above n 10, 12.

⁵⁹ Baldwin and Cave, above n 10, 12.

⁶⁰ Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 126.

⁶¹ Baldwin and Cave, above n 10, 13.

⁶² Ibid 14.

⁶³ Ogus, *Regulation: Legal Form and Economic Theory*, above n 3, 33.

2.4.1.5 Anti-Competitive Behaviour

In some instances, firms behave in an irresponsible manner; for instance, by setting a low price for products with the aim of driving other sellers of similar products out of business. Whilst some, particularly large firms, may have the resources and capacity to sustain losses, other small firms may not. Large firms may then revert to their original pricing and dominate the market, after the competition has been eliminated.⁶⁴ These forms of behaviour are usually only possible where a firm possesses market power, which requires analysis of factors such as barriers to entry. In such circumstance regulation is viewed as appropriate to control such practices.⁶⁵

2.4.1.6 Unequal Bargaining Strength

As explained by Baldwin and Cave, regulation is also warranted to ensure that consumers are not unfairly treated due to unequal bargaining strength.⁶⁶ Individuals may, for instance, be unfairly disadvantaged by their inability to negotiate in their best interest during a crisis, such as in the case of employment benefits in a period where the unemployment rate is high.⁶⁷

2.4.1.7 Conclusion

In conclusion, economic regulation is considered necessary to provide a solution to market failure when the market, on its own, is incapable of addressing the failure. There are, however, other mechanisms which can assure that the market functions adequately; for example, when a company 'issues guarantees, uses brand names or advertising campaigns to signal quality', which may address information failures in the market.⁶⁸ In each case, in order to determine whether regulation is justified, it is necessary to engage in an analysis of the precise source of market failure, and then to determine whether

⁶⁴ Baldwin and Cave, above n 10, 13.

⁶⁵ Ibid.

⁶⁶ Ibid.

⁶⁷ Ibid.

⁶⁸ Hertog above n 9, 232.

regulation is the appropriate response, or whether the failure can be addressed in some other way.

2.4.2 Rationales for Social Regulation

Apart from dealing with market failure, regulation may be justified by the extent to which it is considered desirable to pursue non-economic social objectives. As explained in the Victorian Guide to Regulation, which was produced by the Victorian Department of Treasury and Finance, the key social objectives pursued by government regulation include:

- *Redistributive goals*, which involve reducing social inequality and assisting the disadvantaged by, for example, taxation and social welfare policies.
- *Policing of crime*, which is considered necessary to reduce the risk of criminal activity.
- *Human rights goals*, including protecting the vulnerable and disadvantaged by, for example, providing community facilities.
- *Environmental objectives*, including the protection of natural resources.⁶⁹

If overarching social objectives, such as the promotion of health and safety, are considered highly important, regulation may be justified even where, applying a strict cost-benefit analysis, it may be economically inefficient.

2.4.3 Main Criticisms of Economic and Social Regulation

Theories that regulation is needed to promote the public interest, whether to deal with market failures or to promote non-economic social objectives are known as public interest theories. Public interest theories maintain that government regulation aims to assure publicly desired results that the market fails to guarantee.⁷⁰ The rationale that regulation is necessary in the public interest has, however, been criticised by 'private interest' theories of regulation.

⁶⁹ Victorian Guide to Regulation 2007, above n 40, 2-2 – 2-3.

⁷⁰ Hertog above n 9, 223.

Early theories of regulation were premised on the belief that regulation was needed to promote the public interest, especially in rectifying market failure.⁷¹ However, this perception has been challenged by critics of public interest regulation, who essentially argue that regulation is 'purchased' by industry, so that, rather than serving the public, it benefits private groups whose aims are maximization of profits.⁷² The critics of public interest theories of regulation developed what are known as private interest theories of regulation or 'capture' theory.

Stigler and Peltzman were the most prominent to claim that regulation serves the interest of private groups.⁷³ Applying this analysis, private groups who offer political support are those that benefit most from regulation.⁷⁴ In other words, there is a market for regulation in which governments confer benefits in the form of favourable regulation, in return for political support. In addition to claiming that government regulators are susceptible to 'capture' by private interests, private interest theorists identified other flaws with the public interest justifications for regulation. As pointed out by Hertog, for example, empirical studies of regulation tended to establish that, in practice, it provided little or no benefit to the public.⁷⁵ For example, studies demonstrated that regulation had little influence on monopolies, resulting in price increases in certain competing sectors (such as air traffic), or that it was possible for consumers (and some producers) to actually benefit from less government regulation.⁷⁶ Largely as a result of the criticisms of private interest theorists, from the late 1970s, deregulation came to be seen as a better alternative to traditional regulation in the public interest, at least in some industry sectors.

While private interest theories of regulation have been influential, especially in the deregulation movement, they have not been immune from criticism. In particular, Stigler

⁷¹ Ibid 225.

⁷² See generally George J Stigler, 'The Theory of Economic Regulation ' (1971) 2 *The Bell Journal of Economics and Management Science* 1; Sam Peltzman, 'Towards a More General Theory of Regulation' (1976) 19 *Journal of Law and Economics* 211.

⁷³ Ibid.

⁷⁴ Ibid.

⁷⁵ See generally Hertog above n 9, 233.

⁷⁶ Ibid.

and Peltzman's analyses have been criticised, in that they fail to recognize that regulation comes about through a complex process.⁷⁷ For example, although the public elects the legislators who enact specific legislation, and who might have an incentive to respond to particular interest groups, policies are necessarily implemented by regulators who may not necessarily be susceptible to capture.⁷⁸ Hence, unless it can be established that interest groups affect the outcomes of elections and influence the implementation of policies, it cannot simply be assumed that regulation directly results from the influence of interest groups.⁷⁹

Other criticisms of private interest theories include that they lack the ability to explain certain observable aspects of regulation. For example, such theories fail to account for the extent to which regulation may serve the interests of those groups who did not influence the enactment of the relevant legislation. As Posner points out, regulation may serve the interest of 'small business and non-business such as dairy farmers, pharmacist, barbers, trackers, and union labours', who have little influence in the enactment of legislation.⁸⁰

2.4.4 Conclusions

As explained in this section of the chapter, the first stage in analysing any form of regulation is to precisely identify the problem that the regulation seeks to resolve. The traditional theories of regulation distinguish between economic regulation and social regulation. Economic regulation is considered to be justified in the public interest when it addresses market failures. In determining whether economic regulation is justified, it is necessary to be precise in identifying the market failure at issue. Social regulation, on the other hand, is considered to be justified in the public interest when it is necessary to achieve certain non-economic social objectives, such as the redistribution of income, the promotion of health and safety, or the protection of the environment.

⁷⁷ Viscusi, Harrington Jr and Vernon, above n 46, 390.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Posner, above n 7, 341.

The naïve view that regulation promotes the public interest has, however, been criticised by private interest theorists who have claimed that, in practice, regulation is often produced to benefit organised private interest groups. On this view, economic regulation may, in practice, benefit the interests of regulated industries more than the interests of society as a whole. Moreover, given the difficulties of objectively assessing regulation designed to pursue social objectives, social regulation may be even more susceptible to regulatory capture than economic regulation.

While it is important to bear in mind the criticisms of private interest theories, however, such theories, by their very nature, can provide no guidance as to when regulation may be necessary. Rather, these have operated to provide justifications for the removal of regulation, or deregulation, when some forms of regulation have proven to be counter-productive. Consequently, as illustrated by official government policy documents, such as the Australian Government *Office of Best Practice Regulation Handbook* and the *Victorian Guide to Regulation*, it is still necessary to have recourse to public interest theories in order to explain why regulation may be needed. At the same time, the criticisms made by private interest theories of regulation remind us that not all regulation is good regulation, and that sometimes regulation may cost more than it is worth. That is why it is necessary to engage in a rigorous analysis to ensure that regulation is both efficient and effective. The next section of the chapter therefore applies the above analysis to examine the rationales for regulating advertising.

2.5 REGULATING DECEPTIVE ADVERTISING

The key issues surrounding the regulation of advertising are explored in this section of the chapter. The main reason for regulating advertising is to ensure that consumers are not misled by preventing deceptive advertising. This section of the chapter therefore explains what is meant by deceptive advertising, why deceptive advertising must be regulated and how the problems arising from deceptive advertising may be resolved.

2.5.1 Deceptive Advertising

Deception is generally accepted as meaning ‘the manipulation of information to gain advantage’.⁸¹ However, an advertisement may not be recognized as deceptive unless it deceives consumers through false claims, or causes them to hold a false belief.⁸² Deceptive advertising usually takes one or more of the following forms: (1) a false statement; (2) a true but incomplete statement with regard to a material fact or (3) an omission of a statement.⁸³ However, irrespective of the form it takes, any claim carried in an advertisement which is misleading, or which has the potential to be misleading is, as explained below, worthy of regulation.⁸⁴

2.5.2 Rationale for Regulating Deceptive Advertising

The rationale for the regulation of deceptive advertising broadly include (1) to prevent harm and (2) to rectify a market failure, in particular information asymmetry between advertisers and consumers. The principal objective is generally to protect not only consumers, but also to protect the businesses of genuine advertisers from dishonest advertisers. A further objective is to ensure sustainability of market for quality products.

⁸¹ Paul H Rubin, Law and Economic Research Paper Series: ‘Regulation of Information and Advertising in Barry Keating (ed) *A Companion to the Economics of Regulation*’ (Blackwell Publishing 2004), 1.

⁸² Richard Craswell, ‘Interpreting Deceptive Advertising’ (1985) 65(4) *Boston University Law Review* 658, 668.

⁸³ See generally Paul H. Rubin, *Information Regulation (Including Regulation of Advertising)* (1999) 1, *Edward Elgar Encyclopaedia of Law and Economics*, 271, 280.

⁸⁴ Craswell, ‘Interpreting Deceptive Advertising’, above n 82, 658.

2.5.2.1 The Harms Caused by Deceptive Advertising

Deceptive advertising is regulated because it causes various types of harm to consumers.⁸⁵ First, it causes consumers to 'waste money' if the products fail to perform as claimed in the advertisements.⁸⁶ Second, it also causes bodily harm to consumers if the advertised products are not safe, but have been falsely claimed to be otherwise.⁸⁷ Third, psychological harm may also be caused by deceptive advertising, as consumers, who are disappointed when products do not perform as claimed, may suffer from depression and unhappiness.⁸⁸

Deceptive advertising is also regulated to protect honest competitors from losing business due to deceptive claims made by dishonest advertisers.⁸⁹ Because such advertising has a negative impact on consumers' perceptions, it may culminate in consumers treating all advertising, or advertisements for particular kinds of products, as potentially deceptive.⁹⁰ An honest seller who provides consumers with accurate and reliable information may not be able to convince consumers of their credibility if consumers are not able to distinguish between honest and dishonest sellers.⁹¹

2.5.2.2 Market Failure and Information Asymmetry

As explained at [2.4.1], the main rationale for economic regulation is that intervention is needed to deal with market failure. As further explained, a market failure is a situation

⁸⁵ See Roger E Schechter, 'The Death of The Gullible Consumer: Towards A More Sensible Definition of Deception' (1989) *University of Illinois Law Review* 571, 580.

⁸⁶ Ibid.

⁸⁷ See Eric J Topol, 'Failing the Public Health: Rofecoxib, Merck, and the FDA' (2004) 351(17) *New England Journal of Medicine* 1707, 1707.

⁸⁸ John Tomlinson and David Wright, 'Impact of Erectile Dysfunction and Its Subsequent Treatment with Sildenafil: Qualitative Study' (2004) 328 *BMJ* 1037.

⁸⁹ See generally Ariel Katz, 'Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry' (2007) 14(1) *Michigan Telecommunication and Technology Law Review* 1, 16.

⁹⁰ Schechter, above n 85, 583.

⁹¹ Katz, above n 89, 16.

where the market is not able to allocate resources efficiently for the benefit of the society as a whole.

As further explained, one source of market failure is information failure. The main justification for regulating deceptive advertising is an information failure known as information deficiency or information asymmetry. Information asymmetry is essentially a situation where there is a lack of adequate information which prevents consumers from making reasoned and informed decisions.⁹²

An information deficiency or asymmetry may occur in advertising because there is an imbalance in the distribution of information; one party (the seller) has more information than the other (the buyer) and may deprive the buyer of that information. As a result of this asymmetry, the buyer is not equipped to make an informed choice.⁹³ The information deficiency, where the buyer is misled about the product, can occur with respect to prices, quantities and/or the qualities of products.⁹⁴

A good example of the operation of an information asymmetry in advertising is Akerlof's theory of a 'lemon's market'.⁹⁵ According to this theory, a lack of information in respect of the quality of a product leads to consumers' inability to assess the quality of the product, resulting in what is known as a 'lemon's market'.⁹⁶ In a 'lemon's market', while consumers are willing to pay high prices for high quality items, their inability to distinguish on the basis of quality means that they rely primarily on price. This results in consumers preferring lower priced products, thereby driving high quality products out of the market.⁹⁷ As Katz explains

⁹² See generally *Guide to Regulation 1998* above n 33, E2; Sullivan Thomas and Brian A Marks, 'The FTC's Deceptive Advertising Policy: A Legal and Economic Analysis' (1986) 64(4) *Oregon Law Review* 593, 620.

⁹³ Baldwin and Cave, above n 10, 12.

⁹⁴ Hertog above n 9, 228.

⁹⁵ George A. Akerlof 'The Market for "Lemons": Quality Uncertainty and the Market Mechanism' (1970) 84 (3) *The Quarterly Journal of Economics*, 488, 490-491.

⁹⁶ Ibid; See Rubin, *Information Regulation*, above n 83, 278.

⁹⁷ Rubin, *Information Regulation*, above n 83, 278.

in the context of pharmaceutical products, this is equivalent to the effective ‘disappearance of the market’.⁹⁸

2.5.3 Means of Addressing the Information Failure

An information failure, such as that which results in a ‘lemon’s market’, may be rectified through mechanisms that ensure that consumers have the requisite information. For example, information about the quality of a product may be obtained from repeat purchases, from warranties offered by the sellers, by accurate information supplied through advertising, or by mechanisms for publicising poor quality products.⁹⁹ However, in practice, in the absence of regulation mechanisms such as this may not be effective to deal with the information failure.

Regulation to correct the information failure may take a variety of forms. For example, government may require the correction of misleading advertising, or may encourage the provision of additional information.¹⁰⁰ In addition, government regulation may require the mandatory disclosure of product information.¹⁰¹ The most common form of regulation is the prohibition of misleading or deceptive advertising. Governments are well-placed to ensure compliance with these forms of regulation, as they can set effective sanctions for non-compliance.

Although government regulation of deceptive advertising is essentially designed to address the information asymmetry, which causes harms to consumers, it cannot always be assumed to be in the best interests of consumers. First, as explained at [2.4.3], applying private interest theories of regulation, as a result of regulatory capture, government intervention may serve private interests, and not the public interest. Second, government regulation may impose more costs on business than the benefits obtained from regulation.

⁹⁸ Katz, above n 89, 15.

⁹⁹ Ibid 33.

¹⁰⁰ Robert Pitofsky, ‘Beyond Nader: Consumer Protection and the Regulation of Advertising’ (1977) 90 *Harvard Law Review* 661, 664; See generally Howard Beales, Richard Craswell and Steven C. Salop, ‘The Efficient Regulation of Consumer Information’ (1981) 24(3) *Journal of Law and Economics* 491, 514 -531

¹⁰¹ Beales, Craswell and Salop, above n 100, 527.

While applying the different modes of regulation, which are discussed below, at [2.7], may address some of the weaknesses of government regulation, an assessment of the costs and benefits of regulatory action is required in order to determine, first, whether the costs and benefits justify regulatory intervention and, secondly, the kind of regulation that may be justified.

2.6 REGULATING THE ADVERTISING OF MEDICINAL PRODUCTS

This section of the chapter explains and analyses the rationale for regulating the advertising of medicinal products. In doing so, it emphasises the special characteristics of medicinal products, which call for more stringent regulation than that which applies to most other types of products. As explained immediately above, regulation of advertising in general is justified to correct the information asymmetry between advertisers and consumers. This section of the chapter explores the application of this justification in the particular context of the regulation of the advertising of medicinal products.

2.6.1 Medicinal Products and the Justification for Regulating Advertising

As will be further explained at [4.4], a number of reviews have been undertaken of the regulation of medicinal products in Australia, including a comprehensive review, known as the Galbally review, which examined the regulation of drugs, poisons and controlled substances against the principles of Australia's National Competition Policy.¹⁰² The Galbally review concluded that regulation of these products was justified as the market could not be relied upon to deal with the following market failures:

- *information asymmetry* – where sellers have greater information and knowledge than buyers;
- *externalities* – where accidental or deliberate misuse of these substances could result in harm to individuals and the wider community; and
- *merit/demerit goods* – where individuals may not make judgements in their own best interest, e.g. on the use of narcotics.¹⁰³

According to the Galbally Review, in the absence of appropriate regulation, consumers would not be fully informed about the consequences of their choice, as they would lack sufficient understanding of:

- the substances and products needed to treat particular conditions;
- the risks associated with particular substances;

¹⁰² Rhonda Galbally, *Review of Drugs, Poisons and Controlled Substances Legislation-Final Report Part A* (January 2001). ('Galbally Review').

¹⁰³ Ibid, 13.

- the way in which products containing the substances need to be used safely and to achieve optimal health benefits;
- the potential interactions with other medicines or foods;
- contraindications with certain medical conditions and
- poisonous substances that may be very dangerous if used inappropriately, whether intentionally or unintentionally.¹⁰⁴

As explained in the Galbally Review, the regulation of medicinal products imposes two broad forms of control: limitations on access to such products and restrictions on the way in which such products are marketed.¹⁰⁵ The first set of controls includes drug approval processes, post marketing surveillance, and the reporting of adverse reactions. The second set of controls, on the other hand, includes restrictions on:

- which products may be advertised, for what conditions and in what way;
- the labelling, packaging and manufacture of the products;
- the way in which products are supplied, stored, displayed and offered for sale and
- the records which must be kept and reports provided on the supply of the products.¹⁰⁶

The two sets of regulatory controls on medicinal products (limitations on the access to such products and limitations on the marketing of the products) are designed to be mutually reinforcing.

This section of the chapter expands the analysis undertaken in the Galbally Review by explaining, in more detail, the rationales for regulating the advertising of medicinal products. To begin with, a reliance on inaccurate and deceptive advertisements of medicinal products can cause harms over and above any financial losses, including potentially serious bodily harm. Misleading advertising of medicinal products may cause consumers to falsely believe that the products are safe and free from side effects, or that the use of the products could replace medical treatments.¹⁰⁷ Unlike advertisements for

¹⁰⁴ *Galbally Review*, above n 102, 13.

¹⁰⁵ *Ibid* 14.

¹⁰⁶ *Ibid* 14-15.

¹⁰⁷ *Schechter*, above n 85, 580.

other products or commodities, such as cameras or vacuum cleaners which, if misleading, cause only financial harm to consumers, the advertisement of medicinal products can cause bodily harm or fatalities if information is not accurately conveyed. In this respect, Craswell has argued that ‘injuries caused by deception could be viewed as fundamentally similar to those caused by industrial accidents or dangerous products’.¹⁰⁸ All of this suggests a need for social regulation, over and above the case for economic regulation set out in the Galbally Review.

The distinctive features of medicinal products, however, also reinforce the case for economic regulation. Given the potential for deceptive advertising of medicinal products to result in physical harms, this can obviously lead to further economic harms for society in the form of expenditure of scarce resources on the treatment of patients. Moreover, if deceptive advertising results in the proliferation of inferior products (which may occur if, as explained at [2.5.2.2] a ‘lemon’s market’ develops), this could erode consumer confidence in the health system as a whole. Finally, from a broader perspective, if sufficient people suffer adverse health effects from deceptive advertising there will be a drop in the productivity of society as a whole.¹⁰⁹

While the uncontrolled advertising of medicinal products may result in significant costs to society, it is undesirable to ban such advertising altogether. This is essentially because a ban would deprive consumers of valuable information, which is an essential function of advertising. In addition to the social benefits of advertising in general, there are particular benefits that arise from the advertising of medicinal products.

Health-related information, which is disseminated in the advertisements of medicinal products, has the potential to benefit consumers in a number of ways. Consumers may be better informed about drugs and certain medical conditions, and about the availability of new drugs or treatments for medical conditions which consumers would otherwise be unaware of.¹¹⁰ They may also be able to recognize medical conditions that are often under-

¹⁰⁸ Craswell, ‘Interpreting Deceptive Advertising’, above n 82, 679.

¹⁰⁹ *Best Practice Regulation Handbook 2010*, above n 36, 3-4. As the Australian government *Office of Best Practice Regulation Handbook* explains, the need to promote productivity is the major objective of ensuring efficient and effective regulation.

diagnosed or under-treated.¹¹¹ The advertisements may also facilitate discussions with physicians regarding health conditions, tests or treatment options that may have been overlooked by physicians.¹¹²

Therefore, while the regulation of the advertising of medicinal products is justified, the form of regulation must fully take into account the costs and benefits of regulation. This necessarily involves striking a balance between the objectives of eliminating deceptive advertising, on the one hand, while ensuring that valuable consumer information is not suppressed, on the other.

As the later chapters of this thesis explain, different jurisdictions have adopted differing approaches to establishing this balance. For example, as described in Chapter 5, the United States permits direct-to- consumer advertising (DTCA) of prescription drugs, which is prohibited in almost all other jurisdictions. This reflects an approach to regulation that favours the provision of information to consumers over the potential harms caused by DTCA of prescription drugs. Other jurisdictions, including Australia and Malaysia, however, favour striking the balance more in favour of regulating to prevent harmful advertising, and therefore prohibit DTCA of prescription drugs. A major objective of this thesis is to determine precisely how the balance between promoting the benefits of advertising, while minimising the costs, should be struck in Malaysia. With this in mind, an economic analysis of the costs and benefits of regulating the advertising of medicinal products is addressed below at [2.9]. Before turning to this, however, the chapter introduces and analyses the modes of regulation, ranging from government regulation to self-regulation.

¹¹⁰ Isaac D. Montoya, Gwen Lee-Dukes and Dhvani Shah, 'Direct -To-Consumer Advertising: Its Effects on Stakeholders' (2008) 37(2) *Journal of Allied Health* 116, 116.

¹¹¹ Ibid; John E Calfee, 'Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs' (2002) 21(2) *Journal of Public Policy and Marketing* 174.

¹¹² Ibid.

2.7 MODES OF REGULATION

As indicated at [2.3] above, applying the principles of best practice regulation, once the problem to be addressed by regulation is sufficiently identified, the range of feasible policy options that may be employed to deal with the regulatory problem must be analysed. The first stage in the analysis of the available policy options involves an assessment of the various modes of regulation. The different modes of regulation dealt with in this thesis are: (1) government regulation; (2) self-regulation; (3) co-regulation and (4) enforced self-regulation. This section of the chapter explains the main modes of regulation, and the relative advantages and disadvantages of each of the modes.

The modes of regulation essentially refer to choices about who is responsible for particular aspects of a regulatory system. The modes of regulation that may be adopted range on a continuum from government or 'command and control' regulation, at one end of the spectrum, to pure self-regulation, at the other. This section of the chapter begins by explaining traditional government regulation before turning to an examination of alternative modes of regulation.

2.7.1 Government ('Command and Control') Regulation

Although known by different terminologies, such as statutory regulation,¹¹³ public authority regulation,¹¹⁴ or the 'command and control' model of regulation,¹¹⁵ government regulation, in essence, refers to the state having the sole 'capacity to command and control'.¹¹⁶ Traditionally, most regulation was government, or 'command and control', regulation. Like other modes of regulation, government regulation has both strengths and weaknesses.

¹¹³ Paul Verbruggen, 'Does Co-Regulation Strengthen EU Legitimacy?' (2009) 15(4) *European Law Journal* 425, 428.

¹¹⁴ Carmen Palzer, 'Co-Regulation of the Media in Europe: European Provisions for the Establishment of Co-Regulation Frameworks' (2002) *IRIS Plus Legal Observation of the European Audio Visual Observatory* 1, 2.

¹¹⁵ See Black, *Critical Reflection on Regulation*, above n 4, 2.

¹¹⁶ *Ibid* 3.

The main strengths of government regulation lie in the facts that it is established democratically, and that it can employ the force of law to ensure regulatory compliance.¹¹⁷ The force of law means that compliance can be enforced by virtue of the state's monopoly of legal authority. Moreover, government regulation is considered to be more efficient and effective in monitoring than less centralized modes of regulation, since a centralized government is seen to be able to gather a large number of reports on violations and evaluate the effectiveness of a particular approach to monitoring violations.¹¹⁸ Furthermore, it has been argued that centralized regulation by the government is advantageous because the accumulation of expertise is considered present at a relatively lower cost.¹¹⁹ In other words there are economies of scale and scope in the centralization of regulation in public authorities.

However, command and control regulation is not free from weaknesses. Government regulation often faces resource constraints and information scarcity.¹²⁰ Firstly, as there are diverse demands on government resources, insufficient resources may be available for effective regulation. Secondly, government has less information about the conditions existing in a regulated industry than the industry itself. Consequently, given this lack of information, government rule-making and enforcement strategies may be inefficient. In particular, this may result in over-regulation or regulatory delays, which effectively hinder economic activity.¹²¹ Command and control regulation has therefore been criticised for imposing unnecessary burdens and costs on industry. Accordingly, countries such as Australia,¹²² some European countries,¹²³ the United Kingdom¹²⁴ and the United States¹²⁵

¹¹⁷ Baldwin and Cave, above n 10, 35 & 78.

¹¹⁸ See Sauwakon Ratananwijitrasin and Eshetu Wondemagegnehu, *Effective Drug Regulation*, (World Health Organization 2002), 92.

¹¹⁹ Baldwin and Cave, above n 10, 135.

¹²⁰ Edward J Balleisen and Marc Eisner, 'The Promise and Pitfalls of Co-Regulation: How Governments Can Draw on Private Governance for Public Purpose' in David Moss and John Cisternino, (eds) *New Perspectives on Regulation* (2000) 127, 133 & 138.

¹²¹ Gary Bank, 'Reducing The Regulatory Burden: The Way Forward' (Inaugural Public Lecture delivered at Monash Centre for Regulatory Studies, University Law Chambers, Melbourne, 17 May 2006); *Taskforce Report on Reducing Burden* above n 2.

¹²² *Ibid.*

¹²³ Communication from the Commission of the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, (2009) 'Third Strategic Review of Better Regulation', 2; Communication from the Commission of the European Parliament, The Council, The

have conducted comprehensive reviews of centralized government regulation with the aim of reducing the burdens imposed by this form of regulation on businesses. Because of the weaknesses of command and control regulation, there is now general acceptance that alternative modes of regulation, which are explained immediately below, may be more effective.¹²⁶

2.7.2 Alternative Modes of Regulation

As explained in a recent OECD report examining alternatives to traditional regulation, the first response by governments to a perceived policy problem is often to resort to command and control regulation.¹²⁷ Nevertheless, given the disadvantages of traditional government regulation, there has been an increased interest in exploring alternative modes of regulation. As the OECD report points out:

Alternative policy instruments can often achieve policy objectives at lower cost and more effectively than traditional, command and control instruments. They can therefore be a means of reducing administrative burdens imposed on businesses and others.¹²⁸

European Economic and Social Committee and the Committee of the Regions, (2008) 'Second Strategic Review of Better Regulation'.

¹²⁴ Colin H Kirkpatrick and David Parker, *Regulatory Impact Assessment: Towards Better Regulation?* (Edward Elgar Publishing, 2007); Stephen A. Carter, Better Regulation Executive, Department for Business, Enterprise and Regulatory Reform (BERR) United Kingdom, (Annual Review 2008) 'Making It Simple'; Secretary of State for Constitutional Affairs and Lord Chancellor by Command of Her Majesty, The Law Commission (Consultation Paper No 302) in the Report to the Parliament of the United Kingdom by the (October 2006) *Post-Legislative Scrutiny*, 22; Graham Mather and Frank Vibert, Executive Summary, 'Reducing The Regulatory Burden: The Arrival of Meaningful Regulatory Impact Analysis (July 2004); Philip Hampton, *Reducing Administrative Burdens: Effective Inspection and Enforcement* (The Hampton Review – Final Report, 2005).

¹²⁵ Office of Information and Regulatory Affairs Office of Management and Budget, 'Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities' (2010).

¹²⁶ See generally Gunningham, Grabosky and Sinclair, above n 1; Stephen Breyer, 'Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives and Reform' (1979) 92(3) *Harvard Law Review* 549, 578; Healy and Braithwaite, above n 4.

¹²⁷ Glen Hepburn, *Alternatives to Traditional Regulation*, OECD Report, 2009, 10.

¹²⁸ *Ibid* 8.

This section of the chapter examines the main alternatives to traditional government regulation which are relevant to the regulation of the advertising of medicinal products, namely self-regulation, co-regulation and enforced self-regulation.¹²⁹ Although the three alternative modes of regulation share some common features, they use quite different regulatory strategies and techniques. As explained by Baldwin and Cave, alternative modes of regulation can be distinguished by reference to the following three characteristics: (1) the extent to which regulation is delegated by government; (2) the extent of government involvement in regulation and (3) the amount of 'legal force attached to rules'.¹³⁰ As we will see, there are strengths and weaknesses in the various mixes of government and industry involvement in the alternative modes of regulation.

2.7.2.1 Self-Regulation

Self-regulation, which is also known as private regulation,¹³¹ in its purest form, refers to private organisations regulating the behaviour of their members through a degree of control and supervision.¹³² In broader terms, it may be defined as 'the possibility for economic operators, the social partners, non-governmental organizations or associations to adopt amongst themselves and for themselves common guidelines...'.¹³³

Self-regulation involves industry formulating rules and codes to govern the members of industry, and is premised upon the voluntary participation by members in regulation.¹³⁴ Applying the criteria suggested by Baldwin and Cave, pure self-regulation is distinguished from the other alternative modes of regulation (co-regulation and enforced self-regulation) in that there is no government involvement and the rules are not legally binding.¹³⁵

¹²⁹ See *Guide to Regulation 1998* above n 33, B2.

¹³⁰ Baldwin and Cave, above n 10, 125-126.

¹³¹ Balleisen and Eisner, above n 120, 131.

¹³² See Baldwin and Cave, above n 10, 63.

¹³³ European Parliament Council Commission 'Inter-institutional Agreement on Better Law Making' (2003) *Official Journal of the European Union*, 1, 3.

¹³⁴ Palzer, above n 114, 2.

¹³⁵ Baldwin and Cave, above n 10, 125-126.

The main strengths of self-regulation, in comparison with government regulation, are that, first it has much more flexibility, including the availability of strategies which government regulators lack.¹³⁶ For instance, it possesses the flexibility to establish rules much more quickly than government. Second, there are no great problems with compliance, as adherence to rules is entirely voluntary.¹³⁷ In so far as there are problems with compliance, these relate mainly to violations by those who do not subscribe to the system of self-regulation. Third, as the regulators come from the industry, they have the specialised experience needed to address the concerns arising from malpractices.¹³⁸ Similarly, self-regulators are presumed to be efficient in regulating the relevant conduct as, for example, monitoring costs are less, there being no excessive costs incurred when securing information regarding members and their activities.¹³⁹ Furthermore, self-regulators are commonly involved in an ongoing conversation with industry; for example, by announcing decisions in industry publications. As Black has claimed, ongoing inter-industry communications may be important in promoting regulatory compliance.¹⁴⁰

Self-regulation, however, has important weaknesses. The main weaknesses, as summarized by Baldwin and Cave, include: (1) that the regulators may seek to serve the private interests of their members as opposed to the public interest;¹⁴¹ (2) that they may lack accountability and the force of law;¹⁴² (3) that their credibility or procedural fairness may be questionable;¹⁴³ (4) that non-members are left unregulated¹⁴⁴ and (5) the

¹³⁶ Ibid 73; Gunningham, Grabosky and Sinclair, above n 1, 41-50.

¹³⁷ Ida Madieha Azmi, 'Content Regulation in Malaysia: Unleashing Missiles on Dangerous Web Sites' (2004) 3 *Journal of Information, Law and Technology*, 3.

¹³⁸ See Jeffrey S. Edelstein, 'Self-Regulation of Advertising: An Alternative to Litigation and Government Action' (2003) 43(3) *Idea* 509, 517-528.

¹³⁹ Baldwin and Cave, above n 10, 127.

¹⁴⁰ See generally Julia Black, *Rules and Regulators* (Clarendon Press, 1974), 30.

¹⁴¹ Baldwin and Cave, above n 10, 73.

¹⁴² Ibid.

¹⁴³ Ibid 73 & 130.

¹⁴⁴ Ibid 128.

regulators lack democratic legitimacy, as they are private unelected authorities that represent specific interests.¹⁴⁵

One of the key disadvantages of self-regulation is the relatively weak enforcement powers of self-regulators, which essentially derive from the fact that their decisions lack the force of law.¹⁴⁶ Consequently, self-regulation may be unsuitable for the regulation of certain types of products and services. For example, self-regulation is generally regarded as unsuitable if it involves the regulation of high-risk products or major health issues, as it may not ensure sufficient community safeguards.¹⁴⁷ Another important disadvantage of self-regulation is that consumers may lack confidence in this mode of regulation. Given that, as suggested by Black, effective regulation depends upon consensus building and fostering conversations with interpretative communities, consumer confidence in the system of self-regulation is necessary for the overall success of this mode of regulation.¹⁴⁸ Consumers, however, ordinarily view industry self-regulation as less rigorous than other modes of regulation, as the rules of self-regulatory bodies are drafted by members of the industry, who naturally face the temptation of promoting the self-interest of their own members.¹⁴⁹ Hence, consumers and consumer advocates, in general, tend to regard command and control regulation as more reliable and effective than self-regulation.

Further, as pure self-regulation is voluntary, a self-regulatory system that lacks the cooperation of key industry players may be unable to regulate effectively. It is fundamental to the success of a system of self-regulation that industry groups cooperate in complying with the guidelines or rules established by the self-regulator.¹⁵⁰ For example, while industry self-regulation of the advertising of prescription drugs in New Zealand has been described

¹⁴⁵ Anthony Ogus, 'Rethinking Self-Regulation' (1995) 15 *Oxford Journal of Legal Studies* 97, 98.

¹⁴⁶ Balleisen and Eisner, above n 120, 129

¹⁴⁷ See generally *Guide to Regulation 1998* above n 33, D4-5.

¹⁴⁸ See generally Black, *Rules and Regulators*, above n 140, 30.

¹⁴⁹ Thomas W Reader, 'Is Self-Regulation The Best Option For the Advertising Industry in the European Union? An Argument for the Harmonization of Advertising Laws through the Continued Use of Directives' (1995) 16 *University of Pennsylvania Journal of International Business Law* 181, 209 & 214.

¹⁵⁰ Erin J. Asher, 'Lesson Learned from New Zealand: Pro-active Industry Shift Towards Self-regulation of Direct-To-Consumer Advertising Will Improve Compliance With the FDA' (2006) 16(3) *Albany Law Journal of Science & Technology* 599, 610 - 611.

as working well,¹⁵¹ the key factor in that success has been the willing co-operation of all sectors of industry, including the media.¹⁵² Enforcement of self-regulation in New Zealand is not a problem, as the media does not publish or broadcast advertisements for prescription drugs unless pre-approval for the advertisements has been obtained.¹⁵³

2.7.2.2 Co-Regulation

Co-regulation may be defined to mean a ‘mechanism which combines binding legal legislative and regulatory action with actions taken by the actors most concerned, drawing on their practical experiences’.¹⁵⁴ In the Inter-institutional Agreement on Better Law Making (IIA), produced by the European Parliament Council Commission, it is defined as a ‘mechanism whereby a legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, social partners, non-governmental organizations, or associations)’.¹⁵⁵ According to the UK’s Better Regulation Task Force, ‘co-regulation involves some sort of legal underpinning and can therefore be described as self-regulation with a legislative backstop’.¹⁵⁶

Essentially, co-regulation is a form of regulation which combines some of the characteristics of both self-regulation and government regulation. It is a model which is premised upon a self-regulatory framework, with public authorities stipulating the legal basis for the framework.¹⁵⁷ It involves a partnership between government and industry associations with the aim of achieving the objectives set by the government.¹⁵⁸

¹⁵¹ Ibid 618.

¹⁵² Ibid.

¹⁵³ Ibid 620.

¹⁵⁴ See Palzer, above n 114.

¹⁵⁵ See European Parliament Council Commission ‘Inter-institutional Agreement on Better Law Making’ (2003) *Official Journal of the European Union* 1, 3.

¹⁵⁶ Better Regulation Task Force (UK), *Routes to Better Regulation: A Guide to Alternatives to Classic Regulation* (2005) 26.

¹⁵⁷ Palzer, above n 114, 2.

¹⁵⁸ See Verbruggen, above n 113, 428.

A distinctive feature of co-regulation is the delegation of particular tasks of the public authority to the industry, and the monitoring of the delegated tasks by the public authority.¹⁵⁹ Other important features of co-regulation include the government's responsibility for establishing regulatory criteria to be met, accreditations, complaints handling procedures and/or sanctioning.¹⁶⁰ While the government retains an oversight role, industry is responsible for formulating the codes of practice which spell out the nature of responsible practices, and which provide a structure for complaint handling.¹⁶¹

In some respects, co-regulation can be seen as a development from self-regulation. Nevertheless, there are vital differences between the two modes of regulation. First, in self-regulation, the government has no involvement, whereas in co-regulation, the government plays an important role.¹⁶² Second, self-regulation depends upon voluntary agreement by organisations to abide by the rules established by the industry associations in order to ensure responsible practices.¹⁶³ Non-compliance is subject to punishments such as financial penalties or exclusion from membership, but there is no power to discipline non-members. However, with co-regulation, market players are obliged to abide by rules established by the industry, even though they are not members of the industry association. The reason for this is that, if a 'player' in the market does not comply with the rules, punishments are imposed by the State.¹⁶⁴

There are, nevertheless, considerable uncertainties in determining precisely what amounts to co-regulation. In particular, drawing a precise line between government regulation and co-regulation creates some difficulties in determining: (1) precisely how much government involvement is possible before the system ceases to be classified as co-regulation and is

¹⁵⁹ Palzer, above n 114.

¹⁶⁰ Ibid 5.

¹⁶¹ Ibid.

¹⁶² See generally Ogus, *Rethinking Self-Regulation*, above n 145, 100.

¹⁶³ Ibid.

¹⁶⁴ See generally Palzer, above n 114, 2.

better classified as government regulation and (2) how much detail in spelling out a statutory scheme is possible if the system is going to remain a system of co-regulation.¹⁶⁵

Regardless of the difficulties in properly characterising co-regulation it may be preferred to both government regulation and self-regulation because, to an extent, it combines the best characteristics of the two models in a single model.¹⁶⁶ With co-regulation, the public sector obtains the support of industry self-regulation, and therefore is able to save on the costs of regulation.¹⁶⁷ Self-regulators, on the other hand, are able to enjoy the freedom and flexibility of self-governance without compromising the level of accountability expected of them.¹⁶⁸

Co-regulation is not, however, without weaknesses. In particular, co-regulation will be ineffective unless the industry regulators are committed to the regulatory objectives set by government, and allocate sufficient resources to carry out their role in regulation.¹⁶⁹ Moreover, co-regulation also depends upon a degree of commitment by the regulated industry itself. For example, small firms (or firms working under a narrow profit margin) which do not have the competence, resources and management proficiency to implement changes and reforms required in co-regulation, may not perform well.¹⁷⁰

Ultimately, as explained by Balleisen and Eisner, for co-regulation to be credible, it must be premised upon an analysis of five main factors: (1) how concerned the self-regulators are about the reputation of their business;¹⁷¹ (2) how much flexibility do the self-regulators possess so as to reflect special features of their firms;¹⁷² (3) whether there are sufficient 'bureaucratic capacity, autonomy and ethos' with self-regulators which are necessary to

¹⁶⁵ Ibid 7.

¹⁶⁶ See *Guide to Regulation 1998* above n 33, B2 and E11.

¹⁶⁷ Balleisen and Eisner, above n 120, 129.

¹⁶⁸ Ibid 145.

¹⁶⁹ See generally Balleisen and Eisner, above n 120, 134.

¹⁷⁰ Balleisen and Eisner, above n 120, 134.

¹⁷¹ Ibid 132.

¹⁷² Ibid 134.

implement regulatory changes;¹⁷³ (4) how much of transparency is practised in a regulatory process¹⁷⁴ and (5) to what extent are self-regulators made accountable for their actions. In other words, the effectiveness of co-regulation depends, in large measure, on the effectiveness of mechanisms for monitoring the performance of industry regulators.¹⁷⁵

Determining the extent to which the factors identified by Balleisen and Eisner are satisfied by a particular regulatory regime is not without challenges. Depending upon the form of delegation by government to industry, there can be considerable complexities in the regulatory system, opening up possibilities for ‘miscommunication of information, shirking and opportunistic behaviours and vulnerability’.¹⁷⁶ For instance, if authority for a particular regulatory function is not clear, then industry and government may point the finger at each other for perceived regulatory shortcomings. In short, ensuring a regulatory structure which maintains a high level of accountability, and is supported by precise regulatory goals, transparent monitoring and adequate inspection, is far from easy.¹⁷⁷

2.7.2.3 Enforced Self-Regulation

Enforced self-regulation, which is also known as ‘meta-regulation’ and ‘responsive regulation’,¹⁷⁸ is best regarded as a specialized form of co-regulation. Like co-regulation, it is a mode of regulation which is carried out through the employment of specific rules that are designed by firms and ratified by government agencies.¹⁷⁹ Enforced self-regulation, as described by Ayres and Braithwaite, is centred on two key concepts: (1) ‘public enforcement of privately written rules’ and (2) ‘publicly mandated and publicly monitored private enforcement of rules’.¹⁸⁰

¹⁷³ Ibid.

¹⁷⁴ Ibid 135.

¹⁷⁵ Ibid 137.

¹⁷⁶ Ibid 134.

¹⁷⁷ Ibid 134-136.

¹⁷⁸ Healy and Braithwaite, above n 4.

¹⁷⁹ Baldwin and Cave, above n 10, 134-135.

¹⁸⁰ Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1994), 116.

Over and above this, however, as Ayres and Braithwaite point out, enforced self-regulation is distinguished from co-regulation in that it involves *negotiations* between State and individual firms in order to establish tailor-made rules to regulate particular firms, while co-regulation is concerned with the government ratifying or overseeing the control employed by the self-regulation.¹⁸¹ In other words, enforced self-regulation is an essentially collaborative process, whereas co-regulation is more 'top down', with government setting the overall parameters of the regulatory framework and monitoring the performance of industry regulators.

Enforced self-regulation is based on the idea that regulation should involve the utilization of 'mechanisms which are responsive to the context, conduct and culture of those being regulated', and as such, it is believed to ensure greater compliance by those being regulated than other modes of regulation.¹⁸² Accordingly, rules are devised in close collaboration with industry to match the needs of the regulated firms, taking into account the risks and costs associated with regulated activities.¹⁸³ Like co-regulation, enforced self-regulation may be a cost-effective option for the government as a portion of the cost of regulation is borne by those being regulated rather than by the government.¹⁸⁴

As opposed to co-regulation, and reflecting the collaborative model, a distinct feature of enforced self-regulation is that it uses a combination of soft techniques of persuasion, before resorting to harsh enforcement strategies.¹⁸⁵ In particular, enforcement is carried out 'progressively through different compliance seeking strategies', in a pyramid-like system.¹⁸⁶ This pyramid approach, which was first formulated by Braithwaite, considers persuasion as the first option in the regulation of behaviour, with punishment as the last

¹⁸¹ Ibid 102.

¹⁸² Healy and Braithwaite, above n 4, 56.

¹⁸³ Ayres and Braithwaite, above n 180, 110.

¹⁸⁴ Ibid 114.

¹⁸⁵ Healy and Braithwaite, above n 4, 57.

¹⁸⁶ Ibid; John Braithwaite, 'Responsive Regulation and Developing Economics' (2006) 34(5) *World Development* 884, 886.

resort.¹⁸⁷ In other words, in this model, persuasion, which is at the base of the pyramid, escalates to punishment, which is at the top of the pyramid.¹⁸⁸ This regulatory model also incorporates a readiness to de-escalate the regulatory response when it is deemed necessary.¹⁸⁹ Essentially, it is claimed that enforced self-regulation resolves the uncertainty of deciding between ‘when to punish and when to persuade’,¹⁹⁰ establishing a significant amount of flexibility in formulating regulatory responses.

Enforced self-regulation has distinct advantages over other modes of regulation. In particular, enforced self-regulation has the advantage of implementing specifically tailored rules, which have been developed through a collaborative process, and which are responsive to industry needs. Such rules avoid some of the difficulties that arise from broadly couched rules set by government that attempt to deal with all eventualities, and which are often either too stringent or overly permissive.¹⁹¹ Moreover, in terms of enforcement, enforced self-regulation may be more effective than other modes of regulation in that there is less capacity for industry to exploit loopholes as it employs precise and particularised rules that have been collaboratively developed.¹⁹² Finally, enforcement costs are likely to be lower with enforced self-regulation than with other modes of regulation, as persuasion, which is at the base of the pyramid of regulation, is less costly than punishments, which must entail costly litigation.¹⁹³

Despite the clear advantages of enforced self-regulation, like all modes of regulation, it has weaknesses. In fact, the features of enforced self-regulation that give rise to the advantages of this mode of regulation can also lead to disadvantages. For example, while ‘firm specific rules’ may respond to the needs of industry, this may reflect the private

¹⁸⁷ Ibid.

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

¹⁹⁰ Ibid.

¹⁹¹ Baldwin and Cave, above n 10, 134.

¹⁹² See Ayres and Braithwaite, above n 180, 115.

¹⁹³ Ibid 115.

interests of industry members, instead of the broader public interest.¹⁹⁴ Alternatively, even if a rule is devised in the best interest of the public, there is nothing to say that it is necessarily a good rule, as the industry regulator may be ill informed or inefficient.¹⁹⁵ For example, ‘firm specific’ rulemaking is only practically possible with large firms which possess sufficient expertise, funding or resources to perform this task.¹⁹⁶ Consequently, the advantages of an industry group having more experience and understanding of the conditions in a particular industry, must be weighed against the potential disadvantages arising from industry acting in its own interests, and the possibility that industry groups may perform their regulatory roles inefficiently or ineffectively.

2.7.3 Conclusion

All modes of regulation, along the continuum from government regulation to self-regulation, have distinct advantages and disadvantages. On the one hand, government regulation may be rigid, inflexible and slow to adapt to changing economic and technological realities. On the other hand, however, it possesses democratic legitimacy, and governments are best placed to pursue the public interest. As opposed to government, industry may possess greater specialised expertise, resources and time, and may be more responsive to changing industry conditions. Private industry, however, lacks democratic legitimacy, and industry groups may pursue their own interests in preference to the public interest.

Between the two extremes of government regulation and self-regulation, there are two related, and important, modes of regulation, namely co-regulation and enforced self-regulation. While both of these modes of regulation attempt to incorporate the best features of government regulation and self-regulation, neither is beyond reproach, as both have significant potential weaknesses. For example, while enforced self-regulation may be more responsive to the needs of industry than other modes of regulation, this poses the possibility of regulation serving the interests of the industry rather than the broader public interest. Furthermore, the participation of industry groups in regulating an industry may lead to cooperation for anti-competitive purposes, such as raising barriers to entry. Finally,

¹⁹⁴ Baldwin and Cave, above n 10, 135.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid.

whatever mode of regulation is adopted, it is important that compliance and enforcement costs are monitored to ensure that the costs of regulation do not exceed the benefits.

While traditional command and control regulation retains some advantages, it is, however, fair to say that pure government regulation is falling out of favour. Increasingly, in Western democracies, there is a tendency to rely on self-regulation and forms of co-regulation. In making recommendations for Malaysia, it is therefore important to be familiar with the respective advantages and disadvantages of alternative modes of regulation. The following table, which draws upon a recent Occasional Paper produced for ACMA, summarises the advantages and drawbacks of self-regulation and co-regulation.¹⁹⁷

¹⁹⁷ *Optimal Conditions for Effective Self- and Co-regulatory Arrangements 2010*, above n 38, 15.

Table 2.1 Advantages and Drawbacks of Alternative Modes of Regulation

Advantages	<ul style="list-style-type: none"> ▪ greater flexibility and adaptability ▪ potentially lower regulatory costs ▪ ability to harness industry knowledge and expertise to address industry-specific and consumer issues ▪ quick and low-cost complaints-handling and dispute resolution mechanisms
Disadvantages	<ul style="list-style-type: none"> ▪ possibility of raising barriers to entry in an industry ▪ possible anti-competitive activities ▪ danger of regulatory capture ▪ potential to increase government compliance and enforcement costs

In sum, the appropriate mode of regulation cannot be determined in the abstract, but must be determined by considering a range of factors, including the cost of imposing, maintaining or complying with a particular regulatory regime and, most importantly, the specific harms sought to be addressed by regulation. The question of the appropriate mode of regulation for the advertising of medicinal products, along the spectrum from government regulation to self-regulation, is returned to in Chapter 6 of this thesis, with a view to making recommendations for regulation in Malaysia. The next section of this chapter, however, introduces an analysis of the particular rules that may be used in regulating the advertising of medicinal products.

2.8 Rules and Enforcement of Rules

As explained immediately above, regulation can be seen as a continuum, with centralized government regulation at one extreme and self-regulation at the other. Nevertheless, regardless of the mode of regulation (meaning decisions about who is responsible for particular parts of a regulatory regime) regulation must be implemented by rules. There are two main factors that are critical in determining the effectiveness of regulation: firstly, the way in which rules are drafted and, secondly, the ways in which rules are enforced.

This section of the chapter first examines the different forms of rules and the inherent limitations of rules, before explaining the main problem in drafting good rules, and how this problem may be addressed. As the Victorian Guide to Regulation points out in referring to different forms of rules:

In developing good regulation to address problems, it is important to assess the appropriateness of all forms of legislation and other instruments.¹⁹⁸

Secondly, this section of the chapter examines the effectiveness of the enforcement of rules.

2.8.1 Types of Rules

Rules are of broadly two kinds which this thesis refers to as formal and informal rules. Formal rules, the main instrument of government regulation, consist of primary legislation and delegated (or secondary) legislation. Primary legislation consists of Acts passed by Parliament. Delegated legislation, on the other hand, consists of a variety of instruments including regulations, bylaws, and ordinances, which are created by subordinate bodies under the authority set out in statutes.¹⁹⁹ In a Westminster system, the subordinate bodies may include: (1) the executive which, in Australia, is the Governor-General (or Governor) in

¹⁹⁸ *Victorian Guide to Regulation 2007*, above n 40, 2-5.

¹⁹⁹ See generally Michael Meek, *Australian Legal System* (Thomson Lawbook, 4th ed 2008) 81.

Council; (2) government ministers; (3) local authorities such as councils; (4) statutory bodies such as corporations; (5) universities or (6) professional bodies.²⁰⁰

Primary legislation is usually drafted in general terms so as to avoid the need for frequent changes.²⁰¹ Delegated legislation, on the other hand, supplements primary legislation by providing greater specificity to the legislation, so as to assist in the regulation of an activity or behaviour, while not altering the aims or objectives of primary legislation.²⁰² A range of considerations must be taken into account in determining whether a rule should be included in primary legislation or secondary legislation, such as the extent to which the rule affects individual rights, whether it relates to a significant policy question and whether it imposes criminal penalties.²⁰³

In the United States, as opposed to Westminster systems, Federal administrative bodies, or agencies, are also empowered to make delegated legislation in the form of rules and regulations.²⁰⁴ Rules and regulations made by Federal agencies take priority over State laws when they are made validly pursuant to Federal legislation.²⁰⁵ Nevertheless, similar considerations apply in determining whether a rule should take the form of primary legislation or delegated legislation made by a regulatory agency.

As opposed to formal rules, informal rules consist of industry codes or guidelines established by the private sector. Unlike primary and delegated legislation, strictly speaking, informal rules are non-binding. Obviously, between formal rules, on the one hand, and informal rules, on the other, there are a range of rule-types which may be formulated by the private sector but which, nevertheless, are binding.

²⁰⁰ Ibid; See generally R.A. Hughes and G.W.G Leane, *Australian Legal Institutions: Principles, Structure and Organisation* (LawBook Co, 2nd ed, 2003), 243.

²⁰¹ *Victorian Guide to Regulation 2007*, above n 40, 2-5.

²⁰² See generally Meek, above n 199; Hughes and Leane, above n 200; *Victorian Guide to Regulation 2007*, above n 40, 2-5.

²⁰³ *Victorian Guide to Regulation 2007*, above n 40, 2-6.

²⁰⁴ Alan E. Farnsworth, *An Introduction to the Legal System of the United States* (Oceana Publication, 2nd ed, 1983), 56.

²⁰⁵ Ibid 56.

Decisions about the form of rules (whether they should take the form of primary legislation, delegated legislation or informal rules) are related to decisions about the appropriate mode of regulation. Thus, primary legislation has greater democratic legitimacy, but less flexibility than other forms of rules, while informal rules have considerable flexibility, but less accountability. Nevertheless, there are particular features of rules which must be taken into account in designing an effective regulatory system, regardless of whether the rules take the form of primary legislation, delegated legislation or informal rules. These features of rules are dealt with immediately below.

2.8.2 Ensuring Compliance with Rules

In order to assess the effectiveness of rules, it is important to first understand the objective of rule-making. Rules are essentially drafted with a view to ensuring that they are complied with.²⁰⁶ In other words, rules are formulated in a manner that can deter the occurrence of an undesirable act or encourage socially desirable activity.²⁰⁷

The extent to which rules are drafted so as to best ensure compliance is essential to assessing the effectiveness of rules. Several factors influence compliance with rules. For example, the costs of compliance with a rule clearly influence their effectiveness. As suggested by Becker, if rules are drafted so that they are very costly to comply with, then rules may well be disobeyed.²⁰⁸ The most important influence on the effectiveness of rule-making is the fact that, due to imperfect information, rule-makers necessarily draft rules that are either over-inclusive or under-inclusive. The next section of this chapter explains the problem of the imprecision of rules, and how this problem may be addressed.

²⁰⁶ See generally Robert Baldwin, 'Why Rules Don't Work' (1990) 53 *Modern Law Review* 321, 329.

²⁰⁷ See generally Issac Ehrlich and Richard A Posner, 'An Economic Analysis of Legal Rulemaking' (1974) 3 *Journal of Legal Studies* 257, 262.

²⁰⁸ See generally Gary S Becker, 'Nobel Lecture: The Economic Way of Looking at Behavior' (1993) 101(3) *Journal of Political Economy* 385, 390.

2.8.3 Addressing the Imprecision of Rules

Although rules may be relied upon to regulate behaviour or conduct, there are inherent limitations in rules, which hinder effective regulation. An important limitation includes the over-inclusiveness and under-inclusiveness of rules, which means that rules are necessarily imprecise.

The term 'over-inclusive' refers to a situation where conduct which was not intended to be regulated is, in fact, caught by regulation. The term 'under-inclusive', on the other hand, refers to a situation where conduct which was intended to be regulated is excluded from regulation.²⁰⁹ These situations are generally brought about by rules being formulated either too broadly or too narrowly. Lack of knowledge, vision and foresight (in other words, imperfect information) on the part of those responsible for drafting rules, which cannot possibly address all possible contingencies, leads to rules being poorly designed.²¹⁰

Given that the imprecision of rules is a problem that cannot be avoided, it is necessary to understand how the problem can be minimised. A number of ways have been suggested for addressing the imprecision of rules. Baldwin, for example, proposes what he calls a 'compliance-orientated approach' to address the limitations of rules.²¹¹ In particular, he argues that rules are generally not complied with because 'the regulated' lack adequate information about what is required of them, or lack the initiative to find out what is required.²¹² According to Baldwin, rules are best formulated to ensure compliance if they are targeted on the following four questions:

- What are the key hazards?
- Who creates these hazards?
- Which enforcement strategies will best influence the mischief makers/hazard creators?

²⁰⁹ See Ehrlich and Posner, above n 207, 268.

²¹⁰ Colin S Diver, 'The Optimal Precision of Administrative Rules' (1984) 93 *Yale Law Journal* 65, 98.

²¹¹ See generally Baldwin, above n 206, 336-337.

²¹² *Ibid* 329.

- Which rule-types best compliment those strategies?²¹³

Black, on the other hand, has suggested that the limitations found in rules may be best addressed by the use of different rule-types, interpretative communities and what she terms a 'conversational model'.²¹⁴ First, according to Black, it is often the choice between two types of rules, a 'rule' and a 'standard', that is the key choice to be made by rule-makers. While rules are detailed and precise, standards are less precise, but flexible.²¹⁵ While both rules and standards have strengths and weaknesses, Black argues that 'standards' may allow for the use of a purposive approach, and thereby permit greater flexibility than more prescriptive, detailed rules.²¹⁶

Secondly, Black claims that the use of 'interpretative communities' may also address weaknesses in the formulation of rules. By 'interpretative communities', Black refers to all those who are involved in applying and interpreting a rule.²¹⁷ In essence, she argues that if a consensus can be built amongst these communities it will promote compliance.²¹⁸ For example, a mutual understanding of the problem will enable the problem of 'creative compliance' to be detected and addressed. 'Creative compliance', as described by McBarnet is 'the use of technical legal work to manage the legal packaging, structuring and definition of practices and transactions, such that they can claim to fall on the right side of the boundary between lawfulness and illegality'.²¹⁹ Essentially, where 'creative compliance' is practised, the letter of the law may be complied with, but the spirit of the law breached. According to Black, consensus building can deter these undesirable practices.

²¹³ See Baldwin, above n 206, 321 & 337.

²¹⁴ See generally Black, *Rules and Regulators*, above n 140, 20, 30 & 37.

²¹⁵ Ibid 20.

²¹⁶ Ibid 20.

²¹⁷ Ibid 30.

²¹⁸ Ibid.

²¹⁹ Doreen McBarnet 'Enforcing Ethics: New Strategies for Tackling Creative Compliance' Paper Prepared for presentation at workshop ESRC/GOVNET on The Dynamics of Capital Market Governance: Evaluating the Conflicting and Conflating Roles of Compliance, Regulation, Ethics and Accountability Australian National University, Canberra 14-15 March 2007) 1.

Thirdly, Black suggests that compliance can be improved by altering the way in which rules are applied.²²⁰ By this, she effectively means the use of a conversational model of regulation, where ongoing consultation and negotiations between 'the regulated' and the regulators restrict differences in understanding rules.²²¹

2.8.4 Enforcement of Rules

Once rules are drafted, they must be effectively enforced. Regulation includes a range of enforcement strategies that may be used by government, regulators and industry. According to Bhagwat, a basic distinction may be drawn in the way in which rules are enforced between ex-ante review, on the one hand, and ex-post enforcement, on the other.²²² Ex-ante review is, in essence, a form of control which is imposed before the violation of a law. Common forms of ex-ante review include: (1) licensing or (2) pre-clearance or pre-approvals, such as pre-clearance of an advertisement.²²³ Ex-post enforcement, on the other hand, is concerned with enforcement violations after they occur.²²⁴ Ex-post enforcement includes administrative enforcement (which essentially means enforcement by regulators), and judicial enforcement (which means enforcement by the courts). This section of the chapter explains ex-ante and ex-post enforcement, and the strengths and weaknesses of each of these forms of enforcement.

2.8.4.1 Ex-ante review

Ex-ante review usually involves a regulator either granting or denying pre-approval, or pre-clearance, or a licence.²²⁵ Pre-approval or pre-clearance, for example, operates to prevent irreparable harm that may be caused by violations of a rule. According to Bhagwat,

²²⁰ See generally Black, *Rules and Regulators*, above n 140, 37.

²²¹ Ibid.

²²² Ashutosh Bhagwat, 'Modes of Regulatory Enforcement and the Problem of Administrative Discretion' (1999) 50 *Hastings Law Journal* 1274, 1278.

²²³ Ibid.

²²⁴ Ibid.

²²⁵ Ibid 1283.

‘irreparable harm’ is a harm which ‘society may consider unacceptable’.²²⁶ An example of this is where there may be ‘serious injury to health or death to substantial population’.²²⁷

Ex-ante review may be less costly than ex-post review, which involves regulators ‘finding, investigating and prosecuting violations’.²²⁸ However, there are certain weaknesses with ex-ante review. The weaknesses are usually associated with the wide discretion this confers on regulatory agencies to prevent behaviour, and the extent to which the discretion is carried out in an appropriate manner. A good example of this problem is where regulatory approval is not granted in a timely manner, thereby preventing companies from engaging in activities which may well be beneficial.²²⁹

2.8.4.2 Ex-Post Enforcement

Ex-post enforcement refers to enforcement once there has been a violation of the law. As argued by Baldwin and Cave, ex-post enforcement may very well determine the success of regulation.²³⁰ If the other regulatory strategies, such as pre-approval fail to prevent violations, ex-post enforcement must deal with the problem by punishing the wrong-doer, or compensating consumers, or both.²³¹

A system of monitoring violations is a common example of ex-post enforcement. Monitoring operates to identify violations and facilitate measures to prevent violations from recurring. In essence, two types of monitoring may be pursued, namely, passive or proactive. Passive monitoring refers to the discovery of violations of laws from the reports of competing companies²³² or consumers, whereas proactive monitoring refers to the responsible agency randomly checking conduct, such as advertising materials, for

²²⁶ Ibid 1310.

²²⁷ Ibid.

²²⁸ Ibid 1311.

²²⁹ Ibid 1315- 1316.

²³⁰ Baldwin and Cave, above n 10, 96.

²³¹ See generally Ibid.

²³² Ratananwijitrasin and Wondemagegnehu, above n 118, 104-105.

violations of laws.²³³ Monitoring can either be scheduled, thereby ensuring regular but predictable monitoring, or spontaneous, which may take those who are monitored, such as advertisers, off guard.

Irrespective of the types of monitoring which may be carried out, it must be carried out cost-effectively.²³⁴ As suggested by Jackson and Rosenberg, a system of monitoring is likely to be most effective if it employs selective monitoring, accompanied by stringent penalties.²³⁵ They recommend a method of selective sampling, whereby the regulator may select just one item from a number of items for inspection, thereby reducing the costs of more comprehensive monitoring. If the item is found to be in breach, the penalty is based on the total number of items.²³⁶ Because the penalty imposed is high, selective monitoring is designed to more effectively deter prohibited acts and is able to achieve the same result as individually monitoring items, at a fraction of the cost.²³⁷

Although monitoring may be essential to the effectiveness of ex-post enforcement, as it increases the chances of harmful conduct targeted by regulation being detected, the deterrence value of ex-post enforcement also depends upon the extent to which serious consequences, such as fines or imprisonment, follow.²³⁸ There are, nevertheless, limits on the extent to which regulation can rely on ex- post enforcement. These limits relate mainly to the potentially high costs of ex-post strategies.²³⁹ For example, enforcement which entails imprisonment obviously involves the costly construction and operation of prisons.²⁴⁰

²³³ See generally Robert Jackson and David Rosenberg, 'A New Model of Administrative Enforcement' (1983) 93 *Virginia Law Review* 1983.

²³⁴ Ibid 1984-1985.

²³⁵ Jackson and Rosenberg use a method which they call as 'single-outcome sampling' in their analysis. Ibid.

²³⁶ For example, in the instance of registration of vehicles, if a company is found to have only registered two out of its five vehicle and the cost of fine per vehicle is \$100, then if one the day of inspection, the unregistered vehicle is happened to be inspected, the cost of penalty is will be \$500 (the total payable for five vehicles). See *ibid*.

²³⁷ Jackson and Rosenberg, above n 233, 1984-1985.

²³⁸ See generally Baldwin and Cave, above n 10, 98.

²³⁹ Ashutosh Bhagwat, above n 222, 1312.

²⁴⁰ Steven Shavell, 'The Optimal Structure of Law Enforcement' (1993) 36 *Journal of Law and Economics* 256, 258.

Moreover, legal proceedings to enforce rules are necessarily costly. Effective ex-post enforcement therefore involves balancing the benefits of deterring harmful behaviour against the costs of monitoring or punishing the targeted behaviour.

2.8.5 Conclusion

In summary, the preceding section of the chapter explored the two main ways in which regulation may promote compliance: the formulation of rules and the use of enforcement strategies. The formulation of rules creates compliance difficulties as a lack of information may mean that they are either over-inclusive or under-inclusive. As Black points out, regulation may either take the form of relative precise rules or more flexible standards.²⁴¹ The appropriate degree of specificity in drafting rules is a complex issue. Nevertheless, as Black further suggests the problems of ensuring compliance with rules may be addressed, in part, by promoting consensus among interpretative communities, or an ongoing ‘conversation’ between regulators and the regulated.²⁴²

Compliance may also be promoted through the adoption of appropriate enforcement strategies. As Bhagwat suggests, enforcement may take the form of ex-ante review or ex-post enforcement, each of which has strengths and weaknesses.²⁴³ Given the advantages and disadvantages of different enforcement strategies, it is likely that compliance is best promoted by a mix of strategies, including both ex-ante review and ex-post enforcement. Determining the precise nature of the mix is, however, quite a complex task.

²⁴¹ See generally Black, *Rules and Regulators*, above n 140, 20.

²⁴² *Ibid* 20, 30 & 37.

²⁴³ Bhagwat, above n 222, 1278.

2.9 ASSESSING EFFICIENCY AND EFFECTIVENESS OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS

As explained immediately above, the effectiveness of rules depends upon the ways in which rules are drafted and the strategies that are used to enforce the rules. As Katz suggests, however, any form of regulatory intervention may lead to either under-deterrence or over-deterrence.²⁴⁴ An assessment of any form of regulation depends upon an understanding of what is meant by under-deterrence and over-deterrence.

Under-deterrence occurs when regulation is insufficient to prevent the occurrence of a prohibited event.²⁴⁵ For example, in the context of the regulation of deceptive advertising, fines imposed or sanctions ordered may be insufficient to avoid the recurrence of the deceptive advertising.²⁴⁶ Although this may be rectified by increasing the penalties or sanctions, merely increasing penalties only partially solves the problem, as manufacturers may continue to keep products on the market without engaging in any form of activity that would reveal accurate information regarding the products.²⁴⁷ The regulatory strategy pursued must therefore be more sophisticated than merely increases penalties.

Over-deterrence, on the other hand, occurs where the courts impose high penalties or sanctions that are disproportionate to the prohibited act.²⁴⁸ Like under-deterrence, over-deterrence may end up causing more harms than benefits. In particular, over-deterrence may penalise some good quality products, driving them out of the market.²⁴⁹

In order to determine the appropriate level of regulation so as to avoid as much as possible both under-deterrence and over-deterrence, it is important to undertake an economic analysis of regulation. Accordingly, this section of the chapter explains the main forms of

²⁴⁴ Katz, above n 89, 32.

²⁴⁵ Ibid.

²⁴⁶ Ibid.

²⁴⁷ Ibid.

²⁴⁸ Ibid.

²⁴⁹ Ibid.

economic analysis, including cost-benefit analysis, before applying cost-benefit analysis to the regulation of advertising of medicinal products.

2.9.1 Economic Analyses of Regulation

The economic evaluation of regulation ordinarily consists of four main types of analysis: (1) cost-benefit analysis; (2) cost-effectiveness analysis; (3) cost-utility analysis and (4) cost-minimization analysis.²⁵⁰ This chapter, however, examines only two kinds of analysis: (1) the cost-benefit and (2) cost-effectiveness analyses, as these kinds are presumed to be the most suitable forms of analysis for assessing the effectiveness of the regulation of advertising.

2.9.2 Cost-Benefit Analysis and Cost-Effectiveness Analysis of Advertising Regulation

The efficiency and effectiveness of any particular project is ordinarily gauged using either a cost-benefit analysis or a cost-effectiveness analysis.²⁵¹ This section of the chapter explains cost-benefit analysis and applies it to the regulation of advertising. A cost-benefit analysis is, in essence, an analytical tool established by economists to assess if a particular project, when compared with other projects, can be pursued in an efficient manner.²⁵² In cost-benefit analysis, in order to assess the efficacy of a particular initiative, every item is given a value and is quantified in terms of the costs incurred and benefits accrued.²⁵³

In the context of regulating advertising, cost-benefit analysis refers to the analysis of whether the costs of regulating advertising outweigh the benefits derived from it. The costs taken into account are broadly quantified in terms of time spent, or labour employed and

²⁵⁰ Robert J Brent, *Cost Benefit Analysis and Health Care Evaluations* (Edward Elgar Publishing, 2003), 6.

²⁵¹ Fred Anderson, et al., 'Regulatory Improvement Legislation: Risk assessment, Cost-benefit Analysis, and Judicial Review' (2000) 11(1) *Duke Environmental Law & Policy Forum* 89, 92.

²⁵² Brent, above n 250, 7.

²⁵³ *Ibid.*

materials used. The benefits, on the other hand, are assessed by reference to the willingness to pay by the group deemed to benefit from the regulation.²⁵⁴

There have been considerable differences in the findings of among scholars who have applied cost-benefit analysis to the regulation of deceptive advertising.²⁵⁵ In a pioneering analysis, Craswell emphasised the importance of engaging in an explicit cost-benefit analysis in regulating deceptive advertising.²⁵⁶ As Craswell argues:

Deceptive ads should be viewed in the same fashion as potentially dangerous products whose risks must be balanced against the difficulty of reducing those risks.²⁵⁷

In assessing the difficulties of reducing the risks of deceptive advertising, Craswell emphasised the costs involved in doing so, including the costs of using corrective advertisements, inserting qualifying statements or completely removing an advertisement.²⁵⁸ In essence, Craswell argues that corrective advertising, whilst it may rectify the perception of one consumer, may nevertheless be harmful to others, potentially bringing about new injuries which can be more serious than the original deception.²⁵⁹ He also postulates that the corrective language itself deceives other consumers.²⁶⁰ Although corrective advertising is just one form of regulation, Craswell's analysis effectively

²⁵⁴ Anderson, above n 251, 92; *Guide to Regulation 1998* above n 33, B4. The guide suggests that group which is affected by regulatory initiative when assessing costs and benefits This group can range from: '(1) government, business and consumers; (2) commonwealth, state/territory or local government; (3) small, medium and large businesses, importers and exporters; (4) within consumers, groups with different level of ability to process information and (5) within groups, age, language, physical, cultural, gender, family...'. associated with regulation must be identified in such categorisation.

²⁵⁵ Craswell, 'Interpreting Deceptive Advertising', above n 82, 689; Ivan L Preston and Jef I. Richards, 'Consumer Miscomprehension And Deceptive Advertising: A Response to Professor Craswell ' (1988) 68 *Boston University Law Review* 431.

²⁵⁶ Craswell, 'Interpreting Deceptive Advertising', above n 82, 689.

²⁵⁷ *Ibid* 660.

²⁵⁸ *Ibid* 689.

²⁵⁹ *Ibid*.

²⁶⁰ *Ibid*.

illustrates the important point that the costs of regulating advertising may sometimes outweigh the advantages of regulation.

In a similar vein, Craswell argues that regulations that require information to be inserted into advertisements could cause injury, in the sense that too much information, or 'information overload', could cause consumers to miss out on valuable information.²⁶¹ Conversely, and equally importantly, entirely eliminating a deceptive advertisement is also 'costly' to those who are not misled by the advertisements in that there is a loss of valuable information to those who obtain some benefits from the advertisements.²⁶² Consequently, applying Craswell's analysis, the costs incurred from regulatory interventions, such as requiring corrective advertising or prohibiting advertising altogether, must be fully taken into account, and weighed against the harm caused by deceptive advertisements, with a particular form of regulation only being justified if the costs incurred by regulation are less than the harms caused by the advertising.²⁶³

In response to Craswell, however, other scholars have suggested that he over-emphasises the costs of regulation, while under-emphasising the advantages of regulation. For example, Preston and Richards suggest that the extent to which deceptiveness is reduced, and the benefits derived from remedial actions, such as corrective advertising or outright prohibition, outweigh the minimal cost of remedial action.²⁶⁴ Similarly, Schechter, whilst acknowledging Craswell's innovative analysis, observes that Craswell 'overstates the possibility of non-existent alleged costs'.²⁶⁵

Overall, then, despite Craswell's analysis, the overwhelming weight of scholarly opinion supports the view that, in applying a cost-benefit analysis, the benefits of regulating

²⁶¹ Ibid 690.

²⁶² Ibid 680 & 689.

²⁶³ Ibid.

²⁶⁴ Preston and Richards, above n 255, 432 & 437; Richard Craswell, 'Regulating Deceptive Advertising: The Role of Cost Benefit Analysis' (1991) 64 *Southern California Law Review* 549. Craswell's counter-argument was that Preston and Richards were concerned with question of what the advertisement was trying to communicate, and not whether the subjects were persuaded by the advertisement, or what they believed about the advertised product. Craswell was assessing the cost and benefits of deceptive advertising standards and therefore focused on the effect of advertisements on consumers' ultimate beliefs: at 564-565.

²⁶⁵ Schechter, above n 85, 599.

deceptive advertising outweigh the costs of doing so. Craswell's analysis is, however, extremely important in reminding us of the importance of taking into account all of the potential costs in determining the form of regulation to apply to deceptive advertising. For example, it may be that while advertising that actively deceives consumers should be prohibited, some degree of confusion may be acceptable if an advertisement also communicates valuable information. Moreover, it may be that not all corrective advertising has positive effects, suggesting that if corrections are ordered, care should be taken in formulating the kind of corrections mandated.

The application of cost-benefit analysis to matters concerning public health is sometimes criticised, with cost-effectiveness analysis claimed to be more suitable.²⁶⁶ In cost-effectiveness analysis, as opposed to cost-benefit analysis, the cost of a project is quantified in terms of monetary value and this is compared with the benefits measured in natural units, for example, the number of years of human life that are saved.²⁶⁷ The reluctance to place a monetary value on human life in order to quantify the costs and benefits explains why some have claimed that cost-effectiveness analysis should be preferred in the context of analysing the regulation of matters relating to public health, such as the advertising of medicinal products.²⁶⁸ The difficulties encountered in adequately taking into account the relatively intangible values associated with health effects, however, means that, in practice, it is quite difficult to apply cost-effectiveness analysis to the regulation of advertisements of medicinal products.²⁶⁹ Nevertheless, the importance of fully taking into account the value of human life, and the importance of good health, suggests that we should err on the side of caution in regulating areas that have important effects on community health. Therefore, although as Craswell suggests, the costs of regulation need to be fully recognised, there is a good case to be made, when it comes to regulating the advertising and supply of potentially harmful medicinal products, for regulation to err on the side of over-deterrence rather than under-deterrence.

²⁶⁶ Brent, above n 250, 8; Anderson above n 251, 93.

²⁶⁷ See Anderson above n 251, 92.

²⁶⁸ Ibid 93.

²⁶⁹ *Galbally Review*, above n 102, 17.

Having introduced the rationale for regulating deceptive advertising at [2.3], and the economic analysis of regulation at [2.9], we are now in a position to examine the regulation of the advertising of medicinal products, which is undertaken immediately below.

2.9.3 Economic Analyses for the Regulation of the Advertising of Medicinal Products

The essential starting point for the analysis of the regulation of advertising of medicinal products is to identify the main objective of regulation which, as explained at [2.5] and [2.6] above, is to redress the information asymmetry which gives rise to consumers having inadequate or incorrect information about medicinal products.²⁷⁰ To achieve this objective, regulation must affect a change in the behaviour of those who disseminate deceptive advertisements. In doing so, regulation must balance the advantages of protecting consumers from deceptive or harmful regulation against the costs of regulation. In order to assess the appropriate level of regulation, this thesis applies a cost-benefit analysis, relying mainly on the analysis carried out by the Galbally Review in evaluating the Australian regulatory regime. Although this thesis considers that a cost-benefit approach is justified, it is important to bear in mind that the main objective of the Galbally Review was essentially to analyse the effects of the Australian regulatory regime on competition, which clearly influenced it in adopting the cost-benefit approach.

The Galbally Review conducted a comprehensive cost-benefit analysis of the efficiency of regulatory controls of drugs, poisons and controlled substances, which include medicinal products. In doing so, it reviewed the extent to which the benefits of the controls outweigh the costs incurred from regulation. In general terms, the approach adopted by the Review involved an analysis of:

- the objectives of the legislative controls, including the nature and the magnitude of the health problem that the controls seek to address;
- whether controls would restrict competition, including the likely effect of any restriction on competition and the economy;
- whether there are non-regulatory ways to achieve this;

²⁷⁰ Ibid 51.

- the costs and benefits of and the overall effects of the drugs, poisons, and controlled substance legislations and alternative less restrictive approaches and
- the extent to which the level of controls may be reduced, without compromising on achieving the objectives and in doing so, increase competition.²⁷¹

Applying the cost-benefit approach, the Galbally Review concluded that a comprehensive system of regulatory control of poisons and medicinal products is essential as it provides a net benefit to the community, largely in the form of addressing the adverse health effects that would occur in the absence of regulation. Taking into account the costs of regulation, however, the Review recommended reducing the level of regulation in some areas, including: (1) some aspects of advertising; (2) supply of product samples; (3) licensing and (4) recording and reporting.²⁷² This thesis focuses on the Review's analysis of the regulation of advertising.

To begin with, the Review identified the important benefits that flow from the regulation of advertising of medicinal products, namely, preventing:

- inappropriate use of medicines where doctors have succumbed to patient pressure to prescribe;
- undermining of doctor-patient relationships;
- confused and misinformed consumers;
- anxiety through exaggerated promotion of disease risks;
- wide use of medicines in community, without adequately taking into account the risks;
- increased harm and possibly fatalities, especially with self-diagnosis;
- acceptance of medicines as 'life solutions', rather than preferable alternatives, such as diet and exercise;

²⁷¹ Ibid 2

²⁷² Ibid 49.

- escalation of costs to subsidised medicines and patients' visits to doctors, especially where consumers engage in 'doctor shopping'.²⁷³

As can be seen, all of these potential harms arise from the information asymmetry between industry and consumers. As opposed to the benefits of addressing these harms, however, the Review was careful to note that, even in the absence of regulation, there are important potential benefits that may arise from the advertising of medicinal products. Consequently, the Review pointed out that, provided advertising is informative and constructive, it could result in the following benefits which flow from greater consumer information:

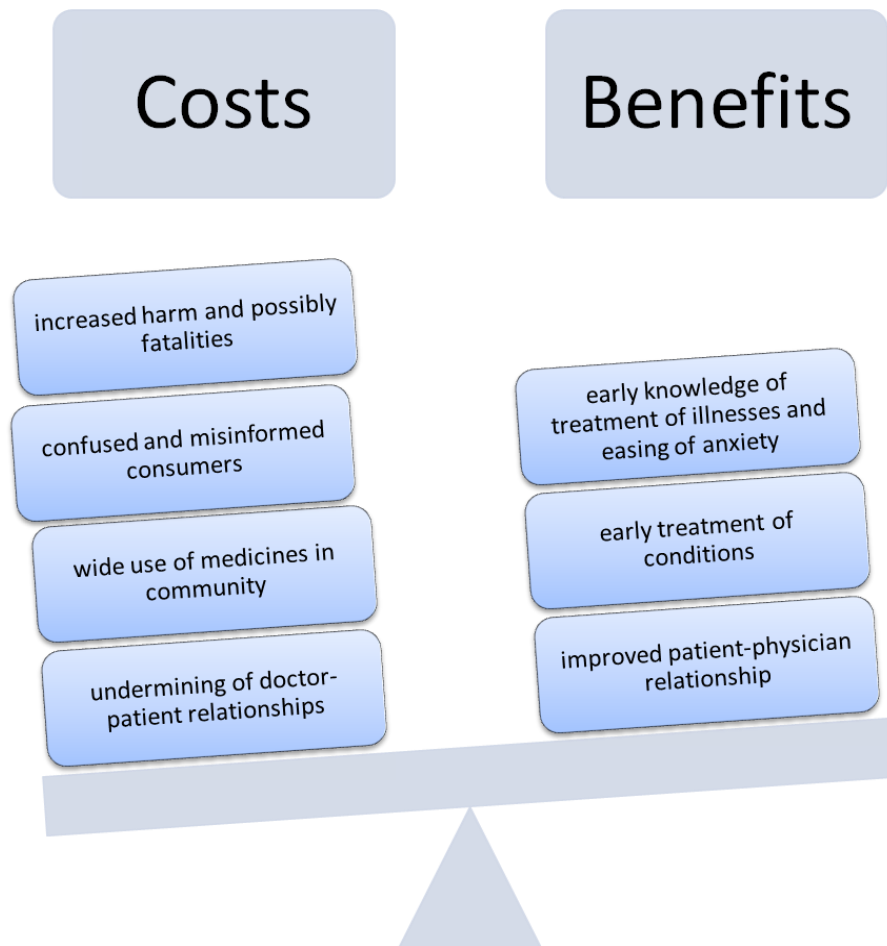
- Some doctors may react constructively to consumer pressure.
- The doctor-patient relationship may, in some cases, be improved.
- There may be earlier knowledge of treatment possibilities, which can reduce anxiety.
- There may be earlier treatment of medical conditions.
- In some cases, self-diagnosis may be beneficial, and may lead to consumers presenting to health professionals.
- Innovative new medicines may be promoted.²⁷⁴

The relative costs and benefits of advertising of medicinal products are summarised in the accompanying Diagram 2.2.

²⁷³ Ibid 52.

²⁷⁴ Ibid.

Diagram 2.2 Costs & Benefits of Advertising of Medicinal Products



As the Review pointed out, and as suggested by those who favour cost-effectiveness analysis, the application of cost-benefit analysis to medicinal products is controversial in public health analysis. Nevertheless, while not precisely identifying all costs and benefits, the Review concluded that it was possible to form an assessment of, firstly, the desirability of regulating advertising and, secondly, the costs and benefits of particular forms of regulation.

Firstly, regarding the desirability of regulation, the Review acknowledged that regulation that prevents or restricts advertising imposes costs. In particular, the Review emphasised the costs that arise from preventing suppliers of medicines from competing freely in the market through advertising. In other words, if a supplier cannot advertise to consumers, it is effectively prevented from differentiating its products from competitors. Despite the costs, however, the Review concluded that, on balance, regulatory restrictions on advertising are justified because of the potential for very high costs to the community (which the Review referred to as ‘the known potential for tragic risk’) if advertising is not regulated.²⁷⁵ In this respect, the Review stated:

To remove all regulation of medicines and poisons would give rise to too many points of possible failure in the health system for the public interest to be served and significantly erode the benefits they provide. Each hazard point inherent in the risks of harm ... can be shown to exist. The precise probabilities of each of them occurring are often unclear, but there are so many hazards that the overall likelihood of harm is high.²⁷⁶

In other words, in the important area of public health, the Review favoured the application of what is known as the ‘precautionary principle’, meaning essentially that where risks to health are high, it is better to err on the side of caution.

Secondly, however, while acknowledging the need for the regulation of advertising, the Review pointed out that not all forms of regulation are necessarily good. Applying an approach suggested by the need to balance over-regulation and under-regulation explained at [2.8] above, the Review concluded that, in assessing the appropriate form of regulation, it is necessary to take into account the costs of different kinds of regulatory controls. In undertaking this analysis, the Review distinguished between regulatory restrictions that apply to advertising prescription medicines and restrictions on advertising pharmacy-only medicines.

²⁷⁵ Ibid 53.

²⁷⁶ Ibid.

Prescription medicines, which are medicines that are only available to consumers with a prescription from a doctor, can be advertised directly to consumers in the United States, but not in Australia or Malaysia. In examining the different regulatory regimes, the Review concluded that there would be no net public benefit in relaxing the restriction on direct-to-consumer advertising (DTCA) of prescription medicines in Australia. In reaching this conclusion, the Review was especially concerned at the potential effects of unrestricted advertising on consumers, who do not have the training and experience of health professionals. For example, the Review considered that permitting advertising to consumers would be likely to increase the demand for new and high-priced medicines, perhaps at the expense of cheaper but effective alternatives.²⁷⁷ Moreover, the Review suggested that permitting direct-to-consumer advertising of medicinal products would increase the costs of treatment, as doctors would need to spend time explaining why a heavily advertised product may not necessarily be the best treatment. These issues are taken up in more detail in Chapter 6 of this thesis.

Pharmacist-only medicines are medicines that do not necessarily require a prescription, and are only available from a pharmacy. As explained in Chapter 4, in Australia, some limited advertising of pharmacist-only medicines is permitted under a form of co-regulation. In applying a cost-benefit approach to the question of whether advertising of pharmacist-only medicines should be permitted, the Review pointed out that, in this case, the level of harm that might result from advertising depends upon the effectiveness of supervision by pharmacists.²⁷⁸ Moreover, the Review also noted that the dangers to health, and hence the potential costs, are much less for pharmacist-only medicines than for prescription-only medicines.²⁷⁹ Even so, however, applying the precautionary principle, the Review concluded that there was no case for further relaxing the restrictions on advertising pharmacist-only medicines.

²⁷⁷ Ibid 56.

²⁷⁸ Ibid 57.

²⁷⁹ Ibid 58.

In reaching this conclusion, the Review stated that:

... relaxation of the advertising controls would lead to an increase in the number of poisoning and medicinal misadventure incidents because of increased consumption. There will always be a proportion of poisonings and medicinal misadventures which are unpredictable. While the numbers of such adverse events could be expected to increase with increased consumption, the level of such adverse events when compared with the number of units consumed may not change.²⁸⁰

As with the issue of direct-to-consumer advertising of prescription medicines, this issue is explored in more detail in Chapter 6 of the thesis.

If we apply the cost-benefit approach adopted by the Galbally Review to the regulation of the advertising of medicinal products, we therefore reach the following preliminary conclusions. Firstly, in dealing with vital public health issues, cost-benefit analysis must be careful to take into account the potential for tragic consequences to health and life. This therefore suggests that, in designing a regulatory regime, we should apply the precautionary principle, and err on the side of minimising risks to health and life. Secondly, however, it is important to recognise that there are some benefits in permitting advertising, such as a potential increase in consumer information, and increased competition. Thirdly, in examining the precise regulatory controls to apply to advertising, it is important to take into account all potential costs and benefits, including the costs of regulation. Fourthly, and finally, if we apply the precautionary principle, there is good case for prohibiting advertising to consumers of some medicinal products, particularly those that represent a high health risk. The question then becomes one of determining the appropriate shape of the regulatory regime, such as determining the mode of regulation. The general cost-benefit analysis introduced in this chapter is applied in more detail to particular regulatory issues in Chapter 6 of the thesis.

²⁸⁰ Ibid 58.

2.10 CONCLUSION

Regulating advertising is a complicated and expensive business and may require a combination of techniques in addition to regulation; nevertheless, regulation is ordinarily viewed to be better suited to manage or prevent market abuses, or protect society from harm caused by deceptive advertising.

This chapter examined various issues concerning regulation for the purpose of ascertaining the characteristics of a suitable mode of regulation for the advertising of medicinal products. It examined the meaning and rationale of regulation, to enable a better understanding of the role of regulation and the justification for the restrictions that result from regulation. It also explored the best practice of regulation which government ought to consider when determining an appropriate mode for regulating the deceptive advertising of medicinal products.

The chapter contrasted the government regulation with alternative modes of regulation and highlighted the advantages and disadvantages of the different modes of regulation. In order to assist decision making regarding the adoption or rejection of a particular mode of regulation, the chapter examined the economic analyses which are appropriate for the regulation of deceptive advertising of medicinal products. It contrasted two forms of economic analyses: (1) the cost-benefit analysis and (2) cost-effectiveness analysis, and highlighted the debate surrounding the use of cost-benefit analysis in matters concerning healthcare.

The following finding emerges from the examination in this chapter: that the term 'regulation' is broadly defined and regulation is used as a mode to control behaviour or conduct across a broad spectrum of field. The idea of regulation gradually grew to encompass both governmental and non-governmental control. Non-governmental regulation which is referred to as the alternative mode of regulation in this chapter has certain benefits over the 'command and control' model, but its success is dependent upon several factors. In between government and purely non-governmental regulation (or self-regulation), lies co-regulation and enforced self-regulation, which is viewed favourably by most Western countries since it possess the flexibility, specialised skills and resources for effective regulation, and is backed by legal sanctions.

It was noted that the regulation of advertising of medicinal products required a careful analysis of the informative value of advertising. Whilst it was necessary to propose a more stringent regulation for the advertising of medicinal products than those of most other types of products, care had to be paid to the informative value that such advertising provides. It was also noted that regulation must balance the advantages of protecting consumers from harm caused by deceptive advertising against the cost of regulation. Hence, the determination of an appropriate form of regulation necessitated that an economic analysis which weighed all costs and benefits of the regulation, be carried out.

This thesis relies heavily on the cost-benefit analysis related to the regulation of medicinal products presented in the Galbally Review. The Review, having considered all costs associated with the regulation and the benefits which may potentially be achieved from such advertising, essentially took the stance that it may be advisable to restrict advertising of prescription drugs as such advertising presents a high risk to consumers. However, it found no case for further relaxing the restrictions on advertising of pharmacist-only-medicines as this poses less risk to consumers.

The main arguments put forward in the chapter are intended as an introduction to the analysis to be used in Chapter 6 which compares amongst other things, the mode of regulation of the advertising of medicinal products in Malaysia (government regulation), with the modes utilised in Australia (co-regulation) and the United States (government regulation). The next part of this thesis, which consists of Chapters 3, 4 and 5, examines the regulation of the advertising of medicinal products in the three jurisdictions mentioned above, namely, Malaysia, Australia and the United States, respectively. These chapters discuss and analyse how the advertising of medicinal products is regulated in those respective jurisdictions.

CHAPTER 3

AN OVERVIEW OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS IN MALAYSIA

3.1 INTRODUCTION

This chapter examines the regulation of advertising of medicinal products in Malaysia in order to prepare the ground for a comparative analysis in Chapter 6. This chapter is divided into five (5) main sections.

Section [3.2] of the chapter examines the types of products which fall within the classification of medicinal products. Products sold as medicinal products are commonly known as drugs in Malaysia and are regulated by the Drug Control Authority under the *Control of Drugs and Cosmetics Regulations 1984* Malaysia. These products broadly include prescription drugs (PD) and non-prescription drugs (NPD) and products which fall in the interfaces between 'food and drugs' or 'food and cosmetics'.

Section [3.3] of the chapter investigates the rules which are applied in the regulation of advertising of medicinal products. The advertising rules in Malaysia are prescribed in various pieces of legislation, depending on the types of goods and services being offered to the consumer. In respect of medicinal products, four pharmaceutical laws which include: (1) the *Medicines (Advertisement and Sale) Act 1956* (Malaysia); (2) the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia); (3) the *Poisons Act 1952* (Malaysia) and (4) the *Sale of Drugs Act 1952 (Revised 1989)* (Malaysia), and the accompanying regulations (Malaysia) govern the advertising. In addition, laws which include: (1) the *Consumer Protection Act 1999* (Malaysia), (2) the *Trade Descriptions Act 1972* (Malaysia) and (3) *Indecent Advertisement Act 1953* (Malaysia) that govern the advertising in general are also examined.

The pharmaceutical industry is also governed by regulatory codes and guidelines, namely (1) *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia); (2) the *Guidelines on Medical Products and Appliances 2009* (Malaysia) and (3) the *Guidelines for Controls of Cosmetic Products 2009* (Malaysia). These are also explored.

The regulatory control employed in the regulation of the advertising of medicinal products is reviewed in section [3.4.] of this chapter. The control is based upon a model of statutory regulation. Two federal authorities: (1) the Medicine Advertisement Board (MAB) of the Pharmaceutical Services Division of the Malaysian Ministry of Health and (2) the Drug Control Authority of the National Pharmaceutical Control Bureau (NPCB) of the Malaysian Ministry of Health, share the responsibility of ensuring compliance with the regulation.

Section [3.4] of the chapter also examines whether all advertisements of medicinal products are subject to a compulsory pre-market approval by the MAB when the product is registered with the Drug Control Authority. It also explores the implication of the failure to obtain the necessary pre-market approvals. Further, this section investigates the monitoring and the enforcement of violations of law. The extent to which the monitoring and the enforcement of violations of law have been successful in preventing future deceptive advertising of medicinal products is investigated.

Section [3.5] of the chapter concludes with an analysis of the limitations in the system. It makes the observation that the existing system for regulating the advertising of medicinal products has flaws at two stages: before and after the dissemination of advertisements, and that the system lacks adequate resources to monitor deceptive advertising. In addition, the system of judicial enforcement has drawbacks, which deters adequate enforcements.

3.2 CLASSIFICATION OF MEDICINAL PRODUCTS IN MALAYSIA

In Malaysia, drugs are defined broadly so as to include products which are intended for medicinal purposes. Under section 2 of the *Sale of Drugs Act 1952* (Malaysia), the term 'drug' is defined as '[including] any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for medicinal purposes'. The term 'medicinal purposes' is further elaborated to mean any of the following purposes: '(a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease; (b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition; (c) contraception; (d) inducing anaesthesia; (e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function; (f) controlling body weight; and (g) general maintenance or promotion of health or well-being'.¹

A range of products that are intended to be used for medicinal purposes may fall within the classification of drugs by this definition. Products such as food, dietary supplements and cosmetics (hereafter referred to as health-related products (HRPs)) may also qualify as drugs. Instances when these products fall within the classification of drugs and the implications of the classification are explored in this section.

3.2.1 Range of Products Classified as Medicinal Products

As noted in [1.5] of Chapter 1, the term 'medicinal products' ordinarily refers to products with medicinal value or products that are claimed to be used for medicinal, remedial or therapeutic purposes, such as diagnosing, curing, mitigating, treating or preventing diseases. However, under the Malaysian regulatory regime, products may be categorized as medicinal products if they fall within the scope of definition of the term 'drug'. Under this definition, both prescription drugs and non-prescription drugs are medicinal products. HRPs however, may be categorized as medicinal products, if found used or intended to be used for medicinal purposes. Section [3.2.1.1] discusses the manner in which prescription

¹ See *Sale of Drugs Act 1952* (Malaysia) s 2.

drugs and non-prescription drugs are described, and [3.2.1.2] – [3.2.1.4] set out instances when HRP's are classified as medicinal products.

3.2.1.1 Prescription Drugs and Non-Prescription Drugs

Two classes of drugs are distributed in Malaysia: (1) prescription drugs and (2) non-prescription drugs.² The terms, prescription drugs and non-prescription drugs, are not defined in the legislation. A prescription drug is, however, known as a pharmaceutical product in Malaysia. It is defined as '...any pharmaceutical or biological product (irrespective of patent status and/or whether it is branded or not) which is intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.'³

The difference between prescription drugs and non-prescription drugs lies in the fact that prescription drugs can only be obtained through a physicians' prescription, whereas non-prescription drugs do not require a prescription.⁴ The composition and ingredients of prescription drugs are considered to be potentially harmful to patients and consequently a prescription by physician is a prerequisite. Non-prescription drugs, on the other hand, are drugs which are considered to be relatively safe because of their low potential for side effects and contraindications.⁵ They are drugs used by consumers to treat symptoms by self-medication.⁶ In addition, there is also a category of non-prescription drug, known as pharmacy-only-medicines (POM), which do not require a physician's prescription, and can only be sold in a pharmacy under the supervision of a pharmacist.

² See Drug Control Authority, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia, *The List of Registered or Notified Products* <http://www.bpfk.gov.my/search/search_product.asp>. ('*The List of Registered or Notified Products*').

³ See the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) s 1.2.

⁴ It may be noted that the term 'prescription' is defined as 'any written or oral instructions to the seller or supplier to supply any poison or medicine containing any poison, for the purposes of the medical, dental or animal treatment of any person or animal, given by any person', under section 24(2) of *Poisons Act 1952* (Malaysia).

⁵ *The List of Registered or Notified Products*, above n 2.

⁶ *Ibid.*

If prescription and non-prescription drugs are marketed in a pharmaceutical dosage and intended to be used or used for medical purposes, irrespective of whether they are manufactured in Malaysia or imported, they are required to be registered with the Drug Control Authority of the Ministry of Health. The Drug Control Authority is the executive body established under the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia).⁷ It is charged with ensuring that safe, quality and effective pharmaceutical products are distributed in Malaysia.⁸ It is responsible for implementing the registration scheme for: (1) pharmaceutical products which contain scheduled poisons; (2) pharmaceutical products which do not contain scheduled poisons and are other than traditional medicines; (3) traditional medicines (as from 1 January 1992) and (4) cosmetics.⁹

Drugs are listed in the National Essential Drugs List (NEDL), which provides a catalogue of registered (or notified products) based on active ingredients.¹⁰ The list consists of two parts, namely (1) the essential drugs list and (2) the supplementary list. The essential drugs list includes 'preparations needed for primary and secondary healthcare treatments commonly used by medical officers and paramedics in primary healthcare facilities'.¹¹ The category contains 358 chemical entities and 605 preparations.¹² The supplementary list consists of drugs used by specialist for tertiary level treatment, and contains 257 chemical

⁷ *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) s 3.

⁸ See the Drug Control Authority, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia, *Introduction to DCA* <<http://www.bpfk.gov.my/>>.

⁹ *Ibid.*

¹⁰ See *The List of Registered or Notified Products*, above n 2. The online database is a cumulative list comprised of drugs registered with the Drug Control Authority. Items listed includes: (1) the products; (2) the registration numbers in the form of (MALxxx); (3) the notification numbers (NOTXXXXK), which is applicable only for cosmetics; and (4) the name of product registration holders or manufacturers. The registration for product takes the following format, MAL200824420T or MAL200825567X. The alphabetical code at the end of the numeric code indicates the classification under which the products are registered. For example, the alphabetical code A is used for products classified as scheduled medicines, X for those classified as non-scheduled medicines, T for traditional medicines, K for cosmetics, C for contract manufactured, E for export only, R for repacked and S for second source. See *The List of Registered or Notified Products*, above n 2.

¹¹ See National Pharmaceutical Control Bureau, Ministry of Health Malaysia, *National Essential List of Registered or Notified Products* <<http://www.pharmacy.gov.my/html/nedl.htm>>. ('*National Essential List of Registered or Notified Products*').

¹² *Ibid.*

entities and 391 preparations.¹³ Both these lists enable those who prescribe, manufacture or use drugs to identify the category of drugs.¹⁴ The categorisation of drugs is reviewed and updated regularly.¹⁵

3.2.1.2 Food

Food products are regulated under the *Food Act 1983* (Malaysia) and *Food Regulations 1985* (Malaysia). Food is defined as ‘include[ing] every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation, preservation, of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substance’, under section 2 of the *Food Act 1983* (Malaysia).

The *Food Act 1983* (Malaysia) aims to ‘protect the public against health hazards and fraud in the preparation, sale and use of food, and for matters incidental thereto or connected therewith’.¹⁶ *Food Regulations 1985* (Malaysia) was established by the Minister under the powers conferred in section 34 of the *Food Act 1983* (Malaysia).¹⁷ The regulations prohibit certain claims in the labels and advertisements; medicinal or therapeutic claims are included.¹⁸

¹³ Ibid.

¹⁴ Ibid

¹⁵ See *List of Registered or Notified Products*, above n 2.

¹⁶ See Preamble of the *Food Act 1983* (Malaysia).

¹⁷ The regulation of nutrient labeling and claims was gazetted in 2003. See P.U. (A) 88/2003 of the *Food Act 1983* (Malaysia).

¹⁸ *Food Regulations 1985* (Malaysia). The point is that the rules which are applicable to label is also applicable to advertisements. The term ‘label’ is defined as ‘[including] any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, painted, embossed, or impressed on, or attached to or included in, belonging to, or accompanying any food’ under section 2 of the *Food Act 1983* (Malaysia). The definition of the term ‘label’ is broad and could be argued as inclusive of advertising, in the absence of any express exclusion. Further, the term ‘accompanying’ in the definition of label could be widely construed as including advertising. The term ‘advertisement’ is defined as ‘[including] any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or other disposal of any food’ under section 2 of the of the *Food Act 1983* (Malaysia).

Claims which are prohibited under the regulation include words reflecting the following: (1) an indication that ‘...food will provide adequate source of all essential nutrients except as otherwise permitted...’ under the regulations¹⁹ or (2) an implication that consuming a ‘...balanced diet or combination of variety diet cannot supply adequate amount of all nutrients’.²⁰ Further, the use of the word ‘pure’ is prohibited unless the food is of the ‘strength, purity or quality prescribed by the regulation and is free from any other added substance apart from those essential in the processing of such food...’.²¹ In addition, words such as ‘compounded’, ‘medicated’, ‘tonic’ or ‘health’, or any other words of the same significance are also not permitted, unless it is in accordance with the regulations.²² Despite claims of an ‘absence of beef or pork or its derivatives, lard or added alcohol, if foods ...or [their] additives contain them’ they are similarly prohibited,²³ unless they are a substance to which the regulations do not apply or one that consumers expect to find in food.²⁴ Consequently, the making of these claims would result in the commission of an offence which is punishable with imprisonment for a term not exceeding three years or a fine or both.²⁵

There are, however, four types of nutrient claims about food that are allowed.²⁶ These are: (1) nutrient content claims about the level of a nutrient contained in a food such as ‘low’ or ‘free’;²⁷ (2) nutrient comparative claims that compare the nutrient levels or energy of two or more foods such as ‘less than’, ‘fewer’, ‘increase’, ‘more than’, ‘light’ or ‘extra’;²⁸ (3) claims

¹⁹ *Food Regulations 1985* (Malaysia) reg 18 (6) (a).

²⁰ *Ibid* reg 18 (6) (b).

²¹ *Ibid* reg 18 (2) (a) and (b).

²² *Ibid* reg 18 (3).

²³ *Ibid* reg 18 (4).

²⁴ *Ibid* reg 18A (1) (a) and (b).

²⁵ *Food Act 1983* (Malaysia) 17 (1).

²⁶ *Food Regulations 1985* (Malaysia) reg 18A (3).

²⁷ *Ibid* reg 18C (1).

²⁸ *Ibid* regs 18D (1) and (2).

for enrichment, fortification or other words of similar meaning²⁹ and (4) nutrient function claims that describe 'the physiological role of the nutrient in the growth, development and normal functions of the body'.³⁰

The nutrient function claims are not to imply or state that the nutrient could cure, treat or prevent a disease,³¹ but they are allowed to state that; (a) calcium aids in the development of strong bones and teeth; (b) protein helps build and repair body tissues; (c) Iron is a factor in red blood cell formation; (d) Vitamin D helps the body utilize calcium and phosphorus; (e) Vitamin B1/Thiamine is needed for the release of energy from proteins, fats and carbohydrates; (f) Vitamin B2/Riboflavin is needed for the release of energy from protein, fats and carbohydrates; (g) Niacin is needed for the release of energy from proteins, fats and carbohydrates; (h) folic acid is essential for growth and division of cells; (i) Vitamin B12/Cyanocobalamin is needed for red blood cell production; (j) Vitamin C enhances absorption of iron from non-meat sources; or (k) Magnesium promotes calcium absorption and retention.³²

Ordinarily, health claims regarding food products will be published in a pyramid structure, which comprises a variety of food that provide all nutrients required for good health. Cereals and grains are at the base of the pyramid where the largest portion that must be consumed for maintenance of good health is stipulated. This is followed by fruits and vegetables, fish, chicken, lean meat, beans, tofu and a glass of milk.³³ The top level of the pyramid indicates those foods to be least consumed because of their negative impact on health. Those foods include salt, oils and sugar.³⁴

Diagram 3.1 shows the pyramid structure for healthy consumption.

²⁹ Ibid reg 26 (7). Claims are permissible if the reference quality as specified Table 11 of the Twelfth Schedule is complied with.

³⁰ *Food Regulations 1985* (Malaysia) reg 18E (1).

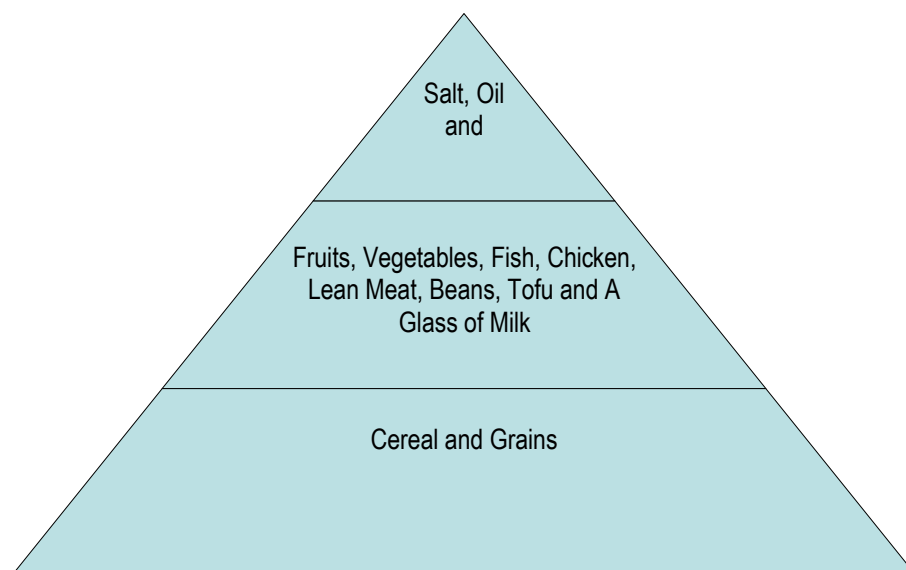
³¹ Ibid regs 18E (2).

³² *Food Regulations 1985* (Malaysia) reg 18E (4). There are not permissible unless the written approval of the director is obtained.

³³ See generally Fatimah Arshad, 'Functional Foods from the Dietetic Perspective in Malaysia' (2003) *The Journal of the Dietitians Association of Australia*.

³⁴ Ibid.

Diagram 3.1 Pyramid Structure for Healthy Consumption



There is a category of food, namely 'special purpose food' that carries health-related claims in its advertisements and yet is not classified as a medicinal product. 'Special purpose food' is 'food ...described as particularly suitable for consumption by persons requiring special nutritional needs'.³⁵ This includes: (1) infant formula;³⁶ (2) follow-up formula;³⁷ (3) canned food for infants and children;³⁸ (4) cereal-based food for infants and children;³⁹ (5) low energy food;⁴⁰ (6) formula dietary food⁴¹ and (7) special dietary food with

³⁵ *Food Regulations 1985* (Malaysia) reg 388 (1).

³⁶ Infant formulas are food sold as 'an alternative for human milk for the feeding of infants' under this regulation. Ibid reg 388 (1).

³⁷ Follow-up formulas are described as food 'intended for use as a liquid part of the weaning diet for an infant from sixth months on and for children'. See Ibid reg 389A (1).

³⁸ Canned food for infants and children are explained as 'any wholesome food or mixtures of wholesome food that is sold as suitable for feeding to infants or specifically suitable for feeding to children', under this regulation. Ibid reg 390 (1).

³⁹ Cereal-based food for infants and children is comprised of 'cereals, nuts or legume or a combination of these and flour derived from them, cooked or uncooked, which may be enzyme treated and so fragmented as to permit dilution with water, milk or other suitable liquid'. Ibid reg 391 (1).

⁴⁰ Low energy food is 'special purpose food that is particularly suitable for a person adopting a restricted energy diet'. Ibid reg 392 (2).

low sodium content including salt substitutes.⁴² This category of food is designed to satisfy particular dietary requirements which exist because of a 'physical or physiological conditions or specific disease or disorder'. Foods within this category may pledge claims reflecting their specific purposes, general medicinal or therapeutic claims are, however, not permitted.⁴³

There is also a category of products sold in the Malaysian market which is not described as either a food or a drug. These are generally termed as the product in food and drug interface.⁴⁴ Food may fall under the category of 'food and drug interface', by virtue of its intended use, compositions or ingredients.⁴⁵ When it does, the need is to decide on whether such a product is essentially food or drug, and which authority regulates it. If it is food, it would be regulated by the Food Safety and Quality Division (FSQD), and if it is a drug, it would be supervised by the National Pharmaceutical Control Bureau (NPCB).⁴⁶ However, if there is uncertainty, the product is referred to the Committee for Classification of Food and Drug Interface Product. This Committee resolves the issue by using a method of 'percentage calculation' of food ingredients and its therapeutic properties, or by the claims and indication in advertisements or labelling.⁴⁷ For example, food which contains '80% or more of food ingredients than pharmacological and/or therapeutic properties' is considered food.⁴⁸ Alternatively, food which contains more than '80% of pharmacological

⁴¹ Formula dietary food is food described on label as 'being suitable for a complete diet when consumed in accordance with direction contained in the label'. See Ibid reg 393(1).

⁴² Special dietary food with low sodium content including salt substitutes is food with 'special dietary value as the result of the reduction, restriction or removal of sodium and includes salt substitutes with low sodium content'. See Ibid reg 393A (1).

⁴³ See *Food Regulations 1985* (Malaysia) reg 18 (6)(d).

⁴⁴ Food Safety and Quality Division, Ministry of Health, Malaysia, *Guide to Classification of Food-Drug Interface Products* Appendix 1 <http://fsq.moh.gov.my/modules/xt_conteudo/index.php?id=220> ('See *Guide to Classification of Food-Drug Interface*').

⁴⁵ See Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Food and Drug Inter-face Advertisements* <http://www.pharmacy.gov.my/html/MAB/advertisement_board_f.htm>.

⁴⁶ *Guide to Classification of Food-Drug Interface Products*, above n 44.

⁴⁷ Ibid. The 'intended use' of the product is also a basis for deciding whether it should be classified as food or a drug.

⁴⁸ *Guide to Classification of Food-Drug Interface*, above n 44.

and/or therapeutic properties' is treated as drugs.⁴⁹ Products, which are considered 'pure form', that is close to 100% of food ingredients comprise vitamins, minerals, amino acids, fatty acids, fibre, enzymes', are classified as food.⁵⁰ Also, products containing 'solely natural ingredients that are not traditionally used as food and possess medicinal value, such as alfalfa, spirulina, royal jelly, noni juice, rooibose tea and other herbal products' are considered as drugs.⁵¹ These are, in essence, functional food. When is unclear whether a product is a drug or food, it is usually treated as a drug and regulated by the NPCB.⁵²

3.2.1.3 Nutrient Supplements

Products that enrich or complement a person's diet are referred to as 'nutrient supplements' in the *Food Act 1983* (Malaysia) and *Food Regulations 1985* (Malaysia). Nutrient supplements are articles or substances that 'include any mineral, vitamin, amino acid, or nucleotide which, and when added, either singly or in combination to food, improves or enriches the nutrient content of food'.⁵³ For these supplements, nutrients claims as prescribed in Table 1 of the Twelfth Schedule of the *Food Regulations 1985* (Malaysia) are permitted,⁵⁴ however, therapeutic claims are not permitted.⁵⁵

3.2.1.4 Cosmetics

Cosmetics are governed by the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia), which was promulgated under section 26 (1) of *Sale of Drugs Act (1952)* (Malaysia).⁵⁶ Cosmetics are also subject to the requirements under the ASEAN Cosmetics

⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² Ibid.

⁵³ See the *Food Regulations 1985* (Malaysia) reg 26(1).

⁵⁴ Ibid reg 26 (1).

⁵⁵ Ibid reg 18(6)(d).

⁵⁶ Section 27 of *Sale of Drugs Act (1952)* (Malaysia) provides that 'the provisions of this Act so far as they are applicable may be extended by regulations made under this Act to apply to tobacco, cigars, cigarettes, snuff, soap, cosmetics and toilet preparations in like manner as the said provisions apply to drugs'.

Directives, which, in Malaysia, are mirrored in the *Guidelines for Control of Cosmetic Products 2009* (Malaysia).

Cosmetics were initially subject to registration with the Drug Control Authority prior to being manufactured, sold, supplied, imported or possessed for sale under section 7 (1) (a) of the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia); However, they are currently subject to notification. Commencing from 1 January 2008, the system of registration of cosmetics has been replaced by a system of notification.⁵⁷ This system requires manufacturers and advertisers to declare their compliance with the ASEAN Cosmetic Directive to the NPCB.⁵⁸

Cosmetics are broadly defined as 'any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, on the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or teeth and the mucous membranes of the oral cavity for the exclusive or main purpose of cleaning, perfuming or protecting them, or keeping them in good condition, or changing or modifying their appearance, or correcting body odours', under section 2 of the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia). Three basic criteria are used to decide whether a product is a cosmetic. There are: (1) the site of application; (2) the intended purpose and (3) the composition and ingredients. First, cosmetic products include products that are applied or placed on the external parts of the human body.⁵⁹ They do not appear to include those products which are internally consumed or injected. Second, if the purpose of these products is to clean, perfume, change appearance and/or correct body odours and/or protect various parts of the human body and keep them in good condition, as opposed to therapeutic purposes, then they are considered as cosmetic.⁶⁰ The third criterion is derived from their composition or ingredients. For classification purposes, an analysis will be made based on the component of the product.⁶¹ The focus of

⁵⁷ See *Guidelines for Control of Cosmetic Products 2009* (Malaysia) s 5.

⁵⁸ National Pharmaceutical Control Bureau, Ministry of Health, Malaysia, *New Procedure for Control of Cosmetics Products in Malaysia* < <http://202.144.202.76/bpfk/index/cfm?menuid=34>>

⁵⁹ See the *ASEAN Cosmetic Claims Guidelines (2007) Appendix III* s 2.

⁶⁰ Ibid.

⁶¹ Ibid.

this thesis is on the classification by way of 'intended use' and therefore this second criterion is discussed further.

A list of the claims which are unacceptable in advertisements for cosmetics is provided in Annex 1 Part 9 of *Guidelines for Control of Cosmetic Products 2009* (Malaysia). Claims regarding dandruff, cellulite, bust contouring, anti-bacteria, caries, hair-loss, acne and mouth wash, are permissible provided no 'functional claims' are made.⁶² For example, advertisements for cosmetics are not permitted to declare that: (1) a hair product could 'eliminate dandruff permanently or restore hair cells, or [that] hair loss can be arrested or reversed'; (2) that 'skin products could prevent, reduce or reverse the physiological changes and degeneration conditions brought about by ageing, or remove scars or [enable a consumer to] lose centimetres...';⁶³ (3) a nail product can enhance growth as a result of its application; (4) that depilatories could stop or retard or prevent hair growth or (5) that deodorants and anti-perspirants could completely prevent sweating or perspiration.⁶⁴ The making of such claims will result in the commission of an offence under section 30(1) and (2) of the *Control of Drugs and Cosmetics (Amendment) Regulation 2007* (Malaysia).⁶⁵

3.2.1.5 Traditional Medicines

Traditional medicine is defined as 'any product used in the practice of indigenous medicine, in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the un-extracted or crude extract form, and a homeopathic medicine'.⁶⁶ 'Homeopathic medicine' is 'any pharmaceutical dosage form used in the homeopathic therapeutics system in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated'.⁶⁷

⁶² Ibid s 3.

⁶³ Ibid.

⁶⁴ Ibid.

⁶⁵ *Guidelines for Control of Cosmetic Products 2009* (Malaysia) s 18.

⁶⁶ See the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) s 2.

⁶⁷ Ibid.

The use of traditional medicine is widespread in Malaysia and is considered to be an important element of the healthcare system. Traditional medicines are regulated as a separate category of products. From 1992, they have been subjected to registration, and from 1997 to Good Manufacturing Practice (GMP).⁶⁸ Further, a National Policy on Traditional and Complementary Medicine (T/CM) was launched in 2001⁶⁹ and then, in 2004, the Traditional and Complementary Medicine Division in the Ministry of Health was established.⁷⁰ A Traditional Medicine Act is also being prepared.⁷¹ Although regulated as a separate category, the advertisements for traditional medicines are not permitted to make medicinal or therapeutic claims, unless they are classified and regulated as drugs.⁷²

3.2.2 Implication of Classification of Products as Medicinal Products.

Advertisements for HRPs such as food, nutrient supplements, and cosmetics are not permitted to carry medicinal or therapeutic claims. If they do, they will be classified and regulated as medicinal products. The implication of classification as medicinal products is that these products are subject to drug safety controls before they are sold to the public. This section examines the drug safety controls which are employed before the products are made available in the market.

Drug safety controls require that products are proven safe and effective through scientific testings before they may be marketed. It also imposes, amongst other things, that (1) drug registrations; (2) quality controls; (3) post-marketing surveillance including adverse reaction;⁷³ (4) drug inspection⁷⁴ or (5) issuance of directives or guidelines to manufacturers

⁶⁸ See Traditional Complementary Medicine, Chronology of Medical System Development in Malaysia <<http://210.19.208/NHICContent/tcm.aspx?contentid=CTN00809>>; Also see generally 'Traditional and Complementary Medicine' (2006) 1(1) *Bulletin BPTK Malaysia* 1.

⁶⁹ Ibid.

⁷⁰ Ibid.

⁷¹ Ibid.

⁷² See the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (1) (a); *Guidelines on Medical Products and Appliances 2009* (Malaysia) s 4.1 (a).

⁷³ *Malaysian National Medicine Policy 2007* s 1.2.2.

regarding quality, safety and efficacy⁷⁵ are carried out so as to monitor their safety during their clinical use.

In Malaysia, continuous availability of safe and effective medicinal products is achieved through a process called 'selection of medicines'.⁷⁶ The selection is made based on an analysis of the 'disease pattern, [a drug's] cost-effectiveness and therapeutic advantage'.⁷⁷ Essentially, this means that medicinal products which are clinically relevant, cost-effective and vital for the management of common diseases affecting the majority of the patients are selected.⁷⁸ The selection is made by a panel called the Ministry of Health Drug List Review Panel, and upon selection, these products are listed in the Ministry of Health Drug Formulary.⁷⁹

It might be useful to note that there is no specific provision in the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) that specifies the standard for the assessment of drug safety and efficacy controls. The requirements to be complied with, however, are stipulated in Guidelines - the *Malaysian Guidelines for Good Clinical Practice 2004* and *Guidelines for Application of (CTIL) and Clinical Trial Import License Clinical Trial Exemption (CTX) 2009* (Malaysia). These guidelines are drawn in accordance to the legal requirement of the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia), *Sale of Drugs Act 1952* (Malaysia) and *Poisons Regulation (Psychotropic Substances) 1989* (Malaysia) where control over substances are stipulated.

The *Malaysian Guidelines for Good Clinical Practice 2004* adopts the basic principle outlined by the International Committee on Harmonization of Good Clinical Practice (ICH-GCP) with some modification to suit local condition. The Guideline provides the requirement to be met with regard to the 'design, conduct, performance, monitoring,

⁷⁴ Ibid.

⁷⁵ See the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) s 29 (1).

⁷⁶ *Malaysian National Medicine Policy 2007* s.2.2.1.

⁷⁷ Ibid.

⁷⁸ National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia, 'Drug Formulary' at <http://www.pharmacy.gov.my/index.cfm?menuid=7#MOH_Drug_Formulary>

⁷⁹ Ibid.

auditing, recording, analyses, and reporting of clinical trials^[80] that provides assurance that the data and reported results are credible and accurate and that the rights and integrity and confidentiality of trial subjects are protected'.⁸¹

The *Guidelines for Application of (CTIL) and Clinical Trial Import License Clinical Trial Exemption (CTX) 2009* (Malaysia) must be complied with if the products are essentially: (1) products including placebos which are not registered with the Drug Control Authority and are intended to be imported for clinical trial purpose; (2) a 'product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for unapproved indication or when used to gain further information about an approved use and (3) 'an unregistered product manufactured locally for the purpose of the clinical trial'.⁸²

In summary, products which are classified as medicinal products are ordinarily perceived to be safer and effective than otherwise, because they are subject to drug safety controls. Drug safety controls include scientific testings to ensure that a product is safe and effective before it is marketed. This control is intended to complement the advertising controls which are carried out after the product is approved for marketing. The advertising controls are discussed in the following section.

⁸⁰ A 'clinical trial' means 'an investigation or series of investigations on persons conducted by or under the direction and supervision of persons with scientific training or experience for the purpose of finding out about, or determining the safety, effectiveness and other aspects of any products'. See the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) s 2.

⁸¹ *Malaysian Guidelines for Good Clinical Practice 2004* s 1.28.

⁸² *Guidelines for Application of (CTIL) and Clinical Trial Import License Clinical Trial Exemption (CTX) 2009* (Malaysia) s 2.

3.3 THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS

The pharmaceutical industry in Malaysia is governed by a combination of legislation, accompanying regulations, Codes of Conduct and industry guidelines. The legislation broadly includes: (1) the *Poisons Act 1952 (Revised 1989)* (Malaysia); (2) the *Sale of Drugs Act 1952 (Revised 1989)* (Malaysia); (3) the *Medicines (Advertisement & Sales) Act 1956 (Revised 1983)* (Malaysia); (4) the *Registration of Pharmacists Act 1951 (Revised 1989)* (Malaysia) and (5) the *Dangerous Drugs Act 1952 (Revised 1980)* (Malaysia). The regulations that accompany each of these Acts also apply. In addition, Cosmetics is governed by the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia).

The Codes of Conduct include: (1) the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia); (2) the *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) and (3) the *Communications and Multimedia Content Code 2004* (Malaysia). The main guidelines are: (1) the *Guidelines on Medical Products and Appliances 2009* (Malaysia) and (2) the *Guidelines for Control of Cosmetic Products 2009* (Malaysia).

The government regulatory bodies that are responsible for the regulation of medicinal products include: (1) the Pharmaceutical Services Division (PSD) of the Ministry of Health, Malaysia; (2) the National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health, Malaysia; (3) the Drug Control Authority of the Ministry of Health and (4) the Medicine Advertisement Board (MAB) of the Ministry of Health. The main self-regulatory bodies that are responsible for the regulation of medicinal products include: (1) the Pharmaceutical Association of Malaysia (the PhAMA); and (2) the Advertising Standard Authority Malaysia (the ASAM). There is also the Communications and Multimedia Content Forum which regulates internet contents.

The advertising of medicinal products is governed by (1) the *Medicines (Advertisement and Sale) Act 1956* (Malaysia); (2) the *Sale of Drugs Act 1952 (Revised 1989)* (Malaysia) and (3) the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia). The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is administered by the MAB, whereas the *Sale of Drugs Act 1952 (Revised 1989)* (Malaysia) and the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia) are administered by the Drug Control Authority. The

advertising of prescription drugs, which is permitted only to members of the medical profession, is governed by the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia), under the aegis of the PhAMA. The self regulatory code, *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia), which governs advertising in general including the advertising of medicinal products, is administered by the ASAM.

This section of the chapter examines the rules governing the advertising of medicinal products, as stipulated in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). The general laws, namely the *Consumer Protection Act 1999* (Malaysia), the *Trade Descriptions Act 1972* (Malaysia) and the *Indecent Advertisement Act 1953* (Malaysia) are also examined. Whilst the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) has drawbacks that impede the regulation of advertising of medicinal products, the general which aim to protect consumers from misleading advertisements are inapplicable to the advertising of medicinal products. These laws are nevertheless discussed because they have the potential to regulate the advertising of medicinal products if certain restrictions are removed, as will be seen in [3.3.1] of this chapter. The self-regulatory codes of practice and industry guidelines are also examined although they are not regarded as definitive statements of law. They are explored because of their potential to play an important role in the regulation of advertising of medicinal products. How comprehensive these laws are in governing the advertising of medicinal products is examined so as to enable an assessment of their effectiveness in regulating the advertising of medicinal products at [6.3.2] of Chapter 6.

3.3.1 Laws that Govern the Advertising of Medicinal Products in Malaysia

3.3.1.1 The *Medicines (Advertisement and Sale) Act 1956* (Malaysia)

The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is the primary legislation that governs the advertising and sale of medicinal products in Malaysia. It prescribes regulations for the advertising of medicines, appliances, remedies, skills and services related to medical and health claims. It prohibits advertising regarding the prevention or treatment of diseases and conditions of human beings as specified in its Schedule. The

types of illnesses or conditions listed in the Schedule to the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) are: (1) diseases or defects of the kidney; (2) diseases or defects of the heart; (3) diabetes; (4) epilepsy or fits; (5) paralysis; (6) tuberculosis; (7) asthma; (8) leprosy; (9) cancer; (10) deafness; (11) drug addiction; (12) hernia or rupture; (13) disease of the eye; (14) hypertension; (15) mental; (16) infertility; (17) frigidity; (18) impairment of the sexual function or impotency; (19) venereal disease; (20) nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse.⁸³ The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) also prohibits the advertising of (1) the ‘practice of contraceptive among human beings’;⁸⁴ and (2) the ‘improve[ment] [of] the conditions or functioning of the human kidney or heart’, or the ‘improve[ment] [of] sexual functions or sexual performance of human beings’.⁸⁵ Advertising relating to a diagnosis of a disease as specified in the Schedule,⁸⁶ abortions,⁸⁷ and skills and services relating to the ‘treatment or prevention or diagnosis of any ailment, disease, injury, infirmity or conditions...’⁸⁸ are also disallowed.

Furthermore, the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) prescribes the requirements for pre-approval of advertisements by the MAB before advertisements are disseminated to the public.⁸⁹ The MAB is the statutory regulatory body or board responsible for the regulation of the advertising of medicinal products. The MAB, established under section 7(a) of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) sets policies, directives and guidelines for advertisements for medicines, appliances, remedies, skills and services that relate to medicinal and health claims. The MAB also deals with matters related to the issue, or the refusal to issue approvals of

⁸³ See the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (1)(a).

⁸⁴ Ibid s 3 (1) (b).

⁸⁵ Ibid s 3 (1) (c).

⁸⁶ Ibid s 3 (1) (d).

⁸⁷ Ibid s 4.

⁸⁸ Ibid s 4A.

⁸⁹ Ibid s 4B.

advertisements and cancellations of approvals of advertisements.⁹⁰ Its powers also include investigations of commission of offences,⁹¹ examination of witnesses⁹² and entering of premises for seizure of prohibited items.⁹³ These are also specified in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). Punishments for non-compliance with the advertising regulations,⁹⁴ and the defences that are available to persons charged with breaches of the regulations are also stipulated in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia).⁹⁵

The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is further supplemented by a guideline, namely, the *Guidelines on Medical Products and Appliances 2009* (Malaysia). This guideline was approved by the MAB through its Meeting Bill 8/2009 dated 18th August 2009, and it took effect on 1st September 2009.⁹⁶ It contains extensive rules governing dissemination of advertisements of medicinal products. For example, it requires advertisements to carry information that is reliable, accurate, truthful, informative, balanced, up to date, and capable of substantiation and in good taste.⁹⁷ It prohibits (1) the making of medicinal claims or therapeutic claims;⁹⁸ (2) the dissemination of 'misleading or unverifiable [claims] or omissions likely to induce medically unjustifiable use or ...undue risks'⁹⁹ and (3) the dissemination of 'any statement or visual presentations which directly or by implication, omission, ambiguity or claim, mislead consumers about any product'.¹⁰⁰ It forbids advertisements which: (1) contain advice, recommendations and endorsements by

⁹⁰ See *Medicine Advertisements Board Regulations 1976* (Malaysia) s 5. The MAB's establishment, constitution and authorities are also stipulated under regulation 2 of the *Medicine Advertisements Board Regulations* (1976).

⁹¹ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 6 B.

⁹² *Ibid* s 6C.

⁹³ *Ibid* s 6D.

⁹⁴ *Ibid* s 5.

⁹⁵ *Ibid* s 5 (3).

⁹⁶ *Guidelines on Medical Products and Appliances 2009* (Malaysia).

⁹⁷ *Ibid* s 5.

⁹⁸ *Ibid* s 4 (1) (a).

⁹⁹ *Ibid* s 5.

¹⁰⁰ *Ibid* s 5.2.

any category of persons belonging to the medical profession, which include doctors, dentist, pharmacists, scientist, nurses and other paramedics;¹⁰¹ or by association or persons who appear as the qualified person;¹⁰² (2) contain testimonials of certain groups;¹⁰³ (3) exploit the lack of experience, superstitions or religious belief;¹⁰⁴ (4) encourage violence or illegal or dangerous activities;¹⁰⁵ (5) disparage the medical profession or discredit another product;¹⁰⁶ (6) mislead or are likely to mislead consumers;¹⁰⁷ and (7) exaggerate claims.¹⁰⁸ Certain specific claims referring to (1) sexual weakness, ageing, loss of virility;¹⁰⁹ (2) baldness;¹¹⁰ (3) weight reduction;¹¹¹ (4) vitamins and infections;¹¹² and (6) functional claims,¹¹³ are also unlawful in advertisements.

The *Guidelines on Medical Products and Appliances 2009* (Malaysia) emphasise that advertisers must observe a standard of morality or decency in their advertisements¹¹⁴ and

¹⁰¹ Ibid s 5.1.1 (a).

¹⁰² Ibid s 5.1.1 (b).

¹⁰³ *Guidelines on Medical Products and Appliances 2009* (Malaysia) s 5.5.1. 'Certain groups' refer to testimonials of professional, scientific associations or a body or organisation or persons well-known in public life, sport and entertainments.

¹⁰⁴ *Guidelines on Medical Products and Appliances 2009* (Malaysia) s 5.1.3.

¹⁰⁵ Ibid ss 5.1.4 and 5.1.5.

¹⁰⁶ Ibid s 5.1.6.

¹⁰⁷ Ibid s 5.2.

¹⁰⁸ Improper words, phrases or methods of presentation in advertisements are prohibited. Words such as 'fabulous', 'fantastic', or 'superior' are not allowed in the advertisements. Also, false claims such as 'natural', 'natural remedy' or claims that lead consumers to over-estimate the value of product are not permitted by this section. See Ibid s 5.7.1.

¹⁰⁹ In essence claims pledging that a product can improve sexual weaknesses, or retards controls or treats premature ageing are not permissible. Ibid s 5.8.1.

¹¹⁰ This regulation prohibits claims that guarantee that baldness can be prevented or cured, or the thinning of the hair can be arrested, reversed or reduced or that hair growth can be stimulated. Ibid s 5.8.2.

¹¹¹ Ibid s 5.8.3.

¹¹² Claims implying that life would be endangered by not consuming a vitamin or that vitamins would give adequate protection against viral infections are prohibited. Ibid s 5.8.4.

¹¹³ Ibid s 5.8.5. Also, functional claims must be approved by the Drug Control Authority before they are for publication. See Ibid s 5.8.5.

¹¹⁴ Ibid s 5.1.2.

adequately substantiate the advertisements disseminated to consumers.¹¹⁵ It decrees that advertisers make certain cautionary statements in the advertisements, and adequately warn consumers regarding the risk involved in using medications, such as: (1) 'This is a herbal product'; (2) 'This preparation contains X% alcohol'; (3) 'Excessive vitamin intake may be detrimental to your health'; (4) 'Not to be taken by children below 16 years old'; (5) 'If symptoms persist, please consult your doctor'; (6) 'Please consult doctor for interpretation of the result'; (7) 'This is a traditional preparation' and (8) 'Should be taken with a balanced diet and regular exercise'.¹¹⁶

It can be seen from the above that the rules governing the advertising of medicinal products in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) and the *Guidelines on Medical Products and Appliances 2009* (Malaysia) are detailed and comprehensive. The list of prohibited claims is clearly stated. However, despite this, advertisements that carry claims which are not permissible are still found.¹¹⁷ This is likely to be due to the fact that the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) has loopholes which prevent adequate regulation of the advertising of medicinal products. The limitations of the Act are raised and discussed immediately below.

In order for the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) to succeed against recalcitrant advertisers, it must be established that advertisements under question were directed at the public. It must be shown that the materials were published for public viewing. This can easily be proved if advertisements were in newspapers (as newspapers are meant for the public to read); however, with pamphlets or brochures, for example, which are produced by drug companies for pharmacies, medical practitioners and certain other professionals, it is difficult to establish that they were indeed directed at the public. The advertisements are placed in a location or spot where the public is bound to read

¹¹⁵ Ibid s 5.3. Medical statements or references to clinical, trials and test must be substantiated by 'authoritative evidence acceptable to the MAB': at s 5.4.1.

¹¹⁶ Ibid s 5.9.1.

¹¹⁷ See the Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Case Reports* <http://www.pharmacy.gov.my/html/MAB/advertisement_board_legal_action_f.htm>. ('Case Reports Compilation'). A compilation of advertisements which carried prohibited health-claims are listed in the official website belonging to the Medicine Advertisement Board.

them. But advertisers (or manufacturers) are able to escape liability by invoking section 5 (3)(b) of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), which exempts the application of the rule unless it can be shown that the advertisements are directed at the public. If the advertisements are directed at categories of persons permitted by law, then the advertisers are not liable. This categories of person include medical practitioners, dentists, nurses, midwives, pharmacist, and those person undergoing training as registered medicinal practitioners, dentist, nurses, midwives and pharmacist.¹¹⁸

A further limitation is that the fine imposed for violation of law is insufficient to deter breaches or non-compliance with the law. The fine ranges from RM3,000.00¹¹⁹ or less, or imprisonment for a year, or both for first offenders, to an amount not exceeding RM5,000.00¹²⁰ or two years imprisonment or both for subsequent convictions.¹²¹ In practice, however, the maximum has not been imposed.¹²²

In addition, the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) does not define the term 'deceptive advertising'. Instead, it generally prohibits: (1) advertisements without approvals from the MAB; (2) non-compliance with the approved formats and (3) the making

¹¹⁸ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 5 (3) (b).

¹¹⁹ This amount is equivalent to USD951.00 at USD 1:3.15MYR as at 2 December 2010.

¹²⁰ This amount is equivalent to USD1,584.00 USD 1:3.15MYR as at 2 December 2010.

¹²¹ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 5 (1) (a) & (b).

¹²² For example, (1) Yum Nam Hair Care Sdn. Bhd., was charged for publishing an article titled 'The solution to all your hair problems' in the Star Newspaper, contravening section 4A of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), and was fined 1,500.00; (2) Rodiah Binti Tok Kechil, was charged for publishing XKL Care Capsule which 'claimed to reduce fatigue, reduce toxins and fats and prevent acne and skin problems, without the approval from the Medicine Advertisement Board, in contravention of section 4B *Medicines (Advertisement and Sale) Act 1956* (Malaysia) and was fined 1,000.00; (3) Svenson Hair Center Sdn Bhd was charged for claiming to treat hair loss problems, scalp problems and dandruff, in contravention of section 4A of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) and was fined 400.00 and given 60 days imprisonment; (4) TRN Marketing (M) Sdn Bhd, was charged for claiming that its product could remove toxins from the body without obtaining the approval from the MAB and contravened section 4B of *Medicines (Advertisement and Sale) Act 1956* (Malaysia) and was fined 500.00 and given 14 days imprisonment; (5) Toh Kok Kin was charged for promoting foot reflexology that claimed to cure 22 types of illnesses, in contravention of section 4A of *Medicines (Advertisement and Sale) Act 1956* (Malaysia) and was fined 700.00 and given one month imprisonment. Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Legal Action: Court Case Report* at http://www.pharmacy.gov.my/html/MAB/advertisement_board-legal_action.htm >. ('*Legal Action: Court Case Report*').

of prohibited claims in advertisements.¹²³ Compliance with the format as suggested by the MAB is deemed crucial, although MAB's basis for determining compliance or non-compliance with the format, or the basis on which it determines the format of advertisement for highly exaggerated category, is not clearly stipulated.¹²⁴ The problem envisaged with the lack of explanation and proper description regarding what constitutes deceptive advertising, is that it would allow for uncertainty and inconsistency in decisions by the courts when interpreting the term 'deceptive advertising'.

The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) was enacted in 1957, and revised in 1983. It was last amended in 1990.¹²⁵ The 1990 amendment introduced some changes to the Act. It specified the types of claims which are prohibited in advertisements,¹²⁶ the categories of person to whom such advertisements may be advertised,¹²⁷ and the requirement to obtain pre-approval of advertisements before advertisements of medicinal products may be disseminated to the public.¹²⁸ The meaning of the term 'advertisements' was provided;¹²⁹ however, the meaning of the term 'deceptive advertisements' was not given.

¹²³ Medicine Advertisement Board of the Pharmaceutical Service Division of the Ministry of Health, Malaysia *Guidance For The Advertisers, Media And Agencies* <http://www.pharmacy.gov.my/html/MAB/advertisement_board_f.htm>.

¹²⁴ Ibid. The *Guidelines on Medical Products and Appliances 2009* (Malaysia) stipulates the restrictions and prohibitions in relations to health claims in advertisements, however samples of formats are not made available on the official website to MAB.

¹²⁵ Malaysia, *Parliamentary Debate, Senate*, 25 June 1990, 1380 (Tuan Mohammed Farid Bin Arrifin). Also see generally Malaysia, *Parliamentary Debate, House of Representative*, 12 June 1990, 3340 (Tuan Haji Mohammed Amin bin Haji Daud).

¹²⁶ They include therapeutic claims regarding diseases and condition specified in the Schedule, regarding the practice of contraceptives, improving the condition or functioning of the human kidney, heart, or sexual function or performance of human being. See *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (1).

¹²⁷ Such advertisements may be directed to the following category of people; (1) member of local or public authority; (2) members of governing body of a public hospital; (3) registered medical practitioners; (4) registered dentists; (5) registered nurses and midwives; (6) registered pharmacist, chemists, and wholesalers and retailers in Sabah and Sarawak; (7) persons undergoing training to become registered - medical practitioners, dentists, nurses or pharmacist. See *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (2).

¹²⁸ Ibid s 4 B.

¹²⁹ Ibid s 2.

3.3.1.2 The *Trade Descriptions Act 1972* (Malaysia)

The *Trade Descriptions Act 1972* (Malaysia) is the principal Act governing trade descriptions and advertising in Malaysia. It is considered unlawful under the Act to make a 'trade description which is false to a material degree.'¹³⁰ Advertisements which are misleading are considered as false trade description under section 5 (2) of the Act and are prohibited.¹³¹

The Act governs the advertising of goods in general; however, it is inapplicable to the advertising of immovable properties¹³² and to statements made by professional.¹³³ It is also thought to be inapplicable to the regulation of deceptive advertisements of medicinal products. This is because the Act is designed to regulate products that fall within the definition of the term 'goods'. The term 'goods' is defined in the *Trade Descriptions Act 1972* (Malaysia) as '...inclu[ding] ships, aircraft, vehicles, animals, plants and growing plants and all kinds of movable property'.¹³⁴ This definition does not stipulate whether 'goods' would include products which are intended for medicinal purposes. It is possible that matters concerning medicinal products are intended to be solely governed by pharmaceutical laws and not by the *Trade Descriptions Act 1972* (Malaysia). A detailed search of the Consolidated Subject Index of Mallal's Digest (Fourth Edition) between 1932 to 2009 revealed a total number of 22 cases of false trade description cases dealt with under the *Trade Descriptions Act 1972* (Malaysia). These cases dealt with issues concerning the infringement of intellectual property rights.

¹³⁰ *Trade Descriptions Act 1972* (Malaysia) s 5.

¹³¹ *Ibid* s 3.

¹³² See definition of the term 'goods' in section 2 of the *Trade Descriptions Act 1972* (Malaysia).

¹³³ *Trade Descriptions Act 1972* (Malaysia) s 15. The Act prohibits any persons from giving any false indication that goods or services supplied by him are supplied or approved by any person including any government or government department or agency or any international body or agency whether in Malaysia or abroad.

¹³⁴ *Ibid* s 2.

3.3.1.3 The *Consumer Protection Act 1999* (Malaysia)

The *Consumer Protection Act 1999* (Malaysia) regulates deceptive conduct in trade practices. It aims to protect consumers against misleading and deceptive conduct, false representations, and unfair practices.¹³⁵ The issue is whether the Act governs deceptive advertising of medicinal products.

The Act applies to goods which are 'primarily purchased, used or consumed for *personal, domestic or household purposes* and includes: (1) goods attached to, or incorporated in, any real or personal property; (2) animals including fish; (3) vessels and vehicles; (4) utilities and (5) trees, plants and crops...'.¹³⁶ Medicinal products are not specified within the definition of the term 'goods', and therefore the *Consumer Protection Act 1999* (Malaysia), like the *Trade Descriptions Act 1972* (Malaysia), is unlikely to apply to the regulation of advertising of medicinal products. A suggestion is made to widen the definition of the term 'good'; however, no recommendation has been made for the *Consumer Protection Act 1999* (Malaysia) to apply to the medicinal products.¹³⁷

3.3.1.4 *Indecent Advertisement Act 1953* (Malaysia)

The *Indecent Advertisement Act 1953* (Malaysia) is designed to suppress indecent or obscene advertisements and advertisements relating to the treatment of venereal disease, nervous disabilities or other complaints or infirmity arising from or relating to sexual intercourse...'.¹³⁸ The application of the Act is, however, limited to prohibition of matters of an obscene nature and advertisements relating to sexually transmitted diseases. In other words, the Act does not regulate the advertising of medicinal claims unless it concerns the publication of indecent, obscene or sexually transmitted diseases.¹³⁹

¹³⁵ See the *Consumer Protection Act 1999* (Malaysia) ss 9 to 12.

¹³⁶ *Ibid* s 3.

¹³⁷ See Indrani Thuraisingham, et al., *Review of Consumer Protection Act 1999* (2007) Malaysia 7. The proposal was that the Act should apply to all kind of goods which are bought for personal, domestic and household purposes. Currently confusions caused by the definition include: (1) the use of the word 'primary'; and (2) the order of items included in the definition – fish, tree, plants.

¹³⁸ *Indecent Advertisement Act 1953* (Malaysia) s 6.

¹³⁹ *Ibid* s 6.

3.3.1.5 Conclusion

In summary, the *Consumer Protection Act 1999* (Malaysia), the *Trade Descriptions Act 1972* (Malaysia) and the *Indecent Advertisement Act 1953* (Malaysia) which regulate the deceptive advertising of goods and services in general, do not govern the advertising of medicinal products, but have the potential to govern if restrictions are removed. The *Consumer Protection Act 1999* (Malaysia) and the *Trade Descriptions Act 1972* (Malaysia) may be applicable if the term ‘goods’ is given a broader meaning.

The *Medicines (Advertisement and Sale) Act 1956* (Malaysia), on the other hand, is detailed, but has loopholes, which obstruct the control of dissemination of deceptive advertising. The loopholes could be closed so as to enable more effective regulation by considering the use of industry codes of practice and guidelines. The following section analyses how these industry codes of practice and guidelines may play a part in facilitating the regulation of deceptive advertising of medicinal products in Malaysia.

3.3.2 Codes of Practice and Industry Guidelines that Govern the Advertising of Medicinal Products

Three main codes of conduct prescribe guidelines for responsible advertising of medicinal products. They are: (1) the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) which illustrates the standards for ethical promotion of prescription drugs to healthcare professional;¹⁴⁰ (2) the *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia), which prescribes the principles governing the advertising that is primarily commercial¹⁴¹ and is disseminated in print advertisements and (3) the *Communications and Multimedia Content Code 2004* (Malaysia), which stipulates guidelines for, amongst others, advertising in the electronic media.¹⁴² In addition, the *Guidelines for Control of Cosmetic Products (2009)* (Malaysia)

¹⁴⁰ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia).

¹⁴¹ The code applies to advertisements disseminated by non-commercial organisation and individuals. *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) 2.2.

¹⁴² See the *Communications and Multimedia Content Code (2004)* (Malaysia) Part 3.

prescribes the advertising rules and standards for cosmetic products. These codes and guidelines are examined in this section.

3.3.2.1 The *Pharmaceutical Association of Malaysia (PhAMA) Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia)

The *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) prescribes guidelines to assist its members to use legitimate methods of advertising in advertisements of prescription drugs. For example, the code requires that there be: (1) a presentation of accurate, fair and objective materials,¹⁴³ in conformity with high ethical standards;¹⁴⁴ (2) substantiation of claims either by 'reference to approved labelling or scientific evidence';¹⁴⁵ (3) avoidance of disguises of promotions¹⁴⁶ and (4) a presentation of complete information regarding the name and address of the licence holder or the business name,¹⁴⁷ published studies,¹⁴⁸ product name and date of advertisements, and properties of products as approved in Malaysia based on minimum abbreviated prescribing information.¹⁴⁹ These rules are applicable to print as well as electronic media. Electronic media advertising is, however, additionally required to identify the pharmaceutical company and the intended audience, and ensure that contents and presentations in the website are appropriately presented to the intended audience.¹⁵⁰ The Code is administered by the PhAMA, the self-regulatory body that is responsible for the regulation of prescription drugs.

¹⁴³ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) s 8. Materials broadly include artwork, graphics, and illustrations.

¹⁴⁴ *Ibid* s 3.1.

¹⁴⁵ *Ibid* s 3.1.1.

¹⁴⁶ Disguising promotions as clinical assessments, post-marketing surveillance and experience programs conducted with a primary scientific purpose or educational purpose is prohibited. *Ibid* s 2.5.

¹⁴⁷ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) s 4.1.

¹⁴⁸ *Ibid* s 4.2.

¹⁴⁹ The minimum abbreviated prescribing information includes the following: Contraindications, Precautions, Dosages, Indications and the Side Effects. See *Ibid* s 4.10.

¹⁵⁰ *Ibid* s 6.1.

3.3.2.2 The *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia)

The *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia), which is administered by ASAM, prescribes the standards to be complied with in respect of advertisements disseminated in the print media. Print media includes advertising in leaflets, circulars, posters, billboards, cinemas, and advertising claims on packs, labels and at point of sale.¹⁵¹ This Code contains general guidelines, which are applicable to all advertising¹⁵² and specific guidelines that are applicable to specific categories of advertisements.¹⁵³ The main guidelines include that an advertisement: (1) must be 'legal, decent, honest and truthful'¹⁵⁴ and 'prepared with a sense of responsibility';¹⁵⁵ (2) conforms with principles of fair competition;¹⁵⁶ (3) 'project[s] Malaysian culture, identity and the multi-racial character'¹⁵⁷ and (4) is capable of substantiation.¹⁵⁸

The *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) also prescribes the rules for making various types of claims in advertisements. For example, the Code stipulates the manner in which claims concerning value of goods or use of the word 'free', 'up to...' or 'from...' is to be made. It also stipulates the manner in which various types of advertising and issues related to the advertising should be dealt with. The types of advertising and issues include: direct supply, wholesale, comparison, disparagement and denigration, testimonials, protection of privacy of the individual, safety, guarantees, money-back guarantees, stridency, sensitivities, subliminal advertising, outdoor, identification of advertisement, switch selling, unsolicited home visits, inertia selling and non-availability of

¹⁵¹ See the *Malaysian Code of Advertising Practice (Third Edition) (2008)* Pt 1 s 3.4 (i). The broadcast media, online, electronic media and other telecommunications are governed by the Content Code under the administration of the Communication and Multimedia Content Forum of Malaysia: at s 1.

¹⁵² *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) ss 1 to 22.

¹⁵³ *Ibid* Appendix A – P.

¹⁵⁴ *Ibid* s 1.1.

¹⁵⁵ *Ibid* s 1.7.

¹⁵⁶ *Ibid* s 1.8.

¹⁵⁷ *Ibid* s 1.2.

¹⁵⁸ *Ibid* s 4.1.

advertised products.¹⁵⁹ In addition, it explains that advertisements containing testimonials or endorsements must relate to the personal experience of persons providing testimonials or endorsements.¹⁶⁰ Further, advertisements referring to the efficacy of a product must 'justifiably attribute to the use of the product.'¹⁶¹

The Code also contains specific prohibitions on advertisements of medicinal products and products that carry general health claims,¹⁶² slimming products,¹⁶³ and vitamins and minerals.¹⁶⁴ Moreover, testimonials of persons well known to the public¹⁶⁵ and claims in reference to specific illnesses or conditions are also forbidden.¹⁶⁶ A crucial principle that is emphasised is that all claims concerning health must be substantiated. Here, the Code insists that advertisers hold evidence for claims such as: (1) medical claims; (2) claims that refer to 'tests, trials, research, doctors' preferences or prescribing habit...' and (3) claims declaring that the product emanated from any hospital or official source.¹⁶⁷ A breach of these provisions gives rise the advertisers be punished by either 'withholding advertising space', or 'withdrawing trading privileges'.¹⁶⁸ Advertisers may also be punished through

¹⁵⁹ Ibid ss 4 to 22.

¹⁶⁰ Ibid s 9.

¹⁶¹ Ibid s 9.3.

¹⁶² *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) Appendix B.

¹⁶³ Ibid Appendix D.

¹⁶⁴ Ibid Appendix I.

¹⁶⁵ People well known in public life, sports entertainment and professional bodies are not allowed. See Ibid Appendix B s 5.8.

¹⁶⁶ Functional claims concerning: (1) abortifacient; (2) analgesics; (3) bust developers; (4) contraceptives and birth control; (5) corns; (6) cosmetics; (7) depilatories; (8) gargles; (9) hay fever and other allergic conditions; (10) headaches; (11) height increases; (12) herbal homeopathic and acupuncture remedies; (13) hypnosis, hypnotherapy, psychology, psychoanalysis or psychiatry; (14) hormones and cell extracts; (15) indigestion remedies; (16) laxatives; (17) piles; (18) polyunsaturated fat; (19) pregnancy advertising services and counselling, pregnancy testing, sterilisation, vasectomy; and (20) prescription drugs; (21) prevention of ageing; (22) protein claims; (23) rheumatic and allied pain; (24) scheduled medicine; (25) toothpastes and other similar products; (26) vitamin and minerals; (27) sexual weakness and loss of virility. See Ibid Appendix B s 6.

¹⁶⁷ Ibid Appendix B ss 4.1, 4.3, and 4.8, respectively.

¹⁶⁸ *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) s 1(i).

adverse publicity, since the ASAM also publishes details of the outcome of investigations for public viewing.¹⁶⁹

The Code may be presumed to be effective in regulating the advertising of medicinal product because it has the participation of key industry players in its regulation. The Code has been established by members of ASAM which includes advertisers, advertising agencies and the media.¹⁷⁰ It has the support of (1) the Association of Accredited Advertising Agencies Agent Malaysia; (2) the Malaysian Advertiser Association; (3) the Malaysian Newspaper Publishers Association and (4) the Media Specialist Association.¹⁷¹ Presumably there will be a general consensus to comply with the provisions of the Code.

3.3.2.3 The Communications and Multimedia Content Code 2004 (Malaysia)

The *Communications and Multimedia Content Code 2004* (Malaysia),¹⁷² provides guidelines for, amongst others, the advertising standards to be adhered to with regard to advertising in the electronic media.¹⁷³ A cardinal principle in the *Communications and Multimedia Content Code 2004* (Malaysia) is that the advertising must not be ‘indecent, obscene, false, menacing or offensive in character with intent to annoy, abuse, threaten and harass any person, or prepared without a sense of responsibility’.¹⁷⁴ It also emphasises that substantiation of claims are held by advertisers, and that claims are not unduly ‘...exaggerated in value, accuracy, scientific validity or practical usefulness of the product’.¹⁷⁵

The *Communications and Multimedia Content Code 2004* (Malaysia) seeks to regulate advertisements disseminated in the electronic media and as such may be presumed as

¹⁶⁹ Ibid.

¹⁷⁰ *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia).

¹⁷¹ Ibid.

¹⁷² The Code was established under section 213 of the *Communications and Multimedia Act 1998* (Malaysia).

¹⁷³ *Communications and Multimedia Content Code 2004* (Malaysia) Part 3.

¹⁷⁴ Ibid s 3.0.

¹⁷⁵ Ibid s 4.1 (viii) (b).

suitable to regulate medicinal claims that appear on the Internet; however, the Code had made an express declaration that matters concerning healthcare products are to be directed to the MAB.¹⁷⁶ The regulation of dissemination of advertisements of medicinal products on the Internet thus falls within the purview of the MAB.¹⁷⁷

3.3.2.4 Guidelines for Control of Cosmetic Products

The *Guidelines for Control of Cosmetic Products 2009* (Malaysia) prescribes the requirements to be complied with and standards to be adhered to by advertisers of cosmetic products. This guideline has been prepared in accordance with the ASEAN Cosmetic Directives by the Cosmetic Technical Working Group (CWTC), a group of members from the NPCB and the cosmetic industry.¹⁷⁸ The aim is to ensure that a harmonized regulatory system is in place for the regulation of cosmetic products.¹⁷⁹

The primary principles in the *Guidelines for Control of Cosmetic Products 2009* (Malaysia) are that the advertisements: (1) should 'contain information that is reliable, accurate, truthful, informative, balanced, up to date, capable of substantiation and in good taste; (2) should not 'contain misleading or unverifiable statements or omissions likely to induce use or give rise to undue risk'; (3) should observe standards of morality and decency; (4) should be honest and truthful and (5) should be substantiated or be capable of substantiation.¹⁸⁰ Non-compliance with these rules gives rise to offences that are punishable under section 30(1) and (2) of the *Control of Drugs and Cosmetics (Amendment) Regulation 2007* (Malaysia).¹⁸¹

¹⁷⁶ Ibid s 8.1.

¹⁷⁷ Advertisements placed in Internet fall within the scope of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) by virtue of the definition of the 'advertisement' in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) which includes '...any announcement made orally or by any means of producing and transmitting light or sound' as including advertisements See *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 2.

¹⁷⁸ *Guidelines for Control of Cosmetic Products 2009* (Malaysia) s 1.

¹⁷⁹ Ibid.

¹⁸⁰ Ibid s 19.

¹⁸¹ Ibid s 18.

3.3.3 Conclusion

In summary, rules governing the advertising of medicinal products are found in Medicines (Advertisement and Sale) Act 1956 (Malaysia), the *Guidelines on Medical Products and Appliances 2009* (Malaysia), the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) and the *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia). Whilst *Medicines (Advertisement and Sale) Act 1956 (Malaysia)* is the primary legislation which governs the advertising of medicinal products, the *Guidelines on Medical Products and Appliances 2009* (Malaysia) contains regulations which complement the Medicines (Advertisement and Sale) Act 1956 (Malaysia). The *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) and the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia), on the other hand, are industry guidelines, which are administered by ASAM and PhAMA, respectively. It has been noted that these guidelines are detailed and comprehensive; however, being self-industry codes, their applicability is restricted to their members.

This chapter continues to investigate the controls employed in the regulation of the advertising of medicinal products. It examines the system of pre-approval of advertisements, complaint handlings and enforcement. It also explores controls employed by both the MAB and self-regulatory organisations.

3.4 REGULATORY CONTROL AND ENFORCEMENT OF ADVERTISING OF MEDICINAL PRODUCTS IN MALAYSIA

The regulatory controls applied to the advertising of medicinal products have limitations. There are systemic inadequacies in the system which impedes the overall control of deceptive advertising of medicinal products. Three types of controls are examined: (1) pre-market approval of advertisements (2) monitoring of non-compliance with advertising law and (3) enforcement.

3.4.1 Pre-Approval of Advertisements

In Malaysia, advertisements that carry medicinal claims are vetted and approved by the MAB before they are put in the public domain.¹⁸² They are filtered (reviewed) for not only untrue, misleading and highly exaggerated claims, but also for prohibited medicinal claims,¹⁸³ via a process of pre-market approval of advertisements. However, advertisements for prescription drugs, which are regulated by the PhAMA, are not pre-approved by the MAB before they are disseminated to the members of the medical profession. Instead, their 'final text and layout' are certified by a senior official of the Company'.¹⁸⁴ Senior official refers to either a doctor or a pharmacist.¹⁸⁵

Pre-market approvals of advertisements are granted by the MAB through two methods: (1) the 'Fast Track';¹⁸⁶ or (2) the 'Normal Track'.¹⁸⁷ The Fast Track System is a system which is applied to advertisements where: (1) the advertisement had been approved earlier; (2) there are no changes or minimal changes from the approved version and (3) the application is for renewal and the new application does not go beyond the list of indications

¹⁸² *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 4B.

¹⁸³ *Ibid* ss 3, 4 and 4A.

¹⁸⁴ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) s 10.3.

¹⁸⁵ *Ibid* s 10.3.

¹⁸⁶ See the Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Application Procedure* <http://www.pharmacy.gov.my/html/MAB/advertisement_board_application.htm>. ('Application Procedure')

¹⁸⁷ *Ibid*.

as approved by the Drug Control Authority.¹⁸⁸ The 'Normal Track' process is where advertisements are examined for the first time.

Advertisements that fall under the category of the 'Fast Track Approval' process are reviewed and assessed within three to five working days of receipt, whereas those advertisements that fall under the 'Normal Track' process are approved within four to six weeks of receipt.¹⁸⁹ Advertisements that are duly approved via these two methods are then granted an approval number, such as K.K.L.I.U 2008/123/A or K.K.L.I.U 2008/123/B.¹⁹⁰

Before seeking approval from the MAB, advertisers are advised to ensure that the following requisites are complied with: (1) that pharmaceutical products have been properly classified as food, cosmetics or nutrient supplements; (2) that the advertisement has complied with the guidelines issued by the respective bodies, for example, that an advertisement for food has followed the guidelines issued by the Food Quality Control Division of the Ministry of Health; (3) that the advertisement has been prepared in accordance with the format which is 'in-line' with the guidelines issued by the MAB; (4) that the advertisement makes no reference to medicinal claims and (5) that application forms are accurately completed and submitted to the Secretariat of the MAB.¹⁹¹

Approvals are only issued to advertisers who have complied with all of these requirements as well as the format prescribed by the MAB. The approval numbers (K.K.L.I.U) obtained

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

¹⁹⁰ The letters 'A' or 'B', at the end of the approval number indicates the types of media that the advertisements are published in. There are a total of 18 codes devised for various types of media. For example: (1) The letter A refers to newspapers and newspaper inserts; (2) The letter B refers to television, video, and cinema; (3) The letter C refers to radio (talk show, or radio program); (4) The letter D refers to radio (jingles, a short radio advertisement); (5) The letter E refers to directories (Yellow Pages, a handbook, etc); (6) The letter F refers to a billboard; (7) The letter G refers to the point of sale (shelf talker, wobblers, leaflet holder, bunting); (8) The letter H refers to a credit card, a members card, flight ticket docket; (9) The letter I refers to a leaflet, pamphlets, brochure, flyers; (10) The letter J refers to a poster; (11) The letter K refers to magazines, catalogue, members copy and magazine inserts; (12) The letter IT refers to Internet and SMS; (13) The letter V refers to a vehicle (LRT, Bus, Van, etc); (14) The letter M refers to calendars and diaries; (15) The letter N refers to bulletins and newspapers; (16) The letter P refers to banners; (17) The letter T refers to t-shirts; and (18) The letter L refers to miscellaneous. See Ibid.

¹⁹¹ See generally the Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Guidance to Advertisers: Responsibility of the Advertisers Prior to Advertising the Products with Medical or Health Claims*

<http://www.pharmacy.gov.my.html/MAB/advertisement_board_application.htm>.

must be prominently displayed on the advertisement.¹⁹² Advertisements that fail to follow these requirements are considered illegal advertisements.¹⁹³ To date, cases reported for illegal advertising have been in respect of prohibited claims specified in the Schedule to sections 3, 4A and 4B of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), which had either failed to obtain the necessary pre-approval or to comply with the approved formats.¹⁹⁴ The offenders, however, were not tried in the courts as they pleaded guilty to the offences and paid the fines.¹⁹⁵

3.4.2 Monitoring Violation of Advertisements

The system of regulatory control includes a monitoring program that seeks to ensure advertisements in all publications are scrutinized. In essence, monitoring violation of laws regulating the advertising of medicinal products is carried out by three different bodies or agencies. First, an investigation unit within the Pharmacy Enforcement Division, which is set up to investigate violations of law, monitors the advertisements. An Advertisement Control Team within this unit is entrusted with the responsibility of investigating complex claims in advertisements and media such as the electronic media.¹⁹⁶ Second, the regulator receives assistance from enforcement officers from other states, which includes monitoring of non-compliance with rules. Any violation found in the different states in Malaysia is reported to the MAB. Thirdly, the monitoring is carried out by an independent body, MediaBanc Sdn. Bhd, which is engaged by the MAB to carry out proactive monitoring of the Internet.¹⁹⁷

¹⁹² Ibid.

¹⁹³ Interview with: (1) Yogeswary a/p V Markandoo, the Deputy Director of Pharmacy Enforcement Division; (2) Nor Aza Binti Hassan, the Assistant Deputy Director of Pharmacy Enforcement Division; and (3) Azlinda Binti Abdul Samad, the Assistant Deputy Director of Pharmacy Enforcement Division, all from the Medicine Advertisement Board, Pharmacy Enforcement Division Ministry of Health Malaysia, (Personal Interview, 18 May 2007). ('the Interview').

¹⁹⁴ *Case Reports Compilation*, above n 117.

¹⁹⁵ See *Legal Action: Court Case Reports*, above n 122 and the accompanying text.

¹⁹⁶ Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Medicine Advertisement Board Annual Report (2006)* (Malaysia) 8.

¹⁹⁷ Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Medicine Advertisement Board Annual Report 2007* (Malaysia); Interview above n, 193.

The MAB is understaffed and under resourced to carry out active monitoring and therefore it relies on complaints from consumers and advertisers, an outside source to monitor deceptive advertisement. It realised that monitoring alone is insufficient to detect violations and therefore the MAB encouraged the cooperation of various parties involved in, or responsible for the dissemination of advertisement; it introduced a dialogue sessions with relevant parties.¹⁹⁸ The main targeted groups are the media and the advertising agencies.¹⁹⁹ The aim of the dialogue sessions is to enable the sharing of information regarding how controls over dissemination of deceptive advertising may best be achieved.²⁰⁰

3.4.3. Enforcement

The general form of enforcement that is carried out includes: (1) complaint handling and (2) judicial enforcement. The usual procedure is to first resolve the deception through complaint handling. Any failure to comply with the orders granted in the complaint handling will result in the matter being taken to court. This section highlights the types of orders made in complaint handling and the sanction ordered for violations of the advertising laws in judicial enforcement. It also examines the types of sanction that are imposed by self-regulators on their members.

3.4.3.1 Complaint Handling

The MAB's powers are limited with regard to the types of orders that it can make under the system of complaint handling. It may, upon receiving a complaint from a consumer, investigate the claim and issue a warning letter to the advertiser, requesting the advertiser to remove the advertisements. A total of two hundred eighty eight letters were issued against editors and advertisers in 2007, and one hundred and twenty seven in 2008.²⁰¹ The MAB may also inspect, remove and detain any advertisement which its officers believe is

¹⁹⁸ Ibid.

¹⁹⁹ Ibid.

²⁰⁰ Ibid.

²⁰¹ Medicine Advertisement Board of Pharmaceutical Service Division of the Ministry of Health, Malaysia, *Medicine Advertisement Board Annual Report 2007 and 2008*.

deceptive.²⁰² However, its powers are limited to requesting the deletion from advertisements, statements or those parts of statements ‘...which bring undesirable thoughts and impression to viewers’.²⁰³ It is not empowered to request a cease-and-desist, or a publication of corrective advertising, or impose fines. Although, it may bring the matter to court if advertisers fail to comply with its order, there are certain conditions that must be complied with before the matter can be brought to court.²⁰⁴ These conditions, which are drawbacks in the system of judicial enforcements, are discussed in the following section [3.4.3.2].

3.4.3.2. Judicial Enforcement

The system of judicial enforcement in Malaysia has obstacles which hinder the prevention of deceptive advertising. For example, the MAB is unable to initiate a legal action in court unless there is a complaint lodged by consumers and the ‘prosecution’ is sanctioned by a public prosecutor. In other words, the MAB may not bring an action on its own accord, and in circumstance when there is a complaint lodged, the MAB has to first obtain a written authorisation from the Public Prosecutor before it can charge the advertiser in court.²⁰⁵ Furthermore, the presence of the complainant on the day of the hearing is crucial, and securing the complainant’s presence in court is not an easy task for the MAB.²⁰⁶ Because matters are frequently postponed due to a back log of cases, complainants are generally not in favour of attending court for the hearing.²⁰⁷

²⁰² See the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 6D.

²⁰³ *Guidelines on Medical Products and Appliances 2009* (Malaysia) s 3.2. The MAB’s main role is to approve or reject applications for advertisements, or to withdraw or cancel any advertisements previously approved. It also makes policies concerning advertisements ‘relating to services, medicines, appliances and remedies with medical claims. See *Medicine Advertisement Board Regulations 1976* (Malaysia) s 5.

²⁰⁴ The conditions may be summarised as: (1) sanctions of public prosecutor before an action can be brought; (2) presence of complainant in court is crucial; (3) complaints must be lodged before an action can be initiated.

²⁰⁵ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 6F (1).

²⁰⁶ *The Interview*, above n 193.

²⁰⁷ *Ibid.*

A further drawback is that the imposable sanctions under the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) are too small to prevent deceptive advertising. The penalties imposed for breaches of rules are insignificant, and as such are ineffective in discouraging dishonest advertisers from disseminating deceptive advertising. As noted at [3.3.1.1], the penalties are: (1) a fine not exceeding RM3,000²⁰⁸ or imprisonment for any term not exceeding one year or both, in respect of a first conviction and (2) a fine not exceeding RM5,000.00²⁰⁹ or imprisonment for a term not exceeding two years or both, in respect of a subsequent conviction.²¹⁰ These are penalties imposed for contraventions of sections 3, 4, 4A and 4B of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia).²¹¹ Offenders, who often plead guilty to the charges and pay the fines, regard fines as a cost of advertising. As a result, no cases involving deceptive medicinal claims in advertisements have been challenged and tried in courts.

3.4.3.3 Enforcement by Self Regulatory Organisations

Self-regulatory organisations seek to eradicate deceptive advertising by imposing broader sanctions for non-compliance with, or violation of the provisions than those ordered in a judicial proceeding, but these sanctions are limited to their members, and thereby prove to be a less effective method of control for deceptive advertising by non-members. Nevertheless, the support provided by self regulatory organisations with regard to the control over the advertising of medicinal products and the extent to which this support could assist in halting deceptive advertisements is worth exploring. PhAMA and ASAM are the two main self-regulatory bodies involved in the regulation of advertising of medicinal products in Malaysia and therefore enforcement measures adopted by these two industry associations are explored.

²⁰⁸ This amount is equivalent to USD 951.00 at USD1:3.15MYR as at 2 December 2010.

²⁰⁹ This amount is equivalent to USD1,584.00, at USD1:3.15MYR as at 2 December 2010.

²¹⁰ See the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 5 (1).

²¹¹ *Legal Action: Court Case Reports*, above n 122 and the accompanying text.

(a) *Pharmaceutical Association of Malaysia (PhAMA)*

PhAMA through its Ethics Committee considers complaints lodged with it, and if it finds a breach of rules, one or more of the following orders may be granted: (1) a penalty of RM25,000.00²¹² or up to RM50,000.00²¹³ if there are repeated breaches.²¹⁴ (By repeated breaches it means that the offender breaches the same section or sections of the code with the same product claim); (2) a discontinuance of the offending material²¹⁵ and (3) an issuance of a retraction statement.²¹⁶

The fines imposed by the PhAMA are higher than those imposed by the MAB and therefore have greater potential to deter deceptive advertising; however, there is a hindrance within the system which may prevent adequate control. It is presumed that fewer complaints may be brought against advertisers as the administrative fee imposed for lodging a complaint is exorbitant. Complaints against members are required to be lodged with an administrative fee of RM3,000.00.²¹⁷ It is alleged that the fee of RM3,000.00²¹⁸ goes 'towards the cost of outside advice'; nevertheless, it is a factor that discourages the making of complaints.²¹⁹ On the other hand, it may be argued that the fee of RM3,000.00 will ensure that only genuine matters which are substantiated with sufficient evidence are brought forward.

Although the imposition of such high fees may prevent lodgement of complaints, if complaints are lodged, matters are investigated and the names of companies that have

²¹² Equivalent to USD7,924 at USD1:3.15MYR as at 2 December 2010.

²¹³ Equivalent to USD15,848, at USD1:3.15MYR as at 2 December 2010.

²¹⁴ See *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) Part: Operation of the Code, s 1.

²¹⁵ *Ibid* s 4.

²¹⁶ *Ibid* s 4.

²¹⁷ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) Part: Operation of the Code. Further details such as: (1) the alleged breach(s); (2) details about the company concerned; and (3) the promotional material are also required to be submitted. Before a complaint is lodged, parties are encouraged to attempt a settlement of the alleged breach and provide proof or evidence that attempts were made but failed: at s 1.

²¹⁸ This amount is equivalent to USD 951.00 at USD1:3.15MYR as at 2 December 2010.

²¹⁹ See *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) Part: Operation of the Code, s 1.

breached the rules are published. It is assumed that the adverse publicity obtained from such publication will serve as an effective method of preventing misconduct in advertising. However, decisions of the committee are not published to the public.²²⁰ Therefore the imposition of high fees is not justifiable.

(b) *The Advertising Standard Authority Malaysia (ASAM)*

ASAM administers and handles complaints from the public regarding breach(s) of provisions in the *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia).²²¹ The punishment for breach or non-compliance with rules includes: (1) denial of access time and (2) adverse publicity.²²² Unlike PhAMA, complaints lodged with ASAM seem to be investigated free of charge,²²³ and as such there is less likelihood of hesitation in lodging complaints regarding the dissemination of deceptive advertising.²²⁴

(c) *The Communications and Multimedia Content Forum of Malaysia*

The Communications and Multimedia Content Forum of Malaysia (hereinafter referred to as the 'Content Forum') administers the *Communications and Multimedia Content Code 2004 (Malaysia)* and deals with matters related to the administration of the Code.²²⁵ The Content Forum handles complaints concerning breach and non-compliance with the *Communications and Multimedia Content Code 2004 (Malaysia)* through its Complaints Bureau.²²⁶ It investigates complaints regarding advertisements, as well as conduct which is perceived to be in breach without necessarily following a complaint.²²⁷ The sanctions for

²²⁰ Ibid.

²²¹ *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) s 1 (i).

²²² Ibid.

²²³ Ibid. No fees or charges are indicated for complaints.

²²⁴ Ibid s 1 (i).

²²⁵ *Malaysian Communication and Multimedia Act 1998* s 212.

²²⁶ *Communications and Multimedia Content Code 2004* (Malaysia) Part 8 s 2.4.

²²⁷ Ibid s 3.4.

breach of rules include: (1) imposition of fine not exceeding RM50,000.00;²²⁸ (2) removal of the content and (3) cessation of the offending act.²²⁹ It also includes the publication of the outcome of the conclusion of an inquiry, resulting in adverse publicity for the alleged company.²³⁰ However, the regulation of the advertising of medicinal products is outside the scope of the Content Forum's responsibility as it has specifically stipulated that matters concerning the advertising of medicinal products are under the purview of the MAB.²³¹

3.4.4 Inadequacies in the System of Regulatory Controls

The preceding sections have highlighted the weaknesses in the system of regulatory control. It has been noted that the MAB is given broad powers in respect of pre-approval of advertisements and removal of claims that are deceptive and unsuitable for public viewing before advertisements are disseminated to the public. It also appears to have sufficient authority to satisfactorily scrutinise any violation of advertising of medicinal products through its system of monitoring. However, the enforcement powers given to MAB under the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) are limited. The fines imposed are too low to prevent future non-compliance or violation of rules. The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) also encumbers the regulator who wants to bring a legal action by requiring that complainant to be present, and that the prosecution is endorsed by public prosecutors. These restrictions cause delays and costs to the advertisers, regulator and consumers. Moreover, the MAB is understaffed and resourced to carry out effective regulation of deceptive advertising.

On the other hand, the self-regulatory system appears to possess more stringent requirements for non-compliance and violation. Their sanctions broadly include higher fines, adverse publicity and removal from membership of the self-regulatory organisation. However, the group of self-regulatory organisations which controls and monitors the

²²⁸ Equivalent to USD15, 848 at USD1:3.15MYR as at 2 December 2010.

²²⁹ *Communications and Multimedia Content Code 2004* (Malaysia) Part 8 s 8.0.

²³⁰ *Ibid* s 9.2.

²³¹ *Ibid* Part 3 s 8.1. The support given by the *Communications and Multimedia Content Code 2004* (Malaysia) is, nevertheless, discussed here to ease an explanation in Chapter 6, namely a recommendation to lift the restriction on the regulation of medicinal products advertising.

advertising of medicinal products is unable to regulate advertisements placed by non-members despite its sanctions being broader and its fines, higher.

3.5 CONCLUSION

In this chapter, the regulation of the advertising of medicinal products in Malaysia was examined and the following was discovered. With regard to ascertaining the types of products which fall under the classification of medicinal products, it was found that an 'intended medicinal purpose' is important for the determination of medicinal products. Hence, advertisements of products such as food, nutrient supplements and cosmetics, which carry therapeutic claims, result in the product being classified as a medicinal product. It was also learned that, if therapeutic or medicinal claims are made for products in advertisements, those products must meet the criteria for classification as medicinal products; there are no exceptions.

In [3.3], it was discovered that the primary legislation that regulates the advertising of medicinal products in Malaysia is the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). However, the legislation has weaknesses which obstruct effective regulation of the advertising of medicinal products. Both the *Consumer Protection Act 1999* (Malaysia), and the *Trade Descriptions Act 1972* (Malaysia), which regulate the advertising of goods and services, are inapplicable to the regulation of the advertising of medicinal products by reason of the fact that the term 'goods' as defined in the legislation, is not inclusive of categories of products that carry an intended medicinal purpose.

In [3.3], the self-regulatory codes and guidelines, which contain detailed rules to be followed by members of self-regulatory organisations was also examined. It was noted that non-compliance with rules was accompanied by punishments which are comparatively broader than those prescribed under *Medicines (Advertisement and Sale) Act 1956* (Malaysia); however, punishments only apply to members.

In [3.4], the regulatory controls that applied to the advertising of medicinal products in Malaysia were explored. It was established that the system of pre-market approval for advertisements of medicinal products is carried out by the MAB. The MAB emphasizes that advertisers comply with formats approved by the MAB. Any non-compliance with the format has been deemed to be illegal advertising, but no clear direction as to what constitute illegal advertising is given. In this section monitoring violations, carried out by government departments and by an independent body, MediaBanc Sdn. Bhd was also

explored. However, monitoring of violations by Mediabanc Sdn Bhd is limited to Internet advertising. It was noted that MAB's lack of adequate staff and resources to monitor deceptive advertising is sought to be addressed by engaging in dialogue sessions with the advertisers and advertising agencies.

Lastly the section explored the system of enforcement and discovered that there are weaknesses in the overall system of enforcement. It was found that: (1) the legal actions are largely complaint based and therefore an action cannot be brought without a complaint and a complainant and (2) the fines imposed for breach of rules are trivial and therefore non-compliant advertisers have preferred to pay a fine.

Sanctions imposed by group of self-regulators was also discussed in this section, and whilst the sanctions are broad and relatively severe compared to those imposed under *Medicines (Advertisement and Sale) Act 1956* (Malaysia), there were problems with the enforcement of self-regulation. A self-regulatory organisation, such as the PhAMA, which imposes high penalties or requests for publication of retraction statements, requires that an administration fee of RM3,000.00²³² be paid for the lodgement of complaints. This was argued to be a deterring factor in the lodging of complaints.

In conclusion, this chapter has identified and highlighted the limitations in the regulation of advertising of medicinal products in Malaysia. The recommendations to redress the limitations are discussed in Chapter 6. In Chapter 6, the regulation of advertising of medicinal products is compared and contrasted with that in Australia and the United States. The following chapter investigates the regulation of the advertising of medicinal products in Australia.

²³² USD951.00 at USD1:3.15MYR as at 2 December 2010

CHAPTER 4

THE REGULATION OF THE ADVERTISING OF MEDICINAL PRODUCTS IN AUSTRALIA

4.1 INTRODUCTION

In Australia, medicinal products are known as therapeutic goods. Although this terminology is different to that used in other jurisdictions, therapeutic goods are, in essence, products with medicinal values or with claimed medicinal values.¹ This chapter examines the regulation of the advertising of therapeutic goods in Australia so as to establish the foundation for a comparative analysis in Chapter 6. It consists of four main sections, each dealing with different aspects of regulation.

Section [4.2] describes the types of products that fall within the classification of therapeutic goods. There are, in essence, three classes of therapeutic goods in Australia: (1) prescription drugs; (2) non-prescription drugs and (3) complementary medicines. However, there are also products, such as food or cosmetics, which carry therapeutic claims and fall within the classification of therapeutic goods unless exempted. The circumstances under which these products fall within the classification and/or are exempt from the classification are described in this section.

Section [4.3] examines the regulation of advertising of therapeutic goods in Australia. The advertising of therapeutic goods is governed by three legislative regimes: (1) the Commonwealth; (2) the States and Territories and (3) self-regulation. At the Commonwealth level, there are two legislative regimes, one that applies specifically to advertisements of therapeutic goods and one that regulates advertising in general. The regime that specifically applies to advertisements of therapeutic goods is governed by the *Therapeutic Goods Act 1989* (Cth), with detailed rules set out in the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code 2007* (Cth). The

¹ *Therapeutic Goods Act 1989* (Cth) s 3.

regime that applies to advertising in general is specified under Part V of the *Trade Practices Act 1974* (Cth). These laws are discussed at [4.3.2] of this chapter.

At the States and Territories level there are also two regulatory regimes: (1) a regime that applies specifically to advertisements of therapeutic goods and (2) a regime that regulates advertising across-the-board. In addition, advertisements of therapeutic goods are also subject to rules prescribed under industry codes of practice established by the peak industry associations: (1) Medicine Australia (the 'MA'); (2) the Australian Self-Medication Industry (the 'ASMI') and (3) the Complementary Healthcare Council of Australia (the 'CHCA'). Rules which are applicable to the advertising of prescription drugs and non-prescription drugs, food and cosmetics as prescribed in the legislation, regulations and codes are examined. These are examined at [4.3.1].

The regulatory controls, namely, (1) pre-approval of advertisements; (2) complaint-handling and (3) enforcement, are examined in section [4.3.2]. The discussion of the system of pre-approval of advertisements of therapeutic goods includes a description of two types of approval that are required. The types of advertisements which are subject to or exempt from pre-approval are also discussed in this section. The manner in which complaints regarding non-compliance with advertising rules are handled is subsequently looked at, examining whether complaints are handled in a timely way and whether the forms of sanctions imposed are sufficient to prevent the re-occurrence of advertising misconduct. Section [4.3.2] also looks at the judicial enforcement that is carried out in the regulation of therapeutic goods. Here, it explores the orders granted by the courts and the extent to which the order facilitates the prevention of deceptive advertising.

Next, section [4.4] of the chapter examines the reviews conducted of the current system of regulation of therapeutic goods. The three main reviews, which have been commissioned by the Federal Government, namely, (1) the Review of Drugs, Poisons and Controlled Substances Legislation by Rhonda Galbally; (2) the Review of Advertising Therapeutic Products in Australia and New Zealand by Toogoolawa Consulting Pty Ltd and (3) the Review of Complementary Medicines by the Expert Committee on Complementary Medicines, are assessed. Issues raised and recommendations proposed by the review committees in respect to controls over the advertising of therapeutic goods are considered in this section as a partial introduction to an analysis in [6.3.3] of Chapter 6, which deals

with recommendations to improve the existing regulation of advertising of medicinal products in Malaysia. The attempts by the Australian Government to jointly regulate the advertising of therapeutic goods in conjunction with the New Zealand Government and the issues that caused this effort to fail are also set out in this section.

Section [4.5] concludes the chapter by identifying the strengths and weaknesses of the system of regulation of therapeutic goods advertising in Australia. The considerable complexities in the regulation of therapeutic goods in Australia are highlighted.

4.2 CLASSIFICATION OF THERAPEUTIC GOODS IN AUSTRALIA

4.2.1 Range of Products Classified as Therapeutic Goods

In Australia, both prescription and non-prescription drugs fall within the definition of the term ‘therapeutic goods’, which is further examined at [4.2.1.1]. Complementary medicines are classified as therapeutic goods under the *Therapeutic Goods Act 1989* (Cth). Products such as food and cosmetics, however, fall within the classification of therapeutic goods when they are intended for a therapeutic use, and are unclassified when they fall within ‘exceptions’. The circumstances under which such products are exempted from that classification are considered at [4.2.1.2] and [4.1.2.3]. The aims are: (1) to determine the categories of products that qualify as therapeutic goods and (2) to ascertain the impact of the classification of products as therapeutic goods.

4.2.1.1 Prescription and Non-Prescription Drugs, Pharmacy-Only-Medicines and Complementary Medicines are Therapeutic Goods

As specified by the definition of the term ‘therapeutic goods’ in the *Therapeutic Goods Act 1989* (Cth), products which are used therapeutically or represented as being for therapeutic use, or likely to be taken to be for therapeutic use, are regarded as therapeutic goods.² The term ‘therapeutic use’ is defined to include use in ‘preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals, or influencing, inhibiting or modifying a physiological process in persons or animal’ and ‘...influencing, controlling or preventing conception in persons’.³

According to this definition, both prescription and non-prescription drugs fall within the category of therapeutic goods as they are ordinarily used to prevent, diagnose, cure or alleviate a disease or illness. However, therapeutic goods fall into a multi-level

² Ibid. The term therapeutic goods is defined to mean ‘[goods] that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for; (i) therapeutic use or; (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or (b) [goods] included in a class of goods the sole or principal use of which is, or ordinarily is a therapeutic use or a use of a kind referred to in subparagraph (a) (ii) or (iii)’. Ibid.

³ *Therapeutic Goods Act 1989* (Cth) s 3.

classification that ranges from Schedules 2 to 8.⁴ Schedule 2 substances refer to pharmacy medicine for which advice of a pharmacist is available if necessary. Schedule 3 substances refer to Pharmacist-Only-Substances, which include substances that are obtainable only from a pharmacist, but without a doctor's prescription.⁵ Schedule 4 substances are the Prescription-Only-Substances the use or supply of which should be by, or on, the order of a medical practitioner and should be available from a pharmacist on prescription.⁶ Schedule 8 substances are controlled substances, substances which are restricted because they may be subject to abuse, misuse and physical or psychological dependence.⁷

Products which are classified as therapeutic goods are required to be either registered or listed in the Australian Register of Therapeutic Goods ('ARTG'), which is a database containing information about therapeutic goods for human use, based on the ingredients, dosages of the products and the promotional claims.⁸ These drugs are either registered or listed in the ARTG based on a risk assessment. They are assessed according to the seriousness of the risk involved, namely the potential for harm, toxicity and side effects.⁹ Drugs are registered if they are of high risk and listed if they are considered of low risk.¹⁰

4.2.1.2 Food

Food is governed by the *Food Standards Australia New Zealand Act 1991* (Cth) and *Food Standards Australia New Zealand Regulation 1994* (Cth). Food is regulated by the Food Standards Australia New Zealand (FSANZ) which is the regulatory agency for food. Food which has been classified as therapeutic goods by the Therapeutic Goods Administration

⁴ National Coordinating Committee, on Therapeutic Goods, *Scheduling Policy Framework for Medicines and Chemicals* (July 2010).

⁵ Ibid 18 and 19.

⁶ Ibid 20.

⁷ Ibid 25.

⁸ See *Therapeutic Goods Act 1989* (Cth) s 9A.

⁹ Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Medicines Regulation and the Therapeutic Goods Administration* <<http://www.tga.gov.au/html/medregs.htm>>.

¹⁰ Ibid.

under section 7 of the *Therapeutic Goods Act 1989* (Cth) is, however, regulated by the Therapeutic Goods Administration. Section 7 enables the Secretary to the Department of Health and Ageing to declare food products (or any product) as therapeutic goods when necessary.¹¹ For example, a product known as ‘Celanese’ has been declared a therapeutic good since 3 December 1998. Similarly, fibre sold in capsules and shark cartilages have been declared therapeutic goods since 8 February 1999 and 14 April 1999, respectively.¹² In general, food which are found to be represented as having a therapeutic use or purpose are referred to the Therapeutic Goods Administration for determination of their class.¹³

The advertising of food is governed by two main codes: (1) *Australia New Zealand Food Standards Code* (the ANZFS Code) and (2) the *Code of Practice on Nutrient Claims in Food Labels and in Advertisements* (the CoPoNC). The advertising is also governed by section 52 the *Trade Practices Act 1974* (Cth) and the Fair Trading legislation.¹⁴

Advertisements of food are permitted to carry nutrient content claims which are in accordance with the Policy Guidelines established by the Australia and New Zealand Food Regulation Ministerial Council.¹⁵ This policy guideline sets out policy principles relevant to the regulation of nutrient content and health claims.¹⁶ Nutrient claims are claims about the effect of nutrients in the food. Nutrient claims are defined in Standard 1.2.8 of the *Australia New Zealand Food Standard Code* as ‘a representation that states, suggests or implies that a food has a nutritional property whether general or specific and whether expressed affirmatively or negatively, and includes a reference to (1) energy; (2) salt, sodium or potassium; (3) amino acids, carbohydrate, cholesterol, fat, fatty acids, fibre, protein, starch

¹¹ See the Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Section 7 Declaration – Food or Therapeutic Goods? Background*.’ (2006) <<http://www.tga.gov.au/cm/cmreg-aust.htm>>. (‘Section 7 Declaration – Food or Therapeutic Goods’).

¹² Ibid.

¹³ Ibid.

¹⁴ See Food Standards Australia New Zealand *Final Assessment Report- Proposal P293 – Nutrition, Health and Related Claims* (11 April 2008). (‘Final Assessment Report- Proposal P293’).

¹⁵ Ibid.

¹⁶ Ibid [ii] - [iii].

or sugars; (4) vitamins or minerals; (5) any other nutrient or (6) a biologically active substance'.¹⁷

Food advertisements are, however, not permitted to carry therapeutic claims except for one type, namely, a claim relating to 'maternal folate consumption with reduced risk of foetal neural tube defects in women around the time of conception'.¹⁸

In April 2008, the FSANZ proposed the use of seven additional claims in labels and advertisements.¹⁹ These claims have been suggested in a 'guideline document' called the 'draft standard'.²⁰ The draft standard, which was prepared in response to the policy guidelines,²¹ sets out details surrounding the making of the nutrient, health and related claims.²² It categorised health claims into three types, namely (1) nutrient content claims, which are 'claims regarding the presence or absence of a property of the food, other than a claim about alcohol content'; (2) general level health claims, which are claims that relate a nutrient or substance in a food to its effect on health functions, but not to a serious disease or biomarker of a serious disease and (3) high level health claims, which are claims that 'directly or indirectly refer to a serious disease or a biomarker'.²³ The high level health claims, which are commonly referred to as 'food-disease relationships', must be pre-approved by the FSANZ before they can be disseminated in advertisements.²⁴

A total of eight types of food-disease claims have been proposed for inclusion in labels and advertisements.²⁵ These claims relate to: (1) calcium and vitamin D as a cause of a

¹⁷ See *Australia New Zealand Food Standards Code* Standard 1.2.8.

¹⁸ *Ibid* Standard 1.1.A 2.

¹⁹ *Final Assessment Report- Proposal P293* above n 14, 82 – 85.

²⁰ *Ibid* ii.

²¹ The Policy Guideline recommends, amongst other things, that a guideline document providing details of the nutrient content and general level health claims is made available. *Ibid* 13.

²² *Final Assessment Report- Proposal P293* above n 14.

²³ *Ibid* 18-19.

²⁴ *Ibid* 18-19.

²⁵ *Ibid* 29. Such claims, however, are required to meet the 'compositional criteria based on the nutrient profiling scoring criteria' before pre-approval. *Ibid* 29.

reduced risk of osteoporosis in women aged 65 years and above; (2) calcium as a cause of enhanced bone mineral density; (3) folic acid as a cause of reduced risk of foetal neural defects in women of child bearing age;²⁶ (4) saturated fatty acids associated with a reduction of blood cholesterol, total blood cholesterol, blood low-density lipoprotein (LDL) cholesterol, total serum cholesterol and serum cholesterol; (5) saturated and trans-fatty acids associated with a reduction in blood cholesterol, total blood cholesterol, blood (LDL)-cholesterol, serum LDL-cholesterol, total serum cholesterol or serum cholesterol levels; (6) sodium as a cause for the maintenance of normal blood pressure or reduced blood pressure in adults; (7) increased intake of vegetables and fruits associated with a reduction in the risk of coronary heart disease and (8) high intake of fruit and vegetables with a reduced risk of coronary heart disease.²⁷

These claims, however, are not permissible unless they have met the criteria and conditions for making the claims.²⁸ These are basically: (1) substantiations according to the 'Scientific Substantiation Framework'. Substantiation are determined by either using the FSANZ list of nutrient function statements, deriving claims from the food-disease relationship (for high level health claims), or the use of an authoritative source or systematic review as specified in the Scientific Substantiation Framework; (2) wording conditions, namely, the referencing of food or substance of food to health benefits and (3) nutrient profiling scoring criteria which is essentially an eligibility criteria for food.²⁹ Food-disease claims, other than the eight types proposed by FSANZ must be submitted to FSANZ for pre-approval.³⁰ Here, FSANZ will be guided by principles and procedures set out in an Application Handbook.³¹

²⁶ This claim is already permitted to be carried on advertisements.

²⁷ *Final Assessment Report- Proposal P293*, above n 14, 82 -85.

²⁸ *Ibid* 21.

²⁹ *Ibid*.

³⁰ *Ibid* 29.

³¹ *Ibid*.

The implementation of the draft standard is currently on hold, pending the commencement of the independent review of food labelling law and policy.³² In March 2009, a Consultation Paper on the changes proposed, namely, 'the regulation of general level claims and the revision of the text and structure of draft Standard 1.2.7', has been released by the FSANZ. Seventy one submissions in response to the Consultation Paper have been received and the FSANZ is currently considering submitter comments. It is noted that there will be a delay in the commencement of the independent review of food labelling law and policy, and thus the Ministerial Council has extended reporting period for the FSANZ to complete the review to April 2011.³³ Until such time food products which carry 'food-disease claims' other than the permissible claim³⁴ will be regarded as therapeutic goods.³⁵

There is a category of products known as 'special purpose food', which seeks to deliver adequate nutrition to groups of people who lack sufficient consumption of solid food.³⁶ Four kinds of products are classified as 'special purpose food': (1) infant formula;³⁷ (2) food for infants;³⁸ (3) formulated meal replacement and formulated supplementary food;³⁹ and (4) sports food.⁴⁰ These types of products are designed to treat specific health conditions or cater for a special need, and are thus permitted to carry claims reflecting those conditions or needs.

³²See the Food Standards Australia New Zealand, *Nutrition, Health and Related Claims*, <<http://www.foodstandards.gov.au/consumerinformation/labellingoffood/nutritionhealthandrelatedclaims/>>

³³ Ibid.

³⁴ As stated earlier, the permissible claim is the claim which relates maternal folate consumption and reduced risk of foetal neural tube defects in women around the time of conception.

³⁵ *Australia New Zealand Food Standards Code Standard 1.1.A 2.*

³⁶ Ibid Part 2.9.

³⁷ Ibid Standard 2.9.1.

³⁸ Ibid Standard 2.9.2.

³⁹ Ibid Standard 2.9.3.

⁴⁰ Ibid Standard 2.9.4.

There are also categories of food known as (1) medical food;⁴¹ (2) food supplements for special diets⁴² and (3) macronutrient modified food.⁴³ These are acknowledged in the *Australia New Zealand Food Standards Code*, but no attempts have been made to specify rules or provisions regulating them.⁴⁴

In addition, there is a category known as 'functional food'. Functional food is ordinarily accepted as food which has additional health benefits over and above its basic nutritional values.⁴⁵ This category does not exist as a separate category in the existing regulatory system. It is ordinarily regulated as therapeutic goods by virtue of section 7 of the *Therapeutic Goods Act 1989* (Cth).⁴⁶ It is likely that functional food is not established as a separate category within the regulatory system because the control for functional food exists in other forms.⁴⁷ Functional food does, to a certain extent, overlaps with 'special purpose food' if they provide benefit to a certain group of population.⁴⁸ Some form of declaration distinguishing functional food from other types of food, and thereby providing a specific framework for its regulation is, however, seen as pertinent, and an initiative to provide a declaration with regard to its status is being considered. Both the Therapeutic Goods Administration and the FSANZ have begun to resolve issues relating to the food and medicine interface.⁴⁹ Proposals have been made to declare products in the form of capsules, tablets, and pills as therapeutic goods.⁵⁰

⁴¹ Ibid Standard 2.9.5.

⁴² Ibid Standard 2.9.6.

⁴³ Ibid Standard 2.9.7.

⁴⁴ The relevant pages of the Code are left blank, stated as 'reserved for future inclusion'. Ibid Part 2.9.

⁴⁵ No Seong Kwak and David John Jukes, 'Functional Foods: The Impact on Current Regulatory Terminology' (2001) 12 *Food Control* 109, 109.

⁴⁶ *Section 7 Declaration – Food or Therapeutic Goods*, above n 11; Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Public Submission: Proposed Section 7 Declaration that Products in Capsules, Tables and Pills are Therapeutic Goods* (21 January 2010) <<http://www.tga.gov.au/cm/consult/cons-s7declaration-chc.pdf> - 133k - [pdf] >. ('Public Submission: Proposed Section 7 Declaration in Capsules, Tables and Pills').

⁴⁷ Kwak and Jukes, above n 45, 116.

⁴⁸ Ibid.

⁴⁹ *Public Submission: Proposed Section 7 Declaration in Capsules, Tables and Pills*, above n 46.

⁵⁰ Ibid.

4.2.1.3 Dietary Supplements

Dietary supplements in Australia are referred to as complementary medicines. Complementary medicines include vitamins, herbal medicines, nutritional substances, traditional medicines, homeopathic remedies and aromatherapy products.⁵¹ Defined as a 'therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use',⁵² these categories of products are required to comply with the rules applicable to therapeutic goods.

Complementary medicine is also referred to as 'alternative medicines', 'natural medicines' and 'holistic medicines'. In essence, these are low risk medicines and are intended to be used for relief of symptoms of minor, self-limiting conditions, and for maintaining health and well being, or the promotion or enhancement of health.⁵³

4.2.1.4 Cosmetics

Cosmetic products are regulated by the National Industry Chemicals Notification and Assessment Scheme ('NICNAS') under the *Industrial Chemical (Notification and Assessment) Act 1989* (Cth) (the ICNA Act).⁵⁴ They are also governed by the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*, which is the specific regulation that governs cosmetic products in Australia. In addition, rules pertaining to the regulation of cosmetic products are also specified under the *NICNAS Cosmetics Guidelines 2007* (NICNAS Guidelines).⁵⁵ The NICNAS Guidelines explains the meaning of term 'cosmetics', and details the requirements to be met by cosmetic

⁵¹ *Therapeutic Goods Act 1989* (Cth) Part 6-4.

⁵² The term 'traditional use' refers to 'use of the designated active ingredient that is well documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period; and accords with well-established procedures of preparation, application and dosage'. See *Ibid* s 52F.

⁵³ Therapeutic Goods Administration, Department of Health and Ageing, Australia *The Regulation of Complementary Medicines in Australia*, <<http://www.tga.gov.au/cm/cmreg-aust.htm>>.

⁵⁴ Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Cosmetic Claims Guidelines* <<http://www.tga.gov.au/docs/html/cocslaim.htm>>.

⁵⁵ The Guideline which was drafted in accordance with amendments made to the ICNA Act, in 2007.

products.⁵⁶ It also specifies the types of products that are regulated as cosmetic products and illustrates, by way of examples, products which continue to be regulated as cosmetics. In addition, the consequences of non-compliance with requirements are spelled out.⁵⁷

Cosmetic products are defined as 'substance[s] or preparation[s] intended for placement in contact with any external part of the human body, including the mucous membrane of the oral cavity, and the teeth, with a view to: (a) altering the odours of the body; (b) changing its appearance; (c) cleansing it; (e) maintaining it in good condition; (f) perfuming it or (g) protecting it'.⁵⁸ They are regulated as cosmetics if their purposes are to merely cleanse, maintain, protect, perfume or change appearance, as indicated in the definition.

When cosmetic products have 'therapeutic orientated functions' in addition to their cosmetic function, two factors, the composition and the proposed uses of the products, are considered. First, if there is in the composition of the product, 'an ingredient or a concentration of ingredient which could result in the product [becoming] unsuitable [for use] as cosmetics', then it is referred to the Therapeutic Goods Administration for classification as therapeutic goods,⁵⁹ and second, if the proposed use of the product is therapeutic, then the products are classified as therapeutic goods.⁶⁰

The process of referring to Therapeutic Goods Administration for determination of classification is, to a certain extent, simplified with the introduction of the *Therapeutic Goods (Excluded) Order No 1 of 2008* (the 'TGeo 2008'), which categorizes products into three groups: (1) 'goods that are not therapeutic goods'; (2) 'goods that are not therapeutic goods when used, advertised, or presented in a particular way' and (3) 'goods that are not therapeutic goods, with allowable limited therapeutic use when advertised, represented or

⁵⁶ NICNAS *Cosmetics Guidelines 2007* Part B.

⁵⁷ Ibid Part D.

⁵⁸ *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* s 3.

⁵⁹ See Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Regulation of Cosmetics* <<http://www.tga.gov.au/index.htm>>.

⁶⁰ See definition of 'therapeutic goods' and 'therapeutic use' in the *Therapeutic Goods Act 1989* (Cth) s 3.

presented for supply in a particular way'. Eight types of cosmetic products⁶¹ (with certain allowable claims),⁶² are excluded from classification as therapeutic goods despite therapeutic claims in advertisements.⁶³

4.2.1.5 Implication of Classification as Therapeutic Goods

In the foregoing sections, it has been noted that both prescription and non-prescription drugs and complementary medicines are declared as therapeutic goods. Products, such as food and cosmetics can fall within the classification of therapeutic goods by virtue of their composition, ingredients and intended use. Exemption is, however, granted in some limited circumstances.

Two methods are ordinarily used to determine the classification when there is an overlap between 'food and drugs' and 'cosmetic and drugs'. The matter can be referred to the Therapeutic Goods Administration for clarification, and in the case of cosmetic products, reference can also be made to the TGEO 2008, which provides details of the types of products which fall within the classification of therapeutic goods or representations which result in products being classified as therapeutic goods.

Products which are classified as therapeutic goods are subject to drug safety controls, which involve the requirement to demonstrate that the products are safe and effective

⁶¹ The types of products include: (1) 'tinted bases of foundation (liquids, pastes or powder) with sunscreen'; (2) 'products intended for application to the lips with sunscreen'; (3) 'moisturizing products with sunscreen for dermal application including anti-wrinkle, anti-ageing and skin whitening'; (4) sunbathing products (for example, oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15; (5) antibacterial skin products; (6) anti-acne skin care products (including spot treatments, cleansers, face scrubs and masks); (7) oral hygiene products for care of the teeth and the mouth (for example dentifrices, mouth washes and breath fresheners; and (8) anti-dandruff hair care products. see *Therapeutic Goods (Excluded Goods) Order No. 1 of 2008* s 6.

⁶² For example: (1) sunbathing products with a sun protection factor of at least 4 and not more than 15, may carry representation in connection with the product about pre-mature ageing linked to sun-exposure; (2) anti-bacteria skin products may present as being active only against bacteria; (3) anti-acne skin care products may present as controlling, or preventing acne only through cleansing, moisturizing, exfoliating or drying of the skins; (4) oral hygiene products may pledge benefits which result related to improvements to oral hygiene, including the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and (5) anti-dandruff hair-care products may be presented as controlling and preventing dandruff only through cleansing, moisturizing, exfoliating and drying of the scalp. *Therapeutic Goods (Excluded Goods) Order No. 1 of 2008* s 6.

⁶³ *Ibid* s 6 (a). The products must be classified as cosmetics under the ICNA Act before claims could be made.

based on adequate and scientific testing before they may be marketed. It also includes post-marketing surveillance for adverse reaction and product recalls. The responsibility to ensure that drug safety controls are adequately carried out is entrusted to the Therapeutic Goods Administration under section 63(1) of the *Therapeutic Goods Act 1989* (Cth). Section 63 (1) of the *Therapeutic Goods Act 1989* (Cth) provides that the Governor-General may 'make regulations, not consistent with this Act, prescribing matters: (a) required or permitted to be prescribed by this Act or (b) necessary or convenient to be prescribed for carrying out or giving effect to this Act. Section 63 (2) (g) of the Act further provides that the Governor-General may 'make provision for the testing of therapeutic goods, the inspection of manufacturing operations or the evaluation of data concerning therapeutic goods...'.

Pursuant to section 63 (2) (g) of the *Therapeutic Goods Act 1989* (Cth), regulations pertaining to testing of products have been established in the *Therapeutic Goods Regulations 1990* (Cth). Regulation 28 of the *Therapeutic Goods Regulations 1990* (Cth) provides that a 'relevant test' must be carried out to determine whether particular therapeutic goods (other than medical devices) are goods that conform with a standard applicable to them. The 'relevant test' is specified to include:

- (a) 'a test specified by the Minister in an order under section 10 of the Act for those goods in relation to that standard and
- (b) a test specified in a monograph in the British Pharmacopoeia^[64] in relation to that standard if:
 - (i) those goods are for use in humans and
 - (ii) the Minister has not specified a test in an order under section 10 of the Act for those goods in relation to that standard'.

⁶⁴ The British Pharmacopoeia (BP) is the official collection of standards for UK medicinal products and pharmaceutical substances. Produced by the British Pharmacopoeia Commission Secretariat of the medicines and Healthcare products Regulatory Agency, the BP makes a valuable contribution to public health by setting publicly available standards for the quality of medicines. It contains: (1) Monographs including British Pharmacopoeia (Veterinary) monographs; (2) Test methods; (3) Infrared reference spectra (4) Supplementary information. See the British Pharmacopoeia <<http://www.pharmacopoeia.co.uk/>>.

Section 10 of the *Therapeutic Goods Act 1989* (Cth) provides that;

- (1) The Minister may, by an order published in the *Gazette*, determine that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary)).
- (2) Without limiting the generality of subsection (1), an order establishing a standard for therapeutic goods may:
 - (a) be specified by reference to:
 - (i) the quality of the goods or
 - (ii) the quantity of the goods when contained in specified containers or
 - (iii) procedures to be carried out in the manufacture of the goods or
 - (iv) a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary) or
 - (v) a monograph in another publication approved by the Minister for the purposes of this subsection or
 - (vi) such a monograph as modified in a manner specified in the order establishing the standard or
 - (vii) a standard published by the Standards Australia International Limited or
 - (viii) such other matters as the Minister thinks fit or
 - (b) require that a matter relating to the standard be determined in accordance with a particular test or
 - (c) require that therapeutic goods, or a class of therapeutic goods identified in the order, be labelled or packaged in a manner, or Medicines and other therapeutic goods that are not medical devices kept in containers that comply with requirements, specified in the order.

As explained at [4.2.1.1], therapeutic goods must be either registered or listed in the ARTG before they can be marketed.⁶⁵ The registration or listing is carried out based on a risk evaluation. Therapeutic goods which are high risk are evaluated for quality, safety and efficacy before they are considered for registration in the ARTG.⁶⁶ The evaluation is carried out based on factors such as the 'strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used'.⁶⁷ If upon assessment it is found that the risk associated with the use of the product outweighs the benefits, the product may be refused registration,⁶⁸ otherwise the products are approved for registration. Once approved for registration, further conditions may be imposed, such as a condition on manufacturing, scheduling, labelling, supply (hospital only) and a condition pertaining to Product Information⁶⁹ and Consumer Medicine Information.⁷⁰

Therapeutic goods which are low risk are assessed for quality and safety before they are listed.⁷¹ Low-risk therapeutic goods are listed by manufacturer based on a self-assessment of the risk and are checked through Therapeutic Goods Administration's Electronic Listing Facility software.⁷² Listed therapeutic goods are required to comply with the Code of Good Manufacturing Practices⁷³ and manufacturers are required to hold evidence of product safety and efficacy.⁷⁴

⁶⁵ *Therapeutic Goods Act 1989* (Cth) s 9A.

⁶⁶ *Ibid* s 25(1) (d).

⁶⁷ Therapeutic Goods Administration, Department of Health and Ageing, Australia, *Regulation of Therapeutic Goods in Australia* < <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm> > ('*Regulation of Therapeutic Goods*').

⁶⁸ Therapeutic Goods Administration, Department of Health and Ageing, Australia, *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods* (July 2004) 15. ('*The Therapeutic Goods Administration's Risk Management Approach*').

⁶⁹ 'Product Information' is described as 'information in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods. See *Therapeutic Goods Act 1989* (Cth) s 9D (5).

⁷⁰ *The Therapeutic Goods Administration's Risk Management Approach*, above n 68, 15.

⁷¹ *Therapeutic Goods Act 1989* (Cth) s 26.

⁷² *Ibid* s 26BA; *The Therapeutic Goods Administration's Risk Management Approach*, above n 68, 15.

⁷³ *The Therapeutic Goods Administration's Risk Management Approach*, above n 68, 16.

⁷⁴ *Ibid*.

A system of 'risk management' is used to continuously assess the safety and efficacy of therapeutic goods. 'Risk management', means 'determining the likelihood of a risk being realised, what can cause this and what effect is likely.'⁷⁵ In essence, it is an assessment of how risks posed by therapeutic goods may be reduced to an acceptable level using available measures.⁷⁶ It is acknowledged that therapeutic goods may pose risks at various stages. Risks could be caused by products themselves.⁷⁷ These risks relate to 'ingredients in the products, dosages form of products, strength of products, toxicity, or potential harm through prolonged use'.⁷⁸ There may also be risks from poor manufacturing processes (meaning the product may not contain the relevant ingredients).⁷⁹ Risk may also be caused by the way drugs are prescribed and by the way a patient uses the products (based on information from the label).⁸⁰ Risk management aims to minimize these potential risks to an acceptable level.

Therefore, the implication of classification of products as therapeutic goods is that these products are required to establish that they are safe and effective before they are marketed and during their clinical use. This is carried out through scientific testing of the product and risk assessments at various stages. The manufacturers of these products are, however not required to prove that there is no risk involved in the use of these products, instead that the benefits of using the products outweigh any known risk before the products are made available in the market. The controls imposed before products are advertised to consumers are intended to supplement the advertising controls, which are discussed in the following section.

⁷⁵ Ibid 5.

⁷⁶ Ibid.

⁷⁷ Ibid 8.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Ibid.

4.3 THE REGULATION OF THERAPEUTIC GOODS (MEDICINAL PRODUCTS) ADVERTISING IN AUSTRALIA

In this section, the rules and regulatory controls employed in the regulation of therapeutic goods advertising are examined. The laws that govern the advertising of therapeutic goods are explored in [4.3.1]. In [4.3.2], the regulatory controls, such as pre-market approvals, complaint handling of advertisements and enforcement of violations of laws are examined.

4.3.1 The Laws governing the Advertising of Therapeutic Goods in Australia

The advertising of therapeutic goods in Australia is governed by three legislative regimes: (1) the Commonwealth; (2) States and Territories and (3) industry self-regulatory regimes. Under the Commonwealth regimes, the rules governing the advertising of therapeutic goods, which are set out in the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code 2007* (Cth), are looked at. The advertising rules set out under Part V of the *Trade Practices Act 1974* (Cth) are also examined. In addition, the States and Territories each have their own laws governing the advertising of therapeutic goods, and these are also explored. There are also industry codes of practices, namely the (1) *ASMI Code of Practice 2009*; (2) *Complementary Healthcare Council of Australia Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products 2005*, (hereinafter referred to as *CHCA Code of Practice 2005*) and (3) *Medicine Australia Code of Conduct (Edition 16) 2010* and its Code of Conduct Guidelines.

This section of the chapter details the laws that govern the advertising of therapeutic goods so as to enable an assessment of the extent to which the rules facilitate the regulation of advertising of medicinal products.

4.3.1.1 The Commonwealth Legislative Regime

The Commonwealth regime consists of the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth), the *Therapeutic Goods Advertising Code 2007* (Cth) and the *Trade Practices Act 1974* (Cth). The *Therapeutic Goods Act 1989* (Cth) is the main Commonwealth legislation governing the regulation of therapeutic goods. In the

context of advertising, it prescribes the regulations in relation to (1) pre-approvals of advertisements; (2) uses of prohibited advertisements; (3) uses of restricted and required representations in advertisements; (4) non-compliance with or breach(es) of requirements of advertising as specified under the *Therapeutic Goods Advertising Code 2007* (Cth) and (5) applications for use of restricted representations in advertisements of therapeutic goods. The *Therapeutic Goods Regulations 1990* (Cth), which is made pursuant to the *Therapeutic Goods Act 1989* (Cth), stipulate regulations including rules governing pre-approval of advertisements of designated therapeutic goods (which are therapeutic goods other than prescription drugs) and associated matters. The *Therapeutic Goods Advertising Code 2007* (Cth) stipulates principles governing (1) pre-approvals of advertisements; (2) use of prohibited, restricted and required representations and (3) general principles.⁸¹ In addition, the *Trade Practices Act 1974* (Cth), the Act that governs trade practices and consumer protection in general, regulates advertising across-the-board, including the advertising of therapeutic goods.

Provisions relating to the advertising of therapeutic goods as stipulated in the *Therapeutic Goods Act 1989* (Cth), *Therapeutic Goods Regulations 1990* (Cth) and *Therapeutic Goods Advertising Code 2007* (Cth) are comprehensive and voluminous, and an issue is whether this enhances the regulation of therapeutic goods advertising or otherwise. The provisions in these laws are examined below so as to enable the assessment of this issue at [6.3.3] of Chapter 6.

(a) *Therapeutic Goods Act 1989* (Cth)

The *Therapeutic Goods Act 1989* (Cth) aims to ‘provide for the establishment and maintenance of a national system of control for therapeutic goods and to ensure quality, safety, efficacy and timely availability of therapeutic goods used in Australia, whether produced in Australia or elsewhere or exported from Australia.’⁸² In the context of advertising, it broadly prescribes: (1) the advertising offences;⁸³ (2) the rules governing the

⁸¹ Non-compliance(s) or breach(s) of provisions of the *Therapeutic Goods Regulations 1990* (Cth) and *Therapeutic Goods Advertising Code 2007* (Cth) are actionable under the *Therapeutic Goods Act 1989* (Cth).

⁸² *Therapeutic Goods Act 1989* (Cth) 4 (1) (a).

⁸³ *Ibid* ss 42C (1), (2), (4) and (6).

approval of the use of prohibited and restricted representations⁸⁴ and (3) the exclusion of the application of the Act to advertisements directed at healthcare professionals.⁸⁵

Essentially, the *Therapeutic Goods Act 1989* (Cth) prescribes offences if certain regulatory requirements are not met or prohibitions relating to advertising are not observed. For example, a failure to obtain a pre-market approval for advertisements of therapeutic goods is an offence.⁸⁶ Further, displaying advertisements without approval numbers, displaying false approval numbers and displaying expired approval numbers are offences under the Act.⁸⁷ In addition, it is an offence if the advertisement: (1) contains a prohibited representation without an approval;⁸⁸ or (2) does not contain a required representation;⁸⁹ or (3) contains a restricted representation without an approval.⁹⁰

A prohibited representation is ‘any representation regarding abortifacient actions, treatments, cure or prevention of neoplastic, sexually transmitted diseases (STD), HIV AIDS and/or HCV and mental illness.’⁹¹ A required representation is a statement that must be stated in advertisements regarding the use and characteristics of goods such as, a list of active ingredients, serious adverse effects or other related matters. For example, prominent display of key phrases such as “‘ALWAYS READ THE LABEL’, ‘USE AS DIRECTED’, ‘IF SYMPTOMS PERSIST SEE YOUR DOCTOR OR HEALTHCARE PROFESSIONALS’, ‘YOUR PHARMACIST’S ADVICE IS REQUIRED’, AND ‘YOUR [APPROPRIATE HEALTHCARE PROFESSIONAL] WILL ADVISE YOU WHETHER THIS PREPARATION [PRODUCT NAME] IS SUITABLE FOR YOU/YOUR FAMILY’,” is required representation.⁹² Restricted representations are representations that are not permissible

⁸⁴ Ibid ss 42DD - 42DK.

⁸⁵ Ibid s 42AA.

⁸⁶ Ibid s 42DL

⁸⁷ Ibid s 42C (4) (b).

⁸⁸ Ibid s 42DD (2).

⁸⁹ *Therapeutic Goods Advertising Code 2007* (Cth) s 6 (3). It is an offence if the provisions in the *Therapeutic Goods Advertising Code 2007* is not complied with. See *Therapeutic Goods Act 1989* (Cth) s 42DM.

⁹⁰ *Therapeutic Goods Act 1989* (Cth) s 42DF.

⁹¹ See *Therapeutic Goods Advertising Code 2007* (Cth) Pt 1 Appendix 6.

unless approvals are obtained.⁹³ There is a list of twenty types of serious diseases, conditions, ailments and defects for which the advertising is restricted.⁹⁴

It is also an offence to advertise goods or substances or preparations, which are included in Schedule 3, 4 or 8 of the Poisons Standards,⁹⁵ unless they are listed under Appendix H of the Poisons Standard and made by or on behalf of the Commonwealth.⁹⁶

An important requirement is that all therapeutic goods, unless exempted,⁹⁷ must be entered in the ARTG.⁹⁸ Hence, advertisements for therapeutic goods which have not been entered in the ARTG,⁹⁹ or refer to indications that are not included in the Register, are unlawful in Australia.¹⁰⁰

(b) *Therapeutic Goods Regulations 1990 (Cth)*

The *Therapeutic Goods Regulations 1990* (Cth) came into force alongside the *Therapeutic Goods Act 1989* (Cth) on 15 February 1991. The rules in the *Therapeutic Goods Regulations 1990* (Cth) are established pursuant to Sections 63 (1) and (2) (c) of the

⁹² Ibid s 6 (3).

⁹³ *Therapeutic Goods Act 1989* (Cth) s 42DF.

⁹⁴ They are: (1) cardiovascular diseases; (2) dental and periodontal diseases; (3) diseases of joint collagen and rheumatic disease; (4) diseases of the eye or ear likely to lead to blindness or deafness; (5) diseases of the liver, biliary system or pancreas; (6) endocrine diseases and conditions including diabetes and prostatic disease; (7) gastrointestinal diseases or disorders; (8) haematological diseases; (9) infectious diseases; (10) immunological diseases; (11) mental disturbances; (12) metabolic disorders; (13) musculo-skeletal diseases; (14) nervous system diseases; (15) poisoning, venomous bites and stings; (16) renal diseases; (17) respiratory diseases; (18) skin diseases; (19) substance dependence; (20) urogenital diseases and conditions. See *Therapeutic Goods Advertising Code 2007* (Cth) s 5 (2) & Pt 2 Appendix 6.

⁹⁵ *Therapeutic Goods Act 1989* (Cth) S 42DL (1) (f). The 'Poisons Standard' refers to the Standard for Uniform Scheduling of Drugs and Poison published by the Australian Health Ministers' Advisory Council: at s 52A.

⁹⁶ Ibid s 42DL (3) (b).

⁹⁷ Ibid s 42DL (3) (c).

⁹⁸ Ibid s 9A.

⁹⁹ Ibid s 42DL (1) (g).

¹⁰⁰ Ibid s 22 (5).

Therapeutic Goods Act 1989 (Cth), which enables the Governor-General to prescribe regulations for advertising therapeutic goods.

In the context of advertising therapeutic goods, the *Therapeutic Goods Regulations 1990* (Cth) prescribes regulations concerning approvals of advertisements of designated therapeutic goods. It also establishes committees to deal primarily with matters concerning advertisements and complaint handling. Two committees, namely the Therapeutic Goods Advertising Code Council and the Complaints Resolution Panel (the CRP) have been established pursuant to Regulation 42A and Regulation 42R of the *Therapeutic Goods Regulations 1990* (Cth).

The regulations governing applications for approvals, refusal of approvals, withdrawals of approvals and variation of conditions of approvals of advertisements are prescribed in the regulations. The task of pre-approval of advertisements has been delegated to the 'health products' industry associations, namely the CHCA¹⁰¹ and the ASMI,¹⁰² by the Secretary to Department of Health and Ageing.¹⁰³ Nevertheless, the rules governing approvals of advertisements, stipulated in the *Therapeutic Goods Regulations 1990* (Cth), govern the industry associations.¹⁰⁴ Consequently, orders that can be made by the Secretary of the Department of Health and Ageing in respect of breaches of the *Therapeutic Goods Act 1989* (Cth), *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code 2007* (Cth) are also stipulated.¹⁰⁵ The orders must be made on the recommendations of the CRP.¹⁰⁶

¹⁰¹ The CHCA is the national body that is responsible to promote appropriate use of complementary healthcare and health-product in Australia. See *CHCA Code of Practice 2005* s 2A.

¹⁰² ASMI is a corporate representative for manufactures of non-prescription consumer healthcare products and its functions include ensuring that advertising and promotion are responsible and balanced. *ASMI Code of Practice 2009* s 2.3.

¹⁰³ *Therapeutic Goods Regulations 1990* (Cth) reg 5Q (3) and (4).

¹⁰⁴ *Ibid* regs 5F, 5G, 5H, 5L and 5K. The application for review by the Minister of decisions made by the Secretary to the Department of Health and Ageing and further applications of reviews by the Tribunal of decisions of the Minister on matters related to approvals, variations of approvals and withdrawal are prescribed under Regulation 5M and 5P of the *Therapeutic Goods Regulations 1990* (Cth).

¹⁰⁵ *Ibid* regs 9 (1) (a) - (f).

¹⁰⁶ *Ibid*.

The discussion regarding pre-approval of advertisement is further elaborated at [4.3.2.1] of this chapter.

(c) *Therapeutic Goods Advertising Code 2007 (Cth)*

The *Therapeutic Goods Advertising Code 2007 (Cth)* aims to ensure the ‘... advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.’¹⁰⁷ The provisions under the *Therapeutic Goods Advertising Code 2007 (Cth)* are established pursuant to section 3(1) of the *Therapeutic Goods Act 1989 (Cth)*, which defines the Therapeutic Goods Advertising Code as the code in force under section 42B (1) (a) the *Therapeutic Goods Regulations 1990 (Cth)*. The provisions in this Code are consistent with the *World Health Organization (WHO): Ethical Criteria for Medicinal Drug Promotion 1988*.¹⁰⁸ However, in the event of a conflict between the *Therapeutic Goods Advertising Code 2007 (Cth)* and WHO guidelines, the *Therapeutic Goods Advertising Code 2007 (Cth)* would prevail.¹⁰⁹

The *Therapeutic Goods Advertising Code 2007 (Cth)* prescribes the rules governing the advertising of therapeutic goods which is directed at consumers.¹¹⁰ The rules broadly include: (1) those governing pre-approvals of advertisements of therapeutic goods; (2) prohibitions and restrictions of certain representations in advertisements and (3) requirements for display of key phrases in advertisements.

The *Therapeutic Goods Advertising Code 2007 (Cth)* also sets out the main pre-conditions for approval of advertisements, which include: (1) that pre-approvals are not permitted for advertisements depicting certain types of illnesses or conditions;¹¹¹ (2) that approvals are not to be granted if prominent displays or broadcasts of key phrases in advertisements are

¹⁰⁷ *Therapeutic Goods Advertising Code 2007 (Cth)* s 1 (1).

¹⁰⁸ World Health Organization, *Ethical Criteria for Medical Drug Information*, <<http://apps.who.int/medicinedocs/en/d/Jwhozip08e/7.html>> at 22 October 2010.

¹⁰⁹ *Therapeutic Goods Advertising Code 2007 (Cth)* s 1 (2).

¹¹⁰ *Ibid* s 3 (1) (a).

¹¹¹ As specified under Appendix 6 of the *Therapeutic Goods Advertising Code 2007 (Cth)*.

not adhered to¹¹² and (3) that general principles of advertising ensuring ethical and responsible advertising practices are complied with by advertisers.¹¹³ Adhering to these provisions of the *Therapeutic Goods Advertising Code 2007* (Cth) is crucial, as non-compliance with or breaches of the provisions are regarded as offences of strict liability.¹¹⁴

The Code, however, does not regulate advertisements of therapeutic goods directed at healthcare professionals.¹¹⁵ It also does not regulate *bona fide* news, public interest or entertainment programs or information material which complies with the Price Information Code of Practice.¹¹⁶ The Price Information Code of Practice prescribes the conditions and the mechanisms under which information about the price of prescription medicines and certain pharmacist- only-medicines, may be given to the general public so as to enable them to consider the prices of medicines when deciding to obtain their medicines.¹¹⁷

(d) *Trade Practices Act 1974* (Cth)

Advertisements of therapeutic goods are also subject to the law that regulates advertising in general, namely the *Trade Practices Act 1974* (Cth).¹¹⁸ The *Trade Practices Act 1974*

¹¹² *Therapeutic Goods Advertising Code 2007* (Cth) s 6 (3).

¹¹³ It is specified under section 4 (2) (a) – (j) of the *Therapeutic Goods Advertising Code 2007* (Cth) that, advertisements must not be likely to arouse unwarranted and unrealistic expectations of product effectiveness; be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases; mislead or likely to mislead directly or by implications or through emphasis, comparison, contrast or omission; abuse the trust or exploit the lack of knowledge of consumers or contains language which could bring about fear or distress; contain any matters which is likely to lead persons to believe that they are suffering from a serious ailment or harmful consequences may result from not using the therapeutic product unless it is for sunscreen and consistent with current public health message; encourages or be likely to encourage, inappropriate or excessive use; contains any claims or statements or implication that it is infallible, unfailing, magical, miraculous, or that it is certain, guaranteed or sure cure; contains any claims, statements or implication that is effective in all cases of a condition; contains any claims, statement or implication that the goods are safe or that their use cannot harm or that they have not side effects or be directed at minors except the therapeutic goods listed in Appendix 5.

¹¹⁴ *Therapeutic Goods Act 1989* (Cth) s 42DM (1) and (2).

¹¹⁵ *Therapeutic Goods Advertising Code 2007* (Cth) s 3 (1) (b).

¹¹⁶ *Ibid* s 3 (1) (c).

¹¹⁷ *Price Information Code of Practice 2006* (Cth) s 2 (a) and (b).

¹¹⁸ The *Trade Practices Act 1974* (Cth) aims to 'enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection'. See the *Trade Practices Act 1974* (Cth) s 2.

(Cth) has a broad range of provisions on trade practices and consumer protection. However, the relevant sections of the *Trade Practices Act 1974* (Cth) that govern the advertising of goods (including therapeutic goods) are sections 52, 53 and 55 of the *Trade Practices Act 1974* (Cth).

Section 52 of the *Trade Practices Act 1974* (Cth) prohibits a corporation from engaging in misleading or deceptive conduct, or conduct likely to mislead or deceive, in the course of trade and commerce. It has been interpreted by the courts in numerous cases. For example, terms such as, 'misleading or deceptive' or 'likely to mislead or deceive', which are not defined in the Act, must be understood through case law. In the case of *Weitmann v Katies Ltd*.¹¹⁹, the term 'misleading or deceptive' is interpreted as meaning 'lead astray in action or conduct, to lead into error, to cause to err', and the word 'deceive' is interpreted as meaning 'cause to believe what is false'. In the case of *Mc William Wines Pty Ltd v McDonald's System of Australia Pty Ltd*.¹²⁰, the expression 'likely to mislead or deceive' is interpreted as meaning 'may mislead or deceive' or 'may be expected to mislead or deceive' or 'has a capacity or tendency to mislead or deceive'. Then, in the case of *Global Sportsman Pty Ltd v Mirror Newspaper Ltd*.¹²¹ the word 'likely' is explained as 'real or not remote chance or possibility regardless of whether it is less or more than 50%'.

Section 53 of the *Trade Practices Act 1974* (Cth) prohibits false representations in connection with the supply or possible supply of goods, and section 55 of the *Trade Practices Act 1974* (Cth) prohibits 'conduct that is liable to mislead the public as to the nature, the manufacturing process, the characteristics [and] the suitability for their purposes or the quality of goods'. Numerous cases concerning deceptive advertising have also been dealt with under these provisions.¹²²

¹¹⁹ See *Weitmann v Katies Ltd*. (1977) 29 FLR, 343.

¹²⁰ See *Mc William Wines Pty Ltd v McDonald's System of Australia Pty Ltd* 1980 33 ALR 394, 410.

¹²¹ *Global Sportsman Pty Ltd v Mirror Newspaper Ltd* (1984) ALR 25, 30.

¹²² See generally Ray Steinwall, *Butterworths Annotated Trade Practices Act 1974* (LexisNexis Butterworth, 2010) 407- 478.

(e) *Bodies that Administer the Act, the Accompanying Regulations and the Code*

The *Therapeutic Goods Act 1989* (Cth) and the *Trade Practices Act 1974* (Cth) are Commonwealth legislation, and the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code 2007* (Cth) are the delegated legislation and code, respectively which together govern the regulation of therapeutics goods advertising in Australia. Three main regulatory bodies, namely (1) the Therapeutic Goods Administration; (2) the Therapeutic Goods Advertising Code Council and (3) the Australia Competition and Consumer Commission ('ACCC'), are responsible for administering these Acts, regulations and code.

The *Therapeutic Goods Act 1989* (Cth) and the accompanying *Therapeutic Goods Regulations 1990* (Cth) are administered by the Therapeutic Goods Administration, a national regulator working in cooperation with State and Territory governments and the industry.¹²³ The Therapeutic Goods Administration is responsible for the regulatory control of therapeutic goods in Australia.¹²⁴ Its role includes taking regulatory action against advertisers who violate the law.¹²⁵ It also proceeds with regulatory action when dealing with complaints referred by the Complaints Resolution Panels (CRP)¹²⁶ and other bodies.¹²⁷ The CRP is a committee which is established under section 42R of the *Therapeutic Goods Regulations 1990* (Cth) to 'receive and consider complaints about advertisements ... and also to take action and to make recommendations to the Secretary on the complaint...'.¹²⁸ The Therapeutic Goods Administration may also refer matters to other regulatory agencies such as the ACCC for further actions.¹²⁹

¹²³ Therapeutic Goods Administration, Department of Health and Ageing, Australia, *About the TGA* <<http://www.tga.gov.au/about/about.htm>>; Therapeutic Goods Administration, Department of Health and Ageing, Australia, *What TGA Does* <<http://www.tga.gov.au/about/about.htm>>.

¹²⁴ *Ibid.*

¹²⁵ *Ibid.*

¹²⁶ *Therapeutic Goods Regulations 1990* (Cth) reg 42ZCAI (4) (a) – (i).

¹²⁷ If the complaint concerns a risk to public safety or if a complementary healthcare product has not been included in the ARTG, then the matter is referred to the Surveillance Unit of the Therapeutic Goods Administration for further action. See *CHCA Code of Practice 2005* s 8.4.4.

¹²⁸ *Therapeutic Goods Regulations 1990* (Cth) reg 42S.

¹²⁹ The ACCC takes legal action against companies and individuals for breaches of *Trade Practices Act 1974* (Cth).

The *Therapeutic Goods Advertising Code 2007* (Cth) is administered by the Therapeutic Goods Advertising Code Council (the TGA Code Council). The TGA Code Council ‘considers the requirements for the advertising of therapeutic goods and changes to the *Therapeutic Goods Advertising Code 2007* (Cth)...’.¹³⁰ It considers and accepts submissions made to it on this purpose and advises the Minister accordingly’.¹³¹ It also provides recommendations which assist the Minister in ‘achieving greater uniformity in approval processes and standards for advertising therapeutic goods in specified media and broadcast media’.¹³²

The *Trade Practices Act 1974* (Cth) is administered by the ACCC, the national agency established under section 6A (1) of the Part 11 of the *Trade Practices Act 1974* (Cth) to deal with consumer protection issues under Part V of the Act. The ACCC’s key responsibilities are to ensure that individuals and businesses comply with the Commonwealth competition, fair trading and consumer protection laws.

4.3.1.2 States and Territory Legislative Regimes

The States and Territories have their own laws that govern the advertising of therapeutic goods under two regulatory regimes: (1) a regime that specifically regulates the advertising of therapeutic goods; and (2) a regime that regulates advertising across-the-board. The Rhonda Galbally Review, which was undertaken to examine State and Territory Drugs, Poisons and Controlled Substances Legislation against the Principles of National Competition Policy recommended, amongst other suggestions, that all provisions relating to advertising in State and Territory Drugs, Poisons and Controlled Substances legislation be repealed and that the *Therapeutic Goods Act (1989)* (Cth) is accepted as the principal legislation that controls advertising of medicines for human use.¹³³ The States and

¹³⁰ *Therapeutic Goods Regulations 1990* (Cth) 42B (1) (a).

¹³¹ *Ibid* s 42B (1) (a).

¹³² *Ibid* 42B (1) (b) 2.

¹³³ Rhonda Galbally, *Review of Drugs, Poisons and Controlled Substances Legislation: Final Report Part A* (January 2001), 66 (*‘Galbally Review’*).

Territories agreed to consider this recommendation.¹³⁴ It was noted that the States and Territories had, in general, supported the concept of complementary legislation.¹³⁵

The laws governing the advertising of therapeutic goods in the States and Territories are explored in this section of the chapter so as to assess the extent to which there is a uniform national system of controls on therapeutic goods. The status of both the *Therapeutic Goods Act (1989)* (Cth) and the *Trade Practices Act 1974* (Cth) are explored. It will be seen that whilst some States and Territories have adopted the *Therapeutic Goods Act (1989)* (Cth) by reference into the legislation or by passing complementary legislation, some are yet to have done either. The Fair Trading Acts of the States and Territories which regulate the advertising in general is also applicable in the regulation of advertising of therapeutic goods. The wording of sections 52 and 53 of the *Trade Practices Act 1974* (Cth) is similar to the wording of the Fair Trading Acts of the States and Territories, save for one crucial difference, that sections 52 and 53 of the *Trade Practices Act 1974* (Cth) are applicable to ‘corporations’ whereas the relevant provisions of Fair Trading Acts are applicable to ‘persons’. The wording of section 55 is identical to the wording of the relevant section in the Fair Trading Acts of the States and Territories.

(a) *New South Wales*

In New South Wales, *Poisons and Therapeutic Goods Act 1966* (NSW) ‘...[regulates], [controls] and [prohibits] the supply and use of poisons, restricted substances, drugs of addiction, certain dangerous drugs and certain therapeutic goods...’.¹³⁶ The *Poisons and Therapeutic Goods Regulation 2008* (NSW) provides the regulations for the implementation of the Act. The *Poisons and Therapeutic Goods Act 1966* (NSW) provides that ‘the Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part... apply as a law of New South Wales’.¹³⁷ This means, the *Therapeutic Goods Act 1989* (Cth) will apply as if it was a statute passed by the New South

¹³⁴ Australian Health Ministers’ Advisory Council Working Party, *Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)*, 5. (‘Response to the Galbally Review’).

¹³⁵ *Ibid* 6.

¹³⁶ *Poisons and Therapeutic Goods Act 1966* (NSW), long title.

¹³⁷ *Poisons and Therapeutic Goods Act 1966* (NSW) s 31 (1).

Wales Parliament. The *Therapeutic Goods Act (1989)* (Cth) is adopted by reference into the legislation.

The Fair Trading Acts of the States which regulate advertising in general, are also applicable to the regulation of advertising of therapeutic goods. Sections 42 and 44 the *Fair Trading Act 1987* (NSW) which are similarly worded to sections 52 and 53 the *Trade Practices Act 1974* (Cth) respectively, and section 49 the *Fair Trading Act 1987* (NSW) which is identical to section 55 of the *Trade Practices Act 1974* (Cth) govern the advertising of goods including therapeutic goods.

(b) *Tasmania*

In Tasmania, the *Therapeutic Goods Act 2001* (Tas) regulates ‘... the supply and use...of certain therapeutic goods in Tasmania...’.¹³⁸ The *Therapeutic Goods Regulations 2002* (Tas) provides the regulations for the implementations. The *Therapeutic Goods Act 2001* (Tas) declares that the provisions of the *Therapeutic Goods Act 1989* (Cth) will apply as laws of Tasmania.¹³⁹ The ‘Commonwealth therapeutic goods laws’ may be modified, if necessary.¹⁴⁰ This means, the *Therapeutic Goods Act 1989* (Cth) will apply as if it was a statute passed by the Parliament in Tasmania. The *Therapeutic Goods Act (1989)* (Cth) is adopted by reference into the legislation.

Apart from that, Sections 14 and 16 *Fair Trading Act 1990* (Tas) which are similarly worded to sections 52 and 53 the *Trade Practices Act 1974* (Cth) respectively and section 20 of the *Fair Trading Act 1990* (Tas) which is identical to section 55 of *Trade Practices Act 1974* (Cth) regulate advertising generally, including the advertising of therapeutic goods.

¹³⁸ *Therapeutic Goods Act 2001* (Tas) long title.

¹³⁹ *Ibid* s 6 (1).

¹⁴⁰ *Ibid*.

(c) *Victoria*

In Victoria, the *Therapeutic Goods Act 2010* (Vic)¹⁴¹ provides that ‘the Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part, apply as a law of Victoria.’¹⁴² The *Therapeutic Goods Act 1989* (Cth) applies in full force as if it was passed by the State Government.¹⁴³ Regulations which are necessary to give effect to the Act will be established under section 57(1) (a) of the *Therapeutic Goods Act 2010* (Vic). As in New South Wales and Tasmania, in Victoria, the *Therapeutic Goods Act* (1989) (Cth) is adopted by reference into the legislation.

In addition, rules governing advertising across-the-board are also applicable. Sections 9 and 12 the *Fair Trading Act 1999* (Vic), which are similarly worded to sections 52 and 53 of the *Trade Practices Act 1974* (Cth) respectively, and section 10 of the *Fair Trading Act 1999* (Vic) which is identical to section 55 of *Trade Practices Act 1974* (Cth), govern advertising in general and the advertising of therapeutic goods.

(d) *Queensland*

In Queensland, there are no provisions for adopting the *Therapeutic Goods Act 1989* (Cth) or for implementing regulatory controls complementary to those established under the *Therapeutic Goods Act 1989* (Cth) in the *Health Act 1937* (Qld). The *Health Act 1937* (Qld), the *Health (Drugs and Poisons) Regulation 1996* (Qld) and the *Health Regulation 1966* (Qld) govern the regulation of therapeutic goods including advertising. Sections 101A, 110(1) and 132(s) of the *Health Act 1937* (Qld) prohibit false description of drugs, the advertising of drugs that are harmful or useless, and false or misleading advertisements of drugs and related items. Sections 131 (1), 220 (1) and 292 (1) of the *Health (Drugs and Poisons) Regulation 1996* (Qld) regulate the advertising of controlled drugs, restricted drugs, and poisons, respectively. Further, section 157 (1) of the *Health Regulation 1996*

¹⁴¹ *Therapeutic Goods Act 2010* (Vic) s 1. The section stipulates three main purposes: (1) to provide for the application of the *Therapeutic Goods Act 1989* of the Commonwealth as a law of Victoria; and (2) to provide for the regulation of therapeutic goods in Victoria in circumstances where the Commonwealth Act does not apply and (3) to repeal the *Therapeutic Goods Act 1994* (Vic).

¹⁴² *Ibid* s 6(1).

¹⁴³ *Ibid*.

(Qld) prohibits the advertising of certain types of illnesses and conditions,¹⁴⁴ fictitious testimonials and other related matters.

In addition, the wording of sections 38 and 40 of the *Fair Trading Act 1989* (Qld) is similar to that of sections 52 and 53 *Trade Practices Act 1974* (Cth), and section 44 of the *Fair Trading Act 1989* (Qld) is identical to section 55 of the *Trade Practices Act 1974* (Cth). These prohibit misleading and deceptive advertising, false representations in advertisements and conduct that is liable to mislead the public.

(f) *South Australia*

In South Australia, the rules for advertising therapeutic goods are provided by the *Controlled Substances Act 1984* (SA) and the *Controlled Substances (Poisons) Regulations 1996* (SA), with no provisions adopting the *Therapeutic Goods Act 1989* (Cth) or complementary to the provisions of the *Therapeutic Goods Act 1989* (Cth) in the legislation. The *Controlled Substances Act 1984* (SA) prohibits the advertising of poisons, therapeutic substances and therapeutic devices, and prescribes compliance with regulations in advertising.¹⁴⁵ The detailed regulations governing advertisements are specified in the *Controlled Substances (Poisons) Regulations 1996* (SA).¹⁴⁶ Rules governing across-the-board advertising are also applicable to the regulation of the advertising of therapeutic goods. Sections 56 and 58 of the *Fair Trading Act 1987* (SA), the wording of which is similarly to that of sections 52 and 53 *Trade Practices Act 1974* (Cth) respectively, and section 63 of the *Fair Trading Act 1987* (SA) which is identical to section 55 of the *Trade Practices Act 1974* (Cth), are applicable. The *Therapeutic Goods Act 1989* (Cth) or complementary provisions of the *Therapeutic Goods Act 1989* (Cth) are, however, not adopted in South Australia.

¹⁴⁴ The section has listed 65 types of illnesses and conditions that are prohibited from being advertised to the public.

¹⁴⁵ *Controlled Substances Act 1984* (SA) s 28 (1) and 29.

¹⁴⁶ Regulation 4 of the *Controlled Substances (Poisons) Regulations 1996* (SA) stipulates that the restriction specified in Section 28 (1) of the *Controlled Substances Act 1984* (SA) applies to all poisons listed in Schedule 3, 4 and 8 of the Standard for Uniform Scheduling of Drugs and Poisons unless it is published in a journal circulated predominantly among medical professionals. The Standard for Uniform Scheduling of Drugs and Poisons is published by the National Drugs and Poisons Schedule Committee.

(g) Western Australia

In Western Australia, the regulations for the advertising of therapeutic goods are governed by the *Health Act 1911* (WA), with regulations set out in the *Health (Drugs and Allied Substances) Regulations 1961* (WA). In the context of advertising, the *Health Act 1911* (WA) prohibits false trade descriptions of drugs.¹⁴⁷ The *Health (Drugs and Allied Substances) Regulations 1961* (WA) prohibits the labelling and advertising of therapeutic substances, drugs and medicines of certain types of illnesses or conditions specified under the regulation.¹⁴⁸ This regulation also prohibits fictitious testimonials in the advertisements, and publishing or displaying offending advertisements.¹⁴⁹ However, certain provisions from the *Health Act 1911* (WA) will be amended and the *Health (Drugs and Allied Substances) Regulations 1961* (WA) will be repealed once the Therapeutic Goods Bill 2000 (WA), a complementary legislation adopting the Therapeutic Goods Act 1989 (Cth), is passed.¹⁵⁰ The Therapeutic Goods Bill 2000 (WA) aims 'to promote and facilitate the development of a national system of controls relating to quality, safety and efficacy and timely availability of therapeutic goods and for that purpose to make provisions in the Western Australia for the implementation of controls forming part of such a system complementary and additional to the provisions made by the Therapeutic Goods Act 1989 of the Commonwealth.'¹⁵¹

In addition, the regime that regulates advertising across-the-board is applicable. Sections 10 and 12 of the *Fair Trading Act 1987* (WA), the wording of which is similar to that of sections 52 and 53, and section 17 of the *Fair Trading Act 1987* (WA) which is identical to section 55 of the *Trade Practices Act 1974* (Cth), regulate the advertising of goods, that includes therapeutic goods.

¹⁴⁷ *Health Act 1911* (WA) s 236.

¹⁴⁸ *Health (Drugs and Allied Substances) Regulations 1961* (WA) reg R.01.001. The Regulation list 78 types of illnesses and conditions that are prohibited from being advertised to the public.

¹⁴⁹ *Ibid* reg R.01.002 and R.01.003.

¹⁵⁰ Therapeutic Goods Bill 2000 (WA) s 3. It is still in the status of a Bill as at 20 October 2010.

¹⁵¹ *Ibid* s 3.

(h) *Australian Capital Territory*

In the Australian Capital Territory, regulations for the advertising of therapeutic goods are specified under the *Medicines Poisons and Therapeutic Goods Act 2008* (ACT). The Act prescribes that '[publishing] an advertisement that promotes or encourages the use of a controlled medicine or prohibited substances', is unlawful,¹⁵² unless it is advertised by a dentist, doctor, pharmacist or veterinary surgeon or prescribed by the regulation.¹⁵³ The Act also provides that 'the Commonwealth therapeutic goods laws apply as a law of the Territory.'¹⁵⁴ Apart from local legislation, sections 12 and 14 and 19 of the *Fair Trading Act 1992* (ACT) which are similar to sections 52 and 53 *Trade Practices Act 1974* (Cth) respectively, and section 19 of the *Fair Trading Act 1992* (ACT) which is identical to section 55 of the *Trade Practices Act 1974* (Cth), regulate advertisements across-the-board including therapeutic goods advertising.

(i) *Northern Territory*

In the Northern Territory, the *Therapeutic Goods and Cosmetics Act* (NT) regulates 'the manufacture, distribution, labelling and advertising of therapeutic goods and certain articles of food...'.¹⁵⁵ Sections 37 and 39 of the *Therapeutic Goods and Cosmetics Act* (NT) prohibits the publication of prohibited representations in advertisements of therapeutic goods and the making of false or misleading advertisements, respectively. Section 38 of the *Therapeutic Goods and Cosmetics Act* (NT) prescribes the inclusion of key information such as, the name and address of the person authorising the publication of advertisements and prescribed information. There are, however, no provisions in the *Therapeutic Goods and Cosmetics Act* (NT) that suggest it is adopting the *Therapeutic Goods Act 1989* (Cth) or seen as complementary to it.

In addition, Sections 42 and 44 of the *Consumer Affairs and Fair Trading Act 1990* (NT), the wording of which is similar to that of sections 52 and 53 *Trade Practices Act 1974* (Cth) respectively, and section 47 of the *Consumer Affairs and Fair Trading Act 1990* (NT),

¹⁵² *Medicines Poisons and Therapeutic Goods Act 2008* (ACT) s 66 (1).

¹⁵³ *Ibid* s 66 (3) (a) (b) and (c).

¹⁵⁴ *Ibid* s 157(1).

¹⁵⁵ *Therapeutic Goods and Cosmetics Act* (NT), long title.

which is identical to section 55 of the *Trade Practices Act 1974* (Cth), regulate the advertising of therapeutic goods, amongst others.

Table 4.1 below illustrates the status of the States and Territories in respect to Harmonization with the *Therapeutic Goods Act 1989* (Cth).

Table 4.1 - Status of the States and Territories in respect to Harmonization with the Therapeutic Goods Act 1989 (Cth).

	States and Territories	Laws that regulates the advertising of therapeutic goods	Adopted <i>Therapeutic Goods Act</i> 1989 (Cth)	Complementary to TGA	Have not adopted or not complementary	In the process of adopting
	New South Wales	<i>Poisons and Therapeutic Goods Act</i> 1966 (NSW)	√			
	Tasmania	<i>Therapeutic Goods Act</i> 2001 (Tas)	√			
	Victoria,	<i>Therapeutic Goods Act</i> 2010 (Vic)√	.		
	Queensland,	<i>Health Act</i> 1937 (Qld), <i>Health (Drugs and Poisons) Regulation</i> 1996 (Qld) <i>Health Regulation</i> 1966 (Qld)			√	
	South Australia	<i>Controlled Substances Act</i> 1984 (SA) <i>Controlled Substances (Poisons) Regulations</i> 1996 (SA).			√	
	Western Australia	<i>Health Act</i> 1911 (WA), <i>Health (Drugs and Allied Substances) Regulations</i> 1961 (WA).				√ Therapeutic Goods Bill 2000 (WA) for complementary
	Australian Capital Territory,	<i>Medicines Poisons and Therapeutic Goods Act</i> 2008 (ACT)	√			
	Northern Territory	<i>Therapeutic Goods and Cosmetics Act</i> (NT)		√		

(j) *The Status of the States and Territory Legislation*

Whilst New South Wales, Tasmania and Victoria have adopted the *Therapeutic Goods Act 1989* (Cth), the Western Australia is in the process of passing complementary legislation to pick the *Therapeutic Goods Act 1989* (Cth) by reference, the remaining States and Territory are in the process.¹⁵⁶ It is likely that Queensland, South Australia and Northern Territory are at various the stages of drafting and implementation.

The Gallaby Review identified that the States and Territories by adopting the Commonwealth legislation, there will a considerable saving to the industry, government and consumers.¹⁵⁷ Variations in requirements can make products supply, training or administration more complex and thereby raise costs for the industry, government and consumers.¹⁵⁸ It can make market entry for firms outside a particular jurisdiction, difficult.¹⁵⁹ In some instances, the intended outcome may be the same, but details of the legislation differ and require parties to identify the exact nature of control that applies in all jurisdictions in which they intend to operate.¹⁶⁰ In such circumstances it is recommended, and to which the States and Territories have agreed, to adopt the *Therapeutic Goods Act 1989* (Cth) by reference or by passing complementary legislation. This will ensure uniformity in the regulation of advertising of therapeutic goods.

4.3.1.3 Industry Codes of Practice

The advertising of therapeutic goods is also governed by industry codes of practice. The codes are administered by industry associations, namely, (1) the Australian Self-Medication Industry (the 'ASMI') and (2) the Complementary Healthcare Council of Australia (the 'CHCA') and the Medicine Australia (the 'MA'), which each administer their own codes of practice. These associations play an important role in the regulation of

¹⁵⁶ See *Response to the Galbally Review Report*, above n 134, 6.

¹⁵⁷ *Galbally Review*, above n 133, 94.

¹⁵⁸ *Ibid.*

¹⁵⁹ *Ibid.*

¹⁶⁰ *Ibid* 95.

advertising of therapeutic goods in Australia, because the system of regulation of therapeutic goods advertising is co-regulation.

The co-regulatory system was first established in the 1990s¹⁶¹ with the delegation of power to pre-approve advertisements that require approval prior to publication from the Secretary of the Department of Health and Ageing to the industry association.¹⁶² The ‘shared responsibility’ between the Government and the industry applies, however, not only to pre-approvals of advertisements of therapeutic goods, but also to other related matters. For example, the Therapeutic Goods Advertising Code Council, which considers, amongst other matters, the requirements for advertising therapeutic goods and changes to the *Therapeutic Goods Advertising Code 2007* (Cth), accepts submissions from members¹⁶³ who are representatives from manufacturers or suppliers nominated from the industry associations,¹⁶⁴ advertising industries,¹⁶⁵ healthcare professionals¹⁶⁶ and members nominated by Therapeutic Goods Administration.¹⁶⁷ The Complaint Handling Panels, which consider complaints about advertisements of therapeutic goods and make recommendations to the Secretary,¹⁶⁸ consist of representative from ASMI and CHCA,

¹⁶¹ *Therapeutic Goods Regulations (Amendment) 1997* No. 400 reg 42C

¹⁶² Ibid reg 18 (3); There were also amendments made to the Broadcasting Act in 1991 to permit the delegation of pre-approval power to the Proprietary Medicines Association of Australia (now known as the Australian Self-Medication Industry) for print and electronic media. See John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Therapeutic Goods Administration, Canberra, 2007) 104 & 160.

¹⁶³ Therapeutic Goods Advertising Code Council may appoint sub-committees of its members to inquire into and report on any matter that is within its function. See *Therapeutic Goods Regulations 1990* (Cth) reg 42B (2).

¹⁶⁴ The industry associations named are Complementary Healthcare Council of Australia, Australian Self-Medication Industry, Australian Direct Marketing Association, the Direct Selling Association of Australia and the Medical Industry Association of Australia. See Ibid reg 42C (1) (a) (i), (ii), (iii), (iv) and (v).

¹⁶⁵ The Australian Association of National Advertisers and the Advertising Federation of Australia are the two advertising industries named. See Ibid reg 42C (1) (b) (i) and (ii).

¹⁶⁶ One person nominated from Australian Traditional Medicine Society and the Royal Australian College of General Practitioners, one person nominated jointly by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia and one person by the Royal Australian College of General Practitioners. See Ibid reg 42C (d) (i), (ii) and (iii).

¹⁶⁷ One government member and one other member, both nominated by the Therapeutic Goods Administration will be the members. See Ibid reg 42C (1) (e).

¹⁶⁸ Ibid reg 42S (b).

consumer associations¹⁶⁹ and the healthcare professionals.¹⁷⁰ Similarly, the ASMI and the CHCA also have participants from various groups including a representative from the Department of Health and Ageing.¹⁷¹ This section of the chapter explores how industry codes of practice complement the advertising laws.

(a) *ASMI Code and CHCA Code*

The *ASMI Code of Practice 2009* provides basic rules for regulating the advertising of non-prescription and healthcare products that are directed at consumers and healthcare professionals.¹⁷² The *Complementary Healthcare Council of Australia Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products 2005*, on the other hand, govern the advertising of complementary products in Australia.¹⁷³ These codes of practice have, in addition to their own ethical and industry requirements, incorporated the principles set out in the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods Advertising Code 2007* (Cth).¹⁷⁴ As noted at [4.3.1.3], the ASMI and CHCA have been authorized by the Secretary to the Department of Health and Ageing to pre-approve advertisements of therapeutic goods directed at consumers. In addition, they are also authorized to handle complaints regarding breaches of these rules. The primary requirements for pre-approval of advertisements and complaint handling are specified under the *Therapeutic Goods Regulations 1990* (Cth).

¹⁶⁹ The Australian Consumer Association and the Consumer Health Forum are the two consumer associations named. Ibid reg 42T (c).

¹⁷⁰ Australian Traditional Medicine Society, jointly by Pharmacy Guild of Australia, Pharmaceutical Society of Australia and Royal Australian College of General Practitioners are the healthcare professionals stipulated by the section. Ibid reg 42T(d) (i), (ii) and (iii).

¹⁷¹ The ASMI Panel comprises a lawyer with trade practices experiences, a practising member of RACGP, a community pharmacist, consumer organisations. See *ASMI Code of Practice 2009* s 7.4. The CHCA Panel is made up of practitioners, consumer representatives, representatives from Australian Direct Marketing Association and Direct Selling Association of Australia, observer from Therapeutic Goods Administration, Australian Competition and Consumer Commission and special interest group on invitation. See *CHCA Code of Practice 2005* s 8.3.1.

¹⁷² *ASMI Code of Conduct 2009* ss 3.1 and 5.1.2.

¹⁷³ There are a number of codes regulating complementary medicines in Australia. However, only CHCA Code is discussed in this chapter. The other Codes are; (1) Guidelines for the Tamper-Evident Packaging of Medicine; (2) Complementary Healthcare Products and Medical Devices; (3) Complementary Healthcare Council of Australia Internet Guideline for Complementary Healthcare Products; and (4) Code of Practice for Ensuring Raw Material Quality and Safety. See *CHCA Code of Practice 2005* s 1.7.

¹⁷⁴ See the *ASMI Code of Practice 2009* ss 2 & 3; *CHCA Code of Practice 2005* s 3.

Nevertheless, the *ASMI and the CHCA Codes of Practice* provide additional requirements to be fulfilled in order to supplement the regulations.

(b) *Medicine Australia Code of Conduct (Edition 16) 2010 and its Code of Conduct Guidelines*

In Australia, the advertising of prescription drugs which are directed at health-care professionals is governed by a self-regulatory system, a system where industry associations maintain a standard of practice through the imposition of professional codes of practice, independent of government interventions.¹⁷⁵ The advertising is governed by the *Medicine Australia Code of Conduct (Edition 16) 2010* and its *Code of Conduct Guidelines*,¹⁷⁶ which set out principles for the advertising of prescription drugs.¹⁷⁷ The Schedule 3 drugs which are included in the Appendix H of the *Standard for the Uniform Scheduling of Medicines and Poisons*, which is also known as the Poison Standard 2010, may be advertised to consumers and these are governed by the *Therapeutic Goods Act 1989* (Cth).

The *Medicine Australia Code of Conduct (Edition 16) 2010* specifies the standards of conduct to be maintained by members and companies engaged in the advertising of prescription medicines. It prohibits the promotion of prescription drugs to the general public, but information which is believed to be educational is allowed.¹⁷⁸ Educational material includes a ‘disease education activity’ about the availability of different treatment options, such as the range of prescription drugs, non-prescription drugs and/or alternative treatments, which can be disseminated to the general public.¹⁷⁹ It has been emphasised that the education activity should be limited to the conditions or its recognition, treatment

¹⁷⁵ *Medicine Australia Code of Conduct (Edition 16) 2010; Medicine Australia Code of Conduct Guidelines.*

¹⁷⁶ This guideline is produced as a separate publication and is read in conjunction with the *Medicine Australia Code of Conduct (Edition 16) 2010*.

¹⁷⁷ The *Therapeutic Goods Advertising Code 2007* (Cth) does not govern advertisements of prescription drugs directed at health care professionals. See the *Therapeutic Goods Advertising Code 2007* (Cth) s 3(1) (b).

¹⁷⁸ See *Medicine Australia Code of Conduct (Edition 16) 2010* s 12.3.

¹⁷⁹ *Ibid* s 12.7.2.

options and appropriate treatment necessary to provoke a discussion with healthcare professionals,¹⁸⁰ or to key characteristics of the disease.¹⁸¹

4.3.1.3 Conclusion

In Australia, laws governing the advertising of therapeutic goods are established under both Commonwealth, and States and Territory regimes, and at two levels, specific and general. The *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth), the *Therapeutic Goods Advertising Code 2007* (Cth) and the *Trade Practices Act 1974* (Cth), coupled with States and Territory laws, govern the advertising of therapeutic goods in Australia. Furthermore, industry codes of practice provide additional requirements, so as to promote compliance with the laws. Whilst this ensures that rules governing the advertising of therapeutic goods are comprehensive and detailed, a concern with this regulatory regime is that the laws may have become too complex or complicated for optimum compliance. This issue is raised and dealt with, at [6.3.2] of Chapter 6. The following section explores the regulatory control employed in the regulation of advertising of therapeutic goods.

4.3.2 The Regulatory Control over the Advertising of Therapeutic Goods in Australia

The regulatory controls established over the advertising of therapeutic goods in Australia include: (1) a system of pre-approval of advertisements of therapeutic goods; (2) handling of complaints regarding advertisements of therapeutic goods and (3) enforcement of the advertising rules. These controls are aimed mainly at preventing dissemination of deceptive advertising from reaching consumers and preventing future occurrences of deceptive advertising. The controls, and the manner in which these controls are carried out, are examined in this section of the chapter.

¹⁸⁰ Ibid s12.7.3.

¹⁸¹ Ibid s12.7.4.

4.3.2.1 Pre- Approval of Advertisements

Two types of approvals must be sought in respect of advertising of therapeutic goods. Pre-approvals must be obtained before restricted representations may be used in advertisements of therapeutic goods¹⁸² and before advertisements of designated therapeutic goods are disseminated to the public. Two set of rules must be complied with before an application for pre-approval of advertisements can be made. First, therapeutic goods must be either registered or listed in the ARTG.¹⁸³ The advertisement must, however, initially conform to standards applicable to goods, or any requirements relating to advertising, before an application to register or a listing can be made.¹⁸⁴ Failure to conform to the applicable advertising requirements may result in the registration or listing being cancelled.¹⁸⁵ Accordingly, the advertisement must only refer to indications that are accepted for inclusion in the ARTG.¹⁸⁶ Second, the publication and broadcasting of advertisements must not refer to goods, substances or preparations containing items included in Schedules 3, 4 or 8 of the Poisons Standards, ¹⁸⁷ unless exempted.¹⁸⁸

The application for approval to use restricted representations in advertisements of therapeutic goods must be made to the Secretary of the Department of Health and Ageing. An approval is normally granted if the representations are accurate, balanced and not misleading or likely to be misleading.¹⁸⁹ Notice of approval or refusal will be given within 60 days of the application; otherwise, the application is taken as approved.¹⁹⁰ The Secretary may vary any conditions of approval,¹⁹¹ or withdraw the approval if he or she is satisfied

¹⁸² *Therapeutic Goods Act 1989* (Cth) s 42DF(1).

¹⁸³ *Ibid* s 9A.

¹⁸⁴ *Ibid* ss 25(1) (f) and 26(1) (f), respectively.

¹⁸⁵ *Ibid* s 30(2)(e).

¹⁸⁶ *Ibid* s 22 (5).

¹⁸⁷ *Ibid* s 42DL (f). The Poison Standard refers to the Standard for Uniform Scheduling of Drugs and Poison: at s 52A.

¹⁸⁸ *Ibid* s 42DL (3) (b).

¹⁸⁹ *Ibid* s 42DF(1).

¹⁹⁰ *Ibid* s 42DG (2).

¹⁹¹ *Ibid* s 42DH.

that information given in the application is (1) false or incorrect; (2) the restricted representation has become a prohibited representation, or (3) there has been a breach of condition of approval.¹⁹²

The pre-market approval of advertisements for designated therapeutic goods is sought from the ASMI and the CHCA.¹⁹³ However, not all advertisements are subject to a pre-approval. Only advertisements of designated therapeutic goods that are non-prescription drugs published in specified media are subject to pre-approval before publication.¹⁹⁴ Specified media refers to mainstream media,¹⁹⁵ broadcast media,¹⁹⁶ cinematograph films or advertisements on outdoors display.¹⁹⁷ Media other than specified media are those commonly referred to as ‘under-the-line’ advertisements.¹⁹⁸ These advertisements, although not defined in the Act, the accompanying regulations, or the Code, are generally accepted as advertisements placed on leaflets, indoor posters, catalogues, flyers, brochures and the Internet.¹⁹⁹ Advertisements placed on the Internet are not subject to pre-approval.²⁰⁰ Similarly, advertisements of prescription drugs directed at healthcare professionals are not subject to pre-approval.²⁰¹ Furthermore, advertisements in the

¹⁹² Ibid 42DI.

¹⁹³ See *Therapeutic Goods Regulations 1990* (Cth) regs 5Q (4) (a) and (b). As noted at [4.3.1.3], the responsibility to pre-approve or refuse an approval of advertisements for designated therapeutic goods that are non-prescription drugs has been entrusted to these two industry associations.

¹⁹⁴ *Therapeutic Goods Regulations 1990* (Cth) regs 5Q (4) (a) and (b).

¹⁹⁵ Mainstream media’ refers to ‘...magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions and display [including] display of posters in shopping malls (except inside an individual shop) or in or on public transport and on billboards’. See *Therapeutic Goods Act 1989* (Cth) s 42B and *Therapeutic Goods Advertising Code 2007* s 2.

¹⁹⁶ Broadcast media are ‘...any means (other than a means declared in the *Therapeutic Goods Regulations* to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms.’ See *Therapeutic Goods Act 1989* (Cth) s 42B and *Therapeutic Goods Advertising Code 2007* s 2.

¹⁹⁷ *Therapeutic Goods Act 1989* (Cth) s 42B.

¹⁹⁸ Toogoolawa Consulting Pty Ltd, *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand*, (November 2002) 13. (‘Toogoolawa Report’).

¹⁹⁹ Ibid.

²⁰⁰ See *Therapeutic Goods Regulations 1990* (Cth) reg 5BA.

²⁰¹ See *Therapeutic Goods Act 1989* (Cth) s 42AA (1).

following types of communications are also exempt from pre-approval: (1) electronic mail; (2) narrowcast transmissions;²⁰² (3) short message services (SMS)²⁰³ and (4) multimedia messaging services (MMS).²⁰⁴

The type of medicinal products and the type of publication determine to whom the application for approval should be directed. For instance, pre-approval must be obtained from CHCA for advertisements of designated therapeutic goods that are complementary medicines when these advertisements appear in the mainstream media, cinematograph films or displays.²⁰⁵ Advertisements about designated therapeutic goods that are complementary medicines to be broadcast in the broadcast media are directed to the ASMI.²⁰⁶ Advertisements of designated therapeutic goods that are non-complementary medicines to be published or broadcast in the specified media are forwarded to the ASMI.²⁰⁷

For easy reference and understanding, Table 4.2 sets out the types of advertisements with the bodies or agencies responsible for the pre-approval of advertisements of therapeutic goods.

²⁰² A narrowcast transmission is described as a system where 'the reception of which is limited by being targeted to special interest groups or by being intended only for limited locations (for example arenas or business premises) or by being provided during a limited period or to cover a special event; or because it provides programs of limited appeal or for other reason'. See *Therapeutic Goods Regulations 1990* (Cth) reg 5BA (c).

²⁰³ *Therapeutic Goods Regulations 1990* (Cth) reg 5BA (d).

²⁰⁴ *Ibid* reg 5BA (e).

²⁰⁵ *Ibid* reg 5Q (3); Also see *Therapeutic Goods Act 1989* (Cth) s 42B (a), (c) and (d).

²⁰⁶ *Therapeutic Goods Regulations 1990* (Cth) reg 5Q (4) (a).

²⁰⁷ *Ibid* reg 5Q (4) (b).

Table 4.2 – The Types of Advertisements and the Agency Responsible for their Approvals

Types of Product	Type of Media	Whether an approval is required	Body or agency that is responsible for the pre – approval
Complementary Medicines	Broadcast media	Yes	ASMI
Over the counter medicines (non-complementary)	Broadcast media	Yes	ASMI
Complementary Medicines	Mainstream media	Yes	CHCA
Non-complementary (over the counter medicines)	Mainstream media	Yes	ASMI
Devices	All media	No	N/A
Complementary and Non-complementary	Under-the-line advertisements	No	N/A
Prescription medicines to healthcare professionals	Medical Journals	No	N/A

Although the task of pre-approval has been passed on to industry associations, the industry associations are bound by rules set out in the *Therapeutic Goods Regulations 1990* (Cth). The exercise of this duty must be carried out in the same manner as would be exercised by the Secretary of the Department of Health and Ageing.²⁰⁸ In all circumstances, the conditions set out under Regulation 5G (1) (a) – (e) of the *Therapeutic Goods Regulations 1990* (Cth) must be complied with before the approval can be granted.²⁰⁹ The conditions are that an advertisement: (a) has complied with the provisions of Therapeutic Goods Advertising Code; (b) does not contain a prohibited representation of the goods, whether in expressed terms or by implication; (c) fulfils the required representation condition; (d) does not carry ‘unacceptable presentation of the goods within the meaning of regulation 3A’ and (e) is a restricted representation which has satisfied that ‘the representation is accurate and balanced or the representation is not misleading or likely to mislead’ or ‘the representation is necessary for the appropriate use of the goods’.²¹⁰

²⁰⁸ Ibid reg 5Q (6).

²⁰⁹ Ibid.

²¹⁰ *Therapeutic Goods Regulations 1990* (Cth) reg 5G (1) (a) – (e).

Once approval is granted, approval numbers are allocated, and these numbers must be displayed appropriately. It is an offence if an approval number is not displayed, or an approval number that is different from the approved advertisement is displayed or an expired approval number is displayed.²¹¹

In practice, the ASMI requires its members as well as non-members to submit a copy of advertisements to the ASMI Advertising Service Office and upon approval, members are further required to submit a copy to FreeTV Australia, the Federation of Australia Radio Broadcasters (FARB), Commercial Radio Australia (CRA) or the Australian Cinema Advertising Council (ACAC), where applicable.²¹² The ASMI claims that advertisements are approved within five days.²¹³ Similarly, the CHCA requires that the application is forwarded to the Advertising Services Office of the CHCA for assessment and approval.²¹⁴ The time taken by the CHCA to pre-approve an advertisement is not stipulated.

4.3.2.2 Monitoring of Violation of Advertising Rules

There is no evidence to indicate that the industry associations, the ASMI and the CHCA, are strictly evaluating advertisements before granting approvals, or the number of advertisements which are pre-approved. This information is not made available in the public domain. The increasing number of complaints about advertisements, however, seems to suggest a degree of non-compliance with rules established under Regulation 5G (1) (a) – (e) of *Therapeutic Goods Regulations 1990* (Cth). As will be seen at [4.3.2.2], significant number of these complaints, and cases, involve breaches of the Act, the accompanying regulations and the Code is addressed by the CRP and courts. This is despite the fact that active monitoring is carried out. Both the ASMI Promotional Panel and Medicine Australia Monitoring Committee which are established to monitor advertising

²¹¹ *Therapeutic Goods Act 1989* (Cth) s 42C (4) (a) and (b) (i), (ii) and (iii).

²¹² *ASMI Code of Practice 2009* s 5.3.1.

²¹³ *Ibid* s 11.8.

²¹⁴ *Ibid* s 5.3.1.

materials, claim to proactively monitor selected promotional materials on a regular basis.²¹⁵ Similarly, the CHCA Code Administration Committee maintains that it conducts regular reviews on issues concerning marketing and promotion practices.²¹⁶ In addition, the Therapeutic Goods Administration carries out a range of monitoring activities to scrutinize compliance with the laws.²¹⁷

4.3.2.3 Complaint-Handling Processes

Complaints lodged regarding advertisements in print or broadcast media are channelled to one of four panels: (1) the Complaints Resolution Panel; (2) the ASMI Complaint Handling Panel (the 'ASMI Panel'); (3) the CHCA Complaints Resolution Committee (the 'CHCA Panel') or (4) the MA Code of Conduct Committee. As with pre-approvals, the types of therapeutic goods and the media where they are published or broadcast determine the Panel that will deal with particular complaints. Complaints are also directed to the Therapeutic Goods Administration under certain circumstances. This section examines the process for handling complaints relating to advertisements of therapeutic goods.

(a) Complaints Resolution Panel

Complaints about advertisements of designated therapeutic goods directed at consumers which are published in specified media or broadcast media in contravention of the provisions of *Therapeutic Goods Act 1989* (Cth),²¹⁸ *Therapeutic Goods Regulations 1990* (Cth)²¹⁹ and the *Therapeutic Goods Advertising Code 2007* (Cth)²²⁰ are forwarded to the CRP. The CRP follows a straightforward procedure with regard to complaint handling.

²¹⁵ Ibid s 11.1; *Medicine Australia Code of Conduct (Edition 16) 2010* s 28.2.2.

²¹⁶ *CHCA Code of Practice 2005* s 8.1.5.

²¹⁷ *Regulation of Therapeutic Goods in Australia*, above n 67.

²¹⁸ Sections 22(5), 42C, 42DL, 42DM or 42DP of the *Therapeutic Goods Act 1989* (Cth). See *Therapeutic Goods Regulations 1990* (Cth) reg 42ZCAB (1) (a).

²¹⁹ *Therapeutic Goods Regulations 1990* (Cth) reg 5C, 6, 6A, 6B, and 10.

²²⁰ *Therapeutic Goods Advertising Code 2007* (Cth) ss 4(2)(a) – (j), 4(4), 4(5), 4(6), 4(7), 4(8), 5(1) and (2), 6(1), 6(2) and 6(3).

Upon receipt of the complaint, the CRP will first notify the parties²²¹ by providing details of the complaint.²²² From the written submissions and documentation forwarded, and from the outcome of its inquiries²²³, it then considers whether the complaint is justified. The contents of the advertisement are assessed based on their probable impact on a reasonable person to whom the advertisements are directed.²²⁴ If the CRP finds the complaint justified, it then requests persons apparently responsible to do one or more of the following: (1) withdraw the advertisement; (2) publish a retraction; (3) publish a correction and (4) withdraw a particular claim or representation or request not to use that particular claim or representation unless the person apparently responsible is able to satisfy the CRP that the use of the claim or representation does not contravene the Act, regulations and the Code.²²⁵ Persons apparently responsible are given a 14 days period of grace to comply with the orders of the CRP. Failure to comply with orders will result in the matter being referred to the Secretary of the Department of Health and Ageing, who then imposes sanctions or takes further actions.²²⁶

The CRP handled approximately ninety eight complaints in 2004, one hundred and eight complaints in 2005, one hundred and forty one complaints in 2006, one hundred and five complaints in 2007, one hundred and seventy complaints in 2008, one hundred of fifty six complaints in 2009 and fifty six complaints until May 2010, all of which concerned contraventions of various provisions of the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth), and the *Therapeutic Goods Advertising Code 2007* (Cth).²²⁷ On an average the number of complaints handled have been the same,

²²¹ *Therapeutic Goods Regulations 1990* (Cth) 42ZCAA. 'Parties' refer to the complainants and persons apparently responsible. Person apparently responsible is defined as a person who 'in relation to a complaint about an advertisement or generic information means the person who, based on the complaint and assessment of the Complaint Resolution Panel, appears to be responsible for requesting the publication or insertion of the advertisement or generic information in specified media' under Regulation 42ZCAA of the *Therapeutic Goods Regulations 1990* (Cth).

²²² *Therapeutic Goods Regulations 1990* (Cth) regs 42ZCAC (1) and (2).

²²³ *Ibid* regs 42ZCAD (1) and (2).

²²⁴ *Therapeutic Goods Advertising Code 2007* (Cth) s 3(2).

²²⁵ *Therapeutic Goods Regulations 1990* (Cth) reg 42ZCAI (1) (a) – (d).

²²⁶ *Ibid* reg 9.

²²⁷ Complaint Resolution Panel, Therapeutic Products Advertising Complaints, Australia, *Complaints about Advertisements for Therapeutic Products In Australia* < <http://www.tgacrp.com.au/>>. ('Complaints About Therapeutic Goods').

however, the CRP has not always handled them in a timely manner. For example, for a CRP determination of Complaint No 4-1106 for the product, Xantrax, the first meeting was held on the 15 February 2007 and the final resolution of the matter was achieved on 17 April 2007.²²⁸ The hearing for the product, Nurofen, via Complaint Code 16-0807, began on 12 December 2007 and was resolved on 4 February 2008.²²⁹ The hearing for the product, Thompson's Organic Iron, via Complaint Code No 33-0507, was held on 15 November 2007, but was not resolved till 25 January 2008.²³⁰

Further, the forms of sanctions ordered are considered less effective. The common forms of sanctions ordered by the CRP are withdrawals and retractions of false and misleading advertisements.²³¹ Whilst such sanctions could prevent deceptive advertising reaching the public, they could not, however, erase a false impression that had already been created by false advertisements disseminated to the public. Consumers are not able to know that such advertisements were false unless corrective statements are published.

(b) *ASMI and CHCA Complaint Handling Panels*

Complaints relating to advertisements of therapeutic goods which are non-prescription drugs and complementary medicines are dealt with by the ASMI and the CHCA, respectively. ASMI deals with complaints of members, as well as non-members who have agreed to submit to the process.²³² If a member is found to be in breach of the ASMI Code, then an appropriate sanction is imposed.²³³ The complaint panel may require the member to give an undertaking in writing to discontinue the contravening practice, to cease publication, provide substantiation where necessary, retractions and/or corrective statements and fines.²³⁴ In addition, if provisions of the *Therapeutic Goods Advertising*

²²⁸ Ibid.

²²⁹ Ibid.

²³⁰ Ibid.

²³¹ Ibid.

²³² *ASMI Code of Practice 2009* s 8.0.

²³³ Ibid s 9.2.

²³⁴ Ibid ss 9.2.1 - 9.2.3.

Code 2007 (Cth) are found to have been breached, then the CRP is notified of the breaches.²³⁵

The CHCA Panel handles complaints relating to advertisements of complementary medicines involving members and non-members.²³⁶ It orders appropriate sanctions if it finds a breach of its code. Amongst the sanctions are: (1) to give ‘an undertaking to discontinue any practice which has been determined to constitute a breach of the code’;²³⁷ (2) to recall and destroy offending material;²³⁸ (3) to have the offending material amended at the next print-run;²³⁹ (4) to have future advertising and promotional material pre-cleared²⁴⁰ and (5) to require a repeat offender to appear before the Complaints Resolution Committee.²⁴¹ The Panel can also request the following: (1) ‘lodgement of a bond of at least \$1500 for 12 months to be released provided no further similar or major offences are recorded against the company in that period’, together with an administration fee up to \$250 and (2) ‘forfeiture of a lodged bond’.²⁴² In addition, fines, suspensions or expulsions from memberships or from participation in any advisory and/or defining body of the Complementary Healthcare Council of Australia, can also be ordered by the Complaints Resolution Committee.²⁴³

Complaints concerning risks to public safety, however, are referred to the Surveillance Unit of the Therapeutic Goods Administration for further action.²⁴⁴ Also, if a complementary

²³⁵ Ibid s 8.2.3 (b).

²³⁶ CHCA Code of Practice 2005 s 8.4.1.

²³⁷ Ibid s 8.5.1 (a).

²³⁸ Ibid s 8.5.1 (b).

²³⁹ Ibid s 8.5.1 (c).

²⁴⁰ Ibid s 8.5.1 (d).

²⁴¹ Ibid s 8.5.1 (e).

²⁴² Ibid s 8.5.1 (f).

²⁴³ Ibid s 8.5.1 (h), (i), (j) and (k).

²⁴⁴ Ibid s 8.4.4.

healthcare product has not been included in the ARTG, it is referred to the Therapeutic Goods Administration for further action.²⁴⁵

(c) *MA Code of Conduct Committee*

The MA Code of Conduct Committee addresses complaints made against its members,²⁴⁶ as well as against non-members who have agreed to the complaint-handling process.²⁴⁷ If non-members decline, then the MA Code of Conduct Committee forwards the complaint to the Therapeutic Goods Administration or the Australia Competition and Consumer Commission (ACCC) for further action.²⁴⁸ The members of the MA Code of Conduct Committee include: (1) a Chairman, who is a lawyer with trade practice experience; (2) one representative of the Australian Medical Association; (3) one representative of the Royal Australian College of General Practitioners (RACGP) and (4) one representative of the Australian General Practice Network (AGPN).²⁴⁹

Sanctions in the form of fines are imposed on promotional materials which are found to be in breach of the Code.²⁵⁰ The sanctions or fines imposed may range from \$100,000.00 to \$200,000.00.²⁵¹ Member companies who are dissatisfied with the decision of the MA Code of Conduct Committee are permitted to lodge an appeal against the decision, to a Code of Conduct Appeal Committee.²⁵² The appeal mechanism is designed to ensure that decisions are fair and unbiased.

²⁴⁵ Ibid s 8.4.4.

²⁴⁶ *Medicine Australia Code of Conduct (Edition 16) 2010* s19.1.

²⁴⁷ Ibid s 21.

²⁴⁸ Ibid s 21.

²⁴⁹ Ibid s 20.1.

²⁵⁰ Ibid s 24.3.

²⁵¹ Ibid.

²⁵² Ibid s 25.

(d) *Therapeutic Goods Administration*

The Therapeutic Goods Administration has a role in the complaint handling process despite the delegation of the task to industry associations. The Therapeutic Goods Administration handles complaints of non-prescription drugs that are directed at consumers.²⁵³ It also handles complaints of health-care professionals who are not members of the industry associations and have declined the offer to have the complaints handled by industry associations.²⁵⁴

In summary, the agency to which complaints must be channelled is determined by the types of goods and the media in which they are advertised. Table 4.3 summarises the agencies responsible for handling complaints for the different types of therapeutic goods.

Table 4.3 – The Types of Goods and the Agencies that Handle the Complaints

Types of Goods	Type of Media	Agencies that Handles the Complaints
Designated therapeutic goods directed at consumers	Specified media (mainstream prints, cinematography and out door display)	CRP
Complementary medicines	Under-the-line	CHCA
Non-complementary (over the counter)	Under-the-line	ASMI
Prescription medicines to consumers	Specified and under-the-line	Therapeutic Goods Administration
Prescription medicine to healthcare professionals	Journal predominately circulated among the medical professionals	MA (if member) Therapeutic Goods Administration (if non-member)

4.3.2.4 Judicial Enforcement

Advertisers involved in misleading and deceptive advertisements, irrespective of the media in which they are published or broadcast, are dealt with under sections 52 and 53 of the *Trade Practices Act 1974* (Cth). Misleading and deceptive conduct in the course of trade and commerce is prohibited by section 52 of *Trade Practices Act 1974* (Cth), whereas false

²⁵³ *Regulation of Therapeutic Goods*, above n 67.

²⁵⁴ *Ibid.*

representations made in connection with the supply or possible supply of goods is prohibited by section 53.

Cases on deceptive advertising prosecuted under Part V of the *Trade Practices Act 1974* (Cth) are usually brought by Australia Competition and Consumer Commission (ACCC) on behalf of consumers. The types of orders ordinarily granted for an offence of deceptive advertising include retraction of the advertisement, removal of part of the text from advertisements or the whole advertisement or an order for corrective advertising.²⁵⁵ For example, in the case of *Australian Competition and Consumer Commission v Purple Harmony Plates Pty Ltd*,²⁵⁶ where misleading claims were made that the products had various therapeutic properties and future benefits, in breach of section 52 of the *Trade Practices Act 1974* (Cth), the court ordered that corrective advertising in the form of corrective statements be posted on the website.²⁵⁷ It also ordered that Purple Harmony Plates send letters to all customers who had purchased the product informing them that the representations contained in the promotional material were misleading, and a refund of all money paid by customers.²⁵⁸

Another example is the case of *Australian Competition and Consumer Commission v Hughes*.²⁵⁹ In this case, the ACCC brought an action under sections 52 and 53 of the *Trade Practices Act 1974* (Cth) seeking declaratory orders against the respondent, Hughes, who had, through his website www.crowdedplanet.com misrepresented, amongst other things, that he could supply certain contraceptives at low prices resulting in consumers saving money, and that the contraceptives had performance characteristics, uses or benefits which they did not have. Hughes had also failed to include in the websites crucial warnings and information regarding the use of contraceptives. The court found Hughes's conduct in breach of sections 52 and 53 of *Trade Practices Act 1974* (Cth) and

²⁵⁵ *Australian Competition and Consumer Commission v Purple Harmony Plates Pty Ltd* (No. 3) [2002] FCA 1062. *Australian Competition & Consumer Commission v Hughes (t/a Crowded Planet)* [2002] FCA 270

²⁵⁶ *Australian Competition and Consumer Commission v Purple Harmony Plates Pty Ltd* (No. 3) [2002] FCA 1062.

²⁵⁷ *Ibid* para 34.

²⁵⁸ *Ibid* para 36.

²⁵⁹ *Australian Competition & Consumer Commission v Hughes (t/a Crowded Planet)* [2002] FCA 270.

ordered a number of restraints, which include that he be restrained from: (1) offering to sell or supply oral contraceptives²⁶⁰ to persons in the United States of America; (2) offering for sale oral contraceptives in Australia without disclosing in clear readable terms that it is illegal to supply oral contraceptives without a doctor's prescription; and (3) offering to supply without specifying both the significant risks in taking oral contraceptives without medical advice about their suitability and that there is free medical assistance for those contemplating using oral contraceptives.²⁶¹

²⁶⁰ Microgynon 50 ED, Loette, Levlen ED, Triquilar ED, Logynon ED, Norimin 28 day, Brenda 35ED, Marvelon 28, Femoden ED, Microval, Noriday 28 day, Diane 35 and Norlevo.

²⁶¹ *Australian Competition & Consumer Commission v Hughes (t/a Crowded Planet)* [2002] FCA 270.

4.4 REVIEWS OF THE REGULATORY SYSTEM IN AUSTRALIA

This section of the chapter examines three substantive reviews that have been undertaken of the regulation of therapeutic goods in Australia, including the regulation of the advertising of therapeutic goods. The three reviews are: (1) the Review of Drugs, Poisons and Controlled Substances Legislation by Rhonda Galbally in January 2001 (the Galbally Review);²⁶² (2) the Review of Advertising Therapeutic Products in Australia and New Zealand by Toogoolawa Consulting Pty Ltd in November 2002 (the Toogoolawa Consulting Review)²⁶³ and (3) the Review of Complementary Medicines by the Expert Committee on Complementary Medicines in the Australian Health System in September 2003.²⁶⁴ The issues raised and considered by these Reviews and the recommendations proposed are highlighted in this section of the chapter. The government's response to the recommendations made by these reviews and the extent to which the recommendations have been implemented are also discussed.

First, the Galbally Review, which was undertaken to examine State and Territory Drugs, Poisons and Controlled Substances Legislation against the Principles of National Competition Policy considered various issues including the extent to which the existing controls over the use of substances that have potential harms provide a net benefit to the community as a whole. In the context of advertising therapeutic goods, it weighed the costs and benefits of the existing controls.²⁶⁵ It also considered alternative perspectives to the controls and the associated costs and benefits.²⁶⁶ The review concluded that there was a net public benefit in maintaining the present restrictions on advertising prescription drugs to consumers. The benefits included: (1) less use of inappropriate medicines; (2) fewer patients assertively demanding a particular product to be prescribed; (3) fewer confused or misinformed consumers due to too little knowledge and (4) less acceptance of medicines

²⁶² *Galbally Review*, above n 133.

²⁶³ *Toogoolawa Report*, above n 198,

²⁶⁴ Expert Committee on Complementary Medicines in Health System, *Complementary Medicine in Australian Health System- Report to the Parliamentary Secretary to the Minister of Health and Ageing* (September 2003). ('*Report on Complementary Medicines in Australian Health System*').

²⁶⁵ *Galbally Review*, above n 133, 50.

²⁶⁶ *Ibid.*

as ‘life solutions’ to the detriment of better alternatives such as diet and exercise.²⁶⁷ An issue examined closely by the review was the possibility of allowing direct-to-consumer-advertising of prescription drugs, with the review ultimately recommending that the current prohibition be maintained.²⁶⁸

The recommended changes were mainly in the areas of increasing national uniformity and improving efficiency. Towards informational advertising of scheduled medicines, the review recommended that: (1) all provisions relating to advertising in State and Territory Drugs, Poisons and Controlled Substances Legislation be repealed; and (2) the current system of prohibition on advertising of prescription medicine (Schedule 3, 4 and 8 medicines) be retained, with exemption given in some instances. Price, Consumer Medicine Information (CMI), one-off press releases about the availability of a new medicine which have complied with certain requirements,²⁶⁹ and where advertisements comply with the Standard for Informational Price Advertising and Publication of Consumer Medicine Information may be exempted.²⁷⁰

In April 2003, a working party responded to this review and agreed that all State and Territory provisions on the advertising of medicines be repealed.²⁷¹ It also agreed that the Therapeutic Goods Act’s prohibition on the advertising of prescription drugs (Schedule 3, 4 and 8 medicines) for human use’ be retained, but the *Therapeutic Goods Act 1989* (Cth) be amended to exempt the advertising of the price of these medicines in a catalogue, provided the advertising is informational and not promotional.²⁷² It was also recommended that the ‘Commonwealth amend the *Therapeutic Goods Act 1989* to include all controls on advertising for medicines for human use’. As noted in [4.3.1.2], New South Wales, Tasmania, Victoria and ACT have either adopted the Therapeutic Goods Act by reference

²⁶⁷ Ibid 51.

²⁶⁸ Ibid 58.

²⁶⁹ *Galbally Review*, above n 133, 66. For example, the press release complies with the APMA Code of Conduct and the press release is accompanied by the CMI for the product.

²⁷⁰ *Galbally Review*, above n 133, 66.

²⁷¹ *Response to the Galbally Review*, above n 134, 5.

²⁷² Ibid.

into the legislation or have passed complementary legislation to it. The remaining States and Territories are in the process.²⁷³

Second, the Toogoolawa Consulting Review, which was published in 2002, was initiated in response to a proposal to establish a Trans-Tasman Agency to consistently regulate therapeutic products in Australia and New Zealand. The review was a comprehensive analysis of the regulation of the advertising of therapeutic products in Australia and New Zealand. Accordingly, the review considered various issues concerning the regulation of therapeutic goods advertising including: (1) the rationale for the regulation of therapeutic goods advertising;²⁷⁴ (2) the challenges and problems faced in the current regulation of therapeutic goods advertising;²⁷⁵ (3) the streamlining of pre-approvals of advertisements;²⁷⁶ (4) the handling of complaints²⁷⁷ and (5) the cost and time effectiveness of the system.²⁷⁸ Amongst its recommendations, the review suggested a co-regulatory system for regulating the advertising of therapeutic goods in both Australia and New Zealand,²⁷⁹ and the establishment of a Trans-Tasman Agency to regulate therapeutic goods using a risk management approach.²⁸⁰ For Australia, it was recommended that a new Complaints Panel be established, and in the context of advertising, the Panel be empowered to: (1) order both withdrawal and corrective advertising and (2) make decision on an urgent basis, namely, within twenty one days from the day the complaint is lodged for an order to cease publication, and forty two days in other cases.²⁸¹ It was also recommended that the prohibition on making therapeutic claims in food and cosmetics be lifted and that these products be subject to the requirements of the Therapeutic Goods

²⁷³ Ibid 6.

²⁷⁴ *Toogoolawa Report*, above n 198, 35.

²⁷⁵ Ibid 62.

²⁷⁶ Ibid 72.

²⁷⁷ Ibid 86.

²⁷⁸ Ibid 110.

²⁷⁹ Ibid 82.

²⁸⁰ Ibid 7.

²⁸¹ Ibid 29.

Advertising Code.²⁸² It was suggested that if the food and cosmetics regulators incorporate the Therapeutic Goods Advertising Code or the complaint resolution powers into their legislation, this would enable the therapeutic product advertising regulatory mechanisms to apply to food and cosmetics advertisement which carried therapeutic claim, whilst other aspects of food and cosmetic regulations would still be within the control of the food and cosmetic regulators.²⁸³

However, the recommendation to establish a Trans-Tasman Agency to jointly regulate therapeutic goods in Australia and New Zealand did not materialise, despite the considerable efforts made of both the Australian and the New Zealand Governments.²⁸⁴ In July 2007, it was announced that the New Zealand Government did not have the numbers in Parliament to pass the legislation²⁸⁵ that would enable the establishment of a joint agency with Australia to regulate therapeutic products, and all negotiations would be postponed.²⁸⁶ Nevertheless, the fact that negotiations for harmonization in the regulation of therapeutic goods have been postponed does not mean that the issue will not be revisited. It is possible that the agreement for the establishment of a joint scheme for the regulation of the therapeutic products be revived in future.²⁸⁷

In the meantime, as part of the regulatory program to continue improving the advertising regime for therapeutic goods in Australia, the Therapeutic Goods Administration had, in

²⁸² Ibid 98.

²⁸³ Ibid 98.

²⁸⁴ McEwen, above n 162. For example, following a recommendation in the Toogoolawa review to establish a provisional management board to review further, the Interim Advertising Council (the 'IAC') was established: at 154. The IAC reviewed and prepared a report (the 'IAC report'), which was accepted with minor amendments. This report was published in December 2005 after final consideration by the Therapeutic Products Interim Ministerial Council ('TPIMC'), which comprises of Parliamentary Secretary and the New Zealand Minister and which was established to facilitate the joint scheme for the regulation of therapeutic good: at 55. In the meantime, on 12 December 2003, the Australian Parliamentary Secretary to the Minister for Health and Ageing, and the New Zealand Minister for Health had 'signed a treaty to establish a single bi-national agency to regulate therapeutic goods including medical devices and prescriptions, over the counter and complementary medicines' and in December 2005, announced agreement on the recommended regulatory model for advertising of therapeutic goods and the title of the joint agency as the Australia-New Zealand Therapeutic Products Authority (ANZTPA). The model followed closely the recommendations in the Report of the Interim Advertising Council presented in October 2004: at 165.

²⁸⁵ Therapeutic Products and Medicines Bill.

²⁸⁶ McEwen, above n 162, 165.

²⁸⁷ Therapeutic Goods Administration, Department of Health and Ageing, Australian Government, *Australia New Zealand Therapeutic Products Authority (ANZTPA)* < <http://www.tga.gov.au/tta/index.htm>>.

July 2007, sought comments from interested parties on proposals to improve the regulation pertaining to the advertising of therapeutic goods, with the closing date for consultation 27 August 2010.²⁸⁸ A consultation paper, which highlighted the weaknesses in the existing system of regulation and proposed a number of issues to be considered by the interested parties, was presented to the interested parties.²⁸⁹ The consultation paper identified weaknesses in the system including: (1) that there is 'perceived inconsistency in the approach to handling advertisement in different media'. Not all advertisement are subject to pre-approval. Whilst advertisements of non-prescription drugs which are published in print media and broadcast on radio and television are pre-approved, advertisements on the internet are not; (2) complaints regarding non-prescription drugs which can be made to the CRP are limited to those made on print media, radio and television and (3) the complaint handling mechanism is overloaded, not transparent and its sanctions are insufficient to deter non-compliance or violation of laws.²⁹⁰ Accordingly, the considerations proposed include: (1) whether the current system of pre-approval should be maintained, that is, should all forms of advertising be subject to pre-approval and (2) whether the CRP be reconstituted as an independent body, and be allowed to consider all forms of advertising, and be permitted to apply civil penalties for breaches.²⁹¹

Third, the Expert Committee on Complementary Medicines was established in 2003 to review the regulation of complementary medicines in Australia. The Expert Committee was established to reassure the public and maintain confidence in Australia's reputation as a supplier of high quality and safe medicines, following the recall of more than one thousand and six hundred complementary medicines by the Therapeutic Goods Administration in April 2003.²⁹² In the context of advertising, the report emphasised the need to ensure that consumers have access to reliable information about complementary medicines so as to

²⁸⁸ Therapeutic Goods Administration, Department of Health and Ageing, Australian Government, Consultation: Improving Advertising Arrangements for Therapeutic Goods
< <http://www.tga.gov.au/regreform/cons-advertising.htm>>.

²⁸⁹ Therapeutic Goods Administration, Department of Health and Ageing, Australian Government, *Advertising Therapeutic Goods in Australia: Consultation Paper* (June 2010).

²⁹⁰ *Ibid* 2.

²⁹¹ *Ibid* 5.

²⁹² *Report on Complementary Medicines in Australian Health System*, above n 264, 35.

enable them to make informed choices.²⁹³ The Expert Committee recommended that a study be commissioned to determine: (1) 'the complementary medicine information and skills needs of healthcare professionals and consumers, (2) options for conveying this information to stakeholders and (3) the cost and resources necessary to meet these needs'.²⁹⁴ The Expert Committee also recommended that internet advertising be regarded as mainstream advertising and thereby subject to regulatory controls such as advertising requirements, protocols and complaint handling process.²⁹⁵ It was decided for practical reasons that internet advertisements would not be subject to a pre-approval process.²⁹⁶

These recommendations were considered by Government as necessary to ensure that consumers and health-care practitioners are provided timely access and accurate information about medicines and their use.²⁹⁷ In October 2006, the Department of Health and Ageing commissioned the National Prescribing Service (NPS) to review the consumer and health practitioner information and skills needs in line with that of the Expert Committee.²⁹⁸ Further, save for pre-clearance requirement, the other requirements applicable to mainstream advertising, that is, advertising protocols and complaints resolution processes, are applicable to internet advertising.²⁹⁹

In conclusion, the three substantive reviews have comprehensively scrutinised the regulation of therapeutic goods in Australia, including the regulation of the advertising of therapeutic goods. Other than in the areas of increasing uniformity of application across the states and territories, efficiency of application and the emphasis on internet advertising, the regulations have positively withstood the scrutiny of all three reviews.

²⁹³ Ibid 119.

²⁹⁴ Ibid.

²⁹⁵ Ibid.

²⁹⁶ Ibid 120.

²⁹⁷ Australian Government, *Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health Care System* (March 2005), 26.

²⁹⁸ Implementation of the Government Response to the Recommendations of the Expert Committee on Complementary Medicine in the Health System; the Progress Report (October 2006) 9.

²⁹⁹ Ibid.

4.5 CONCLUSION

This chapter has explained the comprehensive and complex regime for regulating the advertising of therapeutic goods in Australia. In [4.2] the categories of products that fall under the classification of medicinal products were explored, and it was discovered that whilst prescription, non-prescription drugs and complementary medicines are regulated as therapeutic goods, products such as food and cosmetics may also be regulated as therapeutic goods unless they are declared otherwise by orders.

In [4.3], it was discovered that the legal framework for advertising therapeutic goods is comprehensive, but it is also complex, and that there is a lack of uniformity in relation to some aspects of the regime. The two regulatory regimes, namely, the Commonwealth and the State and Territory regimes, have both specific and general laws regulating advertisements of therapeutic goods. However, there is no complete uniformity between the States and Territories in adopting and updating the provisions of the *Therapeutic Goods Act 1989* (Cth), which provides the national framework for the States and Territories to adopt a uniform approach in the regulation of therapeutic goods.

A distinctive feature of the Australian system of the regulation of the advertising of therapeutic goods is that it is predominately co-regulatory: a system that involves both government and industry associations sharing the responsibility of regulating advertisements of therapeutic goods to ensure responsible practices. The strength of the system lies in the participation and cooperation of various industry bodies in regulating the advertising of therapeutic goods. The representation is balanced as the participants include traders, advertisers and consumer groups.

However, the current Australian system of regulating the advertisement of therapeutic goods has some shortfalls. For example, the responsibility for approving or refusing an approval for designated therapeutic goods that are non-prescription drugs lies with both the ASMI and the CHCA. The types of medicinal product and the types of publication determine to whom the application for pre-approval should be directed. Whilst advertisements of complementary medicines to be published or used in mainstream media or cinematograph films or display are forwarded to the CHCA, advertisements of

complementary medicines to be broadcast are directed to the ASMI.³⁰⁰ These arrangements have resulted in the system becoming increasingly complicated.³⁰¹ The task of pre-approval is delegated to two industry associations, but only one is allowed to pre-approve for broadcast materials, namely, the ASMI.³⁰² The implication of this is that an advertiser, who wishes to advertise complementary medicines in the mass media, including both broadcasting and print, would have to send the application to both the ASMI and the CHCA, incurring unnecessary costs and delays.³⁰³ A suggestion was made to have a single body to grant pre-market approval; however, having a single body to pre-approve advertisements was thought to lead to bottlenecks and delays.³⁰⁴ Further, the system is also inconsistent in that it imposes mandatory pre-approval for certain media, while exempting others from these requirements.³⁰⁵ In particular, excluding 'under-the-line' advertisements from mandatory pre-approval undermines the protection against false and misleading representations and unsubstantiated claims that are frequently made on the Internet.³⁰⁶

The complaint handling processes of the CRP and the three industry associations are also not without drawbacks.³⁰⁷ The CRP would ordinarily request the person apparently responsible to withdraw the advertisement, publish a retraction or a correction, withdraw a particular claim or representation or request not to use that claim or representation. If its request is not complied with within 14 days, then it makes recommendations to the Secretary to ensure compliance with the orders. It does not have the power to impose compliance with its orders. Referring matters to another body, the Secretary, for compliance with orders may well cause delay in removing or halting deceptive

³⁰⁰ *Toogoolawa Report* above n 198, 13.

³⁰¹ *Ibid.*

³⁰² *Ibid.*

³⁰³ *Ibid.*

³⁰⁴ *Ibid.*

³⁰⁵ *Ibid.*

³⁰⁶ *Ibid.*

³⁰⁷ *Ibid.* 15.

advertisements.³⁰⁸ In most instances, injuries would have been suffered or expenses would have been incurred as a result of relying on deceptive advertisements before they are removed or corrective measures are taken to erase the impression created by deceptive advertisements.

In [4.4], the reviews that examined the regulation of therapeutic goods including therapeutic goods advertising were explored. The reviews identified the weaknesses in the regulations and provided recommendation which were subsequently considered by the Government. The recommendations made by these Reviews are at various stages of implementation. The examination of the regulation of the advertising of therapeutic goods, as well as the analysis of reviews conducted by the Federal Government, will assist in formulating recommendations to improve the regulation of advertising of medicinal products in Malaysia. These analyses are carried out in Chapter 6.

³⁰⁸ Ibid 86.

CHAPTER 5

AN OVERVIEW OF THE CURRENT REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS IN THE UNITED STATES

5.1 INTRODUCTION

This chapter examines the regulations relating to advertising of medicinal products in the United States for the purposes of a comparative analysis with regulations in Australia and Malaysia in Chapter 6. This chapter is divided into six main sections:

Section [5.2] of the chapter determines the type of products that fall under the classification of medicinal products in the United States and the circumstance under which these products would be exempt from this classification. Medicinal products are known as drugs in the United States, and there are two categories of drugs; prescription drugs and non-prescription drugs. Products including food, dietary supplements and cosmetics (referred to as health-related products ('HRPs') in this thesis) may fall within the classification of drugs when their advertisements carry therapeutic claims. However, not all products are classified as drugs despite therapeutic claims in the advertisements.

Section [5.3] of the chapter explains that the system of regulation of advertising of medicinal product in the United States is a statutory regulation, a system where the regulation is shared by two Federal agencies, namely, the Food and Drug Administration ('FDA') and the Federal Trade Commission ('FTC'). The advertising of prescription drugs (and the labelling of HRPs) is policed by the FDA¹ whereas the advertising of HRPs is governed by the FTC.² The authority to regulate these products is derived from two Federal laws, namely, the *Federal Food Drug and Cosmetic Act 1938* (United States) and the *Federal Trade Commission Act 1914* (United States). Although the roles of the FDA

¹ 21 USC §393 (2008).

² 15 USC § 45 (a)(2) (2008).

and the FTC with regard to regulation overlap, they do not clash, Indeed the agencies have been working together harmoniously under a ‘working agreement,’ since 1962.³

Section [5.4] of the chapter explores the regulation of the advertising of prescription drugs. It examines the regulation from two perspectives: (1) the rules that govern the advertising, in [5.4.1]; and (2) the regulatory controls employed in the regulation, in [5.4.2]. In [5.4.1], the *Federal Food Drug and Cosmetic Act 1938* (United States) which stipulates the rules for marketing of drugs is examined. The *Federal Food Drug and Cosmetic Act 1938* (United States) also makes provisions for the promulgation of basic requirements to be satisfied in relation to prescription drug advertising,⁴ and the rules established accordingly are codified under *Code of Federal Regulation* (CFR), namely, 21 CFR § 202.1(e) (2008). The CFR, which is referred to as the ‘FDA regulation’ in this chapter, is also examined. Section [5.4.2] examines the regulatory controls employed, namely, systems of pre-approval of advertisements, monitoring and enforcement. These controls are thought to prevent dissemination of deceptive advertisements, and the manner in which these controls are carried out is investigated.

Section [5.5] of the chapter examines the regulation of the advertising of HRPs. As in [5.4], this section examines the regulation from two perspectives, namely, the advertising rules and regulatory controls which are employed in the regulation of advertising of medicinal products. The *Federal Trade Commission Act 1914* (United States) stipulates the regulations for the advertising of all products including products such as, non-prescription drugs, food, dietary supplements and cosmetics. The fundamental requirements for advertising these products are codified under Title 15 USC (2008). The implementation of advertising regulations is assigned to the FTC, and the FTC derives the basis for its regulation from principles documented in the Policy Statements. The policy statements are: (1) The Deception Policy Statement;⁵ (2) The Statement on Advertising Substantiation⁶ (3)

³ Memorandum of Understanding, 36 Fed Reg 18,538 (September 1971).

⁴ Section 701(a) of the *Federal Food Drug and Cosmetic Act 1938* (United States) authorizes the FDA to ‘promulgate regulations for efficient enforcement of this Act...’.

⁵ FTC Policy Statement on Deception, Appended to Cliffdale Associations.,, 103 F.T.C 110, 174 (1984) in the Letter from FTC to the Hon John D. Dingell, Chairman, Committee on Energy and Commerce, U.S House of Representatives, Washington D.C (14 Oct 1983), FDA Advertising and Promotional Manual FDAADPROM Appendix 11 (Westlaw, Thompson Publishing Group, 2007) 206. (‘*FTC Policy Statement on Deception*’).

The Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction⁷ and (4) Enforcement Policy Statement on Food Advertising.⁸ These policy statements are examined in [5.5.1] together with a guide, the Dietary Supplement: An Advertising Guide for the Industry. These documents prescribe the standards to be observed when making claims in advertisements. Section [5.5.2] explores the regulatory controls employed, namely, the systems of pre-approval of advertisements, monitoring and enforcement. It examines, among other matters, the involvement of self-regulation in the regulatory controls and the extent to which self-regulation assists in the regulation of HRPs.

Section [5.6] of the chapter examines the challenges faced by the FDA and the FTC in regulating the advertising of medicinal products. It examines First Amendment protection at [5.6.1], the learned intermediary rule at [5.6.2], and the rule on federal pre-exemption at [5.6.3]. These rules seek to limit the authority of the FDA and FTC with respect to the actions which can be brought against advertisers as well as provide sufficient freedom to advertisers to promote their products.

Section [5.7] of the chapter consolidates the main points of analysis regarding the regulation of advertising of medicinal products in the United States which is to be used in the comparative analysis in chapter 6.

⁶ FTC Policy Statement on Advertising Substantiation, 48 Fed Reg 10,471 (1984). (*‘FTC Policy Statement on Advertising Substantiation’*), FDA Advertising and Promotional Manual FDAADPROM Appendix 11 (Westlaw, Thompson Publishing Group, 2007) 211.

⁷ Letter from the FTC to Hon Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, United States Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (December 17, 1980) reprinted in re Int’l Harvester Co., 104 F.T.C 949, 1070 n 3 (1984) (*‘Unfairness Policy Statement’*), FDA Advertising and Promotional Manual FDAADROM Appendix 11 (Westlaw, Thompson Publishing Group, 2007) 198. (*‘Statement of Policy on the Scope of Consumer Unfairness Jurisdiction’*).

⁸ The Enforcement Policy Statement on Food Advertising (May 1994) 59 Fed. Reg. 28,388, FDA Advertising and Promotional Manual FDAADPROM Appendix 11 (Westlaw, Thompson Publishing Group, 2007) 260. (*‘Policy Statement on Food Advertising’*).

5.2 THE CLASSIFICATION OF MEDICINAL PRODUCTS IN THE UNITED STATES

As explained at [1.5], medicinal products refer to products with medicinal values or products that are claimed to be used for medicinal, remedial or therapeutic purposes such as, diagnosing, curing, mitigating, treating or preventing diseases. Products with medicinal value will ordinarily include prescription and non-prescription drugs; however, products such as food, dietary supplement and cosmetics (HRPs) may fall within the classification of drugs by virtue of therapeutic claims in their advertisements. This section of the chapter examines the categories of products which are classified as medicinal products and instances when they are exempt from the classification.

In the United States, medicinal products are known by, and regulated as drugs. There are three factors that determine their classification: (1) intended use;⁹ (2) composition or ingredients¹⁰ or (3) risk posed.¹¹ This chapter, however, focuses on the classification of drugs by means of 'intended use' since the term 'intended use' refers to claims such as diagnosing, curing, mitigating, treating or preventing diseases, carried on advertisements.

In the United States, an article is considered a drug if it falls within the definition of the term 'drug' as prescribed under section 201 (g) (1) of the *Federal Food Drug and Cosmetic Act* 1938 (United States). This section stipulates four categories of products that are classified as drugs. These are:

- '(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary or any supplement to any of them; and

⁹ See 21 CFR. § 201.128 (2008). 'Intended use' refers to claims that pledge therapeutic advantages. See generally *National Nutritional Foods Ass'n v Mathews*, 557 F.2d 325,333-335 (2d Cir. 1977); in this case, manufacturer intended to distribute vitamins A and D for therapeutic uses. Court said that the intention may be inferred from the intention of manufacturers.

¹⁰ For examples see 21 CFR. §§ 333.110 – 160 (2008); 21 CFR. § 310.545 (2008); 21 CFR § 348.10 (2008); 21 CFR. § 310.527 (2008). The use of certain active ingredients or a high concentration of ingredients in the product can result in product being classified as drugs.

¹¹ Jacqueline A.Greff, 'Regulation of Cosmetics That are Also Drugs' (1996) 51 *Food and Drug Law Journal* 243, 255.

- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of a man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C); but does not include devices or their components, parts or accessories.¹²

The term 'drug' is defined broadly and as a result, several inferences can be made. Abood argues that the use of the term 'articles' in the definition of the term 'drug' gives drugs a wider meaning than a 'scientific or medical definition'.¹³ It includes 'chemical and non-chemical compositions'.¹⁴ Therefore, products that are ordinarily referred to as food, dietary supplements and cosmetics that are not necessarily of a chemical composition can fall under the classification of drugs.¹⁵ Further, the term 'intended' as used in section 201 (g) of the *Federal Food Drug and Cosmetic Act 1938* (United States), refers to the intentions of the manufacturer and are determinable from not only what the manufacturer claims to have intended, but also from an objective analysis of the contents of the labels and advertisements.¹⁶

Although a broad category of products may fall under the classification of drugs by virtue of the definition of the term 'drug', not all will qualify as drugs. Some products are exempt despite classification. The instances when products fall outside the classification of drugs are dealt with in [5.2.2].

¹² *Federal Food Drug and Cosmetic Act 1938* (United States) 201 (g) (1), codified as 21 USC § 321(g) (1) (2008).

¹³ Richard R. Abood, *Pharmacy Practice and the Law* (Jones and Bartlett, 5th ed, 2008), 47.

¹⁴ *Ibid.*

¹⁵ *Ibid.*

¹⁶ 21 CFR. § 201.128 (2008); See *National Nutritional Foods Ass'n v Mathews*, 557 F.2d 325,334 (2d Cir. 1977).

5.2.1 Products that Qualify as Drugs in the United States.

Products that fall within the classification of drugs in the United States include products that carry therapeutical claims or products that are 'intended to affect the structure and function of the body'.¹⁷ However, such products sometimes escape from qualifying as drugs. Products such as food, dietary supplements and cosmetics, are in some circumstances, exempt from drug classification even-though they fall within the definition of the term 'drug, as will be seen in this section.

In [5.2.1.1] – [5.2.1.4], the statutory definitions of the terms 'prescription drugs' 'non-prescription drugs', 'food', 'dietary supplements' and 'cosmetics' are examined. Further, the circumstances under which products such as food, dietary supplements and cosmetics are exempt from classification as drugs, despite falling within the definition of drugs, are examined. The objective is to explore the type of products that qualify as drugs and examine the advertising regulations that govern them.

5.2.1.1 Prescription Drugs and Non-Prescription Drugs, and Pharmacy-Only-Medicines

While section 201(g)(1) of the *Federal Food Drug and Cosmetic Act 1938* (United States) prescribes the general term 'drug', the terms 'prescription drugs' and 'non-prescription drugs' are not defined under the Act. However, the way they are meant to be distinguished is clear from the properties outlined by those substances that need a prescription. Drugs that require a prescription are identified in section 503(b)(1) of the *Federal Food Drug and Cosmetic Act 1938* (United States) as:

'A drug intended for use by man which;

- (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

¹⁷ Abood, above n 13, 47. As explained by Abood, an example of products 'intended to affect the structure and function of the body' without a therapeutic function, would be contraceptives that prevent pregnancy and where pregnancy is not a disease.

- (B) is limited by an approved application under section 505 to use under the professional supervision of a practitioners licensed by law to administer such drug; shall be dispensed only
 - (i) upon a written prescription of a practitioner licensed by law to administer such drug; or
 - (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist; or
 - (iii) by refilling any such written or oral prescription of such practitioners is authorised by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist...'.¹⁸

From the wording of section 503(b)(1) of the *Federal Food Drug and Cosmetic Act 1938* (United States), detailed above, it can be understood that drugs are subject to prescription because of their 'toxicity or other potentiality for harmful effect...' or in need of supervision with regard to their method of use or collateral measures. Such drugs are only obtainable with a physician's prescription,¹⁹ and are ordinarily known as prescription drugs. Drugs which do not have such levels of 'toxicity or potentiality for harmful effect' or in need of supervision with regard to their method of use or collateral measures, are not subject to prescription and can be obtained from pharmacies or non-pharmacies outlets such as, supermarkets, retails shops or gas stations.²⁰ Such products are also known as over-the-counter drugs. These drugs are perceived as safe for the general public to use following self-diagnosis, and purchase without a physician's prescription.²¹

¹⁸ 21 USC. § 353(b)(1) (2008).

¹⁹ Ibid.

²⁰ Government Accountability Office, United States, Report to the Ranking Minority Member, Committee on Commerce, House of Representatives, *Non Prescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to be Demonstrated*, GAO/PEMD-95-12 (1995), 10 & 101. ('*Non Prescription Drugs: Value of a Pharmacist-Controlled Class Report*'); William J Mead, 'New Development in the Approval and Marketing of Nonprescription or OTC Drugs' in Ira R. Berry & Robert P. Martin (eds) *The Pharmaceutical Process 2009* (Informa Healthcare, 2nd ed, 2009) 313.

²¹ Non-prescription drugs are known as over -the- counter-drugs and regulated under 21 USC § 330. 2008.

It is useful to note that in the United States, there are only two classes of drugs recognised, namely, prescription drugs and non-prescription drugs.²² Most countries recognise a third class known as 'pharmacy-only-medicine'.²³ 'Pharmacy-only-medicine' refers to a class of medicines that are obtainable from pharmacists without a physician's prescription and in some instances, dispensable by pharmacists.²⁴

The introduction of pharmacy-only-medicine found little favour in the United States. A study conducted by the United States Government Accountability Office, (the GAO) in 1995 found it to be unnecessary.²⁵ The study examined, among other things, the viability of this third class in the United States, and found little evidence supporting the establishment of this class.²⁶ This stance was further supported by a subsequent study in 2009.²⁷ The 2009 study found that the establishment of this class of drugs cannot be considered unless the cost implications are thoroughly investigated.²⁸ Setting up a new class of drugs was considered costly; there were costs involved with establishment of infrastructures including data infrastructure on patient information and consumer privacy, establishment of rules defining pharmacists' roles and responsibilities, and training of pharmacists and pharmacy staff.²⁹

5.2.1.2 Food

Food is defined under section 201(f) of the *Federal Food Drug and Cosmetic Act 1938* (United States) as: '(1) article used for food or drink for man or other animals; (2) chewing gum; (3) article used for components of any such articles'. The question is, however,

²² See Pub.L No. 82-215, 65 Stat. 648 (1951). The Durham-Humphrey Amendment of 1951 to the *Federal Food Drug and Cosmetic Act 1938* (United States) established these two classes of drugs that stand until today.

²³ *Non Prescription Drugs: Value of a Pharmacist-Controlled Class Report*, above n 20, 2.

²⁴ *Ibid.* 2.

²⁵ *Ibid.* 3.

²⁶ *Ibid.* 14–15.

²⁷ See Government Accountability Office, United States, Report to Congressional Requesters *Non Prescription Drugs: Consideration Regarding a Behind-the-Counter Drug Class* (2009), 4 - 6.

²⁸ *Ibid.* 6.

²⁹ *Ibid.* 4-6.

whether food may be classified as a drug within section 201(g)(1) of the *Federal Food Drug and Cosmetic Act 1938* (United States), if found in advertisements to carry a claim for therapeutic use or a claim to ‘affect the structure and function of the body’.

Foods are generally excluded from the classification of drugs. As noted at [5.2.1], section 201(g)(1) (C) of the *Federal Food Drug and Cosmetic Act 1938* (United States) provides that ‘articles (*other than food*) intended to affect the structure or any function of the body of a man or other animals’ are drugs. Foods which are intended for a therapeutic use, however, may qualify as drugs by virtue of section 201(g) (1) (B) of the *Federal Food Drug and Cosmetic Act 1938* (United States) unless they fall under the ‘exception’ provided by section 201(g) (1) (C) of the Act . This section of the Act further states:

‘A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement’.

In essence, the section, section 201(g) (1) (C) of the *Federal Food Drug and Cosmetic Act 1938* (United States), permits food to carry certain types of health-related claims on labels and yet not be classified as a drug, if the requirements specified under section 403 (r) of the *Federal Food Drug and Cosmetic Act 1938* (United States) are complied with. Health related-claims are defined as claims that ‘...characterizes the relationship of any substance to a disease or health related condition...’ and include claims that assert ‘...a relationship between the presence or level of a substance in the food and a disease or health-related message’.³⁰ ‘Disease or health related condition’ as mentioned above in the definition of health-related claims, refers to ‘damage to an organ, part, structure, or system of the body

³⁰ 21 CFR § 101.14(a)(1) (2008) describe broadly the health-related claims as those “that expressly or by implication, including third party references, written statements (for example, brand names including a term such as, “heart”), symbols, (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communications that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related message’.

such that it does not function properly (e.g cardiovascular disease), or a state of health leading to such dysfunction (e.g., hypertension)...'³¹

A related issue which requires some explanation before the requirements specified under section 403 (r) of the *Federal Food Drug and Cosmetic Act 1938* (United States) are explored, is whether section 201(g) (1) (C) of the *Federal Food Drug and Cosmetic Act 1938* (United States) is limited to claims carried on labels and labelling or whether it is also applicable to claims found in advertisements. This question is posed because the section does not make a direct reference to advertisements. The rationale for the rule to be applied in both labels and advertisements will be given in the following paragraph.

It is useful to note that the same set of rules, but with different standards, is used with regard to food labelling and advertisements. A lower standard is used for advertising. The *Nutrition Labelling and Education Act of 1990* (United States) which regulates health-related claims on food labelling, requires the FDA to promulgate rules governing the dissemination of health-related information on the labels, and accordingly FDA promulgated 21 USC § 343 (r) (3) (A), which is a codified version of section 403(r) of the *Federal Food Drug and Cosmetic Act 1938* (United States).³² These rules were complex for advertising and, therefore, the FTC formulated its own policy statement on food advertising, in line with the labelling requirements.³³ The principles are set out in comparison with FDA's food labelling, but pledged to be in harmony with the approach taken by the FDA in food labelling.³⁴ For example, the FTC claims to first investigate if the advertisers have obtained the FDA labelling approvals. If this is done, then it proceeds to investigate if the claims are in violation of the FDA requirements. Only upon being satisfied that these two requirements have been complied with, will it proceed to analyse the

³¹ 21 CFR §101.14 (a) (5) (2008).

³² See Douglas W. Hyman, 'The Regulation of Health Claims in Food Advertising: Have the FTC and the FDA Finally Reached a Common Ground?' (1996) 51 *Food and Drug Law Journal* 191, 191; Abood, above n 13, 49 -50.

³³ Hyman above n 32, 191; *Policy Statement on Food Advertising* above n 8.

³⁴ See Federal Trade Commission, Department of Health and Human Services, United States, *A Brief Review of the FTC's Environmental and Food Advertising Enforcement Programs*, Remarks of Roscoe B. Starek, III, Commissioner of Federal Trade Commission before the Intellectual Property Law Committee of the Chicago Bar Association, Young Lawyers Section, Chicago Illinois, (13 October 1995), 4 ('*A Brief Review of the FTC's Environmental and Food Advertising Enforcement Programs*').

claims.³⁵ Therefore, the same set of rules are applicable to food labelling and advertisements, the standards employed are, however, different.

The requirements specified under section 403 (r) of the *Federal Food Drug and Cosmetic Act 1938* are now examined. In order for health-related claims to be used on labels without the product having to be classified as drugs, the health-related claims would have to belong to the categories of health claims that have been authorized by the FDA and have complied with the standard prescribed by the FDA.³⁶ The FDA has to date authorized twelve types of health-related claims (referred to as the 'FDA authorized claims'),³⁷ and they are claims that relate to (1) 'calcium and osteoporosis'; (2) 'dietary lipid and cancer'; (3) 'sodium and hypertension'; (4) 'dietary saturated fat and cholesterol and heart disease'; (5) '(fiber) containing grain products, fruits, vegetables, and cancer'; (6) 'fruits, vegetables, and grain products that contain fiber, particularly soluble fiber and risk of coronary heart diseases'; (7) 'fruits and vegetables and cancer'; (8) 'folate and neural tube defects'; (9) 'dietary non-cariogenic carbohydrate sweeteners and dental caries'; (10) 'soluble fiber from certain foods and risk of coronary heart disease (CHD)'; (11) 'soy protein and risk of coronary heart disease (CHD)' and (12) 'plant sterol/stanol esters and risk of coronary heart disease (CHD)'.³⁸

These health-related claims, although being authorised, are not permissible on labels unless the standard prescribed by the FDA has been complied with.³⁹ The FDA has stipulated a set of general requirements to be complied with in relation to the dissemination of health-related claims and these are specified at 21 CFR § 101.14 (2008). They include: (1) that the claims must be substantiated by a 'significant scientific experts';⁴⁰ and (2) that

³⁵ Ibid.

³⁶ 21 USC § 343 (r) (3) (A), (B), and (C) 2008. It is to be noted that 21 USC § 343 (r) (3) is the codified version of section 403(r) of the *Federal Food Drug and Cosmetic Act 1938*.

³⁷ 21 CFR. § §101.72 – 83 (2008). It had increased from 8 claims in the year 1996 to 12 in 2008. It has not increase since then. This is the status as at 26 October 2010.

³⁸ See 21 CFR. § 101.72 (2008) to 21 CFR. § 101.83 (2008).

³⁹ 21 CFR. § 101.14 (2008).

⁴⁰ See Ibid § 101.14 (c) (2008). The rule on validity of claims requires that the claim be 'based on the totality of the publicly available scientific evidence...from well designed studies... conducted in a manner which is

the claim must be complete, truthful and not misleading'.⁴¹ In addition, the claim must also illustrate the relationship between the nutrient and disease in a consumer-friendly manner.⁴²

The rule regarding the 'significant scientific agreement' requirement, however, has been relaxed. Health-related claims that 'fall short' of establishing this requirement are currently permissible on labels if they have been argued to be in the best interest of the consumers.⁴³ Such claims are known as 'qualified health claims' and are only required to fulfill the general requirements specified under 21 CFR § 101.14.

Health-related claims are also permissible if they are based on an 'authoritative statement' issued by the 'scientific body of the U.S. Government or the National Academy of Sciences' under section 303 and 304 of the *Food and Drug Administration Modernization Act of 1997* (United States), (the 'FDAMA').⁴⁴ The health-related claims and the qualified health claims, which are authorized, are permissible on food labels and will not result in the product being classified as drugs.

Further, there is also a category of claim known as the 'nutrient content claim', which characterizes the level of nutrients in a food, using terms such as, free, high, low, healthy, light, lite or more.⁴⁵ These are claims that, for example, describe the levels of (1) calorie or

consistent with generally recognized scientific procedures and principle...agreed among expert qualified by scientific training and experience...'. Also see 21 USC § 343 (r) (3) (B)(i) (2008).

⁴¹ 21 CFR. § 101.14 (d) (2) (iii) (2008).

⁴² Ibid § 101.14 (d) (2) (v) (2008).

⁴³ Center For Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, United States, *Claims That Can be Made For Conventional Foods and Dietary Supplements*, (2003) 2<<http://www.cfsan.fda.gov/dms/hclaims.html>>; Abood, above n 13, 52.

⁴⁴ Health related and nutrient claims were initially only permissible if they were authorised by the FDA, however, the FDAMA amended the situation. Sections 303 and 304 of FDAMA amended section 403 (r) (3) and 403(r) (2) and permitted them if they are also based on current, published authoritative statements from scientific bodies. As a result of this amendment, there are two kinds of authorization for health-related claims: (1) the FDA authorised claims; (2) the scientific body authorised claims. See Center For Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, United States, *Guidance For Industry, Notification of a Health Claim or Nutrient Claim Based on an Authoritative Statement of a Scientific* (1998), 1. ('*Guidance For Industry, Notification of a Health Claim or Nutrient Claim Based on an Authoritative Statement of a Scientific*').

⁴⁵ 21 CFR § 101.13 (2008).

sugar;⁴⁶ (2) sodium or salt;⁴⁷ (3) total fat, saturated fat, cholesterol;⁴⁸ or high potency⁴⁹ or good source.⁵⁰ These claims are authorized and are permissible on the label if they satisfy the labelling requirements specified under 21 CFR § 101.54 (a) (2008) to 21 CFR § 101.65 (a) (2008), or they are based on an 'authoritative statement'.⁵¹

In addition to these types of permissible claims on the food labels, namely, the 'FDA authorized claims' qualified claims and the claims based on authoritative statement', which exempt food products from being classified as drugs, the *Federal Food Drug and Cosmetic Act 1938* (United States) recognizes that food can fall under two special categories; (1) food for 'special dietary use';⁵² and (2) 'medical food'.⁵³

Food for 'special dietary use' is food which exists because of a special diet required by those with a : (1) '...physical, physiological, pathological, or other condition, including but not limited to the condition of diseases, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight or the need to control the intake of sodium'⁵⁴ and (2) by those for whom '...age, including but not limited to the ages of infancy and childhood⁵⁵ is a factor. Food for 'special dietary use' also included food that supplements or fortifies 'the ordinary or usual diet with any vitamin or mineral or other dietary property'.⁵⁶ Ordinarily, the labels and advertisements of food for 'special dietary use' are only permitted to carry claims that specifically relate to dietary uses, such as

⁴⁶ Ibid § 101.60 (2008).

⁴⁷ Ibid § 101.61 (2008).

⁴⁸ Ibid § 101.62 (2008).

⁴⁹ Ibid § 101.54 (f) (2008).

⁵⁰ Ibid § 101.54 (c) (2008).

⁵¹ *Guidance For Industry, Notification of a Health Claim or Nutrient Claim Based on an Authoritative Statement of a Scientific*, above n 44, 1.

⁵² 21 CFR. § 105.3(a)(1)(2008).

⁵³ *ibid* § 101.9 (j)(8); Section 5 (b) of the Orphan Drug Act 1983 (USA), Pub. L. No. 97-414, 96 Stat. 2049; 21 USCA § 360 ee (3) (2008).

⁵⁴ 21 CFR. § 105.3(a)(1)(i)(2008).

⁵⁵ Ibid § 105.3(a)(1)(ii)(2008).

⁵⁶ Ibid § 105.3(a)(1)(iii)(2008).

gluten intolerance, and weight loss and weight gains,⁵⁷ and therefore will fall under the classification of drugs if found to be labelled with general claims of disease prevention, treatment, mitigation, cure, or diagnosis. Food for 'special dietary use' is not subject to the FDA's requirements applicable to food, but is instead subject to labelling requirements that are unique for this class of products.⁵⁸

'Medical food' is 'food which is formulated to be consumed or administered internally under the supervision of a physician'.⁵⁹ It is food intended for 'specific dietary management of a disease or condition', based on medical evaluation.⁶⁰ It is specifically formulated to cater for a particular medical need and to be used under medical supervision.⁶¹ Consequently, it may only carry claims that it is specifically designed to meet, and not general claims that pledge to cure, mitigate, treat or prevent diseases.⁶²

A further category of food which exists in the United States is 'functional food'. Such a class is not defined in the *Federal Food Drug and Cosmetic Act 1938* (United States), but is widely used in the United States. Although not legally defined, it has been described as food with 'basic attributes of traditional food, namely, the taste, aroma or nutritive value with ... an additional health benefit'.⁶³ Concerns have been raised, however, as to what category this food will fall under and how it should be regulated.⁶⁴ Hahn, for example, argues that functional food may be regulated based on whether it is food, dietary

⁵⁷ Ibid § 105.3 (a)(1) (2008).

⁵⁸ 21 USC § 343 (j) provides that the label must fully inform the consumers of the values of the dietary uses. Other requirements are provided under 21 CFR. § 105.62 (2008), 21 CFR. § 105.65 (2008), 21 CFR § 105.66 (2008).

⁵⁹ 21 CFR § 101.9 (j)(8); Section 5 (b) of the Orphan Drug Act 1983 (USA), Pub. L. No. 97-414, 96 Stat. 2049; 21 USCA § 360 ee (3) (2008).

⁶⁰ Ibid.

⁶¹ 21 CFR § 101.9 (j)(8)(i) – (v) (2008).

⁶² Ibid.

⁶³ Government Accountability Office, United States, *Food Safety: Improvement Needed in Overseeing the Safety of Dietary Supplements and Functional Foods*, GAO/RCED-00-156 (2000), 3. ('Food Safety: Improvement Needed in Overseeing the Safety Report').

⁶⁴ Martin Hahn, 'Functional foods: What are they? How are they regulated? What claims can be made? (The Dietary Supplement Health and Education Act: Regulation at a Crossroads)' (2005) 31(2-3) *American Journal of Law & Medicine* 305, 306; Susan Onel, 'Functional Food, Nutraceuticals Designer Foods: What Are They and How Are They Regulated?' (2001) *Regulatory Affairs Focus* 14, 16.

supplement, medical food or food for special dietary use.⁶⁵ The FDA, however, maintains that functional food falls under the category of food and thereby is subject to the requirements of food regulations.⁶⁶

In conclusion, some claims exempt food from being classified as drugs and thereby from the drug approval process. Health-related claims, nutrient claims and qualified claims are permitted if they are authorised by the FDA and have complied with the FDA prescribed standards, or that they are based on an authoritative statement. Further, the regulatory regime recognizes that food can fall under other categories such as, 'special dietary food', 'medical food' and 'functional food'. Consequently, foods that fall within these categories are exempted from drugs classification unless labelled with general therapeutic claims.

5.2.1.3 Dietary Supplements

In the United States, dietary supplements are regulated as food by the FDA under the *Dietary Supplement Health and Education Act 1994* (United States).⁶⁷ The *Dietary Supplement Health and Education Act 1994* (United States) was implemented after 'intensive lobbying' by the dietary supplement industry, who did not favour the *Nutrition Labelling and Education Act of 1990* (United States) which regulated dietary supplements. It was considered too restrictive for dietary supplements. The *Dietary Supplement Health and Education Act 1994* (United States) brought some changes; for example, it amended the definition of dietary supplement provided under the *Federal Food Drug and Cosmetic Act 1938* (United States), altered the status of dietary supplement and the FDA's authority over it.⁶⁸

⁶⁵ Hahn, above n 64, 306.

⁶⁶ *Food Safety: Improvement Needed in Overseeing the Safety Report*, above n 63, 4.

⁶⁷ The *Dietary Supplement Health and Education Act* (1994), Public Law 103-417, 103rd Congress.

⁶⁸ *Ibid.*

The term 'dietary supplement' is defined under section 3 of the *Dietary Supplement Health and Education Act 1994* (United States)⁶⁹ as follows;

(ff) The term dietary supplement

- (1) means a product (other than tobacco) intended to supplement the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients:
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) another dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredients described in clause (A), (B), (C), (D) or (E);
- (2) means a product that
 - (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i);⁷⁰ or
 - (ii) complies with section 411(c)(1)(B)(ii);⁷¹
 - (B) is not represented for use as a conventional food or as a sole item of meal or the diet; and
 - (C) is labelled as a dietary supplement.

From the wording of the statutory definition, a broad category of products can be expected to fall within the classification of dietary supplement. All products which contain 'dietary ingredients', and are intended to supplement diet, fall within the classification.⁷² 'Dietary ingredients' may take the form of an extract or concentrates or tablets, capsules, soft-gels,

⁶⁹21 USC § 321 (ff) (2) 2008.

⁷⁰ 21 USC. § 350 (c)(1)(B)(i) 2008. The form described refers to 'capsules, powder, softgel, gelcap or liquid'.

⁷¹ Ibid § 350 (c)(1)(B)(ii) 2008. It refers to forms that are not represented as conventional food or represented for use as a sole item of a meal or of the diet.

⁷² Ibid § 321 (ff) (2) 2008.

gel-caps, liquids, powders or bars.⁷³ They are, however, limited to products intended for ingestion.⁷⁴

The question is whether dietary supplement can be regulated as drugs if their advertisements are found to contain therapeutic claims? Dietary supplements are permitted to carry a claim which: (1) states that the product will ‘benefit a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States’; (2) ‘describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans’; (3) ‘characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function’ or (4) ‘describes general well-being from consumption of a nutrient or dietary ingredient’.⁷⁵ These claims will not cause dietary supplements to be classified as drugs provided that the ‘FDA prescribed standards’ for dietary supplements have been adhered to before they are carried on the advertisements or labels.⁷⁶ The ‘FDA prescribed standards’ requires that the claims are: (1) substantiated, truthful and not misleading and (2) contain a disclosure statement pertaining to the claims: ‘This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease’.⁷⁷

It is clear from ‘the FDA prescribed standards’ that therapeutic claims are not permitted on advertisements of dietary supplements.⁷⁸ However, because dietary supplements are classified as a sub-category of food, the question arises as whether they are allowed to carry claims which are permissible to food labelling. Section 21 CFR § 101.93 (3) (f) (2008) provides ‘... if a label or labelling of a product marketed as a dietary supplement bears a disease claim... the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies’. Therefore, dietary supplements

⁷³ Ibid § 350 (c)(1)(B)(i) 2008.

⁷⁴ Ibid § 321 (ff) (2) (A) (i) 2008.

⁷⁵ Ibid § 343(r)(6)(A) (2008).

⁷⁶ Ibid § 343(r)(6) (B) and (C) (2008); 21 CFR § 101.93 (3) (c) (2008).

⁷⁷ Ibid. This notice must be given to the FDA no later than 30 days that the dietary supplements with such statement have been marketed.

⁷⁸ 21 CFR § 101.93 (3) (c) (2008).

may carry (1) FDA authorized health-related claims; (2) nutrient health claims and (3) qualified health claims. They may also carry ‘affect the structure and function of body claims’.⁷⁹

5.2.1.4 Cosmetics

Cosmetics are defined under section 201(i) of the *Federal Food Drug and Cosmetic Act 1938* (United States) as ‘(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and (2) articles intended for use as a component of any such articles; except that such term shall not include soap’.⁸⁰ They include articles used externally as well as internally. Thirteen categories of products are classified as cosmetics, namely, (1) baby products; (2) bath products; (3) eye makeup; (4) fragrances; (5) hair products (non-colouring); (6) hair colourings; (7) make up other than eye makeup; (8) manicuring; (9) oral hygiene products; (10) personal cleanliness products; (11) shavings products; (12) skin care products and (13) suntan products.⁸¹ Advertisements for these categories of cosmetics must specify the intended use of the products;⁸² and where, cosmetics have a dual purpose (e.g. to beautify and treat) such as acne treatment cosmetics, anti-bacterial face wash, anti-dandruff shampoos and anti-perspirant deodorant, this must also be stated. In instances of dual-purpose, the products may be subject to the labelling requirements of drugs specified under Chapter V of the *Federal Food Drug and Cosmetic Act 1938* (United States).⁸³ Cosmetics that are intended to diagnose, cure, mitigate, treat or prevent diseases fall under the classification of drugs in the United States, and no exemptions are established.⁸⁴

⁷⁹ Ibid § 101.93 (f) (2008).

⁸⁰ 21 USC § 321(i) (2008) (2008).

⁸¹ 21 CFR § 720.4(4)(c) (1) – (13) (2008).

⁸² Ibid.

⁸³ Ibid § 700.11 - 700.35 (2008).

⁸⁴ Ibid § 700.3 (b) (2008).

5.2.1.5 Implication of Classification of Drugs in the United States

Determining the types of products which fall within the classification of drugs in the United States is crucial for a number of reasons. The classification determines the agency that would regulate the advertising. If a product is prescription drug, the advertising will be regulated by the FDA, otherwise it will be governed by the FTC. Moreover, the classification of products as drugs gives greater control to the FDA with respect of its regulation. The FDA, for instance, is able to impose labelling requirements. The labelling requirements of products classified as drugs are more stringent and detailed compared to those which are not considered as drugs, as will be noted from [5.4.1.1].

The primary implication of classification of products as drugs is, however, that these products are subject to a drug safety control, a pre-advertising control. This control involves the requirement to obtain a pre-approval, and the pre-approval is a confirmation that products are safe and effective before they may be marketed.⁸⁵ Products, however, do not, need to show that they are risk free; but they do need to show that the risks associated with their use do not outweigh the benefits derived.⁸⁶ Here, risk evaluation and mitigation strategies are used to determine if the benefit of the product outweighs the risk associated with the use of the drug before the drug is made available to the public.⁸⁷ The analysis considers the following: (1) the estimated size of the population that would use the drug; (2) the seriousness of the disease or condition for which they will be used; (3) the expected benefits of the drug, and (4) the duration of the treatment, its known risk, and potential adverse reactions.⁸⁸ This evaluation is carried out at various stages: (1) initial drug approval stage; (2) post-approval stage; (3) during drug access stage and (4) re-evaluation at post-marketing stage.⁸⁹

The process of ensuring that drugs are safe and effective is long and tedious. Pre-market approval must be obtained from the FDA. This is a confirmation that scientific testing for

⁸⁵ 21 USC § 360 e (2008).

⁸⁶ Ibid § 355 -1 (2008).

⁸⁷ Ibid § 355 -1 (2008).

⁸⁸ Ibid § 355 -1 (2008).

⁸⁹ Ibid § 355 -1(2008).

safety and efficacy of the product has been conducted.⁹⁰ The scientific testing process is complex, involving various types of studies.⁹¹ There is also a requirement that the tests are documented and submitted along with the relevant application for risk assessments.⁹²

In some instances, a post-approval study(ies) of the drug, or a post-approval clinical trial(s) of the drug may be carried out. These particular types of studies are carried out in order to: (1) 'assess a known serious risk' or (2) 'assess signals of serious risk' which are related to the use of drugs.⁹³ They are also carried out to 'identify an unexpected serious risk when available data indicates the potential for a serious risk'.⁹⁴ Further, when there are manufacturing changes after approval is granted, additional approval may be required. The application for further approval must contain information that 'validates the effects of the change on the identity, strength, quality and purity of the drugs'.⁹⁵ Supporting evidence must also be forwarded to show that changes effected do not adversely affect the quality of products.⁹⁶ For instance, a packaging change from a blister pack to a bottle has regulatory implications which are complex.⁹⁷ Where there are chemical compositions, a packaging change may of necessity involve a change in the structure of bulk powder, and supporting

⁹⁰ Ibid §360 e (2008).

⁹¹ See 21 CFR. § 312.21 (2008). The scientific testing or clinical investigation is generally divided into three phases. The first phase is where 'initial introduction of an investigational new drug into humans' is carried out, and it 'includes studies of drug metabolism, structure-activity relationships, and mechanism of action in humans'. Phase 2 includes 'the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug'. Phase three is where studies are 'performed after preliminary evidence suggesting effectiveness of the drug has been obtained'. This is intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling'. 'Drug component, the composition of drug, description of the methods used in and the facilities used for the manufacture, processing must be documented for approval processes, as required under 21 USC. §355 (b) (2008). Further, in some instances animal testing is required and the studies of the 'drug's pharmacologic and toxic effects on animal' must be conducted, as required under 21 CFR. § 312.23(a)(8) (2008).

⁹² 21 USC §355 (2008).

⁹³ Ibid §355 (o) (3) (A) (2008)

⁹⁴ Ibid §355 (o) (3) (B) (2008)

⁹⁵ Ibid §356 (a) (2008)

⁹⁶ Ibid; Leo J Lucisano, Kevin A. Millier, Lorien Armour, 'CMC Postapproval Regulatory Affairs: Constantly Managing Change' in Ira R. Berry & Robert P. Martin (eds) *The Pharmaceutical Process* 2005 (Informa Healthcare, 2nd ed, 2009) 411, 413.

⁹⁷ Lucisano, Millier, and Armour, above n 96.

evidence may have to be submitted to show that changes effected do not affect the quality of the product.⁹⁸

Therefore, the perception is that products which are classified as drugs are ensured to be safe and effective before they are marketed. The level of safety and efficacy is determined by considering if the benefits of using the drugs outweigh the risk associated with the use of drugs. The process involved in ensuring that the products are relatively safe and effective is long and tedious. Furthermore, the FDA is often challenged by manufacturers on the legality of their pre-market approval requirements for health claims and their procedure with respect to standards required for 'significant scientific agreement', as will be seen in [5.6.1] of this chapter.

⁹⁸ Ibid.

5.3 THE REGULATION OF THE ADVERTISING OF MEDICINAL PRODUCTS IN THE UNITED STATES

The regulation of the advertising of medicinal products in the United States will be discussed under two broad headings: (1) the regulation of prescription drugs advertising, at [5.4], and (2) the regulation of advertising of non-prescription drugs, food, dietary supplements and cosmetics which are referred to as HRP, at [5.5]. This section of the chapter discusses the roles and functions of two Federal agencies, namely, the FDA and the FTC in the regulation of the advertising of medicinal products. The objective is to enable a better understanding of the regulation of prescription drugs and the advertising of HRP in [5.4] and [5.5] respectively. In [5.3.1], their establishment, constitution and individual responsibilities of the agencies, are examined and in [5.3.2], their 'shared responsibility'.

5.3.1 The Agencies that Regulate the Advertising of Medicinal Products in the United States

The regulation of the advertising of medicinal products is administered by two Federal agencies, the FDA and the FTC. The FDA oversees the advertising of prescription drugs and the FTC regulates the advertising of other products including non-prescription drugs, food, dietary supplements and cosmetics.⁹⁹

The FDA is established under section 903 of the *Federal Food Drug and Cosmetic Act* 1938 (United States) to promote the public health through adequate clinical research and ensure appropriate marketing of regulated products.¹⁰⁰ It is charged with ensuring the appropriateness of food and cosmetic labelling and the advertising of prescription drugs.¹⁰¹ It is a section in the Department of Health and Human Services (the 'DHHS'), which consist of five main centers: (1) The Center for Biologics Evaluation and Research; (2) The Center for Food Safety and Applied Nutrition; (3) The Center for Drug Evaluation and Research; (4) The Center for Veterinary Medicine and (5) The Center for Devices and Radiological

⁹⁹ 21 USC §393 (2008) and USC 45 § 45(a)(2) 2008.

¹⁰⁰ 21 USC §393 (2008).

¹⁰¹ Ibid.

Health.¹⁰² The regulation of the advertising of drugs is carried out by FDA's Center for Drug Evaluation and Research (the 'CDER') through its Division of Drugs, Marketing, Advertising and Communications (DDMAC).¹⁰³ This Division aims to ensure that information which is truthful, balanced and accurate is communicated to the public.¹⁰⁴

The FTC is the Federal law enforcement agency that administers both consumer protection and competition in commerce. It is authorised under section 5(a)(2) of the *Federal Trade Commission Act 1914* (United States) 'to prevent ...the [use] of ... unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce'.¹⁰⁵ The FTC is assisted by a number of bureaus.¹⁰⁶ The FTC's work relating to consumer protection is pursued by the Bureau of Consumer Protection, with the assistance of seven (7) divisions, namely; (1) The Division of Advertising Practices; (2) The Division of Consumer and Business Education; (3) The Division of Enforcement; (4) The Division of Financial Practices; (5) The Division of Marketing Practices; (6) The Division of Planning and Information and (7) The Division of Privacy and Identity Protection.¹⁰⁷ The regulation of advertising of drugs is policed by the Division of Advertising Practices.¹⁰⁸

The Bureau of Consumer Protection is charged with multiple task. It is commissioned to: (1) conduct investigations and sue for violation of laws; (2) develop rules and policies; (3)

¹⁰² Food and Drug Administration, Department of Health and Human Services *About FDA Centers & Offices* < <http://www.fda.gov/AboutFDA/CentersOffices/default.htm> > .

¹⁰³ Ibid; Government Accountability Office, United States, Report to Congressional Requesters, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, GAO -07-54 (2006) 2. ('*FDA's Oversight of Direct-to-Consumer Advertising Report*').

¹⁰⁴ Center for Drug Evaluation and Research, Division of Drug Marketing Advertising And Communications, Food and Drug Administration, United States, *Federal Mission Statement* at <<http://www.fda.gov/cder/ddmac>>.

¹⁰⁵ 15 USC § 45 (a)(2) (2008).

¹⁰⁶ Three Bureaus which assist the FTC are: (1) the Bureau of Competition which responsible for the promotion and protection of free competitions; (2) the Bureau of Economics that is responsible for the economic analysis, antitrust and consumer protection investigations, assist FTC in its regulations and (3) the Bureau of Consumer Protection. See Federal Trade Commission, Department of Health and Human Services, United States *About the Bureau of Consumer Protection* < <http://www.ftc.gov/bcp/about.shtm> >. ('*About the Bureau of Consumer Protection Report*').

¹⁰⁷ *About the Bureau of Consumer Protection Report*, above n 106.

¹⁰⁸ Ibid.

educate businesses regarding their rights and responsibility in advertising and (4) channel complaints about consumer fraud which have been gathered to law enforcement agencies for further action.¹⁰⁹ Its Division of Advertising Practices monitors the advertising practices, and initiates administrative and enforcement actions in the Federal District Court for violations of orders.¹¹⁰ Further, it also coordinates with the Federal and International Law Enforcement Agencies to detect unfair and deceptive advertising practices.¹¹¹

5.3.2 Shared responsibility between the FDA and the FTC

As noted in the above paragraph, the FDA is responsible for the advertising of prescription drugs and the labelling of food and cosmetics.¹¹² The FTC, on the other hand, is responsible for the advertising of non-prescription drugs, food, dietary supplement and cosmetics.¹¹³ Despite the division (partition) of the regulatory function, they have worked together in regulating the dissemination of information on advertisements. As noted at [5.2.1.2], FTC relies and accepts, the FDA's labelling requirements as guidelines for advertising claims. The FTC has prepared its food advertising policy, known as the Food Advertising Enforcement Policy Statement 1994, in comparison with the labelling requirements of the FDA. Although the FTC differs in the standards applied in advertising, the FTC requires that the FDA labelling requirements be fulfilled as a pre-condition for advertising.¹¹⁴ The approach adopted by the FTC in food advertising is discussed at length at [5.5.1.5].

¹⁰⁹ Ibid.

¹¹⁰ Ibid.

¹¹¹ Ibid.

¹¹² 21 USC §393 (2008).

¹¹³ 15 USC § 45 (a)(2) (2008).

¹¹⁴ *A Brief Review of the FTC's Environmental and Food Advertising Enforcement Programs*, above n 34, 4.

5.4. THE REGULATION OF ADVERTISING OF PRESCRIPTION DRUGS IN THE UNITED STATES

The regulation of the advertising of prescription drugs in the United States is different from most countries because the United States, with the exception of New Zealand, permits 'direct-to-consumer advertising' (DTCA) of prescription drugs.¹¹⁵ The phrase 'direct-to-consumer advertising' ordinarily refers to advertisements that are directed at consumers in various media such as print and broadcast. DTCA of prescription drugs is allowed in the United States because DTCA of prescription drugs is thought of as an appropriate source of information empowering consumers with the ability to make an informed choice.¹¹⁶ However, there have been debates as to whether such advertising is indeed beneficial to consumers.¹¹⁷

This section of the chapter examines the regulation of advertising of prescription drugs in the United States. In [5.4.1], it examines the laws governing the advertising of prescription drugs, which include the *Federal Food Drug and Cosmetic Act 1938* (United States), the FDA regulations and guidance document. The regulatory controls, namely, the system of pre-approval of advertisements, monitoring and enforcement of violation of advertising laws are explored in [5.4.2].

5.4.1. Laws Governing the Advertising of Prescription Drugs

The regulations governing the advertising of prescription drugs are specified under the *Federal Food Drug and Cosmetic Act 1938* (United States), which is the Federal legislation that governs the manufacturing, marketing and the distribution of drugs in the United States.¹¹⁸ The primary rule that regulates the advertising of prescription drugs is section

¹¹⁵ 21 CFR. § 202.1(e) (2008); The advertising of prescription drugs is regulated under section 502 of the *Federal Food Drug and Cosmetic Act 1938* (United States).

¹¹⁶ See Anthony D Cox and Dena Cox, 'A Defense of Direct-to-Consumer Prescription Drug Advertising' (2010) 53 *Business Horizon* 221, 227; Isaac D. Montoya, Gwen Lee-Dukes and Dhvani Shah, 'Direct -To-Consumer Advertising: Its Effects on Stakeholders' (2008) 37(2) *Journal of Allied Health* 116, 118; Jeffrey T Berger, et al., 'Direct-to-Consumer Drug Marketing: Public Service or Disservice?' (2001) 68(3) *The Mount Sinai Journal of Medicine* 197, 199.

¹¹⁷ The advantages and disadvantages of DTCA of prescription drugs are discussed in detail in [6.2.4.1] and [6.2.4.2] of Chapter 6.

502 of the *Federal Food Drug and Cosmetic Act 1938* (United States), and this section is implemented through the FDA regulations, codified at Title 21 CFR § 202.1(e) (2008). It is useful to note that in the United States, legislation is supplemented by regulations established by agencies, which are codified as Code of Federal Regulation (the 'CFR'). These are, in essence, compilations of regulations under various titles and are published yearly. The FDA regulations pertaining to the labelling and advertising of prescription drugs are codified under Title 21 CFR Part 201 and 202 (2008). These rules are applicable to advertisements that are directed at healthcare professionals as well as consumers. The same standards of rules have been used on advertisements directed at health-care and consumers since 1985, the year DTCA of prescription drugs was permitted.¹¹⁹

5.4.1.1 Federal Food Drug and Cosmetic Act 1938 (United States)

Two sections, namely sections 502 (a) and 502 (n) of the *Federal Food Drug and Cosmetic Act 1938* (United States) are important in the regulation of advertising of prescription drugs and these are examined. Section 502 (a) of the *Federal Food Drug and Cosmetic Act 1938* (United States) prohibits false and misleading labelling,¹²⁰ and section 502 (n) of the *Federal Food Drug and Cosmetic Act 1938* (United States) prescribes specific requirements to be fulfilled in relation to advertising and labelling of prescription drugs.¹²¹ It

¹¹⁸ Francis B. Palumbo and C Daniel Mullins, 'The Development of Direct-to-Consumer Prescription Drugs Advertising Regulation' (2002) 57 *Food and Drug Law Journal* 423. Before the *Federal Food Drug and Cosmetic Act 1938* (United States), the *Pure Food and Drug Act of 1906* (United States) governed the food and drugs regulations in the United States. This legislation had a few deficiencies and loopholes. Although it contained provisions regarding labelling, it failed to provide for advertising. Hence false claims that were not on labels were not prohibited. In 1938, the *Federal Food Drug and Cosmetic Act 1938* (United States) was enacted repealing the *Pure Food and Drug Act of 1906* (United States). The *Federal Food Drug and Cosmetic Act 1938* (United States) introduced regulations for prescription drug advertising: at 424-425.

¹¹⁹ Ibid 425. Historically, advertisements of prescription drugs were only directed at medical professionals. However, in 1981, a drug called Rufen, an ibuprofen product, was promoted by Boots Pharmaceuticals, an American subsidiary of a British drug company. The information about the drugs proved to be beneficial to consumers. More drugs were promoted to consumers and the pharmaceutical companies began to argue that the DTCA of prescription drugs benefited consumers. They proposed that DTCA of prescription drug be permitted for the benefit of consumers. Requiring time to contemplate on the proposal, the FDA issued a request for a voluntary moratorium on DTCA of prescription drugs and commissioned studies on the benefits of DTCA. The studies convinced the FDA that DTCA of prescription drugs is beneficial to consumers. The DTCA of prescription drugs, which continues today, was allowed at that point. Soon after, the FDA announced that the regulation applicable to advertisements of healthcare professionals will be also applied to those directed to consumers: at 425 – 426.

¹²⁰ 21 USC § 352 (a) 2008. The prohibition in this section is applicable to drugs, devices, food and cosmetics.

¹²¹ 21 USC § 352 (n) 2008.

stipulates that 'prescription drugs distributed or offered for sale in any state, to contain in all advertisements and other descriptive printed matters issued or caused to be issued by the manufacturer, packer or distributor ... a true statement of':

- (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name;
- (2) the formula showing quantitatively each ingredient of such drugs to the extent required for labels under section 502(e)¹²² and
- (3) such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations...'.¹²³

In essence, section 502 (a) of the *Federal Food Drug and Cosmetic Act 1938* (United States) requires that the content of advertisements be truthful and accurate, and section 502 (n) of the *Federal Food Drug and Cosmetic Act 1938* (United States) requires advertisements to carry complete information including the established names, the ingredients as approved by the labelling requirements and a brief summary of the product's side effects, contraindications and effectiveness.¹²³

In addition to these provisions, the FDA regulations require that the advertisement does the following: (1) reflects a 'fair balance' between the effectiveness of the advertised drugs and the side effects, risks and contraindications;¹²⁴ (2) be consistent with the FDA approved labelling¹²⁵ and (3) that the information is presented in a language comprehensible to consumers.¹²⁶ These three provisions are further elaborated by way of examples in the following paragraph.

¹²² The provision prescribes the regulations concerning the 'designation of drugs or devices by established names'.

¹²³ 21 CFR § 202.1(e) (2008).

¹²⁴ Ibid § 202. 1(e) (5).

¹²⁵ Ibid § 202. 1(e) (6).

¹²⁶ Center For Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, Department of Health and Human Services, United States, *Guidance For Industry: Brief Summary, Disclosing Risk Information in Consumer-Directed Print Advertisements* (January 2004), 6 <<http://www.fda/cder/guidance/5669dft.pdf>>. ('Guidance For Industry: Brief Summary, Disclosing Risk Information in Consumer-Directed Print Advertisements').

First, information is considered as unfairly balanced if, for example (1) comparisons between drugs on safety and efficacy are made without proof;¹²⁷ (2) exaggerated studies are presented;¹²⁸ (3) references to literature or studies on the effectiveness of drugs are presented in a misleading manner;¹²⁹ (4) data or conclusions from non-clinical studies are misrepresented as having clinical significance when in fact they do not¹³⁰ and (5) headlines, sub-headlines or pictorials or other graphics are misrepresented.¹³¹

Second, information is considered as consistent with the 'FDA approved labelling', when labels provide the information required by law.¹³² The 'FDA approved labelling' is of two kinds: (1) The 'FDA-approved patient labelling' and (2) the 'FDA-approved professional labelling'.¹³³ Whilst the 'FDA-approved patient labelling' refers to labels that provide risk and benefit information which can facilitate patient (with the involvement of a physician) on whether to use prescription drugs, the 'FDA-approved professional labelling' refers to labels prepared for an audience of health-care professionals, using technical medical language.¹³⁴

Third, the requirement about providing information on side effects, contradictions and effectiveness on advertisements, is considered to be satisfied when language that is comprehensible and easily accessible is used. To facilitate this, two different methods for disseminating information on side effects, contradictions and effectiveness have been implemented, namely: (1) the use of a brief summary for print media; (2) the use of 'adequate provision' for broadcast media.¹³⁵

¹²⁷ 21 CFR § 202 (1) (e) (6) (ii) (2008).

¹²⁸ Ibid § 202 (1) (e) (6) (v) (2008).

¹²⁹ Ibid § 202 (1) (e) (6) (vi) (2008).

¹³⁰ Ibid § 202 (1) (e) (6) (vii) (2008).

¹³¹ Ibid § 202 (1) (e) (6) (xviii) (2008).

¹³² Ibid § 202. 1(e) (6).

¹³³ *Guidance For Industry: Brief Summary, Disclosing Risk Information in Consumer-Directed Print Advertisements*, above n 126.

¹³⁴ Ibid 4.

¹³⁵ Ibid 5.

Brief summary, in essence, means that the advertisement for a prescription drug discloses information such as side effect, warning, precaution, and contraindication. 'Adequate provision' means that the advertisers provide 'means of access' to the information relating to side effects, contra-indications and effectiveness. An 'adequate provision' can be satisfied by complying with four criteria set out in the FDA's Guidance for Industry (1999), which is summarised as follows:

Advertisers are:

- a) to disclose a toll-free number for consumers to call. Consumers who ring this number should have the FDA approved label for the product read to them. Alternatively, the label should be mailed to them in a timely manner. An appropriate time frame would be within two business day of receipt;
- b) to disclose an Internet web page which can enable consumers to access the FDA approved labels;
- c) to provide an alternative mechanism for consumers without access to the Internet to access to the FDA approved labels of the products and
- d) to disclose a statement which guides consumers to physicians or pharmacists (or other health care providers) so as to ensure that they are additionally informed regarding the products.¹³⁶

This requirement to furnish a brief summary or an adequate provision is, however, not applicable to all types of advertisements.¹³⁷ It is not applicable to advertisements that do not feature an indication regarding the safety and efficacy of drugs.¹³⁸ 'Reminder advertisements', bulk-sale drugs advertisements and advertisements of prescription-compounding drugs are three examples.¹³⁹ 'Reminder advertisements' are advertisements which remind consumers of a particular drug(s) by calling their attention by reference to a name without mentioning the functions of the drugs.¹⁴⁰ They provide the proprietary or

¹³⁶ Center For Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), Food and Drug Administration Department of Health and Human Services, United States, *Guidance for Industry*: (9 August 1999), 2.

¹³⁷ See 21 CFR § 202.1 (e)(2) (2008).

¹³⁸ Ibid § 202.1 (e)(2) (2008).

¹³⁹ Ibid.

¹⁴⁰ Ibid § 202.1 (e)(2) (i) (2008).

established name of the drug or the price of product without the mention of indications or dosage recommended for use of the drug.¹⁴¹ Advertisements of bulk-sale drugs are advertisements that promote sale of drugs in bulk packages, and the bulk packages are ‘packed in accordance with the practice of the trade solely to be processed, manufactured, labelled or repacked in small quantities’.¹⁴² Advertisements for prescription-compounding drugs are advertisements for a ‘...prescription chemical or other compound for use by registered pharmacist in compounding prescriptions...’.¹⁴³

Ordinarily, advertisements of prescription drugs may feature an indication regarding the safety and efficacy of drugs, and when they do, they are subject to the FDA regulations.¹⁴⁴ Failure to comply with the FDA regulations will result in the products being declared ‘misbranded’. Misbranded in a broader sense denotes non-compliance or violation of regulations; however, in the context of advertising, it refers to representations in advertisements that are false or misleading, lacking in material facts, or presentation of improperly balanced risk and benefits information.¹⁴⁵

5.4.2 The Regulatory Controls over the Advertising of Prescription Drugs

Although regulatory controls of advertising of prescription drugs may involve the use of a broad spectrum of strategies to prevent deceptive advertising, the discussion in this section is confined to the main controls employed, namely, systems of pre-approval of advertisements, monitoring and enforcements. The objective is to facilitate a comparative analysis with two other jurisdictions, namely Australia and Malaysia, which similarly employ such regulatory controls, in [6.3.3.2] of Chapter 6.

As explained in [1.5] of Chapter 1, a system of pre-approval of advertisements is a form of control which is used to filter false and misleading advertisements from reaching the

¹⁴¹ Ibid.

¹⁴² Ibid § 202.1(e)(2)(ii) (2008).

¹⁴³ Ibid § 202.1 (e)(2) (iii)(2008).

¹⁴⁴ 21 USC § 352 (a) 2008; 21 USC § 352 (n) 2008; 21 CFR § 202 (1) (e) (6).

¹⁴⁵ 21 USC § 352 (2008).

consumers. The system of enforcement, on the other hand, is a form of control that is employed after the deception has reached consumers. The intention is to prevent the occurrence of future deceptive advertising. Monitoring is carried out to detect violation of laws.

5.4.2.1 System of Pre-Approval of Advertisements

In the United States, pre-approval of advertisement is not compulsory for all types of drugs. Only 'drugs which are approved on an accelerated basis' (referred to as DAAB in this chapter) are required to be pre-approved before they are advertised.¹⁴⁶ DAAB are new drugs that treat serious or life threatening illnesses such as cancers,¹⁴⁷ and they are given initial approval without the immediate proof of 'clinical benefits'. This is because to prove 'clinical benefits' of new drugs may take years, and the seriousness of the illness requires urgent disposal of these types of drugs to consumers.¹⁴⁸ 'Clinical benefits' refers to an improvement in the condition of the patient such as, a 'survival of the disease, disease-free survival or symptom benefits' or a progress to a less serious condition.¹⁴⁹ Therefore, the law prescribes that studies proving the 'clinical benefits' of the drugs may be submitted after pre-approval is granted.¹⁵⁰ Pre-approval for these drugs is, however, a pre-requisite.¹⁵¹

¹⁴⁶ 21 CFR § 314 sub-part H; The regulations governing drugs which are approved on an accelerated basis are codified as 21 CFR § 314.500 – 314.550; Also see Richard L. Schilsky, 'Hurry Up and Wait: Is Accelerated Approval of New Cancer Drugs in the Best Interests of Cancer Patients?' (2003) 21(20) *Journal of Clinical Oncology* 3718, 3719; Center of Drugs Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, United States, *Guidance for Industry – Accelerated Approval Products – Submission of Promotional Material*, 1.

¹⁴⁷ See 21 CFR § 314.500.

¹⁴⁸ Ibid § 314.510 (2008).

¹⁴⁹ See Schilsky, above n 146, 3719.

¹⁵⁰ Ibid 3720. The debate surrounding accelerated approval is whether such an approval is effective and is in the best interest of the patients since rapid drug approvals may not ensure that drug's safety and efficacies. See Ibid. Also see generally Vivian I. Orlando, 'The FDA's Accelerated Approval Process: Does the Pharmaceutical Industry Have Adequate Incentives For Self-Regulation?' (1999) 25 *American Journal of Law & Medicine* 543, 551.

¹⁵¹ 21 CFR § 314. 510 & 520. The regulations regarding the application process for accelerated approvals are set out at 21 CFR § 314.550 (2008) which provides that '... applicants must submit to the agency for consideration during the pre-approval review period, copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the

For all other types of advertisements of prescription drugs, advertisers are not required to obtain a pre-approval before the advertisement is broadcast, published or distributed, although they may voluntarily submit the final copies at the time of dissemination of advertisements for reviews by the FDA.¹⁵²

5.4.2.2 Monitoring of Violation of Laws

The absence of pre-approval for all advertisements in the system of control is not a major hindrance to the regulation of advertising of prescription drugs, if promotional materials are constantly monitored for falsities or violations of laws. In the United States, the Division of Drugs, Marketing, Advertising and Communications, a division within the Center for Drug Evaluation and Research of the FDA, in addition to its own monitoring, also relies on information forwarded by concerned consumers, healthcare professionals and competitors on violations and non-compliance with the laws.¹⁵³ The type of falsities and violations of laws ordinarily monitored include: (1) failure to communicate adequate information about the risks and safety of the drugs;¹⁵⁴ (2) misleading comparative claims;¹⁵⁵ (3) overstating of product efficacy¹⁵⁶ and (4) minimizing risks.¹⁵⁷ Such circumstances lead to regulatory actions being pursued by the FDA against drug manufacturers or companies. The regulatory actions are explored in the following section, [5.4.2.3].

agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement'.

¹⁵² 21 CFR § 314.81(b)(3)(i) (2008). This is to be conveyed on an FDA form; Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use). See 21 CFR § 314.81(b)(3)(i) (2008).

¹⁵³ Center For Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, United States, 'Prescription Drugs Advertising and Promotional Labeling: Promotional Materials Review Process' < <http://www.fda.gov/cder/handbook/advertis.htm>>.

¹⁵⁴ 21 CFR § 202 (1) (e) (6) (ii) (2008).

¹⁵⁵ Ibid.

¹⁵⁶ Ibid § 202 (1) (e) (6) (v) (2008).

¹⁵⁷ Ibid § 202 (1) (e) (6) (vi) (2008).

5.4.2.3 Enforcement of Violation of Laws

In general, two methods of enforcement namely: (1) the regulatory action and (2) the judicial action may be carried out in the regulation of advertising of medicinal products and these are discussed in this section. A regulatory action is usually pursued, first. Failure to comply with requests or orders made at this stage will result in the matter being taken to court.

(a) Regulatory Actions

The regulatory action involves the issuing of letters. Two types of regulatory letters: (1) an untitled letter and (2) a warning letter, are sent out when there is a violation of advertising laws.¹⁵⁸ The 'untitled letter', which is the first letter, is issued for minor offences. This letter explains the contraventions in detail and requires the company disseminating the false advertisements to undertake a specific action, such as discontinuing the dissemination of the advertisement.¹⁵⁹ However, if this letter is ignored or the request in the letter is neglected, the FDA then sends a second letter - the warning letter. The warning letter requires the company to remedy the wrongdoing by taking corrective measures, such as running of corrective advertisements to reverse the wrong impression created by the earlier advertisement, in addition to the discontinuance of the violating advertisements.¹⁶⁰

The FDA, however, has been criticised for being lax in its regulatory control. Records showed that the FDA takes a long time to issue the letters, and fewer regulatory letters have been issued.¹⁶¹ The delay in the issue of letter, and the decline in the number of letters issued, are however, not due to a drop in the number of violations, but due to a

¹⁵⁸ *FDA's Oversight of Direct-to-Consumer Advertising Report*, above n 103, 24 -25; Palumbo and Mullins, above n 118, 429.

¹⁵⁹ Palumbo and Mullins, above n 118, 429.

¹⁶⁰ *Ibid.*

¹⁶¹ From an average of 2 weeks, in the period from 1997 to 2001, a delay of up to 4 months in the period of 2002 to 2005 has been witnessed. See *FDA's Oversight of Direct-to-Consumer Advertising Report*, above n 103, 24. The number of regulatory letters issued dropped from 142 in 1997 to 21 in 2006. See Julie M. Donohue, Marisa Cevalco and Meredith B Rosenthal, 'A Decade of Direct-to-Consumer Advertising of Prescription Drugs' (2007) 357 *The New England Journal of Medicine* 673, 676.

weak regulatory control on the part of the FDA.¹⁶² The explanation given is that the delay is caused by the ruling that required all regulatory letters to be reviewed by the Office of Chief Counsel before issuance. The Secretary of Health and Human Services had mandated that all FDA draft regulatory letters be reviewed and approved by the FDA's Office of Chief Counsel before they are issued.¹⁶³ Further, the volume of advertisements received to be reviewed was not commensurate with the staffing allocated to review them.¹⁶⁴ In a study conducted by the GAO, it was found that whilst the number of advertisements reviewed grew, the number of staff charged to review the advertisements had remained unchanged.¹⁶⁵ As such, the FDA had been able to review only a fragment of the advertisement.¹⁶⁶

Attempts were made to resolve problems posed by the advertising of prescription drugs by suggesting a number of proposals: (1) a mandatory moratorium on advertisements of new prescription drugs, (2) pre-clearance for DTCA of prescription drugs and (3) a mandate for certain language to be included in advertisements. S1082, the *Food and Drug Administration Revitalization Act* proposed these recommendations, and the H.R. 2900, the *Food and Drug Administration Amendments Act (FDAAA) of 2007*, which contained advertising provisions similar to S1082, as it was originally, considered these recommendations, but the advertising provisions were removed from the bill after pressure from the advertising community.¹⁶⁷ Subsequently, the HR 3580, the *Food and Drug Administration Amendments Act of 2007*, which authorizes the *Prescription Drug User Fee Act (PDUFA)* and the *Medical Device User Fee and Modernization Act (MDUFMA)* to collect fees from pharmaceutical and biotechnology companies was introduced and implemented with the aim that it would enable its staff to conduct complex and

¹⁶² Donohue, Cevalasco and Rosenthal, above n 161, 679.

¹⁶³ *FDA Oversight of Direct to Consumer Advertising Report*, above n 103, 4.

¹⁶⁴ Donohue, Cevalasco and Rosenthal, above n 161, 679.

¹⁶⁵ *FDA Oversight of Direct to Consumer Advertising Report*, above n 103, 19.

¹⁶⁶ Ibid 17. It was commented in this study that FDA had failed to document the criteria for prioritizing the material or maintain a record of DTCA material that has been reviewed. This reflected inefficiency on its part.

¹⁶⁷ See Amy Shaw, 'Direct-to-Consumer Advertising (DTC) of Pharmaceuticals' (2008) *ProQuest Discovery Guides*, 6.

comprehensive reviews; but the review were in relation to drug approval processes and not advertising.¹⁶⁸

(b) *Judicial Enforcement*

As a matter of last resort, non-compliance with the law or violations of advertising law is judicially enforced; however, manufacturers who disseminate information regarding prescription drugs rely on the First Amendment Protection to escape stringent control.¹⁶⁹ Prescription drugs have been legally classified as unsafe products,¹⁷⁰ and studies have shown that these products harm consumers, thus stricter controls on advertising are presumably necessary.¹⁷¹ Stricter controls are, however, not employed in the regulation of the advertising of prescription drugs, as will be noted from [5.6], which discusses the challenges posed in the regulation of the advertising of medicinal products in the United States. The discussion pertaining to judicial control is reserved for a later part of the chapter, after the examination of the regulation of the advertising of HRP, since the protection accorded by the First Amendment is applicable to both, the advertising of prescription drugs and the advertising of HRP. This is dealt with in [5.6] of the chapter.

¹⁶⁸Ibid 6; Food and Drug Administration, United States, *Law Strengthen FDA* at <www.fda.gov/oc/initiatives/advance/fdaaa.html>.

¹⁶⁹ See generally Miriam Shuchman, 'Drug Risks and Free Speech: Can Congress Ban Consumer Drug Ads?' (2007) 356(22) *The New England Journal of Medicine* 2236; Brienne Taylor Greiner, 'A Tough Pill to Swallow: Does the First Amendment Prohibit WV From Regulating Pharmaceutical Companies' Advertising Expenses to Lower the Cost of Prescription Drugs' (2007) 140 *West Virginia Law Review* 140.

¹⁷⁰ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). The rationale for its classification as unsafe products is noted in the Restatement (Second) of Torts 402A 1965, where it is explained that:

'[T]here are products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs...Such a product, properly prepared, and accompanied by proper directions, is not defective, nor is it unreasonably dangerous. The same is true of many...drugs...many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician'.

¹⁷¹ The argument in favour and against DTCA of prescription drugs is presented in [6.2.4.1] and [6.2.4.2] of chapter 6. Harm posed by DTCA of prescription drugs is dealt in [6.2.4.2].

5.4.3 Conclusion

The rules governing the advertising of prescription drugs are detailed and comprehensive, but they are also complex. The complexities in the rules can result in advertisers failing to comply with rules, due to lack of understanding of what is required of them. Further, voluminous rules can also burden advertisers with additional costs and delay. The problems associated with complex rules is highlighted and discussed at [6.3.2] of Chapter 6.

The regulatory control over advertisements of medicinal products in the United States has flaws at two stages: before and after dissemination of deceptive advertisements. The FDA does not pre-approve all advertisements that reach the public and as a result fails to detect deceptive advertisements. Subsequently, it also lacks adequate resources (staff) to review the advertisements or take regulatory action upon identification of violations of laws. Attempts are being made to increase financial resources to enable more effective regulation of drugs, but it is yet to be determined if this would enable complex and comprehensive reviews to be carried out on all advertisements and thereby reduce the number of deceptive advertisements.

5.5 THE REGULATION OF THE ADVERTISING OF NON-PRESCRIPTION DRUGS AND FOOD, DIETARY SUPPLEMENTS AND COSMETICS – HEALTH RELATED PRODUCTS (HRP's)

The regulation of the advertising of HRP's is examined in this section. The laws governing the advertising of HRP's, stipulated in the *Federal Trade Commission Act 1914* (United States), policy documents and industry guides are examined at [5.5.1] of this section. The regulatory controls, which are carried out via systems of pre-approval, monitoring and enforcement of violation of rules, are explored at [5.5.2] of this section.

5.5.1 Law Governing the Advertising of Non-Prescription Drugs and HRP's

The regulations for advertising HRP's are stipulated in the *Federal Trade Commission Act 1914* (United States), codified as Title 15 USC (2008). The primary basis for regulating them is stipulated in four policy statements and two industry guides. These policy statements and industry guides do not only interpret the laws administered by the FTC, but also reflect the FTC's enforcement strategy of 'educate and enforce'.¹⁷² The FTC claims to use a 'multi-tool approach' which integrates education and awareness into its enforcement programs.¹⁷³ It aims to educate advertisers and consumers through complaint databases, business guidance, brochures, public workshops and conferences, so as to enable them to protect themselves from misleading advertising.¹⁷⁴

The four primary policy statements that are applicable to the regulation of advertising of HRP's are: (1) The 'FTC Policy Statement on Deception';¹⁷⁵ (2) the 'FTC Statement on Advertising Substantiation';¹⁷⁶ (3) the 'Statement of Policy on the Scope of the Consumer

¹⁷² See generally 'More Than Law Enforcement: The FTC's Many Tools - A Conversation With Tim Muris and Bob Pitofsky' (2005) 72 *Antitrust Law Journal* 773, 779. ('*More Than Law Enforcement*').

¹⁷³ *Ibid.*

¹⁷⁴ *Ibid* 776 -778.

¹⁷⁵ *The FTC Policy Statement on Deception*, above n 5, 206.

¹⁷⁶ *The FTC Policy Statement Regarding Advertising Substantiation*, above n 6, 211.

Unfairness Jurisdiction’¹⁷⁷ and (4) the ‘Enforcement Policy Statement on Food Advertising’.¹⁷⁸ In this chapter, the policy statements are collectively referred to as the ‘FTC Policy Statements’.

The key principles in the ‘Policy Statement Regarding Deception’ and in the ‘Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction’ have been codified as 15 USC § 52 (b) (2008) and 15 USC § 45(n) (2008), respectively. The main principles articulated in the FTC policy statements are that (1) advertising must be truthful and non-deceptive; (2) advertisements must be adequately substantiated and (3) advertisements must be fair. These principles, which form the basis for policing the advertising of HRPs, are examined in [5.5.1.2], [5.5.1.3.] and [5.5.1.4.], respectively. In addition, specific principles which are applicable to food advertising are examined in [5.5.1.5]. An industry guide, the Dietary Supplement: An Advertising Guide for Industry (the ‘DSAGI’),¹⁷⁹ is examined in [5.5.1.6].

5.5.1.1 Federal Trade Commission Act 1914 (United States)

The advertising of HRPs is governed by sections 12 and 5 of the *Federal Trade Commission Act 1914* (United States). Section 12 of the *Federal Trade Commission Act 1914* (United States) prohibits the dissemination of any false advertisement that induces the purchase of food, drugs, devices, services, or cosmetics.¹⁸⁰ ‘False advertisements’ is defined under section 15 of the *Federal Trade Commission Act 1914* (United States), for the purposes of section 12, as those that are ‘...misleading in a material respect...’.¹⁸¹ Section 5 (a) (1) of the *Federal Trade Commission Act 1914* (United States) prohibits two

¹⁷⁷ *Statement of Policy on the Scope of Consumer Unfairness Jurisdiction*, above n 7, 198; 15 USC § 45(n) (2008).

¹⁷⁸ *Policy Statement on Food Advertising*, above n 8, 260.

¹⁷⁹ The Dietary Supplement: An Advertising Guide for Industry, 3. (*The Dietary Supplement Advertising Guide*).

¹⁸⁰ 15 USC § 52 (a)(2) (2008). The section prohibits ‘any person, partnership or corporation from disseminating or cause to disseminate any false advertisements ... by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, services or cosmetics’.

¹⁸¹ 15 USC § 55 (a) (1) (2008).

kinds of conduct: (1) 'unfair methods of competition in or affecting commerce' and (2) 'unfair or deceptive acts or practices in or affecting commerce'.¹⁸²

The *Federal Trade Commission Act 1914* (United States) also empowers the FTC to prevent persons, partnerships or corporations from using unfair methods of competition and unfair or deceptive practices or acts.¹⁸³ It authorises the FTC, among other things, to conduct investigations on deceptive acts and practices and pursue administrative actions, as well as to seek monetary redress and other reliefs.¹⁸⁴ The basis for declaring an act as an 'unfair method of competition' or as 'unfair or deceptive', is not stipulated in the *Federal Trade Commission Act 1914* (United States); instead, it is left with the FTC to formulate. The FTC formulated the base for its regulation and documented these in the FTC policy statements. The key principles relied upon by the FTC when determining if advertisements are deceptive are illustrated in [5.5.1.2] – [5.5.1.6] so as to highlight the manner in which deceptive advertising is regulated in the United States.

5.5.1.2 FTC Policy Statement on Deception

The FTC Policy Statement on Deception describes key principles concerning deceptive acts and practices in advertising. The FTC used to deliberate cases involving deceptive acts and practices without a definition of the phrase 'deceptive acts or practices'. However, in order to provide a basis for its decisions, the FTC reviewed cases and consolidated principles crucial for establishing deception in this policy statement. Principles documented in this policy statement are still used today and stand as cardinal principles for determining deceptive acts and practices.¹⁸⁵

Three elements are crucial to determine deceptive acts and practices: (1) there must be a representation, omission or practice that is likely to mislead the consumer; (2) the deception must be viewed from the perspective of the consumer acting reasonably and (3)

¹⁸² Codified as 15 USC § 45(a)(1) 2008, the provision states that 'unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful'.

¹⁸³ 15 USC § 45 (a)(2) (2008).

¹⁸⁴ Ibid § 45(m) (2008).

¹⁸⁵ *The FTC Policy Statement on Deception*, above n 5, 206.

the representation, omission or practices are material.¹⁸⁶ The representation, omission or practice with the probability of misleading consumers is determined from both express and implied claims, as well as omissions. This is carried out through a number of means including: (1) examining the entire document or phrase in the document; (2) presuming the likelihood of deception, (where it is obvious) or (3) requesting further evidence.¹⁸⁷ Further, the impact of representation omission or practice is considered from the perspective of a reasonable consumer. In the instance where the representation is targeted at a particular group, the reasonable reaction of an ordinary member of the group is considered.¹⁸⁸ Further, representation, omission or practice must be material to constitute deception.¹⁸⁹ The term 'material' is not elaborated, however, certain representations which influence consumer choice in relation to products, or which concern health and safety, have been declared as material. Other examples of material representations include representations that: (1) assist consumers in making an evaluation of the product or services; (2) relate to characteristics of products and services such as purposes, safety, efficacy or cost; (3) concern durability, performance, warranties and qualities and (4) conducts that leads to consumers suffering injuries.¹⁹⁰ The FTC Policy Statement on Deception also stipulates that misleading representation cannot be remedied by incorporating (1) accurate information in the text where headlines are false; (2) written disclosures or fine print or (3) oral statements or labels.¹⁹¹

5.5.1.3 FTC Policy Statement Regarding Advertising Substantiation

The 'FTC Policy Statement Regarding Advertising Substantiation' prescribes, amongst other things, the standard, the procedure for substantiation of claims and the relevance of substantiations in advertisements.¹⁹² 'Substantiation' involves the furnishing of a

¹⁸⁶ Ibid 207.

¹⁸⁷ Ibid.

¹⁸⁸ Ibid 208

¹⁸⁹ Ibid 210.

¹⁹⁰ Ibid.

¹⁹¹ Ibid.

¹⁹² *The FTC Policy Statement Regarding Advertising Substantiation*, above n 6, 211.

‘reasonable basis for claims’ made in advertisements before their dissemination.¹⁹³ This basis must be given at an acceptable level.¹⁹⁴ Advertisers are generally expected to furnish the level of substantiation that advertisements expressly claim to have,¹⁹⁵ but the FTC may request substantiations in relation to implied claims if the claims appear to create false impressions amongst consumers.¹⁹⁶ It is possible that advertisers may not possess substantiation for implied claims that they do not believe they have made. In such an instance, the FTC expects the advertisers to be able to provide substantiation for reasonable interpretations that can be drawn from advertisements.¹⁹⁷ The level of substantiation required is determined on a case-by-case basis by considering several factors: (1) the type of claim and product; (2) the consequence of a false claim; (3) the benefit of a truthful claim; (4) the cost of developing substantiation; (5) the amount of substantiation experts in the field believed as reasonable and (6) expert testimonies or consumer surveys.¹⁹⁸

5.5.1.4 Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction

The ‘Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction’ provides the meaning of ‘unfair methods of competition’ and the manner in which such unfair methods are determined. As noted at [5.5.1.1], section 5 (a) (1) of the *Federal Trade Commission Act 1914* (United States) prohibits ‘unfair methods of competition in or affecting commerce...’ (referred to as ‘unfair trade practices’ in this chapter), but the section does not define the phrase or specify the types of conduct that fall within its scope. The term ‘unfair’ has been left undefined since it was impossible to compile a list of unfair trade practices while these practices are constantly evolving, and laws which govern them are becoming obsolete.¹⁹⁹ In the absence of a definition of the term in the phrase ‘unfair

¹⁹³ Ibid.

¹⁹⁴ Ibid.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid 212.

¹⁹⁷ Ibid.

¹⁹⁸ Ibid 211.

¹⁹⁹ *Statement of Policy on the Scope of Consumer Unfairness Jurisdiction*, above n 7, 199-200.

methods of competition in or affecting commerce’, the FTC applied the principles established in this policy statement, on a case-by-case basis, and in the process interpreted deceptive advertising as within scope.²⁰⁰

The FTC had initially considered three elements under this principle: (1) the presence of an unavoidable substantial consumer injury which is not outweighed by any countervailing benefits to consumers (hereinafter referred to as the ‘consumer injury consideration’); (2) the violation of public policy established by statute, common law, or industry practice and (3) the existence of immoral, unethical, oppressive, or unscrupulous conduct.²⁰¹ However, only one element, namely, ‘consumer injury’, survived as a primary consideration for ascertaining unfairness in advertisements, in an amendment introduced in 1994. The amendment codified the key principles set out in the ‘unfairness policy statement’ under 15 USCA § 45(n) (2008) and rejected public policy as a primary consideration for determination of unfair trade practices.²⁰²

15 USCA § 45(n) (2008) provides that the FTC shall:

‘...have no authority ... to declare unlawful an act or practice on the ground that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumer, which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition... In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination’.

With that, the consideration of ‘consumer injury’ requires the injury to be one which is substantial, with no off-setting benefits, and which is one that could not be reasonably avoided by consumers.²⁰³ ‘Substantial’ was initially described to include monetary and

²⁰⁰ Ibid 199.

²⁰¹ Ibid 202.

²⁰² See J Howard Beales, FTC, ‘The FTC’s Use of Unfairness Authority: Its Rise, Fall and Resurrection’ Speech <<http://www.ftc.gov/speeches/beales/unfair0603.shtml>>. (‘Speech by Beales’).

²⁰³ Ibid.

health safety harm, and not emotional harm or other subjective types of harm such as 'offending taste or social belief of some viewers'.²⁰⁴ However, the test to prove 'substantial injury' is currently to show that the injury is real, and that it must be greater compared to any offsetting benefits.²⁰⁵

5.5.1.5 The FTC Enforcement Policy Statement on Food Advertising

The Enforcement Policy Statement on Food Advertising was issued by the FTC with the aim of clarifying how the FTC would regulate food claims in advertisements. The Congress enacted the *Nutrition Labelling and Education Act of 1990* (United States), which authorized the FDA to promulgate rules on food labelling and the FDA accordingly promulgated the rules.²⁰⁶ The FTC established this statement of policy so as to assist it in the implementation of advertising regulations.²⁰⁷

Although expressed in harmonization with FDA's food labelling, the FTC Enforcement Policy Statement on Food Advertising, in essence, stipulates separate standards for food claims in advertisements. The rules are claimed to be established in harmony with regard to two types of claim: (1) nutrient content claims and (2) health claims. However, the FTC does not automatically adopt the FDA regulations on food labelling, instead it allows for some flexibility in its approach.²⁰⁸ For example, the FDA established certain standards for food labelling and non-compliance with these standards in labelling is considered as violation of the labelling regulations. One such instance is with regard to 'risk-increasing nutrient' for food.²⁰⁹ 'Risk increasing nutrient' refers to nutrients that could increase the risk of certain serious illnesses. The FDA identified four types of nutrients: (1) total fat; (2) saturated fat; (3) cholesterol and (4) sodium, and associated their consumption with an

²⁰⁴ *Statement of Policy on the Scope of Consumer Unfairness Jurisdiction*, above n 7, 200.

²⁰⁵ *Speech by Beales*, above n 202.

²⁰⁶ *Policy Statement on Food Advertising*, above n 8, 263-266.

²⁰⁷ *Ibid.*

²⁰⁸ *Ibid.*

²⁰⁹ *Ibid* 269.

increased risk of illnesses such as cancer, cardiovascular disease and hypertension.²¹⁰ For each of these nutrients, the FDA established a nutrient level and exceeding this nutrient level is considered a violation of the FDA standard.²¹¹ Whilst the FTC adopts this standard, it also takes the view that the likelihood of misleading labelling could be avoided by including a disclosure regarding the significance of the risk-increasing nutrients. Such disclosure is thought to erase wrong impressions that foods do not present any related health risk. Consequently, claims are allowed in advertisements, even though they fall short of the FDA standard.²¹²

Other instances of non-harmonization include where the FDA established nutrient levels such as ‘high’ and ‘low’ for specific nutrients and the ‘minimum nutrient value requirement’ for health claims.²¹³ Claims that fail to meet these requirements are disallowed on labels under the FDA standards. However, they may be permissible under the FTC’s standards if they are ‘qualified, truthful, and non-misleading’.²¹⁴ The FDA has also established a model of ‘health-claim language’, relating health benefits and disease in the context of other influencing factors such as, age, gender, or ethnicity.²¹⁵ The FTC adopts this model, but it is also flexible about the application of this standard. It does not impose on advertisers the necessity to disclose the fact that the ‘risk of the disease depends on many factors’, unless such disclosure prevents consumers from being misled about the significance of the diet.²¹⁶

Therefore, the FTC employs a varied standard for advertising of HRP in certain instances where it is thought that a flexible approach may be used.

²¹⁰ Ibid.

²¹¹ Ibid.

²¹² Ibid.

²¹³ Ibid 270. ‘Minimum nutrient value requirement’ as stipulated in the *Policy Statement on Food Advertising* means that food bearing health claims must contain a ‘sufficient amount of at least six nutrients and substances specified by the FDA’.

²¹⁴ *Policy Statement on Food Advertising*, above n 8.

²¹⁵ Ibid 270.

²¹⁶ Ibid 271.

Apart from policy statements, the FTC has also increasingly relied on industry guides in the regulation of the advertising. In the context of regulating advertising of HRP, the Dietary Supplement: An Advertising Guide for Industry ('DSAGI')²¹⁷ is worth looking at.

5.5.1.6 The Dietary Supplement: An Advertising Guide for Industry (the 'DSAGI')

The Dietary Supplement: An Advertising Guide for Industry (DSAGI) is an industry guide designed to provide a concise approach to making claims regarding dietary supplements in advertisements.²¹⁸ It stipulates rules concerning adequate substantiation of claims in advertisements of dietary supplements.

It specifies the approach to be adopted in determining the level of substantiation of claims required and the standard to be complied with in advertisements, consumers' testimonials, experts' endorsements and on claims based on traditional uses.

Adequate substantiation of claims for dietary supplements involves substantiation based on 'competent and reliable scientific evidence', which is defined by the FTC as 'tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results'.²¹⁹ There is no fixed formula stipulated for determining this; instead, several factors may be considered. These are: (1) the number of studies; (2) the types of studies and (3) the specific parameters like sample size and study duration.²²⁰

With no specified number of studies required to substantiate claims, it is considered sufficient if an independently conducted study, using a replication of research results, is produced.²²¹ It is also sufficient if the type of studies used include 'well controlled human

²¹⁷ *The Dietary Supplement Advertising Guide*, above n 179, 1.

²¹⁸ *Ibid.*

²¹⁹ *Ibid* 8-16.

²²⁰ *Ibid* 10-14.

²²¹ *Ibid* 10.

clinical studies'.²²² Evidence used in the studies must conform to the surrounding body of evidence, even though the evaluation is based on a simple standard, which is that: (1) carefully controlled studies yield more reliable results; (2) a longer duration of testing has a better ability to resolve potential safety hazards and (3) the statistical and clinical significance of findings give weight to evidence.²²³

Although a flexible approach seems to be taken in determining what constitutes a 'competent and reliable scientific study', a strict compliance with this standard is expected of advertisers. For example, consumers' testimonials used to substantiate claims in advertisements must be supported by scientific evidence.²²⁴ Testimonials regarding the safety and efficacy of a product must be representative of what consumers would generally achieve when using the product as opposed to individual experiences of the product, and if otherwise, should be adequately informed through a disclaimer in the advertisement stating that consumers should not expect to experience the attested results.²²⁵ Similarly, claims based on traditional use must be supported by scientific evidence, and if otherwise, to adequately inform consumers regarding the lack of such evidence.²²⁶ Where experts are employed to support claims made in advertisements, it must be ensured that they possess qualifications as experts in the field, and conduct examinations or testing typically recognized as sufficient by those in the field.²²⁷

In summary, the *Federal Trade Commission Act 1914* (United States) had not specified the standards at which the requirements must be complied with. It has not provided the grounds which would justify a cause of action by the FTC. The FTC established these policy statements in order to assist it in the regulation. The principles in these policy statements have been developed over a period of time, on a case-by-case basis and have in the process considered factors that prevented and assisted the regulation of deceptive

²²² Ibid.

²²³ Ibid 14.

²²⁴ Ibid 18.

²²⁵ Ibid 19.

²²⁶ Ibid 20- 21.

²²⁷ Ibid 18 –19.

advertisements. They contain principles which were necessary to ensure adequate consumer protection. The section below proceeds to examine the regulatory controls employed in the regulation of HRPs.

5.5.2 Regulatory Controls on Advertisements of NPD and HRPs

In the context of regulating advertising, the FTC has two aims to achieve: (1) to eliminate deceptive advertising and (2) to promote free flow of accurate information.²²⁸ Both these aims have the noble intention of protecting consumers.²²⁹ However, the FTC has been accused of 'over-regulating' the advertising by bringing inappropriate cases to court.²³⁰ The regulatory controls, which include review of advertisements, monitoring and enforcement, are examined in this section in order to investigate the manner in which these controls are carried out.

5.5.2.1 Monitoring of Violations and Review of Advertisements

As explained in [5.3.1], the FTC's work relating to consumer protection is pursued by the Bureau of Consumer Protection (the BCP). The Division of Advertising Practices within the BCP monitors advertising practices, and initiates administrative action and enforcement in the Federal District Court for violations of orders.²³¹ It does not, however, pre-approve or review advertisements; instead it relies on National Advertising Division (NAD) of the Council of Better Business Bureaus, Inc (the 'CBBB'), an industry-funded self-regulatory body, which reviews advertisements.²³²

²²⁸ 15 USC § 45 (a)(2) (2008).

²²⁹ *More Than Law Enforcement*, above n 172, 779.

²³⁰ Ross D. Petty, 'FTC Advertising Regulation: Survivor or Casualty of the Reagan Revolution?' (1992) 30(14) *American Business Law Journal* 1, 21.

²³¹ Division of Advertising Practices, Federal Trade Commission, Department of Health and Human Services, United States 1 < <http://www.ftc.gov/bcp/about.shtml> >.

²³² John E. Villafranco and Andrew B. Lustigman, 'Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration and National Advertising Division' (2007) 62 *Food and Drug Law* 709. See Pamela Jones Harbour in the Keynote Address of 'Helping the FTC Help You' Effective Self-Regulation is Better Business, at the National Advertising Division Meeting New York, September 2005 < <http://www.ftc.gov/speeches/harbour/050926selfreg.pdf> >.

The NAD reviews nationally disseminated advertisements that are voluntarily submitted for examination for truth and accuracy, adequate substantiation of claims and fairness.²³³ It examines the message conveyed by the claims so as to determine the misleading impressions created. It would ordinarily take approximately 15 days to 2 months to review the advertisement and if it determines that the claims have not been substantiated, it recommends that the claims be modified, removed or discontinued.²³⁴ If advertisers refuse to comply, then it is empowered to use strict techniques which include: (1) press releases and (2) public announcement of advertisers' non compliance.²³⁵ It can also refer matters to the FTC for enforcement of violation of laws, if found to be in breach.²³⁶ A review of advertisements is also carried out by the Council for Responsible Nutrition (CRN), a trade organization for dietary supplements, who partnered the NAD in the review of advertisements of dietary supplements.²³⁷

5.5.2.2 Enforcement of Violation of Laws

The FTC has wide authority with regard to actions that it can take. It is authorised to: (1) seek temporary restraining order and permanent injunctions;²³⁸ (2) request for a cease-and-desist order;²³⁹ (3) issue a press release upon entering a consent decree²⁴⁰ or (4) file civil penalty cases on its own behalf where the Justice Department had refused to file civil penalty cases.²⁴¹ The enforcement that is carried out is twofold. First an administrative

²³³ See National Advertising Review Council, 'White Paper, Guidance for Food Advertising Self-Regulation: An Historical Overview of the Investigations of Food, Nutrition and Weight Loss Advertising of the Children's Advertising Review Unit (CARU) and the National Advertising Division (NAD) 2004. (*'White Paper, Guidance for Food Advertising Self-Regulation'*).

²³⁴ Ibid 44.

²³⁵ Ibid 45.

²³⁶ Ibid.

²³⁷ Villafranco and Lustigman, above n 232, 710.

²³⁸ 15 USC § 53 (b) 2008.

²³⁹ Ibid § 57 (b) (2) (b) (2007).

²⁴⁰ Ibid .

²⁴¹ Ibid § 56 (a)(1)(B) (2008). Civil penalty cases are filed by the Justice Department.

action is pursued, and failure to comply with an administrative order will result in the matter being referred to court for redress.

To begin with, the FTC does not handle individual complaints; instead, it compiles complaints about companies, business practices, thefts, or episodes of violence in the media so as to detect patterns of wrong-doing.²⁴² Upon compilation, it investigates the violations and attempts an agreement with 'the regulated' to stop the disputed practices.²⁴³

'The regulated' is asked to enter into a consent order²⁴⁴ without any admission to guilt and if 'the regulated' refuses, then an administrative complaint is issued and administrative proceeding, which is similar to court trial, is begun.²⁴⁵ At the administrative hearing, if the FTC proves the case against 'the regulated', that the method, act or practice used has violated the law, an initial decision recommending a cease-and-desist order prohibiting the using of the method, act or practice is issued. If the FTC is unable to prove the case then a case-dismissal is granted.²⁴⁶

If violation is found, an order to 'cease-and-desist' may be granted.²⁴⁷ If this order is not complied with, then the matter is referred to court for redress. The FTC can obtain court orders imposing fines on advertiser for false advertising.²⁴⁸ The FTC has aggressively pursued advertisers for false advertising since 1990 and has attempted to punish dishonest advertisers with hefty fines; however, the FTC's success, is only in relation to out of court

²⁴² See Bureau of Consumer Protection, Federal Trade Commission, Department of Health and Human Services, United States, *Before You Submit A Complaint* < <https://www.ftccomplaintassistant.gov/> >.

²⁴³ Ibid.

²⁴⁴ FTC issues a complaint setting out the charges to the alleged company. If the company settles the charges by accepting the consent decree, then the FTC may accept the proposed consent and place the order on record for 60 days for public comment before determining the final order. If the company contests the order, then the complaint is adjudicated before an administrative law judge. See Federal Trade Commission, Office of the General Counsel, *A brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority* (1995), 3. ('*The Federal Trade Commission's Investigative and Law Enforcement Authority Statement*').

²⁴⁵ *The Federal Trade Commission's Investigative and Law Enforcement Authority Statement*, above n 244.

²⁴⁶ Ibid.

²⁴⁷ Ibid.

²⁴⁸ 15 USC § 54 (a) (2008).

settlements which advertisers agree to settle.²⁴⁹ When advertisers challenge them in court, the FTC, more often than not, fights a losing battle. Primary challenges faced in the regulation of advertising of medicinal products are discussed in the following section.

²⁴⁹ See Annys Shin 'A Bitter Pill to Swallow: FTC Fines Marketers of Popular Weight-Loss Remedies for False Ad Claims' *Washington Post* (USA) 5 January 2007, 1.

5.6 CHALLENGES IN THE REGULATION OF MEDICINAL PRODUCTS IN THE UNITED STATES

Both the FDA and the FTC are challenged by rules which aim to protect advertisers from the stringent requirements of the law. The challenges include: (1) the First Amendment protection; (2) the learned intermediary rule; (3) the FDA pre-exemptions. These rules are examined in this section.

5.6.1 First Amendment Protection

Both, the FDA and the FTC are challenged by the First Amendment protection for commercial speech. The US Constitution Amendment 1, the First Amendment, states that 'Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or the right of the people peacefully to assemble, and to petition the Government for a redress of grievances'.²⁵⁰ The protection with regard to freedom of speech is granted by constraining the government, at both Federal and State levels, from suppressing or imposing speech.²⁵¹ The said protection is seen as necessary so as to advance the values of 'individual self-fulfilment', 'attainment of truth', or 'societal participation, social and political decision'.²⁵² However, not all classes of speech are granted the protection. Certain classes of speech, the prevention of which is thought not to raise any constitutional rights, are categorically excluded from the protection through judicial intervention.²⁵³ For example, speech which has low social values or which does not contribute to an exchange of ideas, or which is of no informational value, such as speech which promotes obscenity, fighting words, incitements or defamatory remarks, is excluded from the protection.²⁵⁴

²⁵⁰ US CONST. Amendment 1, The First Amendment.

²⁵¹ See US CONST. Amendment 1, the First Amendment; Nicole Endejann, 'Is the FDA's Nose Growing? The FDA does not "Exaggerate its Overall Place in the Universe" When Regulating Speech Incident to "Off-Label" Prescription Drug Labeling and Advertising' (2002) 35(3-4) *Akron Law Review* 491, 497- 498; Greiner, above n 168, 127.

²⁵² Gail H Javitt, Stanley Erica and Kate Hudson, 'Direct-to-Consumer Genetic Tests, Government Oversight and the First Amendment: What the Government Can (Can't) Do to Protect the Public's Health' (2004) 57 *Oklahoma Law Review* 251, 287.

²⁵³ *Ibid* 288.

²⁵⁴ *Ibid*; Greiner, above n 169, 123.

Speech relating to commercial transactions, which has become known as commercial speech, was similarly excluded from the protection until the benefits in allowing dissemination of information were recognised; a free flow of commercial speech was seen as indispensable for efficient commerce.²⁵⁵ Truthful information about a lawful activity is thought not to be suppressed if the information in itself is not harmful.²⁵⁶ As expressed in the case of *Virginia State Board of Pharmacy v Virginia Citizens Consumer Council*, people are only able to make a rational decision in their best interests if they are adequately informed.²⁵⁷ Therefore, speech can only be restricted if it is justifiable restriction. The test to determine the justifiability was formulated in the case of *Central Hudson Gas and Electric Corp v Public Service Commission of New York*.²⁵⁸

This case illustrates that advertising is protected by the First Amendment when a four pronged test is satisfied.²⁵⁹ The test requires that the court considers a number of questions when determining the validity of a restriction on advertisements, namely, whether; (1) the speech is false, misleading and fosters illegal activity; (2) the state has a substantial interest in prohibiting the speech; (3) the restrictions directly advance the state's interest and (4) the restriction is no broader than necessary to satisfy the state's interest.²⁶⁰ Since the formulation, the test has been considered by scholars in articles concerning a range of products from tobacco advertising²⁶¹ to dietary supplements,²⁶² prescription drugs,²⁶³ and genetic tests.²⁶⁴

²⁵⁵ David C Vladeck and John Cary Sims, 'Why the Supreme Court Will Uphold Strict Controls on Tobacco Advertising' (1997) 22 *Southern Illinois University Law Journal* 651, 673.

²⁵⁶ *Virginia State Board of Pharmacy v Virginia Citizens Consumer Council*, 425 US 748, 789 (Sup Ct 1976).

²⁵⁷ *Ibid.*

²⁵⁸ See *Central Hudson Gas and Electric Corp v Public Service Commission of New York*, 447 U.S 557, (Sup Ct 1980).

²⁵⁹ *Ibid.*

²⁶⁰ *Ibid.*

²⁶¹ David S Modzeleski, 'Lorillard Tobacco v Reilly: Are We Protecting The Integrity of The First Amendment and the Commercial Free Speech Doctrine at The Risk of Harming Our Youth?' (2001) 51 *Catholic University Law Review* 987.

²⁶² Melinda Ledden Sidak, 'Dietary Supplements and Commercial Speech' (1993) 48 *Food and Drug Law Journal* 441; Jennifer E. Gross, 'The First Amendment and Diet Industry Advertising: How "Puffery" in Weight

Advertisements of prescription drugs have been claimed to downplay the risk, obscure the side effects, distort the disease risk information and over-exaggerate the benefits; however, the question is whether these features justify a restriction on its advertising and an exclusion from First Amendment protection. Certain types of products such as tobacco and alcohol advertising warrant an exclusion from the First Amendment protection and justify a greater degree of restriction, or even a total ban on their promotions, as they do not provide benefits to consumers,²⁶⁵ but whether advertisements of prescription drugs should be similarly considered is yet to be clearly established. Prescription drugs are unique in the sense that they are not products for vice, but have been classified as 'legally unsafe products'.²⁶⁶ Their advertising has potential benefits, but these benefits are unascertainable if consumers are not able to comprehend the information regarding the risks involved.²⁶⁷

In respect to claims in advertisements of HRP, the public interest component demands First Amendment protection as well as arguing against the protection. Whilst First Amendment protection allows for dissemination of information to consumers and thereby enables them to make informed decision regarding products, deceptive or misleading information that is disseminated can also harm consumers. The courts in the cases of *Pearson v Shalala*²⁶⁸ and *Whitaker v Tommy G*,²⁶⁹ however, supported that First

Loss Advertisements Has Gone Too Far' (2006-2007) 20 *Journal of Law and Health* 325; W. Emord Jonathan, 'Pearson v. Shalala: The Beginning of the End for FDA Speech Suppression' (2000) 19(1) *Journal of Public Policy & Marketing* 139; Chester S. Galloway, 'The First Amendment and FTC Weight-Loss Advertising Regulation' (2003) 37(2) *The Journal of Consumer Affairs* 2003; David C Vladeck, 'Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v Shalala' (1999) 54 *Food and Drug Law Journal* 535; Amber K. Spencer, 'The FDA Knows best... or Does It? First Amendment Protection of Health Claims on Dietary Supplements.(Case Note)' (2000) 15(1) *B.Y.U Journal of Public Law* 87; Marilyn J. Schramm, 'Constitutional Protection of Commercial Speech Under the Central Hudson Test as Applied to Health Claims' (1996) 51 *Food and Drug Law Journal* 323; Edward Dunkelberger and Sarah E Taylor, 'The NLEA, Health Claims, and the First Amendment' (1993) 48 *Food and Drug Law Journal* 631.

²⁶³ Endejann, above n 251, 491.

²⁶⁴ Javitt, Erica and Hudson, n 252, 251.

²⁶⁵ Modzeleski, above n 260; Norman Giesbrecht, et al., 'Alcohol Advertising Policies in the United States: National Promotion and Control Initiatives ' (2004) 31 *Contemporary Drug Problems* 673.

²⁶⁶ Endejann, above n 251, 491.

²⁶⁷ Javitt, Erica and Hudson, above n 252, 253.

²⁶⁸ *Pearson V Shalala* 164, F.3d 650 (D.C. Cir, 1999).

²⁶⁹ *Whitaker v Tommy G Thompson* 248 F. Supp 2d 1 (U.S. Dist, 2002).

Amendment protection be granted to advertisements of HRP's if certain conditions are satisfied.

In *Pearson v Shalala*, four health claims were presented to the FDA for approval. The FDA, initially refusing four, allowed one,²⁷⁰ on the basis that they lacked substantiations of claim at the required standard, which is the 'significant scientific agreement'.²⁷¹ Since the FDA had not explained the basis for measuring the 'significant scientific agreement', the court held it to be in violation of Fifth Amendment - right to due process.²⁷² In essence, the FDA had failed to explain why it rejected the proposed claim, or to give '...some definitional content to the phrase "significant scientific agreement."' ²⁷³ Declaring that a claim is not approved, without an explanation, is in violation of First and Fifth Amendment protections.²⁷⁴ Further, the The Supreme Court distinguished between inherently misleading and potentially misleading advertising, and held that the '...State may not place absolute prohibition on potentially misleading information, if it can be presented in way that is not deceptive'.²⁷⁵ The rationale is that 'inherently misleading' cannot be made 'non-misleading', whereas the 'potentially misleading' advertisement can be, with the use of a disclaimer.²⁷⁶ Any misconception that arises from a potentially misleading claim is believed to be cured by disclaimers. Therefore prohibiting truth information which is beneficial to consumers was construed to be a violation of First Amendment protection.²⁷⁷

Similarly, the court in the case of *Whitaker v Tommy G* held that the total ban on the health claim, namely, that dietary supplements with antioxidant vitamins might reduce cancer

²⁷⁰ See *Pearson V Shalala* 164, F.3d 650, 653 (D.C. Cir, 1999). The three claims rejected were; (1) dietary fiber-cancer; (2) antioxidant vitamins-cancer; (3) omega-3 fatty acids-coronary heart disease. The claim approved was the 'general folate-neural tube defect claim' - that consumption of folate reduces the risk of neural tube defects.

²⁷¹ *Pearson V Shalala* 164, F.3d 650 (D.C. Cir, 1999).

²⁷² *Ibid* 660.

²⁷³ *Ibid*

²⁷⁴ *Ibid*.

²⁷⁵ *Ibid* 655.

²⁷⁶ *Pearson V Shalala* 164, F.3d 650 (D.C. Cir, 1999).

²⁷⁷ *Ibid*.

risks, violated providers' right to freedom of commercial speech, since the claim was not inherently misleading.²⁷⁸ It was decided that more harm would be suffered by prohibition than otherwise, and that it was in the public interest to allow the claim.²⁷⁹

In conclusion, it may be argued that the protection accorded by the First Amendment to commercial speech materially waters down the control established by the FDA and the FTC. The agencies may not seek to restrict information more than necessary to prevent deceptive advertising. Due regard must be given to the fact that advertisements can provide information to consumer if they are not inherently misleading, and sufficient evidence or basis must be given to restricting advertising; otherwise the restriction will not survive judicial scrutiny.

5.6.2 Learned Intermediary Rule

The product liability rule requires manufacturers of drugs and devices to warn the 'prescribing and health care provider' regarding foreseeable risks of harm from consuming the products.²⁸⁰ That duty is extended to patients if manufacturers know that physicians are not in a position to convey warnings to patients.²⁸¹ In the context of advertisements of medicinal products, the issue is whether this rule is applicable to DTCA of prescription drugs, and if so, the extent to which this rule can be relied upon by manufacturers to protect them from liability for failure to warn in such advertisements.

In the case of *Perez v Wyeth*, Perez had pleaded that the drug company, Wyeth, had failed to provide adequate warning regarding the side effects of using a contraceptive known as

²⁷⁸ *Whitaker v Tommy G Thompson* 248 F. Supp 2d 1, 25 (U.S. Dist, 2002)

²⁷⁹ *Ibid* 43.

²⁸⁰ Section 6 (d) of the Restatement (Third) of Torts: Product Liability (1997) provides that; 'A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warning; or
- (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

²⁸¹ Restatement (Third) of Torts: Product Liability (1997) § 6 (d).

Norplant, which is a prescription drug that is promoted directly to consumers.²⁸² The Supreme Court ruled that the learned intermediary rule does not apply to prescription drugs that are directly advertised to consumers.²⁸³ Manufacturers are bound to provide adequate warning to consumers regarding products' dangerous propensities to patients. The exception is when the advertising of prescription drugs complies with FDA requirements.²⁸⁴

Prior to this case, manufacturers were responsible to warn patient directly where it involved 'lifestyle drugs' which consumers demanded because of their way of life rather than medical treatment,²⁸⁵ or where the government imposed that patient be informed of the risk.²⁸⁶ With regard to DTCA of prescription drugs, however, the issue was left for the developing case to determine if manufacturers are bound to warn consumers.²⁸⁷ The case of *Perez v Wyeth* has dealt with DTCA of prescription drugs and narrowed down the question to be dealt with by courts to whether the FDA requirements have been complied with, and if they have, then there is no duty to warn patients.²⁸⁸

5.6.3 Rule on Federal Pre-exemption

The extent to which State laws are pre-exempted by Federal laws is also a challenge in the regulation of the advertising of medicinal products. Manufacturers have argued that because they have complied with the *Federal Food Drug and Cosmetic Act 1938* (United States) and FDA regulations, they are not bound by State regulations.²⁸⁹ The question is whether manufacturers could escape liability for failure to warn consumers of the dangers

²⁸² *Perez V Wyeth* 734 A.2d 1245 (N.J Sup Ct, 1999).

²⁸³ Ibid.

²⁸⁴ Ibid.

²⁸⁵ Restatement (Third) of Torts: Product Liability (1997) § 6 cmt. e; See generally William A. Dreier, 'Liability for Drugs Advertising, Warnings, And Frauds' (2006) 58(3) *Rutgers Law Review* 615, 618.

²⁸⁶ Ibid.

²⁸⁷ Ibid.

²⁸⁸ *Perez V Wyeth* 734 A.2d 1245 (N.J Sup Ct, 1999).

²⁸⁹ *Colacicco v Apotex Inc* 521 F.3d 253, 271 (Ct App 2008); *Pennsylvania Employment Benefit Trust Fund v Astrazeneca Pharmaceuticals* 499 F.3d 239, 249-250 (Ct App 2007).

of using the product, as required by State laws, on the basis that the FDA or the FTC have approved the use of the claims in labels or advertisings, or have rejected the requirement for warnings in advertisements.²⁹⁰

The rule on pre-exemption stems from the U.S. Constitution Art VI cl. 2, which provides that the 'Constitution, and the Laws of the United States which shall be made in Pursuance thereof and all Treaties made or which shall be made under the authority of the United States shall be the supreme law of the land.' In essence, this rule confers that Federal law will have control over State laws. It is generally acknowledge that there is a harmony between Federal and State law, and that Federal pre-exemption does not occur, other than in the following circumstances: (1) express pre-exemptions; (2) implied pre-exemption and (3) implied conflict pre-exemption.²⁹¹

Express pre-exemption happens where it is expressly stated that the Federal law will prevail over State laws,²⁹² and 'implied pre-exemption', where it is intended by the Congress for the Federal law to have the ultimate ruling over concerns arising in that particular field or industry.²⁹³ 'Implied conflict pre-exemption' occurs where, in a conflict between Federal law and State law, the compliance with both Federal and State regulations is deemed to be physical impossibility, or when the State law 'stands as an obstacle to the accomplishment and execution of the full purpose and objectives of the Congress', then the State law is pre-empted by Federal law.²⁹⁴

Manufacturers are ordinarily not bound to warn consumers of the dangers of using the product, as required by State laws, if the manufacturers have complied with FDA or the FTC requirement for warnings in advertisements. This was ruled in *Colacicco v Apotex*

²⁹⁰ Ibid.

²⁹¹See *Hillsborough County v. Automated Med. Labs.*, 471 US 705, 713 (Sup Ct 1985); Also see Joseph K. Hetrick and David J. Stanoch, 'United States Supreme Court Poised to Rule on the Regulatory Defence in Pharmaceutical Case' *The International Comparative Legal Guide to Pharmaceutical Advertising 2008: A Practical Insight to Cross-Boarder Pharmaceutical Advertising Work* (Global Legal Group, 2008) 1, 24.

²⁹² Ibid.

²⁹³ Ibid.

²⁹⁴ Ibid.

*Inc*²⁹⁵ and *Pennsylvania Employment Benefit Trust Fund and others v Astrazeneca Pharmaceuticals*.²⁹⁶

In the case of *Colacicco v Apotex*, the Supreme Court ruled that manufacturers' failure to warn risk in claims under State law is impliedly pre-exempted by the *Federal Food Drug and Cosmetic Act 1938* (United States) and 'FDA regulations' when the FDA publicly rejected the need for a warning.²⁹⁷ In this case, a father and daughter died after taking anti-depressant drugs known as 'selective serotonin reuptake inhibitors' (SSRI). The State law requires that the labelling includes the warning of the drug association with an increased risk of 'suicidalilty' and the manufacturer had not included this warning. The issue was whether the Plaintiffs could maintain State tort actions against the manufacturer for failure to warn where certain actions by the FDA under the Federal law, pre-exempt the State law. It was decided that the claims were pre-exempted when manufacturer complied with the FDA's requirements.²⁹⁸

A similar ruling was made in the case of *Pennsylvania Employment Benefit Trust Fund and others v Astrazeneca Pharmaceuticals*.²⁹⁹ This case, however, looked at the broad application of the rule. In this case, the pharmaceutical company was sued for unlawful advertising of prescription drugs under the Delaware Consumer Fraud Act (hereinafter referred to as the 'State law'). The issue was whether the FDA approval of prescription labelling pre-exempts State regulations on misleading advertising where the State law requires the advertising to comply with FTC regulation.³⁰⁰ The court drew a distinction between the FDA's and the FTC's responsibilities and duties; but acknowledged the FDA's authority in regulating prescription drug advertising.³⁰¹ The majority in the court held that

²⁹⁵ See *Colacicco v Apotex Inc* 521, F.3d 253, 261 & 272 (Ct App 2008).

²⁹⁶ *Pennsylvania Employment Benefit Trust Fund v Astrazeneca Pharmaceuticals*, 499 F.3d 239 (Ct App 2007).

²⁹⁷ See *Colacicco v Apotex Inc* 521, F.3d 253, 261 & 272 (Ct App 2008).

²⁹⁸ *Ibid*.

²⁹⁹ *Pennsylvania Employment Benefit Trust Fund and others v Astrazeneca Pharmaceuticals*, 499 F.3d 239 (Ct App 2007).

³⁰⁰ *Ibid*.

³⁰¹ *Ibid* 243.

the parameters of advertising laws cannot be framed in a manner that stand as an obstacle to both Congress and the FDA's objectives of protecting consumers of prescription drugs, and accordingly ruled that State laws are pre-exempted by the Federal law.³⁰²

5.6.4 Implication of Intermediary Rule, the Rule on Federal Pre-Exemption and First Amendment Protection

Both the intermediary rule and the rule on federal pre-exemption acknowledge a broader government regulatory authority with respect to regulation of medicinal products. The intermediary rule requires that manufacturers comply with the FDA requirements and the rule on Federal pre-exemption requires that Federal laws are complied with unless exempted. The First Amendment protection of commercial speeches, however, limits the government regulatory controls over advertisements that are inherently misleading. Although there have been arguments that support the idea that the advertising of medicinal products should be denied First Amendment protection, (as noted in [5.6.1]), considering that both the FDA and the FTC are given wide authorities in regulating the advertising of medicinal products under the Intermediary rule and pre-exemption rules, the lesser degree of protection for advertising of medicinal products appears to be reasonable.

³⁰² Ibid 253.

5.7 CONCLUSION

The regulation of the advertising of medicinal products in the United States is examined for the purpose of a comparative study with Australia and Malaysia. The chapter began by identifying the categories of products that fall under the classification of medicinal products, before the regulation that governs them, the agencies that administer the regulations, and the manner in which non-compliance with law is enforced, were examined. The following findings are made.

The regulation of medicinal products in the United States is unique for two reasons: (1) the type of products which fall under the classification of drugs is broad; however, the exceptions under which these products disqualify as drugs are also wide. Because of these exceptions, most HRP's do not fall within the classification of medicinal products and thereby escape the requirement of scientific testing for safety and efficacy and (2) there are only two classes of drugs distributed in the United States: prescription drugs and non-prescription drugs. The third class of drugs, which is 'pharmacy-only-medicine', is not available in the United States. Arguably, the lack of a 'pharmacy-only-medicine' category in the United States justifies DTCA of prescription drugs, which is relied upon to provide consumer information about the drugs.

In [5.3], it has been noted that the responsibility of regulating the advertising of medicinal products in the United States is shared by the two Federal agencies, the FDA and the FTC; however, there is no uniformity in the regulation of labelling and advertising. The FTC's approach in departing from adopting the food labelling requirements in food advertising, (although pledging to be in-line with the labelling requirement) seems to suggest that there may be different standards for similar claims in labelling and advertising, and that this variation in standards may cause confusion to advertisers and consumers.

Section [5.4] of the chapter examined rules governing the advertising of prescription drugs and found that the advertising laws are detailed, comprehensive and voluminous. The regulations set out in the *Code of Federal Regulation* (CFR) contain detailed requirements which advertisements must meet in order to avoid being 'misbranded'. It also sets out the manner in which information in advertisements of prescription drugs must be presented to

consumers so as to enable them to make rational decisions. However, the regulations are complex and complicated, and complexities can hinder compliance with the laws.

Section [5.4] also examined the regulatory controls employed in the regulation of the advertising of prescription drugs. It was found that the FDA had not been aggressive in the regulation; the reason is that it lacked adequate human and financial resource to carry out prompt investigation and enforcement. The FDA attempted to resolve its lack of funds by expanding its financial resources through the collection of fees from pharmaceutical and biotechnology companies. Studies are yet to be carried out on the success of this initiative in addressing concerns of deceptive advertising.

Section [5.5] of the chapter examined the regulation of HRPs. It was discovered that, like the rules for prescription drugs advertising, the regulations for HRPs advertising are comprehensive and detailed. The manner in which the regulation is carried out is specified in FTC Policy Statements which serve as a guide to not only the advertisers, but also to the FTC. They provide the basis for the FTC's cause of action. With regard to regulatory controls, it was found that advertisements are not subject to a compulsory pre-approval of advertisements; however, they are encouraged to be submitted to self-regulatory bodies, for review. Two self-regulators, namely, the NAD and CRN have assisted the FTC with reviews and monitoring of advertisements. Further, the enforcement strategy applied by the FTC supports the idea of educating consumers so as to enable them to protect themselves against deception.

In [5.6] challenges faced by the regulators in the regulation of medicinal products are highlighted. The First Amendment protection on commercial speech, the learned intermediary rule and the rule of pre-exemption have been raised and discussed. It had been argued that these rules, in combination, bring about a balance between government control over advertising and the freedom of speech.

The regulation of the advertising of medicinal products in the United States will be compared with the regulations in Australia and Malaysia. Findings made in this chapter are intended to facilitate the recommendation to improve the regulation of the advertising of medicinal products in Malaysia. The comparative analysis is carried out in the following chapter.

CHAPTER 6

A COMPARATIVE ANALYSIS OF THE REGULATION OF ADVERTISING OF MEDICINAL PRODUCTS IN THE UNITED STATES, AUSTRALIA AND MALAYSIA

6.1 INTRODUCTION

This chapter compares the regulation of advertising of medicinal products in Malaysia with that of the United States and Australia. The analysis presented in the chapter provides the basis for recommendations for reforming the regulation of advertising of medicinal products in Malaysia.

As noted in sections [3.2], [4.2] and [5.2.], in all three jurisdictions two categories of products are referred to as medicinal products. Both prescription and non-prescription drugs qualify as medicinal products because of their medicinal composition or ingredients. However, where there are therapeutic claims carried by advertisements for health-related products (HRPs) including food, dietary supplements and cosmetics, these may also qualify as medicinal products.

Section [6.2] of this chapter analyses the regulation of direct-to-consumer advertising (DTCA) of prescription drugs. The analysis takes into consideration the manner in which drugs are classified, prescribed and promoted in the three jurisdictions. It also considers the diverse approaches adopted to the regulation of DTCA of prescription drugs in the three jurisdictions. The section also explores the advantages and disadvantages of DTCA of prescription drugs, and presents an economic analysis of this issue. The objective of this section is to determine if DTCA of prescription drugs should be permitted in Malaysia, and if so, how it should be regulated.

Section [6.3] of this chapter compares and analyses the regulation of the advertising of non-prescription drugs, and products classified as medicinal, namely the HRPs which fall

within the classification of medicinal products by virtue of therapeutic claims carried on advertisements in the three jurisdictions. This analysis focuses on three key aspects of regulation: (1) the classification of products as medicinal products; (2) rules governing the advertising of medicinal products; and (3) regulatory controls employed in the regulation of the advertising of such products. This section of the chapter also incorporates an economic analysis of these issues, so that a cost effective model of regulation of the advertising of these products in Malaysia can be recommended.

As explained in this chapter, the system of regulation for advertising of medical products must make threshold decisions with regard to two main issues: (1) whether DTCA of prescription drugs should be permitted and regulated in Malaysia or whether Malaysia should continue its ban on DTCA of prescription drugs; and (2) the appropriate model for regulation of permissible advertising of 'products classified as medicinal products'. The concluding section of this chapter sets out the recommendations on these issues.

6.2. THE REGULATION OF ADVERTISING OF PRESCRIPTION DRUGS

The regulation of the advertising of prescription drugs directed at consumers in the three jurisdictions is examined in this section of the chapter. Sections [6.2.1] and [6.2.2] examine the classification of drugs and the prescribing practices in each of these jurisdictions. Subsequently, the promotion of prescription drugs in these jurisdictions is examined in [6.2.3]. The differences in the classification of drugs are set out in order to enhance the understanding of the regulation of advertising of prescription drugs. The relationship between prescribing practices and the advertising of prescription drugs is discussed, since the advertising of prescription drugs is perceived to cause a change in the patient-physician relationship.

Section [6.2.4] then analyses the rationale for regulating DTCA of prescription drugs. The analysis includes an examination of different approaches adopted in the three jurisdictions and an investigation of the advantages as well as the disadvantages of DTCA of prescription drugs. The objective is to establish grounds for making recommendations for appropriate legal reform to the regulation of DTCA of prescription drugs in Malaysia.

6.2.1 Classes of Drugs

In essence, drugs are classified in two distinct ways. First, as explained in [3.2.1], [4.2.1] and [5.2.1], products are classified as drugs if they are therapeutic in nature or intended to be used for therapeutic purposes. The three jurisdictions are in general agreement with regard to which products may be classified as drugs, although exemptions that disqualify them from classification vary in the three jurisdictions. As will be seen in [6.2.3], the regulation of advertising of these products varies in the three jurisdictions, in particular, in relation to the regulation of DTCA of prescription drugs. Second, drugs are broadly categorized into two classes, namely, prescription drugs and non-prescription drugs. However, most countries, including Australia and Malaysia, recognise a third category within non-prescription drugs, pharmacy-only-medicines.¹ As noted at [5.2.1.1], the United States, on the other hand, has only two categories of drug classification: prescription and non-prescription drugs. The regulatory regime in the United States does not provide for

¹ See [3.2.1] of Chapter 3 and [4.2.1] of Chapters 4.

pharmacy-only-medicine, and therefore consumers in the United States are deprived of the benefits of a pharmacist acting as an intermediary and advising them about drugs. On the other hand, the lack of a pharmacy-only-medicines category in the United States is arguably the reason why DTCA of prescription drugs is permitted. Consumers in that jurisdiction therefore rely on DTCA of prescription drugs to provide information about the drugs.

6.2.2 Prescription Drugs: Prescribing Practices and Promotion

Prescription drugs are drugs which cannot be obtained from a pharmacy without a prescription from a physician. In the United States, as noted at [5.2.1.1], the requirement for a prescription from a medical practitioner who is licensed under the law (referred to as a physician in this chapter), is spelled out in the definition of the term 'drug'. The rationale for this requirement is that there is a level of 'toxicity and potential harmful effects' commonly found in these drugs, which requires supervision of its supply to consumers. Also, the method of use, or collateral measures necessary for the use of drugs, supports the need for supervision.

In Australia, the need for a prescription is justified by the risk that the drugs are known to carry. As explained at [4.2.1.1], products which are deemed high risk, and registered in the ARTG as high risk drugs, require a prescription while those which are listed as low risk do not. In Malaysia, drugs are categorized according to their ingredients and compositions as well as their intended purpose. As noted at [3.2.1], drugs are listed as prescription drugs in the National Essential Drugs List based on active ingredients. The requirement for medical practitioners to prescribe drugs is set out in section 21(2) of the *Poisons Act 1952* (Malaysia).

In each of the jurisdictions, prescriptions are written by physicians following a number of considerations, namely: (1) a discussion with patients about their medical conditions; (2) an examination of the degree of severity and prevalence of the conditions; and (3) an evaluation of the side effects of using the specific drugs. The prescription is then forwarded to a pharmacist who dispenses the drugs to the patient. This practice is, however, not uniform in the three jurisdictions. In particular, the practice is somewhat different in Malaysia compared to the United States and Australia. While in the United States and

Australia, patients will generally obtain a prescription from a physician and pass it to the pharmacist to be dispensed, in Malaysia, the practice depends on whether the patient sees a doctor² in a clinic or in a hospital. Where the patient consults a doctor in a clinic, the patient is not given a copy of the prescription; instead, the prescription is passed to the nurse or clinic clerk, who then gives the medication to the patient under the supervision of the doctor.³ In other words, prescriptions are not given directly to patients, but prescription drugs are sold to the patient in a clinic under the supervision of the doctor. Patients may request a prescription from the doctor in order to purchase the drugs from a pharmacy, but this is not a common practice as it is more convenient to purchase them from the doctor's clinic. In a hospital, by way of contrast, the prescription is given to the patient to be passed to the pharmacist, who is actually located in the hospital building.

Although the prescribing requirements in the three jurisdictions do not vary, the practices involved in advertising prescription drugs to consumers do. As stated at [5.4], DTCA of prescription drugs is allowed in the United States, the only other country condoning the practice being New Zealand.⁴ In practice, DTCA of prescription drugs is partially permitted in Australia, but absolutely prohibited in Malaysia. Section [6.2.3] of this chapter explores the diverse approaches followed and the forms of regulation adopted in the United States, Australia and Malaysia, before a detailed examination of the rationales for the diverse positions.

6.2.3 The Advertising of Prescription Drugs in the Three Jurisdictions

DTCA of prescription drugs has been allowed in the United States since September 1985.⁵ Three types of DTCA of prescription drugs are recognized, namely: (1) product-claim

² Medical practitioners are referred to as doctors in Malaysia. In Malaysia, the term 'physician' is generally associated with medical practitioners who are a specialist in a particular field of medicines.

³ This practice is not against the law if the medicine is prepared by the medical practitioner or under immediate supervision of such practitioner'. See *Poisons Act 1952 (Malaysia)* s 19(3).

⁴ Amy Shaw, 'Direct-to-Consumer Advertising (DTC) of Pharmaceuticals' (2008) *ProQuest Discovery Guides*, 3; Pharmaceutical Health and Rational Use of Medicines (PHARM), Pharmac Committee, *Direct-to-Consumer Advertising (DTCA) of Prescription Medicines and the Quality Use of Medicines (QUM)* (April 2004) 1, 2 ('DTCA and QUM 2004'); Janet Hoek and Philip Gendall, 'Direct-To-Consumer Advertising Down Under: An Alternative Perspective and Regulatory Framework' (2002) 21(2) *Journal of Public Policy & Marketing* 202.

⁵ 56 Fed. Reg. 36677 (Sept. 9, 1985).

advertisements; (2) help-seeking advertisements; and (3) reminder advertisements. Of these, only product-claim advertisements, which are advertisements that feature indications regarding the safety and efficacy of drugs, are regulated.⁶ It is a requirement that these claims are accompanied by a brief summary or an adequate provision, as has been explained in [5.4.1.1].

The United States' regulations, administered by the FDA, set out precise and detailed rules governing the dissemination of information on advertisements and labels.⁷ As seen at [5.4.1.1], regulations set out in the *Code of Federal Regulation* (CFR) contain detailed requirements which advertisements must meet in order to avoid being 'misbranded'. These regulations establish the manner in which information in advertisements of prescription drugs must be presented to consumers.

Malaysia and Australia approach the regulation of DTCA quite differently to the United States. While both Malaysia and Australia prohibit DTCA of prescription drugs, there are inadequacies in the law in both jurisdictions which create loopholes, and thereby indirectly enable opportunities for DTCA of prescription drugs. There are different loopholes in each jurisdiction.

In Australia, DTCA of prescription drugs is prohibited by the *Medicine Australia Code of Conduct* (Edition 16) (2010).⁸ However, in practice, ways are found around the prohibition. Australia arguably allows DTCA when 'help seeking advertisements' are permitted through disease awareness campaigns. As noted earlier at [4.3.1.3], in Australia, although the promotion of prescription drugs to the general public is prohibited, information which is perceived to be educational can be allowed.⁹ Hence, educational material which includes a 'disease education activity' about the availability of different treatment options, such as the range of prescription products, non-prescription drugs and/or alternative treatments, can be

⁶ See [5.4.1] of Chapter 5.

⁷ The restrictions on the advertisements of prescription drugs are embodied in the FDA regulation. See 21 U.S.C. § 352 (n) 2008.

⁸ See [4.3.1.3] of Chapter 4.

⁹ See *Medicine Australia Code of Conduct* (Edition 16) 2010 s 12.3.

disseminated to the general public.¹⁰ DTCA of prescription drugs therefore occurs in Australia when advertisers indirectly promote prescription drugs through the communication of messages regarding diagnosis and the treatment of illnesses.¹¹ Eventually a proportion of the consumers who see the advertisements persuade their physicians to prescribe the 'intended' drugs.¹² The influence of the media is so strong that consumers are often able to guess the advertised prescription drugs and request a prescription for the drug.

Such a situation does not occur in Malaysia since public disease awareness campaigns directed at consumers are not allowed to mention pharmaceutical products in any manner.¹³ However, DTCA of prescription drugs indirectly occurs through other means. In Malaysia, as noted at [3.3.1.1], the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), which is the legislation that governs the regulation of medicinal products, prohibits claims regarding product indications or information in advertisements that would encourage the use of medicinal products including prescription drugs. Nevertheless, as noted at [3.3.1.1], unless advertisements are published for public viewing in media such as newspapers, advertisers are not considered in breach of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). Hence, pamphlets or brochures, for example, which are produced by drug companies for pharmacies, medical practitioners and certain other professionals, but which were not meant for public viewing, are not subject to regulation by the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), even though they may be placed in a location or spot where the public is bound to read them. In essence, these are materials that are intended to promote prescription drugs. Advertisers who promote prescription drugs in such a manner are able to escape regulation by invoking subsection 5 (3)(b) of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), by arguing that the publication was not intended for public viewing in the specified media. Further, in Malaysia, as noted at [3.3.2.1], the *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) which illustrates the

¹⁰ Ibid s 12.7.2.

¹¹ See generally Agnes Vitry, 'Is Australia Free from Direct-to-Consumer Advertising?' (2004) 27(1) *Australian Prescriber*, 4–5.

¹² Ibid.

¹³ *PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products (18th Edition) 2010* (Malaysia) Questions and Answers on PhAMA Code, 28.

standards for ethical promotion of prescription drugs to healthcare professionals, provides guidelines to assist its members to use legitimate methods of advertising; however, being a purely self-regulatory code of practice, the code lacks the force of law to ensure that the advertising practices are carried out lawfully.

In summary, the three jurisdictions adopt different approaches to the regulation of DTCA. While Australia and Malaysia regulate DTCA through prohibitions, the United States regulates DTCA of prescription drugs by setting out precise rules as to how advertisements should be disseminated. The decision as to whether to permit and regulate, or to prohibit DTCA of prescription drugs is, based upon an evaluation of the extent to which the advantages of DTCA of prescription drugs outweigh the disadvantages. As explained at [2.9.2] of Chapter 2, DTCA of prescription drugs is perceived, on the one hand, as a source of information which empowers consumers with the ability to make an informed choice,¹⁴ but on the other hand, it is also regarded as a source of misconceptions in consumers which leads to misguided and wrong decisions and adverse health consequences.¹⁵

The question of whether Malaysia should consider permitting and regulating DTCA of prescription drugs cannot be ascertained without exploring the rationales for prohibiting or permitting it. The following section, [6.2.4] examines the advantages and disadvantages of DTCA of prescription drugs in the context of ascertaining an appropriate form of regulation for the advertising of prescription drugs.

6.2.4 Regulating DTCA of Prescription Drugs

There are, in essence, two means of regulating DTCA of prescription drugs. It can be regulated either through controls placed on its dissemination or through an outright prohibition on its dissemination. In the United States, where DTCA of prescription drugs is

¹⁴ Anthony D Cox and Dena Cox, 'A Defense of Direct-to-Consumer Prescription Drug Advertising' (2010) 53 *Business Horizon* 221, 227; Marshall H. Chin, 'The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids' (2005) 5 *Yale Journal of Health Policy, Law and Ethics* 771, 772 & 776.

¹⁵ Julie Donohue, 'A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection' (2006) 84(4) *The Milbank Quarterly* 659, 660; Marvin M. Lipman, 'Bias in Direct-To-Consumer Advertising and Its Effect on Drug Safety' (2006) 35 *Hofstra Law Review* 761, 762.

permitted,¹⁶ it is regulated through controls, while in most countries, including Malaysia and Australia, DTCA is prohibited.

There have been debates about the merits of DTCA of prescription drugs in many developed countries. Whilst in New Zealand a review of the regulation of DTCA of prescription drugs, conducted in 2000, favoured continuing to permit DTCA of prescription drugs,¹⁷ in Australia the 2001 Galbally Review recommended against permitting DTCA.¹⁸ The United Kingdom, Canada and European countries (including Finland, Spain and the Netherlands) have all decided against allowing DTCA of prescription drugs, as it has been concluded that to do so would be more detrimental than beneficial.¹⁹

The decision of whether to continue to prohibit DTCA of prescription drugs in Malaysia, as explained in Chapter 2, must be based on an assessment of whether the benefits of DTCA outweigh its harms. Accordingly, claims made by both proponents and opponents of DTCA of prescription drugs regarding its informational value are investigated in the following sections. Section [6.2.4.1] examines the arguments in favour of DTCA of prescription drugs, whereas section [6.2.4.2] examines the arguments against it. These arguments are largely based on claims made by proponents and opponents of DTCA of prescription drugs, and are mainly derived from experience in the United States, where the debate has been most intense. Section [6.2.4.3] evaluates the relative benefits and detriments of DTCA of prescription drugs, which is then used in [6.2.5] to recommend whether or not DTCA of prescription drugs should be allowed in Malaysia.

¹⁶ The other country where DTCA of prescription drugs is permitted is New Zealand.

¹⁷ 'Direct to Consumer Advertising of Prescription Medicines in New Zealand; (Discussion Paper, Ministry of Health New Zealand, 2000) ('*DTCA New Zealand Discussion Paper 2000*')

¹⁸ Rhonda Galbally, Review of Drugs, Poisons and Controlled Substances Legislation. Final Report Part A (National Therapeutic Goods Administration, Woden ACT 2001) 50 ('*Galbally Review*')

¹⁹ *DTCA and QUM 2004*, above n 4, 2.

6.2.4.1 Arguments in Favour of DTCA of Prescription Drugs

DTCA of prescription drugs is claimed by its proponents to communicate health-related information and to educate the public about healthcare. It is also contended that it leads consumers to obtain necessary care at an early stage, which reduces the necessity for expensive treatments such as surgery and hospitalization. This section examines these claimed benefits.

(a) *DTCA Communicates Health-Related Information*

Proponents of DTCA of prescription drugs argue that it conveys health-related information to consumers, which benefits consumers in many ways.²⁰ It enables consumers to be better informed about drugs and certain medical conditions; it notifies consumers of the availability of new drugs or treatments for medical conditions which consumers would otherwise be unaware of and also helps consumers to recognize medical conditions that are often under-diagnosed or under-treated.²¹ The information gained from DTCA of prescription drugs assists consumers in their discussions with physicians regarding health conditions, tests or treatment options that may have been overlooked by physicians.²²

(b) *DTCA of Prescription Drugs Brings Indirect Benefits*

When DTCA of prescription drugs provides information that is not directly associated with advertised drugs, such as information about obesity, diabetes, depression, diet, exercise and wellness, this general information is perceived to enhance consumers' understanding of healthcare.²³ This has been seen as a positive side-effect of the advertising. Another positive side-effect is that it may encourage compliance with drug therapy, which in turn

²⁰ See generally Cox and Cox, above n 14, 227.

²¹ Isaac D. Montoya, Gwen Lee-Dukes and Dhvani Shah, 'Direct -To-Consumer Advertising: Its Effects on Stakeholders' (2008) 37(2) *Journal of Allied Health* 116, 118.

²² Jeffrey T Berger, et al., 'Direct-to-Consumer Drug Marketing: Public Service or Disservice?' (2001) 68(3) *The Mount Sinai Journal of Medicine* 197, 199.

²³ John E Calfee, 'Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs' (2002) 21(2) *Journal of Public Policy and Marketing* 174, 185.

contributes towards better management of healthcare.²⁴ Hectic lifestyles or plain neglect may contribute toward non-compliance with drug therapy, but DTCA of prescription drugs, by reminding consumers to seek physicians to obtain or refill prescriptions, can prompt compliance with drug therapies, and thereby prevent the deterioration of the health of consumers.²⁵

(c) *DTCA of Prescription Drugs Prevents Costly Treatments*

DTCA of prescription drugs may replace or prevent costly surgery, treatment or hospitalization when it encourages effective drug therapies. Drug therapies may save costs in the long run by averting the need for other costly health care services.²⁶ A positive effect of this is also that it will prevent the crowding of hospital beds. If fewer patients are admitted, this, in turn, provides an opportunity to those with serious illnesses to be attended to in a timely manner.

6.2.4.2 Arguments against DTCA of Prescription Drugs

DTCA of prescription drugs is claimed by opponents to lead to over-prescription and to compromise the physician-patient relationship. It is also claimed to harm patients, whether financially, psychologically or physiologically, by creating unnecessary demands for the drugs or by providing unbalanced, misleading or inadequate information and warnings. In addition, there are general objections that DTCA is too profit-orientated and not genuinely intended to optimize healthcare. This section explores each of these claims.

²⁴ Ibid 186.

²⁵ See generally Prevention Magazine (1999) 'National Survey of Consumer Reactions to Direct-to-Consumer Advertising; Prevention Magazine (2000) 'International Survey on Wellness and Consumer Reactions to DTC Advertising of Rx Drugs'. Also see generally Calfee, above n 23, 180.

²⁶ See generally Peter J. Neumann, et al., 'Drug Costs: Are Pharmaceuticals Cost-Effective? A Review Of The Evidence; Do Drug Treatments Give Value for the Money? Careful Analysis Can Yield Useful Information, This Study Finds' (2000) 19(2) *Health Affairs* 92, 97-99.

(a) *DTCA of Prescription Drugs Influences Consumer Choices*

Choosing a drug treatment requires the expert advice of a physician who has considered factors such as: (1) the prevalence and the degree of severity of the conditions being treated; (2) the effectiveness of the particular drugs to treat the conditions; (3) the possibility of alternative treatments; and (4) the side effects of the drugs and the frequency of the side effects.²⁷ The nature of the products and the vulnerability of those who consume them, necessitate obtaining advice from a physician.²⁸ The choice of drug treatment is, however, thought to be influenced by DTCA of prescription drugs, meaning that it is unqualified consumers, instead of qualified physicians, who effectively make the choice of drugs.²⁹ Consumers, who are influenced by an advertisement, tend to insist that the physician prescribes the advertised drugs.

(b) *DTCA of Prescription Drugs' Distorts Physician-Patient Relationship*

Opponents of DTCA of prescription drugs also argue that it does not lead to patients having informed discussions with their physicians about their medical conditions and the advertised drugs; instead, it results in patients demanding that physicians prescribe the advertised drugs.³⁰ The practice of placing pressure on a physician to prescribe the advertised drugs may cause an erosion of the patient-physician relationship. However, there is no conclusive evidence as to whether this practice alters physician behaviour in the context of distorting the relationship between physicians and their patients as the published studies reveal conflicting findings.³¹ Opponents have, however, argued that

²⁷ Kurt C Stange, 'Time To Ban Direct-To-Consumer Prescription Drug Marketing' (2007) 5(2) *Annals of Family Medicine* 101, 101.

²⁸ Berger, above n 22, 199-200; Editorial, 'Direct-to-Consumer Advertising: Is It Too Late to Manage the Risk?' (2007) 5(1) *Annals of Family Medicine* 4, 5.

²⁹ See generally Stange, above n 27, 101; Gary Humphreys 'Direct-to Consumer Advertising Under Fire *Bulletin of World Health Organisation*' (2009) 87(8), 576.

³⁰ Stange, above n 27, 101; Humphreys above n 29, 576; See generally Sheila Campbell, Congressional Budget Office 'Promotional Spending for Prescription Drugs' (2009) *Economic and Budget Issue Brief*, 1, 1.

³¹ Barbara Mintzes, et al., 'How Does Direct-to-Consumer Advertising (DTCA) Affects Prescribing? A Survey in Primary Care Environments With and Without Legal DTCA' (2003) 169(5) *Canadian Medical Association Journal*, 405. See generally Kathryn J. Aikin, John L. Swasy and Amie C. Braman, Center for Drug Evaluation and Research, Food and Administration, Department of Health and Human Services, United States, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Executive Summary of FDA Survey Research Results*; Richard L Kravitz, et al., 'Influences of Patients'

physicians have, on most occasions, acceded to the demands of patients and prescribed the advertised drugs.³²

(c) *DTCA of Prescription Drugs Promotes Drugs without Proper Investigation into their Safety*

DTCA of prescription drugs tends to promote newly approved medications that may not have the advantage of sufficient 'run time' to firmly establish their safety.³³ In the United States, drugs are tested on approximately 5000 patients, a figure which is hardly substantial as a basis for establishing safety, taking into account the demand for such drugs and the number of patients who may eventually consume them.³⁴ Adverse reactions recorded from a few patients may not accurately represent the reaction of all patients to the drugs.³⁵ In view of the large-scale use of prescription drugs, DTCA of prescription drugs risks the possibility of harming patients when information regarding the availability of drugs for certain illnesses is disseminated without prior proper investigation of side effects and contraindications.³⁶

An example of the potential dangers is the case of the arthritis drug rofecoxib, which is known as Vioxx. Vioxx was advertised by DTCA, but a clinical study later found an increased risk of cardiovascular events, such as heart attack and stroke, after 18 months of treatment, leading to the drug being recalled.³⁷ However, by the time of the recall, the drug

Request for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial' (2005) 293(16) *Journal of American Medical Association* 1995, 1998.

³² Bennet Parnes, et al., 'Lack of Impact of Direct-to-Consumer Advertising on the Physician-Patient Encounter in Primary Care: A SNOCAP Report' (2009) 7(1) *Annals of Family Medicine* 41, 44- 45; Mintzes, et al., above n 31, 409; Kravitz, et al., above n 31, 1998; See generally Martin S. Lipsky and Christine A. Taylor., 'The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising'. (1997) 45(6) *Journal of Family Practice* 495.

³³ See Donna U. Vogt Congressional Research Service (CRS) Report RL 32853, United States, *Direct-to-Consumer Advertising of Prescription Drugs* (25 March 2005), 26.

³⁴ See generally Ibid 5-6.

³⁵ Ibid.

³⁶ Ibid.

³⁷ See Eric J Topol, 'Failing the Public Health: Rofecoxib, Merck, and the FDA' (2004) 351(17) *New England Journal of Medicine* 1707, 1707.

had reached over 80 million American patients who were already taking the medication.³⁸ A similar outcome was seen in the case of a weight loss drug, 'Sibutramine'. Sibutramine, which was sold under different names such as 'Meridia', 'Reductil', 'Ectiva', 'sibutral', 'reduxade' and 'zelium' in different countries, was withdrawn in European countries following a safety review finding that 'Sibutramine' carried a risk of cardiovascular events.³⁹ The drug, however, was not withdrawn from the United States; instead manufacturers agreed to provide stronger warnings to consumers.⁴⁰

In some instances, harm caused by prescription drugs continues even after the use is discontinued, as in the case of the drugs 'Paroxetine' (Paxil) and 'Venlafaxine (Effexor).⁴¹ These drugs were found to cause harm to an unborn child in the twentieth week of pregnancy although their use was discontinued in the first trimester of pregnancy.⁴²

(d) *Financial and Psychological Effects of DTCA of Prescription Drugs*

It has been argued by opponents that not only physical harm may be caused by DTCA of prescription drugs, but also financial and psychological harm. Consumers do not necessarily benefit in terms of the enhancement of their healthcare by consuming the drugs, but they may also be harmed by unnecessary expenses.⁴³ As explained by Kapp, DTCA of prescription drugs may create an inappropriate demand for life-style drugs to treat conditions that do not require pharmacological interventions.⁴⁴ The end result of this will be an increased cost for consumers, with no countervailing benefits. Opponents also argue

³⁸ Ibid.

³⁹ Christine Redmond, 'Sibutramine Ban Will Influence New Obesity Drugs; Weight Loss Drug Withdrawal will Pave Way for New Obesity Treatments', *Suite 101.com* (online) 27 January 2010, <<http://weightloss.suite101.com/article.cfm/sibutramine-ban-will-influence-new-obesity-drugs#ixzz0rRr5IXm1>>

⁴⁰ Ibid.

⁴¹ Sharon Kirkey, 'Antidepressants linked to higher risk of miscarriage', *Calgary Herald* (online) 31 May 2010, <<http://www.calgaryherald.com/news/Antidepressants+linked+higher+risk+miscarriage/3094082/story.html>>

⁴² Ibid.

⁴³ See Peter Lurie, 'DTC Advertising Harms Patients and Should Be Tightly Regulated' (2009) 37 *Journal of Law, Medicine and Ethics* 444, 447.

⁴⁴ Marshall B Kapp, 'Drug Companies, Dollars, and the Shaping of American Medical Practice' (2005) 29 *Southern Illinois University Law Journal* 237, 244.

that DTCA of prescription drugs that are life-style drugs may bring about unhappiness and anxiety amongst those who either cannot afford the advertised drugs, or find them to be ineffective.⁴⁵ For example, a study on men who used 'Sildenafil' for erectile dysfunction revealed that the expectations created by DTCA affected the morale of men who used the drug, only to find that it was ineffective.⁴⁶

(e) *DTCA of Prescription Drugs Promotes Expensive Drugs*

Although DTCA of prescription drugs is described as a 'marketing technique and a way to reach patients directly in order to reduce the information and power imbalance between patient and physician'⁴⁷ or as 'any promotional effort by pharmaceutical companies to present prescription drug information to the general public through the lay media',⁴⁸ DTCA of prescription drugs is, in essence, a marketing tool designed to encourage the purchase of the advertised drugs.⁴⁹

The advertised drugs are usually more expensive than the cheaper versions that are available in generic form. Although there are no clinical differences between the advertised drugs and the generic drugs, consumers may be more inclined to buy the advertised drugs as DTCA leads them to believe that generic drugs are inferior.⁵⁰ Furthermore, as generic drugs are not advertised, consumers are less likely to be aware of their availability.⁵¹

One impact that may arise from DTCA of prescription drugs is that it may put pressure on the viability of benefit schemes such as the Australian pharmaceutical benefit scheme

⁴⁵ Elizabeth A Almasi, et al., 'What Are the Public Health Effects of Direct-to-Consumer Drug Advertising?' (2006) 3(3) *PLoS Medicine* 284, 286.

⁴⁶ John Tomlinson and David Wright, 'Impact of Erectile Dysfunction and Its Subsequent Treatment with Sildenafil: Qualitative Study' (2004) 328 *British Medical Journal*, 1, 4.

⁴⁷ See Chin, above n 14, 775.

⁴⁸ Vogt, above n 33, 1.

⁴⁹ See Chin, above n 14, 775. See Vogt above n 33, 1.

⁵⁰ Prescription Access Litigation (PAL) Drug Advertising at <<http://www.prescriptionaccess.org/learnmore?id0003>>.

⁵¹ Ibid.

(PBS).⁵² In Australia, the PBS provides affordable access to a range of medicines.⁵³ Consumers are able to afford some medications because they are subsidized through this scheme; but unnecessary demand or pricing of prescription drugs will create extra costs to the government, which subsidises these drugs.

(f) *DTCA of Prescription Drugs Fails to Provide Adequate Warnings*

Opponents of DTCA of prescription drugs argue that it fails to convey adequate warnings about the actual risks and benefits, or about possible side effects and contraindications.⁵⁴ Broadcast advertisements, which are aired for one minute or thirty seconds, focus mainly on encouraging consumers to visit their doctors for prescription of the advertised drug.⁵⁵ Less prominent attention is placed on the warnings associated with the drugs.⁵⁶ Similarly, advertisements in the print media emphasize the potential benefits of using the drugs, while warnings are often carried in small print using dull colours and are difficult to understand.⁵⁷

(g) *DTCA of Prescription Drugs Misled Consumers*

Critics argue that DTCA of prescription drugs may cause consumers to believe that the advertised drugs have considerable advantages, when in fact no significant advantages exists or are proven.⁵⁸ These misconceptions are created by explicit language used in advertisements, as well as by images which make the advertised drugs appear better than

⁵² *DTCA and QUM 2004* above n 4, 7.

⁵³ Amanda Biggs, Parliamentary Library, Parliament of Australia, *Pharmaceutical Benefit Schemes An Overview*; Department of Health and Ageing, Australian Government, *Pharmaceutical Benefit Schemes*, <<http://www.health.gov.au/pbs>>

⁵⁴ Chin, above n 14, 776; Lurie, above n 43, 447.

⁵⁵ See generally Andrea M Greene, 'Pharmaceutical Manufacturer's Liability for Direct Marketing and Over-Promotion of Prescription Drugs to Product Users' (2003) 26 *American Journal of Trial Advocacy* 661, 676.

⁵⁶ *Ibid.*

⁵⁷ Lisa M. Schwartz, et al, 'Using a drug facts box to communicate drug benefits and harms. Two randomized trials'. (2009) 150 (8) *Annals Internal Medicine*, 516.

⁵⁸ See generally Jerry Avorn and William H. Shrank, Editorial 'Communicating Drug Benefits and Risks Effectively: There Must Be A Better Way' (2009) *Annals of Internal Medicine* 563, 563.

they are in comparison with other drugs.⁵⁹ For instance, although drugs known as Cox-2 inhibitors were widely promoted by claims promoting high expectations, it was later found that the drugs were not a more effective pain reliever than other non-steroidal anti-inflammatory drugs.⁶⁰ In another instance, an actor was used to falsely convey the imputation that a prescription drug was being recommended by a physician.⁶¹ In this case, an advertisement showed a person who was introduced as the physician who invented 'artificial hearts', promoting the use of the anti-cholesterol drug Lipitor to the audience while rowing a boat across a lake.⁶² The advertisement was later found to be misleading when it was discovered that the physician was not licensed, and that he had not even rowed the boat across the lake.⁶³

(h) *Other Harmful Effects of DTCA of Prescription Drugs*

The opponents of DTCA of prescription drugs also point to disadvantages other than those previously discussed. First, there are claims that DTCA of prescription drugs may change people's attitudes towards healthcare, leading to an assumption that drug therapy is needed to treat all aches and pains, even where a non-drug treatment may be just as efficacious.⁶⁴ This type of advertising causes consumers to prefer a drug-orientated approach, rather than adopting other measures, such as a balanced diet or an alternative therapy.⁶⁵ There are also claims that the drug companies manipulate consumers for their own gains; the drug companies turn patients into their 'agents' and get them to seek physicians to prescribe drugs as per their request.⁶⁶ Secondly, apart from potentially misleading consumers, opponents have argued that there are problems with promotions

⁵⁹ See Josef Winkler, 'You Wanted the Best, You Got the Best! The Current Direct-to-Consumer Prescription Drug Advertisement Dilemma' (2007) 26 (4) *Biotechnology Law Report* 331, 338.

⁶⁰ See Lurie, above n 43, 445; Vogt above n 33, 26.

⁶¹ Humphreys above n 29, 576.

⁶² Ibid.

⁶³ Ibid.

⁶⁴ See Vogt above n 33, 8.

⁶⁵ Ray Moynihan, Iona Heath, and David Henry, 'Selling Sickness: The Pharmaceutical Industry And Disease Mongering' (2002) 324,(7342) *British Medical Journal* 886.

⁶⁶ See generally Lurie, above n 43, 448.

aimed at physicians.⁶⁷ For example, some promotions have misled physicians with respect to the types of studies and data collected, with poor quality studies being presented as reliable.⁶⁸

6.2.4.3 Analysis of the Competing Arguments

It is clear from the above that DTCA of prescription drugs has both potential advantages and disadvantages being, in the words of Kravitz et al, 'neither good nor evil: it is both'.⁶⁹ On the one hand, DTCA of prescription drugs may be helpful in providing consumers with information about the drugs, and in fostering better communication between physicians and patients. On the other hand, however, it may create unrealistic expectations in the minds of patients, who are not well-placed to assess the claims made about the drugs. This section of the chapter examines the arguments for and against DTCA of prescription drugs. It does not attempt a detailed analysis of all arguments in favour and against, but evaluates the primary advantages and disadvantages of DTCA of prescription drugs so as to provide a basis for the recommendation as to whether it should be permitted or otherwise. Once this is accomplished, the next task is to undertake a cost-benefit analysis, which is carried out at [6.2.4.4].

(a) *DTCA May Have A Negative Health Impact*

As explained at [2.6.1], advertisements for medicinal products, including prescription drugs, may provide consumers with important information about the drug such as its benefits and potential side-effects. Hence, advertisements may provide consumers with additional information about illnesses and diseases, facilitating early diagnosis, encouraging the adoption of a healthy lifestyle or prevention of costly treatments, surgery and hospitalization. Finally, advertisements for medicinal products may foster a better

⁶⁷ See generally Henry A Waxman, 'A History of Adverse Drug Experiences: Congress Had Ample Evidence to Support Restrictions on the Promotion of Prescription Drugs' (2003) 58 *Food and Drug Law Journal* 299, 302

⁶⁸ *Ibid.*

⁶⁹ Almasi, above n 45, 285 -286.

physician-patient relationship, by encouraging patients to ask informed questions of their physicians.

However, as explained further at [2.6.1], the promotion of medicinal products may create a false or misleading impression of the qualities of a product, with potentially serious health effects. It has been noted above that DTCA of prescription drugs causes various types of harm: financial, physical and psychological. This occurs when DTCA falsely claims that the advertised drugs (which are more expensive) are superior to other drugs or to their generic versions. Advertisement of prescription drugs also exposes populations to serious side effects before any scientific testing could have the chance to detect adverse reactions, as seen in the case of both 'Vioxx' and 'Sibutramine'. Such advertisements have also caused misery to those consumers who have consumed particular drugs only to find that they did not have the desired effect, as in the case of 'Sildenafil' or 'Viagra'.

The starting point for the analysis is that in all jurisdictions the possible negative health effects of certain medicinal products are potentially so serious that the products are only made available on prescription from a physician. Medicines are made available on a prescription-only basis because it is believed that patients lack sufficient specialized information to equip them to make decisions about whether or not to use the product concerned. Here, the physician's expertise is required in order to make a decision about the suitability of a prescription. However, certain information regarding prescription drugs communicated to consumers results in consumers effectively making that decision. Consumers tend to request the prescription drugs based on their limited understanding from the DTCA of prescription drugs, which may result in inappropriate health care.

(b) Information in Advertisements is Not Balanced

Another issue is that DTCA of prescription drugs does not channel information about the therapeutic benefits of new drugs to patients who might be in need of them. Studies show that advertisers of prescription drugs promote the benefits and downplay the risks so as to ensure that the advertised drugs are purchased. An examination of a number of studies that reviewed the content of advertisements in order to analyse their usefulness, in addition to a range of other things, revealed that DTCA of prescription drugs, on balance, does not provide beneficial information. For example, in a study of 320 advertisements published in

18 magazines between 1989 and 1998, it was found that the majority of advertisements provided minimal information regarding healthcare and that the bulk of information simply promoted the drugs.⁷⁰ The study by Bell et al revealed that whilst there was information regarding the condition treated by the advertised drugs and an explanation of the symptoms of the medical conditions, there was insufficient information about: the success rates of the treatments (9%); the drug mechanism (36%); alternative treatments (29%); and behavioural changes (24%).⁷¹ Further, Loke et al reviewed one hundred and seventy four advertisements from six medical journals in Australia, and found that less than '8% of the claims quantified specific clinical outcomes'.⁷² Abel et al found, from an analysis of thirty nine advertisements for twelve products, that the texts of the advertisements provided twice the amount of information on the medication benefits than the risks, and that information explaining the risks was unreadable.⁷³

Further, where there are regulations that require that sufficient information or warnings regarding the risks of prescription drugs are given to patients, advertisers find ways around the regulations. In the United States, advertisers comply with the relevant regulation only in a literal sense. As noted in [5.4.1.1], in the United States, the regulation requires that advertisements of prescription drugs carry either a brief summary which includes the risks and contraindications, or 'an adequate provision', with a reference that leads to information regarding the particular prescription drug. The print advertisement ordinarily provides information regarding risks in the 'brief summary', but the information is so detailed and technical that consumers generally do not understand the risks involved. Similarly, while the requirement for an 'adequate provision' is also complied with, it is still so burdensome to access that consumers fail to notice the information regarding the risks. Broadcast media, such as television, comply with the regulation by providing information on risks as required by the law, but the advertisements are often run so quickly that consumers fail to

⁷⁰ Robert A. Bell, Michael S. Wilkes and Richard L. Kravitz, 'The Educational Value of Consumer-Targeted Prescription Drug Print Advertising' (2000) 49(12) *Journal of Family Practice* 1092-1098.

⁷¹ Ibid.

⁷² Tim W Loke, Fong Chee Koh and Jeanette E Ward, 'Pharmaceutical Advertisement Claim in Australian Medical Publications' (2002) 177 *Medical Journal of Australia* 291, 293.

⁷³ G.A Abel, et al., 'Direct-To-Consumer Advertising for Bleeding Disorders: A Content Analysis and Expert Evaluation of Advertising Claim' (2008) 6(10) *Journal of Thrombosis and Haemostasis* 1680, 1681.

appreciate the risks. Moreover, the creative way in which television advertisements are presented blinds consumers to the risks associated with the prescription drugs.

(c) *Information Is Not Useful Unless It Is Understood*

DTCA of prescription drugs does not present significant safety information that prevents consumers from using the drugs; instead, it convinces consumers of the therapeutic benefits before the risks are fully known. Although it increases awareness of drug therapies, the awareness is not beneficial unless the patient is 'medically savvy' enough to recognize the benefits of using the drugs. With prescription drugs which are highly technical in nature, an ordinary patient would generally fail to understand the complexities involved in their use. Therefore, physicians may be required to explain the complexities involved in using these advertised drugs. In this regard, physicians are relied upon to overcome the information asymmetry between patients and manufacturer of products which, as explained at [2.5] and [2.6], is the main justification for regulating the advertising of medicinal products.

(d) *DTCA Causes Patient to insist on Prescribing*

Patients who have been exposed to DTCA of prescription drugs may request their physician to explain or clarify medical conditions which they suspect they have, and recommend the suitability of using the advertised drugs. However, this is not always the case. It is argued that DTCA of prescription drugs encourages patients to pressure their physicians into prescribing the advertised products. Studies have shown that physicians have felt pressured to prescribe as requested despite their personal reservations. For example, Parnes et al, found that 12.1% of physicians felt significantly pressured to prescribe advertised drugs and 22.4% were somewhat pressured.⁷⁴ The prescription rate of the advertised drug was more than 50% (namely, 53%), even though this represented a decrease from 80% observed in an earlier study.⁷⁵ Kravitz et al, discovered that physicians

⁷⁴ Bennet Parnes, et al., 'Lack of Impact of Direct-to-Consumer Advertising on the Physician-Patient Encounter in Primary Care: A SNOCAP Report' (2009) 7(1) *Annals of Family Medicine* 41, 44- 45.

⁷⁵ Ibid. Parnes's study assessed a number of indicators, including the frequency at which patient enquiries regarding the advertised drugs led to their prescription. It was found that prescription of the advertised drugs was uncommon. This was primarily believed to be due to the fact that the study was concentrated on patients with low socio-economic status. However, in spite of this, the study found that the prescription rate of the

had prescribed the advertised drugs in 54% of visits made by patients for the antidepressant, 'Paxil'.⁷⁶ The study conducted by Mintzes et al, in 2003 also found that, physicians have been noted to have acceded to the demands made by patients in more than 50% of cases.⁷⁷

(e) *DTCA of Prescription Drug Does Not Necessarily Distort Patient-Physician Relationship*

The extent to which the pressure to prescribe affects the patient-physician relationship is unknown.⁷⁸ It is, however, possible that in the United States the current structure of healthcare, rather than DTCA, contributes to an erosion of this relationship. This structure, which focuses on maximising the number of visits made by patients in a day and rushes patients through clinical examinations, gives little time for discussions about advertised drugs.⁷⁹ Patients are therefore not given an adequate opportunity to clarify queries that they may have about the advertised drugs, and this lack of adequate communication ordinarily leaves patients confused.⁸⁰ Being unable to discuss advertised drugs or, more generally, have adequate discussions about treatment, is perhaps the main factor that distorts the patient-physician relationship. This suggests that DTCA of prescription drugs must be analysed in the context of the entire health care system in each relevant jurisdiction.

advertised drug was still more than 50%, even though it was less than the 80% observed in an earlier study. The drop in the rate of prescription is rationalized by the researchers to be due to a number of reasons, such as: (1) the clinic might have recognized it as being a financial burden on a low income group; (2) patients are less trusting of the pharmaceutical industry; or (3) a change in industry strategy which is not focused on specific medication: 44-45.

⁷⁶ Kravitz, et al., above n 31, 1998.

⁷⁷ Mintzes, et al., above n 31, 411.

⁷⁸ Joel Lexchin and Barbara Mintzes, 'Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No' (2002) 21(2) *Journal of Public Policy & Marketing* 194, 198.

⁷⁹ See generally Avorn and Shrank, above n 58, 563.

⁸⁰ Ibid.

(f) *'Prescription-Only' is Not a Sufficient Safeguard*

It has been argued that prescription drugs are made available on prescription-only basis particularly because of the potential harms associated with their use. It is also because patients lack sufficient specialized information to enable them to make decisions about whether or not to use the product concerned, or to determine an appropriate treatment. Hence, the requirement that it is available on prescription-only basis is to protect patients from their own vulnerability or ignorance.

However, restricting drugs by making them prescription-only is not an absolute safeguard. It has been observed above that DTCA of prescription drugs can persuade consumers to believe that the advertised drugs are superior to any other form of treatment. Consumers, who believe these claims to be true, may ask a physician for the advertised drugs. The physician may agree to prescribe the drug, or if they do not do so, the patient may approach another physician. Therefore, while prescription drugs are only available on prescription, this does not necessarily limit their distribution if consumers can find a way of somehow persuading a physician to prescribe the drug.

In conclusion, the preceding paragraphs have analysed the advantages and disadvantages of DTCA of prescription drugs. It has been noted that the disadvantages outweigh the benefits which can be derived from DTCA. This suggests that DTCA of prescription drugs should not be permitted. As explained at [2.9.2], however, in assessing whether DTCA of prescription drugs should be prohibited, the costs of prohibiting advertising must be taken into account. The following section of the chapter conducts a cost-benefit analysis of the regulation of DTCA of prescription drugs.

6.2.4.4. Economic Analysis of DTCA of Prescription Drugs

Given that there is some form of regulation of all advertising, some form of control is considered desirable irrespective of whether DTCA of prescription drugs is permitted or otherwise. If DTCA of prescription drugs is prohibited, then the controls adopted must ensure that DTCA of prescription drugs does not take place. On the other hand, if DTCA of prescription drugs is permitted, then the controls employed must ensure that the rules pertaining to its dissemination are complied with. An assessment of the appropriate form of

regulatory control cannot be made without an assessment of the costs and benefits of alternative forms of regulation. This section of the chapter therefore considers whether it is cost-effective for Malaysia to permit DTCA of prescription drugs or to continue the ban on DTCA of prescription drugs.

(a) *Cost-Benefit and Cost-Effectiveness Analyses*

As explained at [2.9.1], two kinds of economic analysis, namely, cost-benefit and cost-effectiveness analyses, may be applied to the assessment of regulation, including the regulation of deceptive advertising. As explained at [2.9.2], cost-benefit analysis, as applied to the regulation of advertising, involves an analysis of the costs of regulation as opposed to the benefits. As further explained at [2.9.1], cost-effectiveness analysis, which may be more appropriate in the analysis of public health issues, does not assign a monetary value to measure health effects.

To begin with, it should be noted that this part of the chapter does not attempt a rigorous analysis of all of the relevant costs and benefits of DTCA of prescription drugs; however, it provides the basis for recommendations about the regulation of DTCA of prescription drugs by giving a broad description of the costs and benefits involved. In this analysis, as explained by the discussion of the Galbally Review at [2.9.3], applying the precautionary principle it is important to give appropriate weight in the analysis of issues relating to public health to the potential risks to health and life.

The first stage of the analysis is to examine the costs and benefits of prohibiting DTCA of prescription drugs. As noted at [2.9.3], in applying a cost-benefit analysis, the Galbally Review identified the costs of prohibiting advertising of prescription drugs as including the potential loss of information about the availability of drugs or treatments, the potential decrease in competition between companies that supply drugs, and the associated loss of potential health benefits. The benefits of prohibiting DTCA of prescription drugs, on the other hand, centre on the likelihood of less confusion amongst patients. There would, consequently, be fewer incidents of patients insisting on the prescription of advertised products which will not treat their medical conditions, and there may be fewer cases of patients suffering harm from unknown risks. Furthermore, as consumers would be less misinformed, there would be fewer incidents of drug dependency on prescription drugs.

Moreover, banning DTCA of prescription drugs would lead to less exploitation of vulnerable consumers and fewer tensions between patients and physicians. As the Galbally Review pointed out, as the bulk of DTCA will be for new and expensive drugs, this is likely to distort consumer demand.⁸¹ In addition to imposing unnecessary costs on consumers, in a health system such as Australia's, where government subsidises medicine, this would also add to the costs for government, resulting in a misallocation of resources.

However, the issue is not entirely as easy to resolve as it appears to be from the above analysis. The choice between prohibiting and permitting DTCA of prescription drugs has become complicated with the advent of the Internet. The existence of the Internet raises the question of whether prohibiting DTCA of prescription drugs entirely is practical. The Internet makes available information regarding health, and the information may well come from international sources. Unless there is some feasible way of controlling offshore Internet sites, a complete ban on DTCA of prescription drugs is clearly impossible.⁸² Consumers will continue to obtain information about prescription drugs from international sources. In Australia, for example, in an effort to partially regulate information that was disseminated through the Internet, Australia entered into a Free Trade Agreement with the United States in 2004. This agreement sets out, at annexure 2 clause 5, that:

'Each party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers via the manufacturer's Internet sites...truthful and not misleading information regarding pharmaceutical products that are approved for sale in the party's territory as is permitted under each Party's laws, regulation and procedures....' ⁸³

⁸¹ *Galbally Review* above n 18, 55

⁸² Some control may be established through International conventions, namely by way of reciprocal agreements between countries with similar views. See *DTCA and QUM 2004* above n 4, 14; Also see *DTCA New Zealand Discussion Paper 2000* above n 17, 23.

⁸³ See Department of Foreign Affairs and Trade, Australia United States, 'Free Trade Agreement, National Treatment and Market Access for Goods' 2004. There were arguments as whether this was permitting DTCA of prescription drugs, however, the phrase 'as permitted under each Party's law, regulation and procedure' was read to mean to refer to the current Australia law which prohibits DTCA. See *DTCA and QUM 2004* above n 4, 14.

Even though such an arrangement is in place, however, dissemination of false claims from offshore Internet sites may not be effectively regulated unless there is an adequate system of monitoring claims that are disseminated via the Internet, and this is not likely to be feasible. It seems that the only practical way to address this emerging problem is for increased cooperation between national regulatory authorities.

(b) When DTCA of Prescription Drugs may be Permitted

As explained in [2.7] of Chapter 2, a full assessment of regulation depends upon an analysis of alternative ways of regulating. This section of the chapter therefore analyses the possibility of permitting DTCA of prescription drugs within a tight regulatory framework.

It is possible that DTCA of prescription drugs may be permitted if there is adequate regulation in place to ensure that the advertising is carried out legitimately. In this regard, it was seen in [5.4.1], that the rules in the United States are both comprehensive and detailed. In [5.4.2.3], it was learned that the enforcement, however, is not. The absence of an adequate number of staff to assess the increasing number of advertisements and the delay in the issuance of letters of warning due to a procedural requirement that letters are reviewed by the Office of Chief Counsel, are amongst the reasons for inadequate enforcement. Consumers are therefore harmed by DTCA of prescription drugs before any regulatory action to stop the dissemination may be carried out. Hence, the desired outcomes are not achieved in the United States because the regulatory controls over DTCA of prescription drugs in that jurisdiction are unsatisfactory.

If regulation is to be cost-effective, then obviously the costs of ensuring that advertisers conform to the regulations must not be higher than the benefits that DTCA of prescription drugs may bring about. In addition, the negative consequences of DTCA of prescription drugs must be able to be prevented effectively through regulation.

There would be a need to establish regulations that govern the dissemination of information. Legislation would have to ensure that consumers are provided with an equal balance of information concerning both risks and benefit. It would also be necessary to implement strong penalties for non-compliance with or violation of rules by advertisers as well as by advertising agencies and media outlets that publish non-compliant

advertisements. The costs of setting up an effective system of regulatory controls for DTCA of prescription drugs are likely to be significant. To be effective, a system of regulatory control which includes: (1) pre-approval of advertisements; (2) investigation and monitoring of violations of advertising laws; (3) complaint-handling; and (4) enforcement of violation of laws, would have to be established and sustained.

Effective regulation of DTCA of prescription drugs would involve controlling not only the manufacturers, but also the advertising agencies and all media outlets. The cost of controlling various media can be not only high, but difficult. The use of medicines in certain jurisdictions is ordinarily influenced by cultural beliefs and practice, and in jurisdictions where there are multiple races, the promotion of products through ethnic media may exist.⁸⁴ Ethnic media are ordinarily privately owned and operate on the basis of a low-profit margin, and DTCA of prescription drugs may provide financial support to this type of media.⁸⁵ It is possible that the media will publish the advertisements without verifying the claims made, and this could result in promotion of unsafe products to a section of the population.

(c) *The Mode of Regulation to be adopted if DTCA of Prescription Drugs is Permitted*

If a decision is made to permit DTCA of prescription drugs, a further issue that has to be determined is the mode of regulation to be adopted. Would government regulation as opposed to self-regulation be appropriate for the regulation of DTCA of prescription drugs? As noted at [2.7.1] the government driven 'command and control' mode of regulation is claimed to be inherently narrow, inflexible and have the qualities of either over-deterrence or under-deterrence. Self-regulation, on the other hand, is flexible, fast acting and is better equipped in terms of skill, expertise, financial and human resources than the command and control' model, but lacks effective sanctions and accountability, which are pertinent characteristics for effective regulation of DTCA of prescription drugs.

However, self-regulation can effectively work if there is sufficient fear of government intervention. For example, in New Zealand it is claimed that self-regulation of DTCA of

⁸⁴ DTCA and QUM 2004 above n 4, 15.

⁸⁵ Ibid.

prescription drugs is functioning adequately, largely as a result of the tacit agreement of all parties that industry should not be burdened by more stringent rules.⁸⁶ The New Zealand example illustrates the important point that, in making recommendations for Malaysia, it is absolutely vital to take into account the full social, political and legal context of a particular jurisdiction. Important considerations in assessing any regulatory regime are the commitment of stakeholders to the regulatory regime and the resources allocated to regulation. The following section of this chapter explains the relevance of factors to the recommendation to be made for Malaysia.

6.2.4.5 Why a Continued Ban on DTCA of Prescription Drugs in Malaysia?

As seen in [1.5], in Malaysia, numerous statements in the press have expressed concerns over the uncontrolled dissemination of deceptive advertising. These statements have highlighted the problems caused by advertisements of prescription drugs, despite the ban on these types of advertisements in Malaysia. In essence, the statements show that, in practice, the ban on DTCA of prescription drugs has not stopped promotional information about prescription drugs from reaching consumers. Furthermore, they show that consumers have relied upon false information and subsequently suffered injuries as a result. The regulators in Malaysia have been severely criticised for funding only limited scrutiny of this types of advertisements that have reached consumers by defaults.

If DTCA of prescription drugs is to be permitted in Malaysia, obviously adequate controls, including adequate levels of monitoring and enforcement, would have to be established. For this, two fundamental questions have to be asked: (1) To what extent could the problems posed by DTCA of prescription drugs be managed cost-effectively under the existing Malaysian system of regulation? (2) Should the existing Malaysian system of regulation prove to be ineffective, is there a need to consider establishing a new form of regulation for DTCA of prescription drugs?

Malaysia is still relatively inexperienced into the regulation of advertising, with limited resources available for regulation and, accordingly, does not appear to be sufficiently equipped to deal with the potential problems posed by DTCA of prescription drugs. It would

⁸⁶ See generally *New Zealand Discussion Paper 2000* above n 17, 21-27.

have to establish a comprehensive set of rules to ensure that the advertisements of prescription drugs provide balanced information to consumers in a manner that is easily understood.. There must also be in place an adequate system of regulatory controls, which includes: (1) pre-approval of advertisements; (2) investigation and monitoring of violations of advertising laws, (3) complaint-handling and (4) enforcement of laws. In establishing a regulatory system, Malaysia would need to ensure that the system performed better than the United States regime, where there is both more experience in regulating advertising and more resources available for regulation.

Furthermore, the existing Malaysian system of regulation of advertisements for medicinal products may not be relied upon, for it is inadequate to deter deceptive advertising. As noted in [3.3], the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) has a number of deficiencies which prevent adequate regulation, and these have yet to be addressed. As explained at [3.3.1.1], the sanctions imposed for violations of laws are inconsequential and therefore are insufficient to ensure compliance. Cases that were pursued through the courts were settled with a payment of a fine.⁸⁷ The low fines imposed have simply been treated as the costs of doing business by the advertisers. Further, the types of sanctions available in Malaysia are limited to fines and imprisonment, as opposed to more extensive options available in other jurisdictions, such as corrective advertising or 'cease and desist' orders. In addition, the defense clause in *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is broad; it provides that in order for a charge to succeed, the MAB would have to show that the advertisement was published to the public.⁸⁸ Publication of claims in brochures and pamphlets which were not intended for public viewing is excluded from regulation. These brochures and pamphlets are, at times, accessible to consumers and are a source of information about prescription drugs. Moreover, the MAB is not able to bring an action to court unless the complainant is present and the prosecution is sanctioned or endorsed by a public prosecutor. These limitations, in essence, deter the timely and effective regulation of advertising of medicinal products in Malaysia.

Given these considerations it is clear that the existing regulation of deceptive advertising of medicinal products is inadequate for the regulation of DTCA of prescription drugs.

⁸⁷ See [3.3.1.1] of Chapter 3

⁸⁸ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 3 (2).

Moreover, if DTCA of prescription drugs were permitted, the MAB, which already lacks adequate finance and human resources to monitor violations of deceptive advertisements would be burdened with additional costs. Alternatively, DTCA of prescription drugs could be entrusted to self-regulation, as is the case in New Zealand. However, as explained at [2.7.2.1], pure self-regulation lacks transparency and accountability and therefore its desirability must be questioned. Determining whether self-regulation of DTCA of prescription drugs would work in Malaysia, as it evidently does in New Zealand, would require further independent and in depth research. But the differences between the Malaysian and New Zealand legal and regulatory environments are sufficiently significant to suggest that the New Zealand example is unhelpful.

In sum, then, the arguments against permitting DTCA of prescription drugs in Malaysia far outweigh those in favour. First, as explained above, applying the analysis adopted by the Australian Galbally Review, which gives considerable weight to the precautionary principle, the costs of permitting DTCA of prescription drugs would seem to outweigh the advantages. Secondly, as explained above, in order to minimise the harms, permitting DTCA of prescription drugs would entail high regulatory costs. While it is conceivable that a sophisticated regulatory regime might address some of the social costs of DTCA of prescription drugs, Malaysia clearly lacks the human and financial resources that are available in a jurisdiction such as the United States. Moreover, Malaysia does not have the social, political or legal supports which seem to contribute to the effectiveness of self-regulation in New Zealand.

In addition to the above considerations, the international consensus in this area is clearly opposed to allowing DTCA of prescription drugs. As discussed at [4.4], Australia has concluded that DTCA of prescription drugs is more harmful than helpful while, as noted at [5.4.2.3], the United States is considering a moratorium on DTCA of prescription drugs. Furthermore, as noted at [6.2.4], Canada and some European countries that have conducted reviews of DTCA of prescription drugs have favoured retaining the prohibition.⁸⁹ This thesis therefore strongly recommends that Malaysia should not permit DTCA of prescription drugs.

⁸⁹ *DTCA and QUM 2004* above n 4, 2-5.

6.3 THE REGULATION OF THE ADVERTISING OF PRODUCTS CLASSIFIED AS MEDICINAL PRODUCTS

This section of the chapter examines the advertising regulation of 'products classified as medicinal products' by way of a comparative analysis of regulation in the three jurisdictions dealt with in this thesis, Malaysia, Australia and the United States. This analysis is supplemented by an economic analysis. As will be seen in this section, there is a considerable disparity in the manner in which the advertising of medicinal products is regulated in the three jurisdictions. An important consequence of this disparity is that there is an inequality between the three jurisdictions in the level of protection accorded to consumers.

This section compares and examines three important aspects of regulation. First, section [6.3.1] highlights the disparities in the classification of medicinal products in the three jurisdictions. Here, the types of products that qualify as medicinal products and the regulatory implications of this classification in the three jurisdictions are discussed. In essence, this section examines the relative merits of the different approaches to exempting products from regulation in the three jurisdictions. Secondly, section [6.3.2] compares and analyses the rules governing the advertising of medicinal products in the three jurisdictions. The focus of this section is on examining the comprehensiveness of the rules, which include both formal and informal rules. Thirdly, section [6.3.3] compares and analyses the regulatory controls that are imposed on permissible advertising. The extent to which controls, such as pre-approval of advertisements, and monitoring of violation of laws and enforcement, are effective in preventing deceptive advertising in the three jurisdictions is examined. Finally, section [6.3.4] assesses the three identified issues for the purposes of determining the appropriate form of regulation to govern the advertising of medicinal products.

6.3.1 Classification of Products as Medicinal Products

As explained in [1.5], medicinal products are a group of products with medicinal value, or products which are intended to be used for medicinal, remedial or therapeutic purposes, such as diagnosing, curing, mitigating, treating or preventing diseases. They are referred to

as ‘drugs’ in the United States and Malaysia,⁹⁰ and as ‘therapeutic goods’ in Australia.⁹¹ Both the terms ‘drugs’ and ‘therapeutic goods’ are broadly defined in legislation in the three jurisdictions, thereby allowing for a wide spectrum of products to fall within the respective classifications.

Key phrases in the definitions of these terms mean that products which are capable of, or intended for, a ‘medicinal or therapeutic purpose’ may be recognized as medicinal products. Thus, products such as food, dietary supplements and cosmetics may be regulated as medicinal products when their advertisements include therapeutic claims, unless they are exempted. The exemptions of such products from classification as medicinal products are not, however, uniform in the three jurisdictions. This results in disparities between the products that are classified as medicinal products in the different jurisdictions and, importantly, in the protection guaranteed to consumers.

The classification of an item as a medicinal product ordinarily means that the product is subject to a form of regulatory control, such as an approval process before being sold to the public, in addition to regulatory controls on the advertising of such products. The pre-advertising regulatory controls are essentially designed to ensure that only those products which are proven to be safe and effective are sold in the market. As explained at [2.6.1], advertising regulation of medicinal products is essentially designed to ensure that consumers are given accurate information about such products and not subjected to deceptive advertising practices. As further explained at [6.3.1.5] below, pre-advertising regulatory controls and advertising regulation are designed to complement each other in protecting consumers.

The most significant threshold decision to be taken in regulating medicinal products is whether or not a product falls within the scope of regulation. In particular, while products such as non-prescription drugs (NPD) and food, dietary supplements and cosmetics (HRPs) may well be classified as medicinal products, they may also be exempted from such classification in certain circumstances, thereby escaping regulatory control altogether.

⁹⁰ See [5.2.1] of Chapter 5 and [3.2.1] of Chapter 3.

⁹¹ See [4.2.1] of Chapter 4.

This section of the chapter examines the different classifications of products as medicinal products, and the relevant exemptions from such classification in each of the three jurisdictions. The following sections therefore explain the classification of non-prescription drugs, food, dietary supplements and cosmetic products as medicinal products. Section [6.3.1.5] then analyses the implications of the different systems of classifying medicinal products and makes recommendations about the system of classification to be adopted in Malaysia.

6.3.1.1 Classification of Non-Prescription Drugs (NPD) as Medicinal Products

NPD are invariably classified as medicinal products in each of the three jurisdictions as a consequence of their medicinal composition or ingredients. There are, however, important differences in the types of drugs which fall within the classification of NPD.

As discussed at [3.2.1], [4.2.1.1] and [5.2.2.1], NPD are drugs that are obtained without a physician's prescription. In effect, they are drugs that treat symptoms and medical conditions which consumers are perceived to be perfectly competent to self-diagnose, and therefore, are able to choose for themselves. Some NPD, however, require intervention by a pharmacist. These types of drugs are known as 'pharmacy-only-medicines' ('POM'), and a pharmacist is required to assess their use and consumption. It has been explained at [6.2.1], that the category of POM does not exist in the United States; POMs fall within the classification of NPD in Australia and Malaysia. In Australia, NPD include POM (under schedule 3), pharmacy medicine (under schedule 2) and unscheduled medications.⁹² In Malaysia, on the other hand, NPD are referred to compendiously as non-scheduled drugs, which include POM.⁹³ Attempts to recognize POM in the United States have been unsuccessful, with authorities relying on studies which have concluded that there would be no substantial benefit in the creation of this category.⁹⁴

⁹² See [4.2.1.1] of Chapter 4.

⁹³ See [3.2.1.1] of Chapter 3.

⁹⁴ See [5.2.1.1] of Chapter 5.

6.3.1.2 Food Classified as Medicinal Products

Food, being a substance which is ordinarily consumed as a source of energy and nutritional support for the body, is generally not viewed as a medicinal product.⁹⁵ However, advertisements for food which bear therapeutic claims may result in the food being classified as a medicinal product. In each of the three jurisdictions, the general rule is that food is classified as a medicinal product provided that therapeutic claims are made in the advertisements.⁹⁶ The general rule is, however, subject to exemptions, and the exemptions in the three jurisdictions vary considerably.

As elaborated at [5.2.1.2], in the United States, twelve types of health-related claims are authorized and permitted in advertisements for food, provided they comply with FDA prescribed standards, or are qualified claims, or are based on the authoritative statement. In Australia, as explained at [4.2.1.2], only one type of therapeutic claim is currently permitted, namely, 'maternal folate consumption with reduced risk of foetal neural tube defects in women around the time of conception'. The Food Standards Australia New Zealand (FSANZ) has, however, recommended that an additional seven types of therapeutic claims should be permitted. In particular, the FSANZ proposes to permit claims which are similar to those allowed in the United States, but with fewer exceptions.⁹⁷ In contrast, as noted in [3.2.1.2], Malaysia is yet to recognize any permissible therapeutic claims in food advertisements.

In addition to permitted claims, certain special categories of food products are exempt from being classified as medicinal products in each of the jurisdictions. In the United States, categories of food products, known as 'food for special dietary use' and 'medical food' are

⁹⁵ However, in the practice of Ayurvedic medicine, food is generally varied and consumed for the purpose of healing and curing illness. See generally Burton Goldberg, Larry Trivieri and John W. Anderson, *Alternative Medicine: The Definitive Guide* (Celestial Arts, 2002).

⁹⁶ See [3.2.1.2] of Chapter 3; [4.2.1.2] of Chapter 4 and [5.2.1.2] of Chapter 5.

⁹⁷ Claims that the FSANZ intends to disallow but which are permitted in the United States are, for example, as follows, that: (1) dietary lipid assists in the treatment of cancer; (2) fruits and vegetables assist in the treatment of cancer; (3) dietary non-cariogenic carbohydrate sweetener is not a cause of dental caries; (4) soy protein assists in the treatment of risk of coronary heart disease and (5) plant sterol/stanol esters assists in mitigating the risk of heart disease'. It is proposed that these claims are excluded from the exemptions. See [5.2.1.2] of Chapter 5.

permitted to carry claims which are unique to their uses.⁹⁸ Accordingly, use of such claims, which may include claims regarding the prevention or treatment of a particular medical condition, does not result in food being classified as a medicinal product. In both Australia and Malaysia, on the other hand, a food category known as a ‘special purpose food’, which is similar to ‘food for special dietary use’ in the United States, is allowed to carry specific claims in advertisements.⁹⁹ The category of product known as ‘medical food’ in the United States, however, is not recognized in either Australia or Malaysia.

Finally, food products that are generally known as ‘functional food’ may also be promoted in the three jurisdictions. Functional foods are foods that have been modified with an active ingredient to enhance their bioactivity. Examples of functional foods include drinks with ginseng, omega-3 in eggs or juices with calcium. As seen at [5.2.1.2], in the United States, the FDA regards functional food as falling under the category of food and, consequently, as being subject to food regulations. Advertisements for functional foods may therefore carry claims of health benefits, provided these are permitted under the food regulations.

In Malaysia, however, as noted at [3.2.1.2], foods that fall in the interface between food and drugs, which are, in essence, functional foods, are regulated as drugs if the composition of pharmacological properties is 80% or more. This determination is made by a committee expressly established for this purpose, namely, the Committee for Classification of Food and Drug Interface Products.

In Australia, as noted at [4.2.1.2], functional foods are ordinarily regulated as therapeutic goods by virtue of section 7 of the *Therapeutic Goods Act 1989* (Cth), which enables the Secretary to the Department of Health and Ageing to declare goods or classes of goods, including food products, to be therapeutic goods. Functional food does not exist as a separate category in the existing regulatory system in Australia. It is possible that the reason for this may be that functional food falls under other categories. Functional food, in a way, overlaps with ‘special purpose food’ and complementary medicines. However, the status of functional food is under review. Both the Therapeutic Goods Administration (TGA)

⁹⁸ See [5.2.1.2] of Chapter 5.

⁹⁹ See [4.2.1.2] of Chapter 4 and [3.2.1.2] of Chapter 3.

and the FSANZ are, at present, resolving issues relating to the food and medicine interface.¹⁰⁰ As part of this review, proposals have been made to declare products in the form of capsules, tablets, and pills as therapeutic goods.¹⁰¹ It is presumed that the status of functional foods will be further clarified as a result of the current review process.

6.3.1.3 Dietary Supplements Classified as Therapeutic Goods

In each of the three jurisdictions, dietary supplements are generally accepted as food products which enrich or complement a diet. These products are, however, known by different terms in the three jurisdictions and are not uniformly regulated. They are known as 'dietary supplements' in the United States,¹⁰² as 'complementary medicines' in Australia,¹⁰³ and as 'nutrient supplements' in Malaysia.¹⁰⁴ In the United States and Malaysia, this category of product is classified and regulated as a sub-category of food,¹⁰⁵ whereas in Australia, these products are regulated as therapeutic goods.¹⁰⁶

Dietary supplements are not uniformly exempt from classification as drugs or therapeutic goods in the three jurisdictions. In the United States, advertisements for dietary supplements are permitted to carry therapeutic claims if they are claims duly authorized by the FDA or they are permissible nutritional support claims.¹⁰⁷

In Australia, on the other hand, dietary supplements are regulated as therapeutic goods and no exemptions have been established excluding them from classification as therapeutic goods.¹⁰⁸ Likewise, in Malaysia, dietary supplements are regulated in precisely

¹⁰⁰ See [4.2.1.2] of Chapter 4.

¹⁰¹ [4.2.1.2] of Chapter 4.

¹⁰² See [5.2.1.3] of Chapter 5.

¹⁰³ See [4.2.1.3] of Chapter 4.

¹⁰⁴ See [3.2.1.3] of Chapter 3.

¹⁰⁵ See [5.2.1.2] of Chapter 5 and [3.2.1.3] of Chapter 3.

¹⁰⁶ See [4.2.1.3] of Chapter 4

¹⁰⁷ See [5.2.1.3] of Chapter 5.

¹⁰⁸ See [4.2.1.3] of Chapter 4.

the same way as other foods, and no permissible therapeutic claims have been recognized to exclude them from classification as a drug.¹⁰⁹

6.3.1.4 Cosmetic Products Classified as Medicinal Products

Australia and Malaysia share an identical definition of the term ‘cosmetics’ in their respective legislation. The United States, however, has a slightly different definition. Cosmetics in the United States include items which are not only externally applied, but are also internally consumed.¹¹⁰ Cosmetics are defined under section 201(i) of the *Federal Food Drug and Cosmetic Act 1938* (United States) as ‘(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and (2) articles intended for use as a component of any such articles; except that such term shall not include soap’.¹¹¹ In Australia and Malaysia, on the other hand, cosmetics include only those items which are used externally.¹¹² In Australia, cosmetics are defined as ‘substance[s] or preparation[s] intended for placement in contact with any external part of the human body...’ under the section 3 of the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* (Cth). Similarly, in Malaysia, a cosmetic is defined as ‘any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, on the various external parts of the human body...’ under section 2 of the *Control of Drugs and Cosmetics Regulations 1984* (Malaysia).

The categories of products which are classified as cosmetics are itemised in the United States and Australia, but not in Malaysia. As seen at [5.2.1.4] the United States categorises thirteen types of products as cosmetics. Australia, on the other hand, itemises

¹⁰⁹ See [3.2.1.3] of Chapter 3.

¹¹⁰ See [5.2.1.4] of Chapter 5.

¹¹¹ 21 USC § 321(i) (2008).

¹¹² See [4.2.1.4] of chapter 4 and [3.2.1.4] of chapter 3

eight categories of products (with allowable claims) which will be excluded from the classification of cosmetics, as explained at [4.2.1.4].¹¹³

Cosmetic products are uniformly acknowledged to possess dual functions, and are classified as medicinal products if their advertisements carry therapeutic claims. In the United States and Malaysia there are no exceptions which exempt cosmetics from being classified as drugs if therapeutic claims are made.¹¹⁴ In Australia, however, certain types of cosmetic products are excluded from the classification of therapeutic goods, as noted at [4.2.1.4]. Pursuant to the Therapeutic Goods (Excluded) Order No 1 of 2008, certain types of therapeutic claims also exempt products from being classified as therapeutic goods.¹¹⁵

6.3.1.5 Analysis of the Implication of Classification As Medicinal Products

This section of the chapter explains and analyses the regulatory implications of the different systems of classification explained in the preceding sections, so as to enable recommendations about the system of classification to be adopted by Malaysia, at [6.3.1.6] below.

As explained at [3.2.2], [4.2.1.5], and [5.2.1.5], medicinal products are subject to regulatory controls so as to ensure a continuous availability of safe and effective products. The ‘drug safety controls’, for example, include drug approval processes, post marketing surveillance, and reporting of adverse reactions. The advertising regulation of medicinal products, on the other hand, is designed to complement the drug safety controls, which are pre-advertising controls, essentially by ensuring that accurate information about the quality, safety and efficacy of medicinal products are disseminated to consumers.

¹¹³ The types of products include: (1) ‘tinted bases of foundation (liquids, pastes or powder) with sunscreen’; (2) ‘products intended for application to the lips with sunscreen’; (3) ‘moisturizing products with sunscreen for dermal application including anti-wrinkle, anti-ageing and skin whitening’; (4) sunbathing products (for example, oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15; (5) antibacterial skin products; (6) anti-acne skin care products (including spot treatments, cleansers, face scrubs and masks); (7) oral hygiene products for care of the teeth and the mouth (for example dentifrices, mouth washes and breath fresheners and (8) anti-dandruff hair care products. see *Therapeutic Goods (Excluded Goods) Order No. 1 of 2008*.

¹¹⁴ See [5.2.1.4] of chapter 5 and [3.2.1.4] of chapter 3.

¹¹⁵ See [4.2.1.4] of chapter 4.

As further explained at [3.2.2], [4.2.1.5], and [5.2.1.5], that the primary implication of classification of products as medicinal products in the three jurisdictions is that they are subject to drug safety controls before they may be marketed. In other words, the products must be demonstrated to be safe and effective through scientific testing. However, not all medicinal products are tested and proven to be safe and effective; the types of medicinal products which are tested for safety and efficacy vary in the three jurisdictions. Table 6-1 below illustrates when products such as food, dietary supplements and cosmetics are exempt from classification as medicinal products and, accordingly, from the requirement for scientific testing in the three jurisdictions. As can be seen from the table, compared with Australia and Malaysia, the United States allows more exemptions. Malaysia, on the other hand, does not permit any exemption from drug classification if therapeutic claims are carried on advertisements. Although Australia currently exempts products in relation to which one type of claim is made from regulation, the FSANZ has proposed the introduction of seven additional claims.

Table 6.1: The types of permissible claims on advertisements (and labels) which will not result in the products being classified as medicinal products.

	Malaysia	Australia	USA
Food	*No Permissible Health claims *Nutrient Content Claims	*1 type of claim is currently permissible ¹¹⁶ *7 types of permissible claims proposed. ¹¹⁷ *Nutrients Content Claims *	*12 types of permissible health claims ¹¹⁸ *Claims based on 'Authoritative statements'. ¹¹⁹ * Qualified Claims ¹²⁰ * Nutrient Content Claims. *
Special Dietary Use	*Specific claims	Specific claims	Specific claims
Medical Food	Does not exist	Does not exist	Specific claims
Functional Food	No functional claims allowed	No functional claims allowed	Regulated as food
Dietary Supplements	No permissible claims	No permissible claims	*12 types of health claims permissible for food. *Claims that affect the structure and function of body claims. *Qualified health claims. *Nutrient Claims
Cosmetics	No functional claims	8 types of permissible claims ¹²¹	No functional claims

¹¹⁶ 'Maternal folate consumption with reduced risk of foetal neural tube defects in women around the time of conception'. See Australia New Zealand Food Standard Code Standard 1.1.A 2.

¹¹⁷ An additional seven types of claims have been proposed relating to: (1) calcium and vitamin D as a cause of a reduced risk of osteoporosis in women aged 65 years and above; (2) calcium as a cause of enhanced bone mineral density; (3) saturated fatty acids associated with a reduction of blood cholesterol, total blood cholesterol, blood low-density lipoprotein (LDL) cholesterol, total serum cholesterol and serum cholesterol; (4) saturated and trans fatty acids associated with a reduction in blood cholesterol, total blood cholesterol, blood (LDL)-cholesterol, serum LDL-cholesterol, total serum cholesterol or serum cholesterol levels and (5) sodium as a cause for the maintenance of normal blood pressure or reduced blood pressure in adults; (6) increased intake of vegetables and fruits associated with a reduction in the risk of coronary heart disease; (7) high intake of fruit and vegetables with a reduced risk of coronary heart disease. See [4.2.1.2] of Chapter 4.

¹¹⁸ (1) 'calcium and osteoporosis'; (2) 'dietary lipid and cancer'; (3) 'sodium and hypertension'; (4) 'dietary saturated fat and cholesterol and heart disease'; (5) '(fiber) containing grain products, fruits, vegetables, and cancer'; (6) 'fruits, vegetables, and grain products that contain fiber, particularly soluble fiber and risk of coronary heart diseases'; (7) 'fruits and vegetables and cancer' and (8) 'folate and neural tube defects'; (9) 'dietary non-cariogenic carbohydrate sweeteners and dental caries'; (10) 'soluble fiber from certain foods and risk of coronary heart disease (CHD)'; (11) 'soy protein and risk of coronary heart disease (CHD)' and (12) 'plant sterol/stanol esters and risk of coronary heart disease (CHD)'. See 21 C.F.R. § 101.72 (2008) to 21 C.F.R. § 101.83 (2008); [5.2.1.2] of Chapter 5.

¹¹⁹ They are issued by the 'scientific body of the U.S. Government or the National Academy of Sciences' under section 303 and 304 of the *Food and Drug Administration Modernization Act of 1997* (United States), (the 'FDAMA'). See [5.2.1.2] of Chapter 5.

¹²⁰ These are health-related claims that 'fall short' of establishing this requirement are currently permissible on labels if they have been argued to be in the best interest of the consumers. See Center For Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, United States, *Claims That Can be Made For Conventional Foods and Dietary Supplements*, (2003), 2. Also see [5.2.1.2] of Chapter 5.

¹²¹ The types of products include: (1) 'tinted bases of foundation (liquids, pastes or powder) with sunscreen'; (2) 'products intended for application to the lips with sunscreen'; (3) 'moisturizing products with sunscreen for dermal application including anti-wrinkle, anti-ageing and skin whitening'; (4) sunbathing products (for example, oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15; (5) antibacterial skin products; (6) anti-acne skin care

The significant differences in the exemptions from the classification of products as medicinal products in the three jurisdictions raise the question of whether there is a case for exempting further products from regulation in Malaysia. The paragraph below sets out the rationale for classification of products as medicinal products, with the aim of answering this question.

(a) *Why are Products classified as Medicinal Products?*

(i) *Access to Safe and Effective Products*

The classification of products as medicinal products is designed to ensure that consumers have access to safe and effective health products. In all three jurisdictions, medicinal products are scientifically tested for safety and efficacy before they are marketed. Ordinarily a team of chemists, pharmacologists and scientists, either within a government department or independent from government, reviews a company's data and supporting evidence regarding safety and efficacy of regulated products. Medicinal products will be approved for sale only if they are safe and effective. Post-marketing surveillance is also employed in all three jurisdictions so as to ensure that consumers continue to have access to safe and effective products, even after they are approved for sale.

The drug safety and efficacy assessment criteria, however, differ in the three jurisdictions. As seen at [4.2.1.5] and [5.2.1.5], both Australia and the United States employ a risk management approach to evaluate the safety and efficacy of medicinal products. This means that, while it is assured that medicinal products are safe and effective, the decision to release them onto the market is based on an assessment of whether the risk associated with the use of medicinal products outweighs the benefits derived from consuming the medicinal products. If it does, the medicinal products are refused registration; they may not be marketed to the public.

products (including spot treatments, cleansers, face scrubs and masks; (7) oral hygiene products for care of the teeth and the mouth (for example dentifrices, mouth washes and breath fresheners and (8) anti-dandruff hair care products. There are specific claim allowable in relation to these products. Limited functional claims are allowed. See *Therapeutic Goods (Excluded Goods) Order No. 1 of 2008*.

In Malaysia, on the other hand, as noted at [3.2.2], a selection criterion involving an analysis of disease pattern, cost effectiveness and therapeutic advantages is used. The manner in which this analysis is carried out is not stipulated. However, it appears that medicinal products which, after testing, are found to be safe and effective, are allowed registration, and thereafter distribution, if they prove to be clinically relevant, cost-effective and there are benefits in using the drugs. Importantly, there is no risk assessment in accordance with whether the benefits outweigh the risks associated with the use of medicinal products.

(b) Why are Products Exempted from Classification as Drugs?

(i). Approval Processes are tedious and long

As noted at [3.2.2], [4.2.1.5] and [5.2.1.5], obtaining an approval for product safety and efficacy is a tedious and long process. A sufficient level of information, data and evidence demonstrating safety and quality attributes of the product must be submitted. Reports on all testing, animal and human, must also be submitted. It is also a tedious process to obtain approvals when a product is changed. If changes are effected to the products after an approval is granted, further supporting information and data must be submitted to show that changes effected do not adversely affect the quality of the product. There is also a requirement that known and serious adverse experiences associated with the use of the drug, and any findings from laboratory tests, be provided.

Because the processes involved with approvals are long and tedious, it may be assumed that products which are low-risk may be justifiably exempt from this process. In particular, as health-related products are relatively less harmful than medicinal products, there may be less need for them to be subject to strict drug safety controls.

(ii) Costs Associated with Classification

As noted at [2.9.2.] regulatory costs may be assessed using economic analyses, such as cost-benefit and cost-effectiveness analyses. The costs of regulating medicinal products may be quantified in terms of the costs involved in carrying out the relevant test to prove

drug safety and efficacy, the cost of preventing harm to consumers, and the cost of enforcing a failure to comply with drug safety regulation. The costs may also be quantified in terms of time spent or labour employed, and materials used to carry out these tasks. The benefits must be assessed from the perspective of consumer protection and, in particular, how much effective protection can be ensured through drug safety controls. Moreover, the more effective the protection is, the less will be the costs imposed by adverse health effects arising from unsafe products.

It may be argued that, on the one hand, it may be cost-effective to protect consumers from harm by requiring all potentially unsafe products to undergo testing. On the other hand, it can be argued that it is more cost-effective to exempt low-risk products from costly scientific testing. Malaysia has clearly preferred to limit exemptions from the regulation of medicinal products. It therefore requires all products with medicinal claims to be proven safe and effective before they are marketed. Although there are no explicit policy statements to this effect, this is presumably because it is assumed to be better to ensure that all products with medicinal claims undergo scientific testing, before they are distributed, than to risk the harm caused by consuming unsafe and ineffective products.

It is clearly very difficult to determine the costs and benefits of classifying products as medicinal products in the abstract. Nevertheless, it can safely be assumed, especially given a lack of experience in this area, that the process for exempting products for classification in Malaysia may be less rigorous than the processes in Australia and the United States. Moreover, as explained above, while Australia and the United States apply a risk management approach to regulatory approval, Malaysia applies a different approach. As the possibilities of incorrect classification in Malaysia may be greater than in Australia or the United States, and as the costs of regulatory approval in Malaysia may be lower than the costs in the other two jurisdictions, applying the precautionary principle, it may be preferable for Malaysia to err on the side of caution, and refrain from introducing exemptions from drug safety controls.

6.1.3.6 Recommendations for Malaysia

Medicinal products are subject to drug safety controls in each of the three jurisdictions in order to ensure that they are safe to consume. However, products which may potentially be classified as medicinal products are, in some instances, exempt from classification. Consequently, they are also not subject to drug safety controls.

In both the United States and Australia, applying a risk management approach, products are cleared for marketing if the benefits associated with the use of the products outweigh the risks. In Malaysia, however, products which are proven safe and effective are marketed if they are clinically relevant, cost effective and have therapeutic advantages. As it appears that a comprehensive risk management evaluation is not undertaken in Malaysia, presumably the costs of regulatory approval are less than those in Australia or the United States.

Given the complexities involved in assessing the costs and benefits of exempting particular products from drug safety controls, it is impossible to make any definitive determination for Malaysia. Nevertheless, a preliminary recommendation can be made on the basis of the information available on the comparative regulatory regimes. First, it is clear that Malaysia has limited experience in determining whether products should be exempted from drug safety controls. Secondly, it appears that, given the differences in approach, the regulatory approval process in Malaysia may be less costly than the risk management processes in Australia and the United States, meaning that the costs of regulating products that are exempted from regulation in other jurisdictions may not be significant. Thirdly, in the Malaysian context, where health care may not be as accessible to the general community as in Australia or the United States, it may be preferable to err on the side of caution. It is therefore recommended that the existing system of classification of medicinal products in Malaysia, which does not include the product exemptions found in Australia or the United States, be retained.

6.3.2 Use of Rules in the Regulation of Medicinal Products

This section of the chapter compares and analyses the rules governing the advertising of medicinal products. It summarises and analyses the use of rules to prevent deceptive

advertising in the three jurisdictions dealt with in this thesis. It has been explained at [2.8] that regulation includes controls that involve the use of rules. As explained, rules include formal rules, which consist of primary legislation and delegated legislation, and informal rules, which include industry codes of practices, guidance and guidelines.

Section [6.3.2.1] compares and analyses the use of rules in the three jurisdictions according to the main objective of rule-making. Subsequently, section [6.3.2.2] sets out how a combination of different kinds of rules is used in the regulation of advertising of medicinal products either alone or in combination, may produce different regulatory outcomes. The aim of this section is to enable the recommendation of an appropriate mix of rules for the regulation of advertising of medicinal products in Malaysia and the appropriate mode of regulation to implement the control via use of rules, in [6.3.2.3].

6.3.2.1 Advertising Rules in the Three Jurisdictions

Rules in the three jurisdictions consist of a blend of primary legislation and other rules. While the three jurisdictions employ various types of rules, they differ in the combination of the kinds of rules used. In particular, the use of industry codes and guidelines is significantly different in the three jurisdictions. Moreover, apart from the different combination of rules, the common law principles interpreting the prohibitions on deceptive advertising have developed quite differently in the three jurisdictions.

(a) United States

In the United States, primary legislation is supplemented by a combination of delegated legislation and policy statements. As seen at [5.5.1], the combination of rules establishes a comprehensive and detailed system of regulation. The statute law that governs deceptive advertising is set out in sections 12 – 15 of the *Federal Trade Commission Act 1914* (United States), with the main rules being codified in 15 USC § 45(a)(1) (2008), 15 USC § 52 (a)(2) (2008) and 15 USCS § 58 (1996).

Further, as explained at [5.3.1], delegated legislation in the form of regulations is promulgated by two Federal agencies, namely, the FDA and the FTC. The FTC, which is the agency that regulates the advertising of medicinal products, makes regulations

governing the advertising of such products. The FDA, on the other hand, is responsible for the regulation of advertising of prescription drugs, and therefore formulates rules for their regulation.

The most important FTC actions have involved the development of informal rules to regulate advertising. As explained at [5.5.1.2] – [5.5.1.5], the FTC has documented the principles for deciding deceptive acts and practices in the FTC Policy Statement on Deception, and those relating to claim substantiation and fairness, in the FTC Policy Statement Regarding Advertising Substantiation and the FTC Policy Statement on the Scope of the Consumer Unfairness Jurisdiction, respectively. These Policy Statements, which are based on a substantial body of case law, are relied on by the FTC to regulate advertisers. Moreover, in recent times, the FTC has developed an important guideline to govern the advertising of dietary supplements.¹²²

In the United States, the use of industry codes or guidelines in the regulation of advertising of medicinal products is limited. Both the NAD and the CARU, which are the primary industry self-regulators for the regulation of advertising of products in the United States, are relied upon mainly to review advertisements before they are published, or for resolving disputes or complaints that are sent to these bodies.¹²³ The involvement of self-regulators in regulation, such as the review of advertisements and complaint handling in the three jurisdictions, is examined further below. Therefore, in the United States, while a complex combination of rules is used in the regulation of advertising of medicinal products informal rules is limited.

(b) Australia

As in the United States, a blend of statutory and non-statutory rules is used in the regulation of medicinal products in Australia. In Australia, as explained at [4.3], the advertising of therapeutic goods is governed by laws from three regulatory regimes: (1) Commonwealth; (2) States and Territories and (3) self-regulatory codes. Both

¹²² The Dietary Supplement: Advertising Guide for Industry; See [5.5.1.6] of Chapter 5.

¹²³ See [5.5.2.1] of Chapter 5.

Commonwealth, and States and Territories, jurisdictions have statute laws that govern advertising at two levels: one that applies specifically to the advertising of medicinal products and another to advertising in general.

As explained at [4.3.1.1], the Commonwealth *Therapeutic Goods Act 1989* (Cth) sets out broad principles governing the regulation of therapeutic goods in Australia. It also empowers the Governor-General to ‘...make regulations necessary ... for carrying out or giving effect...’ to the Act.¹²⁴ The *Therapeutic Goods Regulation 1990* (Cth) prescribes the rules for implementing the *Therapeutic Goods Act 1989* (Cth), while the *Therapeutic Good Advertising Code 2007* (Cth) sets out the principles governing advertising. In addition to industry-specific regulation, sections 52, 53 and 55 of the *Trade Practices Act 1974* (Cth), which is the law that governs advertising in general, plays an important role by regulating unacceptable conduct in trade or commerce.

Unlike in the United States, which relies almost entirely on government regulation, Australia has a comprehensive system of co-regulation, which uses informal rules in the form of industry codes of practice to inform and educate advertisers of their obligations. As noted at [4.3.1.3], the industry codes incorporate principles set out in the *Therapeutic Goods Advertising Code 2007* (Cth) and, in addition, require compliance with independently developed ethical and industry standards.

(c) *Malaysia*

In Malaysia, as in Australia, there are essentially two sets of laws governing advertising: one that governs advertising in general, and the other that specifically governs advertising of medicinal products. As explained in [3.3.1], rules governing advertising in general are stipulated in the *Consumer Protection Act 1999* (Malaysia) and the *Trade Description Act 1972* (Malaysia), while rules governing the advertising of medicinal products are set out in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). Unlike the position in Australia, however, the *Consumer Protection Act 1999* (Malaysia) and the *Trade Description Act 1972* (Malaysia), which govern advertising in general, do not apply to the regulation of advertising of medicinal products.

¹²⁴ *Therapeutic Goods Act 1989* (Cth) s 63.

In relation to court-developed rules, unlike in the United States and Australia, there has been no judicial development in Malaysia and, therefore, no opportunity to clarify some of the quite vague provisions in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia). For example, there is no explanation in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) as to what constitutes deceptive advertising and, more importantly, this term has not been clarified judicially.¹²⁵ Instead, advertisements have been considered as illegal advertising where they are disseminated to the public without approval from the MAB, or where there is non-compliance by advertisers with approved formats prescribed by the MAB. The basis upon which the Board determines that there has been non-compliance with the prescribed format is, moreover, not made explicit.

The MAB revised its earlier guideline (2008) and issued the *Guidelines on Medical Products and Appliances 2009* (Malaysia) which provides comprehensive guidelines governing the advertising of medicinal products. As the *Guideline* is a recent initiative, its effects are yet to be felt.¹²⁶ There are also guidelines established by industry but, as explained at [3.3.2], compliance with these guidelines is entirely voluntary. The *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia), for example, is a recent initiative from an industry association, the ASAM. While it is current, comprehensive and detailed, the rules are binding only on the members of the association.¹²⁷

(d) Conclusion

In conclusion, the three jurisdictions use a combination of different forms of rules in the regulation of advertising of medicinal products. Primary legislation is supplemented, to quite different degrees, by delegated legislation, policy guidelines, codes of practice, and industry guidelines. Both the United States and Malaysia regulate the advertising of medicinal products largely through formal rules, and make very limited use of informal rules, such as industry codes or guidelines. Australia, on the other hand, regulates advertising under a system of co-regulation which involves a combination of formal and

¹²⁵ See [3.3.1.1] of Chapter 3.

¹²⁶ See [3.3.1.1] of Chapter 3.

¹²⁷ As seen in [3.3.2.2] of Chapter 3.

informal rules and, therefore, makes greater use of industry bodies in the regulation of advertising of medicinal products.

The combination of different kinds of rules in the three jurisdictions raises the question of which combination is the most effective. This must be assessed by reference to the rationale for using different kinds of rules which, as explained at [2.8.2], is to enhance compliance with the rules. The following section evaluates the use of rules by focussing on how different kinds of rules, and combinations of different kinds of rules, may enhance compliance.

6.3.2.2 An Evaluation of Rules in the Three Jurisdictions

As explained at [2.8], regulation includes controls via the use of rules, and a combination of rules may be used in the regulation of behaviour or activities. In general, the need to use a combination of rules arises because all rules have inherent limitations, which prevent adequate regulation of behaviour or activities. As noted at [2.8.3] rules have been claimed to be inherently vague, indeterminate ‘over or under-inclusive’, and inaccessible. Using different kinds of rules in combination is thought to address some of the inherent limitations in rules and thereby enhance compliance with the law.¹²⁸

As noted at [2.8.3], various methods have been suggested to address the inherent limitations in rules. For example, Baldwin suggested a compliance-orientated approach. He argues that rules which are not easily understood will not be complied with, and therefore rules must be designed in a manner that focuses on improving compliance. Black, on the other hand, suggested three techniques to address the limitations, namely: (1) to use different ‘rule-types’; (2) ‘use and development of interpretative communities’ and (3) to alter the way in which rules are applied, namely the use of a conversational model of regulation, involving consultations and negotiations between regulators and ‘the regulated’.

As explained above, of the three jurisdictions, Malaysia employs the fewest kinds of rules. The following paragraphs explain why this presents a problem for Malaysia.

¹²⁸ See generally Julia Black, *Rules and Regulators* (Clarendon Press Oxford 1974), 20.

(a) *Combinations of Rules to Enhance Compliance*

Primary legislation is ordinarily framed in broad and vague terms in order to cover a combination of events or circumstances or to ‘control a wide span of activity’.¹²⁹ It therefore lacks a degree of clarity as to what is required for compliance with the law. Delegated legislation, codes and industry guidelines, on the other hand, can enable better compliance with legislation, by supplementing the rules in primary legislation. Different outcomes may, however, occur when the rules are used in different combinations.

As explained at [2.8.1], a legislature may pass a broad statute law, while leaving rules about the implementation of the law to delegated legislation. The executive is considered to be better equipped to make detailed rules than the legislature because it possesses the necessary information for the formation of specific rules to address problems as they arise, and is able to respond more expeditiously as circumstances arise.¹³⁰ In some instances, however, certain regulatory tasks may be delegated to industry with, for example, an industry association establishing rules to facilitate regulation.

As explained at [2.8.3], rules are necessarily imprecise, being both over-inclusive and under-inclusive. But the imprecision of rules may be addressed by taking the advice of theorists, such as Baldwin and Black. For example, following Black’s analysis, a combination of both rules and standards may be the best way of designing a system of rules. Furthermore, involving those that are subject to regulation in the making of rules may promote what Black refers to as the ‘conversational model’ of regulation, which will promote compliance with rules. As the next paragraph explains, these conclusions are supported by a cost-benefit analysis of rule-making.

(b) *Costs and Benefits Associated with Formal and Informal Rule-making*

In determining the appropriate level of precision or complexity of rules, it is important to understand the costs and benefits associated with making rules. To begin with, rules must

¹²⁹ Issac Ehrlich and Richard A Posner, ‘An Economic Analysis of Legal Rulemaking’ (1974) 3 *Journal of Legal Studies* 257, 264 & 267.

¹³⁰ See Georg Von Wangenheim, ‘Production of Legal Rules by Agencies and Bureaucracies’, Vol 9300 (2009) *Encyclopaedia of Law and Economics* 562.

be drafted so that they are sufficiently certain to be understood by those who are regulated by the rules. But there are different costs involved in making rules, depending upon how precise the rules might be. On the one hand, the more precise the rules are, the more costly they are to make. On the other hand, however, if rules are not precise or detailed enough, then they will not communicate sufficient information to those that are regulated to ensure compliance.

This problem may be addressed, to an extent, by employing differing combinations of rules with differing degrees of complexity. Thus, as enacting primary legislation through Parliament is relatively costly and time-consuming, it is best that this kind of rule-making takes the form of high-level principles. On the other hand, as industry groups have more information about the conditions in a particular industry, they are best placed to draft detailed rules implementing the less precise principles. Moreover, informal rules, such as industry codes, are more flexible, as it is easier to change this form of rule-making than it is to amend formal rules.

6.3.2.3 Recommendations for Malaysia

(a) Appropriate Mix of Rules

This section of the chapter makes recommendations about the appropriate mix of rules for the regulation of advertising of medicinal products in Malaysia. Before doing so, however, this section reviews some practical issues relating to the operation of rules in the three jurisdictions, which must be taken into account in making any recommendations.

In the United States and Australia, the regulations governing the advertising of medicinal products are generally comprehensive and up-to-date. The regulations have evolved over time, and in the process the scope of the laws has gradually expanded in response to the increasing complexity of the pharmaceutical industry. The position in Malaysia, however, is quite different. In Malaysia, because of the costs of litigation relative to average consumer income, consumers have been slow in bringing matters to court and therefore there has not been the opportunity for the common law to develop. Further, rules in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) are in fact inclined to protect industry,

although ostensibly expressed to be in the interest of consumers. As noted at [3.4.3], the sanctions specified for violations of laws under *the Medicines (Advertisements and Sale) Act 1956* (Malaysia) are relatively inconsequential, and the types of sanctions available are limited. Further, the defence clause is wide and excludes common forms of violations of laws from regulation.¹³¹ The publications of claims in brochures and pamphlets that are not intended for public viewing are excluded from regulation. In addition, action by public prosecutors is required before the regulator can bring an action in court.

The limitations of the Malaysian regulatory regime combine to prevent timely and effective action against industry and, in some instances, avoid effective control over industry activities. Moreover, the MAB, which is sufficiently empowered to establish regulations to address the limitations in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), has not established regulations to make up for any regulatory gaps. The preliminary conclusion that can be drawn is that the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is an example of the concerns expressed by the private theories of regulation explained at [2.4.3], being designed mainly to protect the interests of industry and not to protect consumers. There are clearly significant weaknesses in the Malaysian regime that must be addressed.

Comprehensive rules, such as those in the United States and Australia, are certainly desirable for the regulation of advertising of medicinal products; nevertheless, rules which are comprehensive, yet too complex and complicated, may not ensure adequate compliance or control. As pointed out by Baldwin, it is necessary to ensure that rules are sufficiently specific and precise, and have sufficient accessibility, intelligibility and enforceability.¹³² Rules must also be accompanied by qualities such as transparency, congruence and simplicity, as argued by Diver.¹³³ The mass of rules established in both the United States and Australia are comprehensive, but these systems are too complicated. As noted at [5.5.1], the voluminous rules in the United States for the regulation of advertising fail to provide a simple and practical guide to the problems posed

¹³¹ *Medicines (Advertisement and Sale) Act 1956* (Malaysia) s 5(3).

¹³² Robert Baldwin, 'Why Rules Don't Work' (1990) 53 *Modern Law Review* 321, 321-322.

¹³³ Colin S Diver, 'The Optimal Precision of Administrative Rules' (1984) 93 *Yale Law Journal* 65, 68.

by deceptive advertising. Rules in the United State have become unmanageably complex in their attempt to deal with every conceivable hazard.

In Australia, as noted at [4.3], there are both general and specific laws regulating advertisements of medicinal products in each States and Territories. The *Therapeutic Goods Act 1989* (Cth) and the accompanying regulation provide a national framework for the regulation of therapeutic goods, but this framework is yet to be uniformly adopted by all States and Territories.¹³⁴ The States and Territories also have their own specific and general laws governing the advertising of therapeutic goods, and this leads to a further lack of uniformity in the regulation of therapeutic goods. The general law, section 52 of the *Trade Practices Act 1974* (Cth), which is similarly worded to the relevant provisions in the Fair Trading Acts in the States and Territories, while essential to the regulation of advertising in general, represents a degree of duplication in this area.

Both better substantive and procedural laws for regulatory rule-making are required in Malaysia, and these rules should be simple, transparent and accessible. In this respect, lessons can be learned from the overly-complex American and Australian systems. On the other hand, as argued in this section of the chapter, regulatory compliance is best achieved through a combination of different kinds of rules. Compared with the systems in the two other jurisdictions, Malaysia places too much reliance on formal, government-made rules. While the *MAB's Guidelines on Medical Products and Appliances 2009* (Malaysia) and the *Malaysian Code of Advertising Practice (Third Edition) 2008* (Malaysia) are steps in the right direction, they need to be supplemented by further developments to produce more effective and flexible informal rules. In the terms proposed by Black, efforts should be expended in developing a more 'conversational model' of regulation.¹³⁵ Importantly, these endeavours should be more transparent than is currently the case, as this would serve to avoid the potential for industry to 'capture' government regulation, which appears to be a problem with the current Malaysian regime.

In short, a greater shared effort in terms of time spent, resources gathered and costs incurred in the formulation and implementation of rules is considered appropriate for the

¹³⁴ [4.3.1.2] of Chapter 4.

¹³⁵ [2.8.3] of Chapter 2.

regulation of advertising of medicinal products in Malaysia. This would also assist with improving the resourcing of regulation in Malaysia where, as explained in [3.4.2] of Chapter 3, lacks sufficient funding in the government sector to carry out the regulation effectively. As explained below, the recommendation also involves establishing an effective system of co-regulation in Malaysia.

(b) Alternative Mode of Regulation

This section of the chapter makes the recommendation with regard to the appropriate mode of regulation to be used for the regulation of advertising of medicinal products in Malaysia. However, before doing so, it assesses the advantages and disadvantages of using the varied modes of regulation in Malaysia.

As explained at [2.7], there is a continuum of modes of regulation that ranges from government (or ‘command and control’) regulation to self-regulation. Just as the United States and Malaysia rely primarily on regulation through formal rules, so do they prefer government regulation over alternative modes of regulation. Although Australia has a complex regulatory regime, it provides for alternative modes of regulation through its system of co-regulation. This section of the chapter briefly reviews the advantages and disadvantages of alternative modes of regulation before making recommendations for the mode of regulation to be adopted in Malaysia.

Section [2.7] of Chapter 2 dealt with the four modes of regulation that are most relevant to the regulation of advertising of medicinal products, namely government regulation, self-regulation, co-regulation and enforced self-regulation. Section [2.7] further explained that each of the modes of regulation examined in this thesis has distinct advantages and disadvantages. For example, while government regulation has democratic legitimacy, it tends to be inflexible and slow to adapt to change. At the other extreme, self-regulation is more flexible, and more responsive to the needs of industry, but is susceptible to being captured by the private interests of industry rather than serving the broader public interest. Moreover, industry groups involved in self-regulation may combine to act for anti-competitive purposes.

As further explained at [2.7.3], the appropriate mode of regulation cannot be determined in the abstract, but must take into account factors such as the costs of regulation and the harms sought to be redressed. Further, analysis of the different modes of regulation must depend, to an extent, upon the particular social, political and legal culture of the jurisdiction under consideration. Despite the need for caution, however, there are some clear advantages in mixed modes of regulation, such as co-regulation and enforced self-regulation.

As noted at [2.7.2.2], co-regulation combines features of both government regulation and self-regulation, with a role for industry participation in a regulatory regime underpinned by a legislative framework and government oversight. As such, co-regulation combines the advantages of government accountability and objective-setting, with the flexibility and industry-specific knowledge of industry groups. Nevertheless, the success of a co-regulatory regime depends upon a number of considerations, including the degree of commitment by the regulated industry and the five factors identified by Balleisen and Eisner.

As noted [2.7.2.3], enforced self-regulation differs from co-regulation in that it involves negotiations between government and individual firms in an ongoing collaborative process. Moreover, while co-regulation is essentially ‘top-down’, in enforced self-regulation government and industry regard each other as partners in a common endeavour. As explained at [2.7.2.3], enforced self-regulation has the advantages of implementing specifically tailored rules that have been collaboratively developed and more nuanced enforcement strategies. On the other hand, a system of enforced self-regulation is open to capture by the private interests of the regulated industry.

In general, then, the disadvantages of different modes of regulation may be minimised by combining the best features of government and industry regulation in a mixed system of either co-regulation or enforced self-regulation. In light of the advantages and disadvantages of these two modes of regulation that are spelt out in more detail at [2.7], the paragraphs below examine the relative merits of co-regulation and enforced self-regulation in the context of making recommendations for Malaysia.

While both co-regulation and enforced self-regulation have important strengths, it is important for any recommendation of the appropriate mode of regulation to fully take into account the context of regulation in Malaysia. In particular, enforced self-regulation, as explained by theorists such as Ayres and Braithwaite, depends upon the existence of a relatively sophisticated regulatory culture, with commitments by both government and industry to collaboratively working towards agreed objectives.

There are some features of the Malaysian regulatory regime, explained in Chapter 3, which suggest that, at present, the system of enforced self-regulation may be unsuitable for Malaysia. First, regulation in Malaysia is hindered by a lack of government resources. For example, the MAB is known to be understaffed, leading to deficiencies in monitoring compliance and enforcement. This suggests that a system which relies on the expenditure of a high level of resources on constant negotiations between government and industry is unlikely to be effective. There are simply insufficient resources available to effectively implement self-regulation. Moreover, the deficiencies of government regulation in Malaysia mean that enforced self-regulation would be even more susceptible to 'capture' by industry than the current system of government regulation. Secondly, enforced self-regulation depends upon a regulatory culture in which industry has a strong commitment to regulatory outcomes. In Malaysia, however, the relatively ineffective system of regulation of medicinal products has failed to eliminate unscrupulous operators, or rogues, who continue to profit from unlawful activities. A collaborative approach to regulation, such as enforced self-regulation, is unlikely to be effective to reign in persistently dishonest advertisers.

Although a system of enforced self-regulation would currently seem impractical for Malaysia, aspects of this system are something that Malaysia might aspire to in the future. In the meantime, steps could be taken in this direction by adopting elements of a system of co-regulation. Co-regulation is a preferable option for Malaysia, as it retains an important role for government supervision and enforcement. This effectively provides a safeguard to ensure that regulation does not simply become a tool for promoting the private interests of industry. Given the problem of the lack of resources available for government regulation, co-regulation also has the advantage of transferring some of the costs of regulation to industry. Furthermore, by enlisting the participation of industry within a framework established by government, co-regulation has the potential to foster a culture of compliance. In other words, co-regulation can give industry a stake in regulation.

Although this thesis recommends that Malaysia adopts elements of a system of co-regulation, it is important to bear in mind that, as Balleisen and Eisner point out, the success of such a system depends upon how it is designed. For example, it is important that responsibility for particular regulatory functions is sufficiently certain. Moreover, it is vital that the regulatory is transparent and accountable. This is especially important for Malaysia, as transparency of decision-making has not been a strong feature of government regulation. Finally, even if co-regulation may involve industry sharing some of the burdens of the costs of regulation, it is important that sufficient resources be expended by government to ensure adequate supervision of a co-regulatory system, as well as adequate enforcement of the regime. If co-regulation is to be adopted, it may well be that in the early stages some resources will need to be expended in training industry groups on how best to perform their roles in a co-regulatory system.

While the analysis conducted at [2.7] suggests that there are advantages in enforced self-regulation, this thesis recommends that Malaysia consider the implementation of a system of co-regulation in the regulation of advertising of medicinal products. Although there would be short-term costs in moving away from government regulation and towards co-regulation, it is likely that the longer term benefits, in terms of both efficiency and effectiveness, would justify movement in this direction. Further, adopting a system of co-regulation may have the additional benefit of promoting more of a culture of accountability and transparency that exists under the current system of government regulation. This might be possible, for example, because of the need for government to share more information with industry in co-regulatory system.

6.3.3 Regulatory Controls of Products Classified as Medicinal Products

As has been explained at [2.5.2.1], the primary rationale for regulating the advertising of medicinal products is to prevent the harms to consumers that may arise from the information asymmetry between industry and consumers. The extent to which regulatory controls ensure that this outcome is achieved in the three jurisdictions is examined in this section of the chapter. Accordingly, Section [6.3.3.1] compares the three main types of regulatory controls employed in the regulation of advertising of medicinal products in the three jurisdictions, namely: (1) pre-approval of advertisements; (2) monitoring of non-

compliance with rules and (3) enforcement of violation of advertising rules. The three jurisdictions have a variety of strengths and weaknesses in the system of regulatory controls and these are also explored at [6.3.3.1]. The analysis of the regulatory controls, including their costs and benefits, is carried out at [6.3.3.2]. The objective of this analysis is to enable recommendations for Malaysia for the preferred forms of regulatory controls.

6.3.3.1 The Three Types of Regulatory Controls in the Three Jurisdictions

This section examines the approaches adopted, and strategies used, in administering the three types of regulatory controls identified above in the three jurisdictions. It also explains the bodies responsible for the implementation of these controls, and the main features of the regulatory controls in each of the jurisdictions. The similarities and the differences in each of these controls in the three jurisdictions are then analysed.

(a) Pre-approval of Advertisements

As explained at [1.3.1.2] of Chapter 1, pre-approval of advertisements refers to a process where advertisements are checked for untrue, misleading or highly exaggerated medicinal claims before they are disseminated to the public. This process is carried out to protect consumers from deceptive claims in advertisements. As explained at [2.8.4.1], pre-approval of advertisement is a form of control which is carried out to prevent irreparable harm that may be caused by a violation of rule. Advertisers are required, or encouraged, to submit advertisements for review to either a government regulator or an independent body before the advertisements can be published or broadcast.

This system of pre-approval of advertisements is not uniformly practised in the three jurisdictions. In this respect, four divergent aspects of the system of pre-approval of advertisement are singled out for discussion in this section, namely: (1) whether pre-approval of advertisements is compulsory for all medicinal products and in all media; (2) the nature of the body responsible for the pre-approval of advertisements; (3) whether there is full transparency in the system of pre-approval of advertisements and (4) whether pre-approvals are conducted in a timely manner. This section of the chapter also examines the strengths and weaknesses of the approaches adopted to these aspects of regulation in each of the jurisdictions.

(i) *Compulsory Pre-Approval*

As described in [3.4.1], in Malaysia it is a mandatory requirement for sellers, or advertisers, to obtain pre-approval of advertisements for all products with medicinal claims, irrespective of the medium of dissemination. This is, however, not the case in Australia, where the type of publication determines whether pre-approval is required. In Australia, as explained in [4.3.2.1], advertisements of 'designated therapeutic goods' published in specified media are subject to a pre-approval process. Designated therapeutic goods are therapeutic goods other than prescription drugs, and if advertisements of these products are published in mainstream media, broadcast media, cinematographic films or advertisements on outdoors display they are subject to a pre-approval process. On the other hand, advertisements that are placed on leaflets, indoor posters, catalogues, flyers, brochures and the Internet, are not.

In the United States, as explained at [5.4.2.1], 'drugs approved on an accelerated basis' (DAAB) that are advertised in all media are subject to a pre-approval process. DAAB are new drugs that treat serious or life threatening illnesses, and are given initial approval without the immediate proof of 'clinical benefits'. However, other types of products - prescription drugs and non-prescription drugs, and products such as food, dietary supplements and cosmetics that qualify as medicinal products - are not required to be pre-approved.

(ii) *Bodies that Grant the Pre-Approvals of Advertisements*

The pre-approval of advertisements of medicinal products is granted by different bodies or agencies, and by different processes, in the three jurisdictions. In Malaysia, as seen at [3.4.1], pre-approval is granted by the MAB, a government agency. This agency maintains sole control over the approval of advertisements for the entire country.

In Australia, the government regulator, the Therapeutic Goods Administration, has delegated the task of pre-approval of advertisements to two industry-based regulators, the ASMI and the CHCA.¹³⁶ As explained at [4.3.2.1], advertisements for complementary

¹³⁶ See [4.3.2.1] of Chapter 4.

medicines, disseminated in broadcast media and mainstream media are sent for pre-approval to the ASMI and the CHCA, respectively. Advertisements for non-complementary medicines (over-the-counter drugs), disseminated in the broadcast media and mainstream media, on the other hand, are dealt with by ASMI.

In the United States, as noted at [5.5.2.1], advertisements for medicinal products are not subject to a compulsory review by the FTC, the regulatory agency, but are encouraged to be submitted for review by the NAD, a self-regulatory organization which assists the FTC with the assessment of advertisements. The FTC is also assisted by the Council for Responsible Nutrition (CRN), a trade organization for dietary supplements, in the review of advertisements for dietary supplements.¹³⁷

(iii) *Full Disclosure*

An important aspect of any regulatory regime is the extent to which advertisements which are pre-approved are published. Publishing details of advertisements which are found to be false or misleading may serve a number of purposes: (1) it may inform advertisers of the do's and don'ts regarding making claims in advertisement; (2) it may encourage advertisers to comply with regulations so as to avoid negative publicity; (3) it may also prevent repeated non-compliance and encourage a more vigilant approach to future advertising and (4) it may inform consumers about false and misleading claims in advertisements which may prevent them from consuming the products.

In the United States, reviews of advertisements are made openly available for public viewing;¹³⁸ but the same cannot be said for Australia and Malaysia. In Malaysia, advertisements which were considered illegal were briefly published online for public viewing, but this practice was discontinued in 2005 and has not been revived since.¹³⁹ In

¹³⁷ John E. Villafranco and Andrew B. Lustigman, 'Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration and National Advertising Division' (2007) 62 *Food and Drug Law* 709, 710.

¹³⁸ See 5.5.2.1 of Chapter 5. The decisions by the NAD are press released and published in monthly reports. See Jeffrey S. Edelstein, 'Self-Regulation of Advertising: An Alternative to Litigation and Government Action' (2003) 43(3) *Idea* 509, 521.

¹³⁹ A compilation of advertisements which carried prohibited health-claims are listed in the official website belonging to the Medicine Advertisement Board. See Medicine Advertisement Board of Pharmaceutical

Australia, advertisements which are pre-approved or rejected by ASMI and the CHCA are not published for public viewing.¹⁴⁰

(iv) *Timely Pre-Approvals*

An important aspect in determining the success of the pre-approval of advertisements is the speed at which approvals are granted. Advertisers and industry naturally favour an expeditious approvals process because they could proceed with the advertising without delay. Moreover, if pre-approval is not mandatory, timely approvals encourage advertisers to submit advertisements for review. At present, between 3 to 5 days is taken for pre-approval of advertisements in Australia by the ASMI and the CHCA.¹⁴¹ In Malaysia, it is claimed that approval for the advertising of medicinal products takes between 3 to 6 weeks, unless they are 'fast track approvals', in which case it takes approximately 3 to 5 days.¹⁴² In reality, however, this time frame is not adhered to. In the United States, as discussed at [5.5.2.1], the NAD takes from 15 days to 2 months to review advertisements.

(v) *Summary*

In conclusion, it is noted that each of the three jurisdictions employ a process of pre-approval of advertisements prior to publication, but implement the pre-approval processes differently. In some instances pre-approvals are compulsory for all types of products, and in others it is for all types of media. Further, the bodies that grant approvals are different and pre-approved advertisements are not published in all three jurisdictions. The time taken for granting approval also varies across the three jurisdictions.

Service Division of the Ministry of Health, Malaysia, Case Report
<http://www.pharmacy.gov.my/html/MAB/advertisement_board_legal_action_f.htm>.

See Appendix C of this thesis, for compilation of cases by Ghazali Mansor, Legal Section of the Pharmacy Enforcement Section, Ministry of Health Malaysia.

¹⁴⁰ See [4.3.2.1] of Chapter 4. ASMI reports on its decisions with regard to sanctions, right of appeals and monitoring in its Annual Reports. See *ASMI Code of Practice 2009* s 8. Similarly, CHCA keeps data on the number of complaints lodged and by whom; the number found to be in breach of the code and why; details of the action taken; the number found not to be in breach of the code and why; time taken to deal with complaints, how many items were monitored within each category, and how many monitored were found to be in breach and why and action taken. See *CHCA Code of Conduct 2005* s 8.10.

¹⁴¹ [4.3.2.1] of Chapter 4.

¹⁴² [3.4.1] of Chapter 3.

The differences in pre-approval processes have an influence on other aspects of regulatory controls, namely, the monitoring of violations of laws and the enforcement of sanctions. For example, a jurisdiction which does not compulsorily require ex-ante pre-approval of advertisements must place greater reliance on ex-post enforcement, adopting an active form of monitoring or pursuing more vigorous enforcement. These two forms of regulatory control are dealt with in the following sections.

(b) Monitoring of Violations of Laws

As explained at [2.8.4.2], monitoring is a form of ex-post regulatory control which is carried out after a violation has occurred. It is carried out so as to identify violations of regulations and bring about appropriate measures to prevent violations from recurring. It aims to ensure that promotional activities conform to the standards established by law. This section examines the types of monitoring which are carried out in the three jurisdictions. It explores the similarities and differences in the system of monitoring of non-compliance with the rules so as to gain a perspective on how monitoring is practised in Australia and the United States.

Unlike the system of pre-approval of advertisements, monitoring violations of advertising regulation is fundamentally similar in the three jurisdictions. In each jurisdiction, it is carried out by both government regulators and industry-based bodies. There are, however, important differences in the types of monitoring practised in the three jurisdictions, ranging from monitoring that is relatively proactive to passive, random or spontaneous monitoring.

The three jurisdictions all have, within their respective government departments, investigation units which conduct regular investigations and monitor breaches. For example, in Malaysia, an investigation unit within the relevant government department (known as the Advertisement Control Team) is responsible for the investigation of claims against advertisements that have been found to have breached the advertising laws.¹⁴³ Malaysia has also engaged the services of a private limited company, the MediaBanc Sdn. Bhd, to scrutinize advertisements. The monitoring by this company is proactive, but is

¹⁴³ See [3.4.2] of Chapter 3.

restricted to advertisements placed on the Internet.¹⁴⁴ It appears that proactive monitoring may be limited in Malaysia because of reliance on the system of mandatory pre-approval of advertisements, which may be perceived to be sufficient to control dissemination of deceptive advertising in media other than the Internet. In addition, it may be that insufficient resources have been allocated to monitoring.

As noted at [5.4.2.2], in the United States, the monitoring of violations of laws is carried out by the Center for Drug Evaluation and Research (the 'CDER') through its Division of Drugs, Marketing, Advertising and Communications (the 'DDMAC'). This Division, among other things, identifies violations through monitoring or through complaints from competitors. In addition, monitoring is also carried out by the Bureau of Consumer Protection ('BCP'). As noted at [5.5.2.1], the Division of Advertising Practices within the BCP, among other responsibilities, oversees advertising practices and initiates administrative and enforcement actions for violations in the Federal District Court. In addition to scrutiny by government agencies, advertisements are also constantly monitored by the staff of the NAD.¹⁴⁵ Hence, in the United States, the lack of a system of pre-approval of advertisements is, to an extent, compensated for by active and vigorous monitoring by not only two Divisions of the relevant government department, but also by industry self-regulation.

As seen at [4.3.2.2], in Australia, the Therapeutic Goods Administration monitors violations of advertising laws. In addition, industry self-regulators proactively monitor selected promotional material and activities of member companies.¹⁴⁶ The ASMI Promotional Panel, the CHCA Code Administration Committee and the Medicine Australia Monitoring Committee are the three main industry self-regulatory bodies that monitor non-compliance on a regular and ongoing basis. Despite this, the significant number of complaints and cases involving breaches of the Therapeutic Goods Act, the accompanying regulations and the Code suggests that the level of monitoring may not have been adequate to deter breaches. A study conducted for the World Health Organization (WHO) by

¹⁴⁴ See [3.4.2] of Chapter 3.

¹⁴⁵ [5.5.2.1] of Chapter 5.

¹⁴⁶ See [4.3.2.2] of Chapter 4.

Ratananwijitrasin and Wondemagegnehu on the effectiveness of drug regulation concluded that the monitoring of advertisements in Australia was mostly passive, relying mainly on complaints from consumers and competing companies.¹⁴⁷

(c) *Enforcement*

The final form of regulatory control dealt with in this section of the chapter is the enforcement of violations of advertising laws.¹⁴⁸ Essentially, two forms of enforcement are available in the jurisdictions examined in this thesis: (1) complaint handling and (2) judicial enforcement. As noted at [3.4.3], [4.3.2.3], [5.4.2.3], and [5.5.2.2], as an initial step and prior to resorting to judicial enforcement, a regulator may address complaints filed by competitors, consumers or public interest groups. The usual process is that a regulator investigates these complaints and deals with them administratively. The regulator may require the advertiser to either remove the advertisement or correct it. Subsequently, a failure to abide by this request will result in the matter being referred for judicial enforcement. In some instances, industry associations handle the complaints before the matter is referred to the regulator. In the event of a failure to comply with the request of an industry complaint panel, the matter may be referred to government regulators for further action.

This section of the chapter examines the manner in which the enforcement of violation of advertising rules is carried out in the three jurisdictions. It explores the similarities and differences in the system of enforcement in the three jurisdictions so as to enable an understanding of the rationale for the diverse approaches in the three jurisdictions.

Enforcement differs in the three jurisdictions with regard to each of the following matters: (1) the process of complaint handling; (2) the types of orders that may be granted; (3) recourse to judicial enforcement and (4) the types of sanction imposed and the frequency with which they are imposed. The similarities in the three jurisdictions are that the

¹⁴⁷ Sauwakon Ratananwijitrasin and Eshetu Wondemagegnehu, *Effective Drug Regulation*, (World Health Organization 2002), 104-105.

¹⁴⁸ Robert Baldwin and Martin Cave, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press, Oxford, USA, 1999), 96.

regulatory regimes initially seek to resolve complaints about deceptive advertising through regulatory processes before recourse to formal judicial enforcement.

(i) *Complaint Handling*

In Australia, as seen at [4.3.2.3], four different panels, namely, the Complaint Resolution Panel (CRP) and complaint handling committees within the ASMI, the CHCA and the Medicine Australia, handle complaints regarding deceptive claims of medicinal products in advertisements. The types of products, and the media in which advertisements are published determine the committee or panel which will deal with the complaints. The CRP handles complaints about advertisements of designated therapeutic goods directed at consumers, published in specified media or broadcast media. The ASMI and the CHCA deal with complaints forwarded by consumers or competitors on deceptive claims with regard to non-prescription drugs and complementary medicines, respectively. Finally, the Medicine Australia deals with complaints regarding prescription drugs.

The CRP, where it finds non-compliance with rules and orders for its rectification in a complaint handling process, is not able to impose sanctions for failure to comply with its orders. These matters have to be referred to another authority, the Secretary of the Department of Health and Ageing. Furthermore, the types of sanctions that may be ordered are also limited, namely withdrawal of advertisements or parts of advertisements, or the publication of a retraction or corrections.

The ASMI and the CHCA, on the other hand, may impose a diverse range of sanctions. First, they can require a written undertaking to discontinue the contravening practice or to cease publication of the advertisement. Secondly, where claims made in advertisements have not been appropriately substantiated, the regulators can require that substantiation be given by the complainant. Thirdly, the regulators can require retraction statements, or corrective statements or advertising. Finally, fines may be imposed and, in some instances, members may be expelled or their membership in the industry association suspended.

There are some important differences between the complaints handling system in Australia and the way in which complaints are handled in the United States. As noted at [5.5.2.2], the FTC does not handle individual complaints; instead it handles claims in bulk. It

compiles complaints about companies, business practices, thefts, or episodes of violence in the media so as to detect patterns of wrong-doing. It then leads investigations and prosecutions to address the problems. The usual procedure adopted by the FTC is to first attempt to reach an agreement with 'the regulated' to stop the disputed practices. Accordingly, 'the regulated' are requested to enter into a consent order, without any admission of guilt. On the event of a failure to obey the consent order, an administrative proceeding, which is similar to a court trial, is initiated.

As further noted at [5.5.2.2], the FTC has authority to take a broad range of actions. Its power includes not only 'cease-and-desist' orders, or the publication of corrective statements, but also the ability to publicise a breach by issuing a press release upon entering a consent decree..

In Malaysia, as noted at [3.4.3.1], the MAB may, upon receiving a complaint from an individual or competitor, investigate the claim and issue a warning letter requesting the advertiser to remove the advertisements. Failure to comply with the request may result in the matter being taken to the courts. However, unlike in the United States and Australia, the MAB may not bring the matter to court unless the action is initiated by the complainants themselves and is endorsed by the Public Prosecutor.¹⁴⁹

(ii) *Judicial Enforcement*

With regard to judicial enforcement, as noted at [5.5.2.2] and [4.3.2.4], both the United States and Australia adopt a relatively vigorous approach. As explained at [3.4.3.2], however, Malaysia is not proactive in this area. Moreover, in Malaysia, advertisers who are charged with misleading advertisements commonly plead guilty and pay fines, largely because the fines are relatively small. The problem with this is that pleading guilty to the charge and paying the fines are cost-effective alternatives to challenging the regulators and having the matter tried in the courts, meaning that the penalty is treated as an

¹⁴⁹ Section 6F (1) of the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) prohibits prosecution under the Act unless with the sanction of the Public Prosecutor. By this it means that a written approval must be obtained from the Public Prosecutor before a case can be brought to court.

acceptable cost of doing business. As a result, in Malaysia there have been no cases involving deceptive advertising of medicinal products challenged in courts to date.¹⁵⁰

Judicial enforcement differs profoundly across all three jurisdictions not only due to the frequency with which matters are litigated, but also because of the varied fines ordered. The types of legal remedies that arise as a consequence of the violation of advertising laws and regulations in the United States include: (1) temporary restraining orders and permanent injunctions; (2) criminal prosecutions; (3) cease-desist-orders; and (4) press releases.¹⁵¹ Corrective advertising and hefty fines are also granted.¹⁵² Similarly, in Australia all such legal remedies are available and those who violate the law are aggressively pursued with legal actions. Orders such as removal of advertisements or placement of corrective advertising are commonly granted by the courts.¹⁵³ Malaysia, on the other hand, is comparatively weak in judicial enforcement. Not only have there been minimal fines imposed for the violation of advertising laws, but the courts have not imposed sanctions such as corrective advertising, or cease-desist-orders, so as to effectively deter future occurrences of deceptive advertising.¹⁵⁴

(d) Implementation of Regulatory Controls in the Three Jurisdictions

In summary, it has been noted that the three jurisdictions employ similar forms of control in the regulation of deceptive advertising; however, the three regimes differ in the methods of implementing the controls. The above comparison has indicated that it is important to consider the controls wholistically, as a lack of control, or a lesser form of control, in one aspect of regulation may be made up for by a more stringent form of control in other aspects of regulation. Monitoring and enforcement are clearly less stringent in Malaysia when compared with Australia and the United States, but this may, to an extent, be compensated for by a stricter system of pre-approval of advertisements. The rationale for lesser monitoring may be that it is assumed that deception will be rectified before

¹⁵⁰See [3.4.3.2] of Chapter 3.

¹⁵¹ See [5.5.2.2] of Chapter 5

¹⁵² See [5.5.2.2] of Chapter 5.

¹⁵³ See [4.3.2.4] of Chapter 4.

¹⁵⁴ See [3.4.3.2] of Chapter 3.

advertisements are published or broadcast through the system of pre-approval of advertisements.

Regulatory controls in the three jurisdictions therefore have different strengths and weaknesses. Section [6.3.3.2] of the chapter analyses the strengths and weaknesses of the regulatory controls in the three jurisdictions, so that recommendations can be made to improve the regulatory process in Malaysia.

6.3.3.2 An Evaluation of the Regulatory Controls in the Three Jurisdictions

This section analyses the strengths and weaknesses of the three types of regulatory controls so as to suggest practical solutions to the problem of determining the best mix of regulatory strategies. It does so by examining the costs and benefits of the different types of regulatory control. Once the costs and benefits are analysed, this will enable us to make the appropriate recommendations to deal with the weaknesses in the Malaysian regulatory regime. Hence, each of the three regulatory controls, namely, the pre-approval of advertisements of medicinal products, the monitoring of violation of advertisements, and enforcement of violation of advertising laws are discussed immediately below.

(a) Pre-approval of Advertisements

The Australian regime for pre-approvals of advertisements was reviewed in a report by Toogoolawa Consulting in 2002, known as the 'Toogoolawa Report', as part of a process for determining whether to establish a new Trans-Tasman regulatory agency for the advertising of therapeutic products.¹⁵⁵ Although it was eventually decided not to proceed with the proposed new agency, the analysis presented in the report remains useful in the examination of advertising pre-approvals.

There are three important issues to consider in the analysis of a pre-approvals system: (1) the advertisements which should be subject to pre-approval; (2) the bodies who should be responsible for pre-approving advertisements and (3) the processes adopted for pre-approving advertisements.

¹⁵⁵ Toogoolawa Consulting Pty Ltd, *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand* (November 2002). ('Toogoolawa Report')

First, in relation to the advertisements subject to pre-approvals, the Toogoolawa Report pointed out that, unless some distinction is drawn between products the advertising of which requires pre-approval from those which do not require pre-approval, the system would have too many advertisements to process, which would make regulation unwieldy and too costly.¹⁵⁶ It is therefore important to establish some means for drawing this distinction. As the report went on to explain, given the objectives of regulating the advertising of medicinal products, the dividing line should be logically drawn on the basis of the degree of risk posed by the products, and not on the type of media used to advertise the products.

After pointing out the complexities involved in distinguishing between products on the basis of risk, the Toogoolawa Report made the following observations, which emphasise the importance of understanding that pre-approvals are but one aspect of a comprehensive system of regulatory controls:

... there is no definition that will achieve a perfect risk-based dividing line. However, putting a “best initial effort” in place will be recommended on the basis that a robust complaints process and external auditing procedures would enable the ... [regulator] ... to assess whether the definition was allowing too many risk-bearing advertisements to appear or requiring pre-approval for too many without significant risk.¹⁵⁷

No system for distinguishing advertisements that are subject to pre-approval from those that are not, including the regulatory distinctions drawn in Australia and the United States, is perfect. Nevertheless, this thesis considers that a best practice regulatory system should make a distinction on the basis of a risk-based analysis. Moreover, in doing so, it is important to take into account the ‘precautionary principle’ referred to at [2.9.2], meaning that it matters relating to the protection of health and life, it is normally best to err on the side of caution.

¹⁵⁶ Ibid 76.

¹⁵⁷ Ibid 78.

Regarding the regulatory bodies responsible for pre-approving advertisements, the Toogoolawa Report pointed out that there are inefficiencies involved in having multiple bodies responsible for pre-approvals for different products and different media. The existence of different regulators can, for example, lead to inconsistencies in decision-making. The Report therefore recommended establishes a 'one-stop-shop' for pre-approving advertisements across all media.¹⁵⁸ This thesis agrees that such a proposal would considerably simplify the regimes for pre-approving advertisements in both Australia and the United States, and result in cost-savings for both industry and regulators.

While consolidating regulatory authority is desirable both in terms of consistency and cost-effectiveness, this still leaves the mode of regulation for pre-approvals to be determined. As explained at [6.3.3.1] above, hybrid modes of regulation, such as co-regulation and enforced self-regulation, are generally to be preferred, as they can combine the best features of government regulation and industry self-regulation. As further explained at [6.3.3.2], particular features of the Malaysian regulatory system, including a relative lack of resources for government regulation and the need to develop a regulatory culture, suggest that co-regulation should be preferred in Malaysia. This would, for example, mean that the costs of employing staff to review advertisements could be borne by industry associations, which may be better equipped in terms of human and financial resources than the government. Moreover, a system of co-regulation may have a better chance of successfully controlling deceptive advertising as industry groups likely have a much better understanding of the issues and problems in the industry than does government. The integrity of a co-regulatory system is ensured because the system is backed by the force of law. Furthermore, the threat of litigation if rules are violated provides sufficient incentive needed for compliance with the law. Finally, to improve the efficiency of the regulatory processes, the Toogoolawa Report recommended that the regulatory responsible for pre-approvals be given the ability to delegate certain decisions, especially in relation to lower risk products.¹⁵⁹ This is certainly an option that may be worth exploring.

As was further pointed out at [6.3.3.2], an important advantage of a system of co-regulation, which involves ongoing collaboration between government and industry, is that

¹⁵⁸ Ibid 76.

¹⁵⁹ Ibid 75-6.

it may improve transparency in decision-making. This brings us to the processes adopted for pre-approving advertisements. In general, there are two common weaknesses in the systems for pre-approval of advertisements dealt with in the jurisdictions studied in this thesis: (1) a lack of transparency in decision-making; and (2) delays in the process of pre-approval. Together these limitations seriously hinder adequate regulation of advertising of medicinal products.

Transparency with regard to the types of claims that are approved and/or refused approval is thought to alert advertisers to the prohibited claims as well as, ultimately, to assist consumers. Transparency also ensures the accountability of decision-makers, and provides an educative role, as industry can closely observe the sorts of claims that are denied approval. As the Australian Toogoolawa Report pointed out:

Consistency and transparency are accepted as very important criteria that must be met if any ... advertising scheme is to be successful.¹⁶⁰

Whatever the mode of regulation that is adopted, there may be incentives for decision-making not to be fully transparent. Governments, for example, may not wish information to be revealed that reflects a failure to adequately protect the health of their citizens. Industry, on the other hand, may be embarrassed by information revealed that tarnishes the reputation of firms, potentially leading to lower sales. The benefits of transparency, both in terms of ensuring consistent decision-making and the accountability of decision-makers, far outweigh any disadvantages. Consequently, it is essential for regulators responsible for pre-approval of advertising to publish full reasons for their decisions. As the reasons should be as widely available as possible, it would be helpful for them to be published on the Internet. Any commercially confidential information can, of course, be redacted.

The other problem commonly identified with the processes for pre-approving advertisements for medicinal products is the duration of time taken to grant pre-approvals. Where pre-approval is not mandatory, prompt decisions are thought to encourage submission for review by advertisers. Moreover, as noted in [2.8.4.1], the main problem associated with delays in granting timely pre-approval is that a firm is prevented from

¹⁶⁰ Ibid 96.

engaging in potentially beneficial activities, such as marketing valuable products, until the approval is granted. Any significant delay means lost productivity for the firm, and this can easily result in the firm by-passing pre-approval processes when they are not compulsory. On the other hand, rapid approvals may also be questionable, as it is possible that the advertisements may not be reviewed properly, meaning that false or misleading claims may reach consumers. The objective of pre-approval of advertisements in preventing or filtering deceptive claims so as to protect consumers therefore would not be achieved. Consequently, it is important for regulatory processes to be established which ensure timely decision-making, while not sacrificing the quality of decision-making.

(b) *Monitoring Violation of Laws*

Despite claims of active monitoring, the number of deceptive advertisements in all three jurisdictions has apparently not decreased.¹⁶¹ This clearly raises the question as to whether monitoring in any of the three jurisdictions has been effective. It has been noted that in all three jurisdictions, monitoring of violation of laws by industry or, as in Malaysia, by an independent body, is accepted as part of the overall strategy of regulating in a cost-efficient manner. This section of the chapter therefore seeks to identify the role of monitoring as a regulatory control, and how this role can best be performed.

As noted at [2.8.4.2], a system of monitoring violations is a common system of ex-post enforcement. As further noted, a distinction is drawn between passive monitoring, which relies upon complaints from consumers and competing companies, and proactive monitoring, which involves regular or sporadic checking of conduct. In general, proactive monitoring, whether it is regular or sporadic, is to be preferred to passive monitoring, as it is better for deceptive advertisements to be detected than to wait for consumers or competitors to complain. As with other regulatory controls, however, for proactive monitoring to be effective, sufficient resources – both human and financial – must be allocated. Moreover, it must be borne in mind that a system of monitoring can only be effective as a deterrent if it is accompanied by a stringent system of enforcement.¹⁶²

¹⁶¹ See [3.4.3] of Chapter 3, [4.3.2.3] of Chapter 4 and [5.5.2.2] of Chapter 5.

¹⁶² Robert Jackson and David Rosenberg, 'A New Model of Administrative Enforcement' (1983) 93 *Virginia Law Review* 1983, 1984-1985.

Finally, as noted at [2.8.4.2] the method suggested by Jackson and Rosenberg, namely, a system of selective monitoring accompanied by high penalties, is likely to be the most effective system of monitoring.¹⁶³

Monitoring is an essential part of an overall system of regulatory controls over advertising of medicinal products. This is because reliance on ex-ante pre-approval of advertising alone is likely to lead to under-deterrence. Likewise, reliance solely on passive monitoring, such as consumer complaints, is also likely to be less than effective. Applying the precautionary principle, it is important to ensure that all reasonable steps are taken to protect health and life. Nevertheless, applying cost-benefit analysis, important decisions need to be taken in relation to the amount of resources expended in monitoring compliance. As explained at [2.8.4.2], monitoring must be carried out cost-effectively. This certainly means that sufficient resources, both human and financial, need to be dedicated to monitoring. At the same time, the potentially high costs of ex-post enforcement strategies mean that these resources should not be at the expense of the resources needed for ex-ante pre-approvals. Finally, as further explained at [2.8.4.2], while monitoring increases the chances of harmful conduct being detected, its deterrence value depends upon the extent to which breaches are enforced. A balance must therefore be struck between the mix of regulatory strategies employed, including ex-ante pre-approvals, monitoring and enforcement. The next section of the chapter therefore addresses the issues involved in designing an effective system of enforcement.

(c) *Enforcement*

As noted at [2.8.4.2], given its deterrent value, ex-post enforcement may well determine the success of regulation. A common perception of weaknesses in the regulation of advertising of medicinal products has been that the laws have been poorly enforced. This is especially the case where industry is involved with regulation, as it is perceived to have little independent incentive to impose harsh penalties.

There are some particular features of the advertising of medicinal products that need to be taken into account in designing an enforcement regime. In particular, it is important to fully

¹⁶³ Ibid 1984-1985.

understand the costs involved with enforcement strategies in this area. The nature of advertising is that it may create a lingering impression about the product that can continue to influence consumers even after advertisers cease to advertise.¹⁶⁴ This means that it may be costly to correct this impression. On the other hand, as Craswell argues, removing a false claim from an advertisement also imposes costs, as it may also remove valuable consumer information, or create more confusion.¹⁶⁵ Because different consumers draw different inferences from the act of removal from the residue of the advertisement (after the false claim is removed), and from the incorporation of any new information (corrective statements) or qualifying information (such as a disclaimer), there are bound to be some consumers who will benefit and others who will not.¹⁶⁶ This suggests that enforcement cannot rely solely on removal of advertising or corrective statements and that, if these strategies are employed, care must be taken in their implementation.

As explained at [2.7.2.3], a distinctive feature of enforced self-regulation is a pyramid-like system of enforcement, ranging from soft techniques of persuasion ranging to harsh enforcement strategies. This flexibility in choosing from a range of enforcement strategies allows for the escalation of enforcement depending upon the responses from those who have breached the law, thereby avoiding the need to make once-and-for-all choices between persuasion and punishment. As further explained, this flexible system of enforcement is likely to be more cost-effective than alternative enforcement strategies, as costs are likely to be lower at the persuasion end of the spectrum than the costs associated with punishment.

Although this thesis has argued that it is premature for Malaysia to adopt a model of enforced self-regulation, given the difficulties encountered in enforcing advertising regulation in Malaysia it may be helpful to adopt some aspects of the tiered, or pyramid-like system of enforcement recommended by Braithwaite. As has been noted in this thesis, there has been a complete paucity of legal actions taken to the courts in Malaysia to enforce the medicinal advertising regulatory regime. A major consideration leading to this

¹⁶⁴ Ronald A. Milzer, 'Corrective Advertising and the Limits of Virginia Pharmacy' (1979) 32(1) *Stanford Law Review* 121, 122.

¹⁶⁵ See generally Richard Craswell, 'Interpreting Deceptive Advertising ' (1985) 65(4) *Boston University Law Review* 658, 672-678 and 688.

¹⁶⁶ *Ibid.*

regulatory failure is doubtless the high costs of bringing actions before the courts. As noted at [2.8.4.2] the decision to resort to judicial enforcement is usually considered the last option in an enforcement strategy because of the costs involved for regulators, consumers and courts. The cost of enforcement broadly includes the expenses of processing and prosecuting,¹⁶⁷ as well as the cost of misapplication of law, convicting the innocent and deterrence of permissible behavior.¹⁶⁸ Judicial enforcement is, accordingly, extraordinarily costly in terms of time and money.¹⁶⁹ The time taken to deliberate a case is known to be long and tedious compared to out-of-court settlements or administrative enforcement.¹⁷⁰ Also, enforcement can be associated with hostility and lack of cooperation between the regulator and 'the regulated'. Additionally, harsh judicial enforcement can bring about undesirable negative consequences, such as closure of a business and loss of employment.¹⁷¹

Taking into account all of these considerations, as well as the context of the relatively weak Malaysian enforcement regime, it would therefore seem to be both cost-effective, and effective in terms of increased deterrence, to introduce a flexible system of enforcement, which ranges from relatively soft persuasion to relatively harsh punishment. At the same time, given the resource constraints facing regulators in Malaysia, it is important that the complexity of any enforcement regime be minimized. Nevertheless, this should not prevent Malaysia from taking steps to devise a more effective enforcement strategy. At the lower end of the enforcement pyramid, it may be that techniques such as a formal system of warnings could be implemented. Associated with this, while bearing in mind the difficulties identified by Craswell with redressing deceptive advertising, would be a system of prohibiting advertisements and ordering corrective statements. Reliance on persuasion is, however, only likely to be effective if it is supplemented by the threat of harsher sanctions.

¹⁶⁷ R.M. Brown, 'Administrative and Criminal Penalties in the Enforcement of Occupational Health and Safety Legislation' (1992) 30 *Osgoode Hall Law Journal* 692, 728.

¹⁶⁸ Baldwin and Cave, above n 148, 110.

¹⁶⁹ *Ibid* 98.

¹⁷⁰ *Ibid*.

¹⁷¹ *Ibid*.

At the next level of enforcement, then, it may be desirable to introduce a system of statutory undertakings by industry. If these are breached, or prove ineffective, then recourse would be needed to penalties in the form of fines, which must be set at a level sufficient to promote deterrence. Finally, the ability of the regulator to initiate proceedings before the courts to seek additional remedies, such as injunctions, must be preserved, although this should be the strategy of last recourse. Moreover, given the resource constraints faced by regulators in Malaysia, there would seem to be a role for judicial enforcement to be initiated by private parties, including industry competitors, who may well suffer harms from deceptive advertising by a member of their industry.

While the introduction of a tiered, pyramid-like system of enforcement could, in its early stages, be subject to abuse, such as an over-reliance on ‘soft’ enforcement, the longer term benefits may be significant. If the implementation of the system is appropriately monitored, and provided that there is sufficient commitment to the enforcement regime from both industry and government, it is likely to prove both more efficient and effective than alternative strategies.

6.3.3.3 Recommendations for Malaysia

The existence of a system of regulatory control over advertising does not necessarily mean that the control is fully exercised. Various factors, such as the differences in skills, expertise, the integrity of regulatory agency, the volume of advertisements reviewed and the technological development in the three jurisdictions, influence the outcome of regulation. Despite these differences, identification of factors which deter and/or facilitate effective and efficient regulatory control is important. The analysis in [6.3.3.2] identified the limitations in the three jurisdictions that hinder adequate regulation of advertisement of medicinal products and suggested how they may be addressed. This section provides specific recommendations to improve the existing regulatory system in Malaysia so as to achieve greater efficiency.

(a) *Pre-Approval of Advertisements*

The analysis in [6.3.3.2] shows that a system of co-regulation like that in Australia may be appropriate for the regulation of advertisements of medicinal products in Malaysia. The issue is, however, whether such a system may be implemented in Malaysia.

A system of pre-approval will be able to control deceptive advertising effectively if it is relatively simple and cost efficient. In Australia, as noted in [4.3.2.1], the system of pre-approval is complex, complicated and inconsistent. The types of products as well as the medium of publication determine the agency responsible for pre-approval. Furthermore, not all advertisements that reach the public are pre-approved and therefore consumers are not protected from the harm that could arise from relying on false advertisements. In addition, there are costs and delay implications with two industry associations granting approvals for the same advertisement. Processes are duplicated when an advertiser of complementary medicines who wishes to advertise in both broadcast and mainstream media, is required to seek pre-approval from two agencies. These limitations have been raised and discussed in the Toogoolawa Report.¹⁷²

The system of co-regulation for pre-approval of advertisement, as in Australia, may nevertheless be adopted in Malaysia, and there are ways of addressing the limitations. Where there are limited staff and resources, engaging the services of an industry association or outsourcing the task of pre-approval of advertisements will assist in the efficient functioning of the system. The problems associated with the duplication of processes, such as delays and additional costs may be avoided by working together with a single industry. Here, the MAB may delegate the responsibility of pre-approval to an industry association, namely, the ASAM. As noted in [3.3.2.2], the ASAM, an industry association which prescribes standards to be complied with in respect to advertisements disseminated in print media, contains comprehensive rules governing the advertising of medicinal products and products that carry general health claims. It is likely to possess the relevant skills and expertise to carry out pre-approval on behalf of the MAB, which is understaffed and under-resourced and therefore is unable to carry out timely pre-approvals. The problem of a lack of transparency in the system of pre-approval of advertisements may be addressed by adopting openness, as the United States has done.

¹⁷² [4.4] of Chapter 4.

Therefore, it is recommended that a system of pre-approval in Malaysia is pursued via a system of co-regulation.

(b) Monitoring of Violations of Laws

Malaysia exercises pre-approval of advertisements and thereby is able to prevent a fraction of deceptive advertisements from reaching the public; however, the system of pre-approval is arguably inadequate given the increasing number of deceptive claims in advertisements. Therefore, it might be worthwhile to increase monitoring or to vary the form of monitoring so as to enhance the regulation of advertisements of medicinal products.

Outsourcing the task of monitoring to industry associations, whilst maintaining the power to enforce regulations with government regulators, might be beneficial. Like the Therapeutic Goods Administration in Australia, the MAB may be authorized to delegate the responsibility of monitoring to industry associations such as the ASAM. The ASAM has already in existence a comprehensive set of rules, and the involvement of all industry players such as the advertisers, advertising agencies and the media in the drafting and the implementation of rules. Therefore, it may be presumed that this body is equipped with knowledge regarding the activities of the members of the industry and may be entrusted with the task of monitoring violations of laws.

(c) Enforcement

Imprisonment is argued to be a more costly alternative to monetary sanctions because it utilizes resources. Monetary sanctions, on the other hand, are argued to be costly because they cause over-deterrence. However, the issue is how much deterrence of the prohibited act will be achieved from monetary sanctions or imprisonment. If the amount of the fine is small, the offender may not be adequately deterred, but if the sanction is high, there is the possibility of over-deterrence. In this regard, enforcement which is practiced via the system of enforced self-regulation is seen to be appropriate. The question is whether Malaysia has the resources and capacity to carry out such a form of regulation or there are other cost-effective measures to resolve this.

Implementation of enforced self-regulation involves high costs. In addition, they must also be an industry association that possesses skills, expertise, knowledge, funding and experience, as well as the willingness on the part of the industry association to participate in such a form of regulation. As noted at [2.7.2.3], negotiations and consultation so as to reach a desired outcome is a primary factor in this form of regulation. A proposal would have to be made to industry associations to determine their willingness to adopt this form of enforcement. Nevertheless, the system of enforced self-regulation, if it is implemented and sufficiently monitored, can prove to be both effective and cost-effective in the long run. Costs are likely to be lower at the persuasion stages than the costs associated with imprisonments and hefty fines.

Therefore, under these circumstances, the suggestion is that Malaysia considers implementing some aspects of tiered system of regulation. The recommendation is that Malaysia implements a system of co-regulation. In this system, both industry and government are responsible for enforcements, with overriding enforcement mandated by the government. Malaysia would then retain its current judicial enforcement, but improve its control by varying the types of punishments and/or increasing the amounts of fines. At present, corrective advertising is not ordered in Malaysia, and the same may be proposed. Morrison has convincingly made the case that advertising related to drugs and health related products used by consumers should be taken seriously and that courts should order corrective advertising if there has been false advertising.¹⁷³ This form of advertising is considered relatively appropriate compared to the 'cease and desist' or retraction, because with the latter, what is controlled is only deceptiveness in current advertising; it does not eliminate the lingering effects that remain after the advertisement is removed.¹⁷⁴ Therefore, an approach that removes or minimizes the impact of false information effectively is presumed appropriate for the regulation of deceptive claims in advertisements of products of high risk. In view of the limited resources available in Malaysia, corrective advertising, even if it is sparingly utilized, may prove to be of significant value in regulating advertising practice.

¹⁷³ Thomas C Morrison, 'Corrective Advertising as a Remedy for the False Advertising of Prescription Drugs and Other Professionally- Promoted Medical Products' (1994) 49 *Food and Drug Law Journal* 386, 395

¹⁷⁴ Ronald A. Milzer, 'Corrective Advertising and the Limits of Virginia Pharmacy' (1979) 32(1) *Stanford Law Review* 121, 122-123.

6.3.4. Comparative Analysis of the Regulation of Products Classified as Medicinal Products

A comparative analysis of the regulation of advertising of medicinal products in the three jurisdictions discloses how each regime deals with the challenges posed by the regulation. It provides a new perspective on how to deal with constraints and limitations, and on how to improve the existing regulation.

It has been noted that the three jurisdictions use varied approaches in their regulation of advertising of medicinal products and thereby are challenged differently. Despite these varied approaches, an analysis on how the existing regulation of advertisements of medicinal products can be improved was carried out. This was possible because the aspects of regulation which were identified and compared, provide the understanding of the fundamentals of regulating advertising of medicinal which policy makers can employ when designing the system of regulation. This section of the chapter evaluates the comparative analyses carried out in the preceding section, [6.3.3]. The primary objective is to synthesis the regulation in the three jurisdictions and to provide a conceptual framework for the regulation of advertisements of medicinal products in Malaysia.

6.3.4.1 The Regulation for Advertising of Medicinal Products in Malaysia

Although a divergent regulatory approach for regulating the advertisements of medicinal products was noted, some aspects of regulation were found consistent in the three jurisdictions.

The three jurisdictions, to a large extent, have detailed and comprehensive rules to governing the advertising of medicinal products, but these rules have not been able to halt the proliferation of deceptive claims in advertisements. It has been argued that the rules in Malaysia were designed in a manner that protects industry rather than consumers. The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) has comprehensive regulations concerning the types of activities that are prohibited, or the requirements to be fulfilled with regard to advertising; however, the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) fails to provide severe punishments to prevent deceptive advertising from occurring. Instead, it has a broad defence clause and thereby excludes the application of

the Act in relation to common misconduct. Therefore, while the rules appear to be detailed and comprehensive on paper, in effect, there are various loopholes that prevent adequate regulation of the advertising of medicinal products. It is suggested that the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) be revised to implement the following changes:

- the fines should be increased and the types of sanction are varied to include corrective advertising and
- the regulator should be given a wider discretion which includes the authority to delegate regulatory tasks to industry association.

In addition to these changes in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), a two tiered system, in particular co-regulation which permits the use of a combination of statutory law, regulations and industry guidelines, should be implemented. The flexibility found in self-regulation, namely, the ability to adapt to changes in economic, social and technological advancement is more fully found in a system of co-regulation. Therefore, the suggestion is that Malaysia implements a system of co-regulation with respect to implementation of rules in the regulation of advertising of medicinal products, as in Australia.

Whilst rules are an important consideration, they cannot be evaluated in isolation from other aspects of control. Therefore, an analysis of the regulatory control in the legal system is carried out so as to establish a comprehensive insight into the system of regulation. The regulatory controls in the three jurisdictions have varied drawbacks and limitations. Although regulatory functions are essentially the functions of government regulators, certain jurisdiction (namely, Australia) entrust regulatory tasks such as the pre-approval of advertisement and complaint handling to industry self-regulation, thereby easing the burden on government regulators. In Australia, the government regulator, the Therapeutic Goods Administration, assumes a close working relationship with industry associations, the ASMI and the CHCA, who are given the right to directly influence the regulation of advertising.¹⁷⁵ In the United States, moderate intervention by industries is allowed in the regulation, while principal controls are held by the government regulators, the FDA and the

¹⁷⁵ See [4.3] of Chapter 4.

FTC.¹⁷⁶ In contrast, in Malaysia, control is held by the government regulatory agency, the MAB; intervention by industry in regulation is negligible.¹⁷⁷ The government allows limited intervention from self-regulatory organizations such as the ASAM; however, because ASAM operates on the concept of voluntary participation of members, compliance may not be expected from those who are non-members.

Therefore, with regard to regulatory control, a factor which is important for effective regulation of advertising of medicinal products is greater participation from industry associations in the regulation, in particular, with regard to pre-approval of advertisements and monitoring.

Below is a summary of recommendations with regard to how the regulatory controls can be improved:

- The existing Malaysian system of mandatory pre-approval of advertisements for medicinal products which are disseminated in all media is to be maintained
- Multiple bodies responsible for pre-approval of advertisement have been found to be ineffective and costly, and therefore pre-approval of advertisement by a single body to be considered
- The hybrid system of regulation, namely co-regulation for pre-approval of advertisement and monitoring is noted to be cost-effective and therefore the possibility of delegating the task of pre-approval of advertisement and monitoring to industry association to be considered.
- There is to be full transparency with regard to the types of advertisements which are pre-approved and refused approval, as well as their reasons
- Proactive monitoring which is accompanied by sanctions which are sufficient to promote deterrence to be considered
- The existing system of enforcement to be reformed to a system of co-regulation. However, Malaysia should improve its control by varying the types of punishments and/or increasing the amounts of fines. The types of sanctions should include

¹⁷⁶ See [5.5.2.1] of Chapter 5.

¹⁷⁷ See [3.4.1] of chapter 3.

corrective advertising for high risk products and fines at a level which is sufficient to deter deceptive advertising.

6.4 CONCLUSION

This chapter compared the regulation of the advertisement of medicinal products in Malaysia with that in the United States and Australia. The analysis presented in the chapter provided the basis for recommendations for reforming the regulation of advertising of medicinal products in Malaysia. The chapter examined the advertising regulation of two categories of products, which are referred to as medicinal products in this thesis. It examined the regulation of advertising of prescription drugs in [6.2], and the regulation of the advertising of non-prescription drugs and health related products (HRPs) in [6.3].

The objective in this chapter was to enable two determinations: (1) whether DTCA of prescription drugs should be permitted and regulated in Malaysia and (2) what the appropriate mode of regulation would be for the advertising of non-prescription drugs and HRPs, both of which is permitted, so as to ensure that consumers are adequately protected from deceptive advertising.

The analyses in [6.2.4.3.] and [6.2.4.4.] revealed that it is practical for Malaysia to continue the ban on DTCA of prescription drugs. The arguments found against DTCA of prescription drugs outweighed those in favour. The economic analysis exposed the infeasibility of Malaysian regulation in addressing concerns that may arise from allowing DTCA of prescription drugs. The United States' experience and challenges in the regulation of DTCA of prescription drugs through its dissemination and detailed studies on the subject by Australia further supports that Malaysia should not permit DTCA of prescription drugs.

For non-prescription drugs and HRPs, the analysis at [6.3] showed that it is desirable for Malaysia to reform some aspect of the existing regulation, so as to ensure that consumers are adequately protected against deceptive advertising of medicinal products. It was determined that existing traditional command and control mode of regulation should be changed to mode of co-regulation, for effective regulation. This change was to be with regard to: (1) use of rules in the regulation of advertising of medicinal products and (2) regulatory controls such as pre-approval of advertisements, monitoring of infringements and enforcement employed in the regulation. The existing system of classification where no exemptions are given for therapeutic claims carried on advertisements of medicinal products is, however, to be maintained.

The paragraph below sets out the recommendations made in this chapter.

The existing Malaysian system of classification of medicinal products, where exemptions are not granted for therapeutic claims carried on advertisements of medicinal products, is to be maintained. It was decided that it is better to err on the side of caution and disallow exemptions to medicinal products given that the potential harm which results from using unsafe products is higher than the regulatory costs of ensuring their safety and efficacy. Therefore, it is determined that all medicinal products are subject to a process of scientific testing for safety and efficacy before they are distributed to the public.

With regards to advertising rules, it was suggested that Malaysia, which relies on government made rules, should use an appropriate mix of rules that are simple, transparent and accessible. Malaysia had insufficient opportunity (and is still continuing) to develop the common law and, therefore, it was recommended that Malaysia considers the use of informal rules such as industry guidelines or codes of practices in the regulation of advertising of medicinal products. The key recommendation is that Malaysia adopts a regulatory framework that includes industry participation in the regulation. A shared effort with an industry association, such as ASAM, in the formulation and implementation of rules would be appropriate given the lack of resources available for the government to carry out effective regulation. It was, however, suggested that co-regulation is more suitable in the Malaysian context than enforced-self regulation, since the success of enforced self-regulation largely depends on the extent to which industries are able and willing to cooperate with regulators to ensure that rules are complied with. It also requires sufficient resources (within the industry) to effectively implement the system. Co-regulation, on the other hand, retains government control over enforcement, while transferring some of the costs of regulation to industry.

The regulatory controls, which consist of a system of pre-approval of advertisement, monitoring of infringements and enforcement, was analysed in terms of their effectiveness in controlling deceptive advertising. Having explored the limitations in the system of pre-approval, the following suggestions were made that: (1) the existing Malaysian system of mandatory pre-approval of advertisements for medicinal products, which are disseminated in all media, is to be maintained; (2) pre-approval for advertisements should be granted by

a single body as opposed to multiple bodies; (3) the hybrid system of regulation, namely co-regulation for pre-approval of advertisement is noted to be cost-effective, and therefore the possibility of delegating the task of pre-approval of advertisement to an industry association, such as ASAM, should be considered; (4) transparency with regard to the types of advertisements which are pre-approved and refused approval, as well as their reasons should be practised (this is believed to be necessary to ensure that there is accountability in the actions taken, which is noted as crucial for effective regulation); and (5) whilst rapid approvals have the potential for improper reviewing it is recommended that advertisements are reviewed properly and approvals are given without delay. Prompt approvals were seen as an incentive to advertisers to comply with the system of pre-approval of advertisements.

Monitoring is essential as it enables regulators, upon detecting violations, to take steps to prevent dissemination of deceptive advertising. Therefore it is suggested that proactive monitoring, which is accompanied by sanctions that are sufficient to promote deterrence, should be considered. It is proposed that monitoring by regulators should be supplemented by industry monitoring so as to ensure that violations are detected in a timely manner. This can be carried out cost-effectively under a system of co-regulation.

The existing system of enforcement should be changed to a system of co-regulation. With co-regulation, both industry and the government are responsible for enforcement, but the government has the overriding control. The types of sanctions should be varied to include corrective advertising for high risk products, and fines should be increased to a level which is sufficient to deter deceptive advertising. Given Malaysia's resource constraints, a system of co-regulation as opposed to enforced self-regulation was decided to be appropriate. A system of enforced self-regulation, where persuasion is initially used to encourage compliance, and harsh punishments are resorted to when soft techniques fail, was noted as effective for the regulation of advertising of medicinal products. However, there are relatively high costs involved in implementing enforced self-regulation and Malaysia is not currently equipped to implement this system. Therefore, it was suggested that co-regulation should be adopted.

CHAPTER 7

THESIS FINDING

7.1 INTRODUCTION

The regulation of advertising of medicinal products is an important aspect of consumer protection. Consumers need to be protected from misleading advertisements of medicinal products because reliance on such advertisements causes consumers not only financial harm, but also physical and, potentially, psychological harms. This thesis has compared and evaluated the regulation of advertising of medicinal products in three jurisdictions and provided suggestions to reform the existing regulation of advertising in Malaysia. This is the first study to have comprehensively analysed the regulation of advertising of medicinal products in Malaysia. It is also the first comparative study of the regulation of the advertising of medicinal products in Malaysia, Australia and the United States.

This thesis was prompted by concerns about the apparent proliferation of deceptive claims in advertisements for medicinal products in Malaysia. The main objective of the thesis was to evaluate the adequacy of the regulation of advertising of medicinal products in Malaysia, with a view to making recommendations for improving the Malaysian regulatory regime. In pursuing this objective, this thesis has emphasised the features that distinguish the advertising of medicinal products from advertising of other products. Medicinal products are consumed for particular health purposes, namely to improve health, to reduce pain and suffering, or to prevent diseases or premature death. Hence, deceptive claims with regard to safety and effectiveness, which are carried in advertisements for such products, can have a potentially severe effect on public health. For example, false and misleading claims with regard to the effectiveness of products may result in consumers relying on unsafe or ineffective products, potentially at the expense of products which effectively treat or cure illnesses. As explained in chapter 2, this suggests that policy prescriptions should take into account the precautionary principle, meaning that where risks to health are high, it is better to err on the side of caution.

The importance of ensuring an effective regime for the regulation of advertising of medicinal products is only likely to increase. For example, the literature in this area shows that the pharmaceutical industry has entered a period of remarkable change.¹ There has been an increase in pharmaceutical advertising and, consequently, of sales in response to advertising. However, as sales increase, the regulatory approval times appear to have lengthened, monitoring has become more limited, and the costs of enforcement have risen. Moreover, there is the looming problem of how to regulate advertising of medicinal products by means of the Internet.

This thesis has responded to these challenges by conducting a fundamental review of regulation in this important area, by reference to the main objectives of regulating the advertising of medicinal products. By reviewing the regulation of advertising of medicinal products by reference to the first principles of designing a best practices regulatory regime, the thesis has developed recommendations for fundamental reforms of the Malaysian regulatory regime.

This chapter summarises the research undertaken in this thesis, including the methodology applied, the main arguments presented and the main research findings.

¹ Marvin M. Lipman, 'Bias in Direct-To-Consumer Advertising and Its Effect on Drug Safety' (2006) 35 *Hofstra Law Review* 761; Marshall B Kapp, 'Drug Companies, Dollars, and the Shaping of American Medical Practice' (2005) 29 *Southern Illinois University Law Journal* 237; Marshall H. Chin, 'The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids' (2005) 5 *Yale Journal of Health Policy, Law and Ethics* 771; Julie Donohue, 'A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection' (2006) 84(4) *The Milbank Quarterly* 659; Barbara Mintzes, et al., 'How Does Direct-to-Consumer Advertising (DTCA) Affects Prescribing? A Survey in Primary Care Environments With and Without Legal DTCA' (2003) 169(5) *Canadian Medical Association Journal*, 405.

7.2 THE METHODOLOGY

This section of the chapter recapitulates the methodology employed in this thesis in order to reach reasoned conclusions on the recommendations made for reforming regulation in Malaysia.

7.2.1 Comparative Study

This thesis conducted a comparative legal analysis of the regulation of advertising of medicinal products so as to learn from the experiences of developed countries, specifically Australia and the United States, that have developed best practice means to address the problems posed by deceptive advertising. Australia and the United States were selected for inclusion in the study, as both have accumulated considerable experience in the regulation of advertising of medicinal products. Moreover, there have been significant reviews of the regulatory regimes in each of those jurisdictions, as well as a considerable secondary literature examining issues relating to the regulatory regimes in the two jurisdictions. Finally, as both Australia and the United States are common law jurisdictions, it has been assumed that analysis of the regulatory regimes in these jurisdictions has particular relevance to Malaysia.

Although there are some common features of the regulatory regimes in Australia and the United States, there are also some significant differences. For example, while DTCA of prescription drugs is permitted in the United States, it is prohibited in Australia. Moreover, while Australia has adopted a system of co-regulation, the United States relies almost entirely on government regulation, with some elements of self-regulation. The analysis undertaken in this thesis has effectively compared the regulatory regimes in Australia and the United States, explaining why particular aspects of these regimes may be preferred. But in undertaking this analysis, the thesis has explained the utmost importance of taking into account particular features of the context of regulation in Malaysia, which mean that aspects of the Australian and American regulatory regimes cannot simply be transplanted to Malaysia. First, it is important to understand that there has been much less experience in designing and implementing regulatory regimes in Malaysia than in either the United States or Australia. This suggests that caution is required in adopting regulatory innovations until Malaysia takes steps to develop an effective regulatory culture. Second,

some inadequacies of the regulatory regime in Malaysia can be attributed to a lack of experience with the regime. For example, there are some uncertainties concerning the interpretation of key legislation such as the *Medicines (Advertisement and Sale) Act 1956* (Malaysia), as a result of the lack of legal precedents in this area. Third, there are scarce government resources that are able to be allocated to the regulation of advertising in Malaysia. These significant resource constraints are an important consideration to take into account in formulating any recommendations for a Malaysian regulatory regime.

7.2.2 Economic Analysis

In addition to the comparative legal analysis undertaken in this thesis, the recommendations made in the thesis have been based on an economic analysis of the regulatory regimes. An economic analysis has been conducted because, as explained in chapter 2, regulation essentially involves an intervention in the market. As noted at [2.4.1.2], the main rationale for regulating in the public interest is market failure. As further noted at [2.5.2.2], the main economic rationale for regulating deceptive advertising is the information asymmetry between industry and consumers, meaning that consumers do not have sufficient information to be able to adequately assess the claims made in medicinal advertising.

Although there is a need for regulation to address the problem of deceptive advertising of medicinal products, not all regulation is desirable. As explained at [2.9], inappropriate regulation can lead to either over-deterrence or under-deterrence. As further explained, an economic analysis, such as cost-benefit analysis or cost-effectiveness analysis, is essential in order to determine the appropriate level of regulation. As noted at [2.9.2], this involves balancing the advantages of protecting consumers from deceptive or harmful regulation against the costs of regulation. Applying this to the regulation of advertising of medicinal products, this thesis has emphasised the importance of applying the precautionary principle, so as to take into account the potential for tragic consequences to health or life. The application of this framework of analysis leads to important conclusions, such as that there is good case for prohibiting advertising to consumers of some medicinal products, particularly those that represent a high health risk. The analysis introduced in Chapter 2 of the thesis was applied to particular issues in the regulation of advertising of medicinal products in Chapter 6, so as to lead to the main findings of this thesis, which are explained immediately below.

7.3 THESIS FINDING

7.3.1 The Research Questions and Objectives

The fundamental question in this thesis was: how, in certain respects, the existing system of regulation of advertising of medicinal products can be improved so as to ensure that consumers are adequately protected against deceptive claims in advertisements? The subsidiary questions that were intended to facilitate the answering of the main question include:

- What are the strengths and weaknesses in the current system of regulation of advertising of medicinal products in Malaysia?
- What are the challenges faced in the regulation of advertising of medicinal products and how the challenges are addressed by Australia and the United States?
- Based on a comparative analysis between Australia, the United States and Malaysia, how can the regulation of the advertising of medicinal products in Malaysia be improved?
- How can the regulation of advertising of medicinal products be carried out cost-effectively?

The objective of the thesis has been to enable Malaysia to make two determinations:

- First, should Malaysia permit direct-to-consumer advertising (DTCA) of prescription drugs or should Malaysia continue its ban on DTCA of prescription drugs?
- Second, what form of regulation should Malaysia adopt with regard to the regulation of advertising of non-prescription drugs and HRP's both of which is permitted, so as to ensure that consumers are adequately protected from deceptive advertising?

This study has presented a detailed analysis of the mechanism used for regulation of advertising of medicinal products. Attention has been drawn to the strengths as well as to

the inadequacies, ambiguities and deficiencies in the system of regulation of advertising of medicinal products in the three jurisdictions, which Malaysia can consider when determining an appropriate form of regulation. The findings are given immediately below.

7.3.2 Thesis Findings

The key analysis in the thesis has been with regard to how to enable Malaysia to make two determinations. In attempting to do so, the following main aspects of the respective regulatory regimes were explored: the regulation of direct-to-consumer advertising (DTCA) of prescription drugs; the classification of products as medicinal products in the respective regulatory regimes; the modes of regulation adopted in the regulation of advertising and the respective systems of regulatory controls, including pre-approvals of advertisements, monitoring of infringement; and the enforcement regime. The determinations and the recommendations with respect to each of these aspects are given immediately below.

7.3.2.1 Recommendation 1

Malaysia should continue its ban on DTCA of prescription drugs. It has been found that the costs of permitting DTCA of prescription drugs far outweigh the benefits which can be derived. The potential harm which may be incurred from DTCA of prescription drugs, as well as the costs involved in preventing the harm, is far more detrimental than the benefits which it brings. Malaysia, which is not sufficiently equipped to deal with problems that arise from deceptive advertising of medicinal products, will not be able to address issues that arise from deceptive advertising of prescription drugs. Its existing system of regulation of advertising of medicinal products cannot be relied on, as it has loopholes and deficiencies which hinder adequate regulation, and these have yet to be addressed. As noted in [3.3.1.1], for example, the sanctions imposed and the types of sanctions ordered are insufficient to deter deceptive advertising, prosecutions require sanctions by the public prosecutor, and the defence clause in the *Medicines (Advertisements and Sale Act) 1956* (Malaysia) is so wide that advertisers are generally able to escape liability. Furthermore, as noted in [4.4], Australia, which is better equipped and experienced in the regulation of advertising of medicinal products than Malaysia, and which has conducted detailed studies on viability of DTCA of prescription drugs, has favoured retaining the prohibition. In essence, in Australia it has been found that the costs of prohibiting DTCA of prescription

drugs are lower than the cost of regulating it through its dissemination. Malaysia, which has not had the opportunity to conduct similar studies, can rely on the analysis in these comprehensive studies to support its stance to continue its ban on DTCA of prescription drugs.

7.3.2.2 Recommendation 2

The advertising of non-prescription drugs and HRP, both of which is permitted, is to be continued. However, some aspects of its regulation need to be reformed so as to provide better protection to consumers against deceptive advertising of medicinal products. The existing system of classification of medicinal products, where Malaysia does not permit the exemptions of products found in Australia and the United States is to be maintained. However, the manner in which the advertising of non-prescription drugs and HRP is regulated needs to be reformed. It is proposed that the mode of regulating the advertising of medicinal products, which is command and control, should be reformed to a system of co-regulation.

The paragraphs below set out the recommendations made with regard to the aspects of regulation that were analysed for the purposes of determining how the advertising of non-prescription drugs and HRP can be carried out effectively so as to ensure that consumers are adequately protected. The first task was to determine the types of products that should fall within the classification of medicinal products. This is followed by recommendations with regard to the use of rules in the regulation of advertising of medicinal products, and the regulatory controls that should be employed in the regulation.

7.3.2.3 Recommendation 3

It is argued that because Malaysia may have limited experience in determining the types of products which can be exempted from the classification of medicinal products, and that its regulatory approval process is relatively less costly than its process of assessing exemptions for medicinal products, that it is better to disallow exemptions to the classification of products as medicinal products. Furthermore, there is less access to health care for the general population in Malaysia, and therefore consumers who are harmed by unsafe medicinal products may not be able to obtain immediate medical attention. It is

therefore recommended that there should be no exemptions from classification as medicinal products, meaning that all such products remain subject to a process of scientific testing for safety and efficacy before they are distributed to the public.

7.3.2.4 Recommendation 4

With regards to advertising rules, it was found that, although a combination of rules can enhance compliance, Malaysia employs the fewest kinds of rules in regulating advertising of medicinal products, essentially relying on government made rules. Moreover, Malaysia has had insufficient opportunity to develop the law in this area, since no cases involving advertising of medicinal products have come before the courts. Further, Malaysia has yet to rely on industry guidelines to govern the advertising. Therefore, it is recommended that Malaysia consider the use of an appropriate mix of rules which are simple, transparent and accessible. It is also suggested that Malaysia adopts the use of informal rules, such as industry guidelines or codes of practices, in the regulation of advertising of medicinal products. In other words, the thesis recommends that Malaysia adopts a regulatory framework that includes industry participation.

It has also been noted that the capacity of the Malaysian regulator, the MAB, needs to be strengthened. Linked to a lack of financial resources, is the lack of sufficient staff to carry out the required regulatory tasks. It was noted that co-regulation, as opposed to enforced self-regulation, would be appropriate given the lack of experience, training and human resources to engage in constant negotiation with the industry in a system of enforced self-regulation. Moreover, the success of enforced self-regulation depends largely on the extent to which industry is able and willing to work with regulators to ensure that rules are complied with. In the circumstances, the system of co-regulation was considered as a practical option for Malaysia.

The regulatory controls, which consist of a system of pre-approval of advertisements, monitoring of infringements and enforcement, was analysed in terms of their effectiveness in controlling deceptive advertising. It was found that these three controls have varied strengths and weaknesses. Nevertheless a single solution, such as an adoption of a system of co-regulation, has the potential to significantly improve the Malaysia regulatory

regime. The paragraph below details the recommendations made with regard to each of the regulatory controls.

7.3.2.5 Recommendation 5

With regard to system of pre-approval of advertisements, the following recommendations are made that:

- (1) the existing Malaysian system of mandatory pre-approval of advertisements for medicinal products which are disseminated in all media is to be maintained. It was based on the precautionary principle that when it concerns health and life, it is better not to risk harm;
- (2) multiple bodies responsible for pre-approval of advertisement have been found to be ineffective and costly, and therefore pre-approval of advertisement to be granted by a single body;
- (3) the hybrid system of regulation, namely co-regulation for pre-approval of advertisement is cost-effective method. The MAB, which grants pre-approval, is understaffed and therefore delegating the task of pre-approval of advertisements of medicinal products which are low risk may allow MAB more time to focus on proper reviews and prompt pre-approvals of high risk medicines;
- (4) there is to be transparency with regard to the types of advertisements which are pre-approved and refused approval, as well as their reasons. This is believed to ensure that there is accountability in the actions taken, which is noted as crucial for effective regulation and
- (5) advertisements must be reviewed properly and approvals must be given without delay. Prompt approvals were seen as an incentive to comply with system of pre-approvals.

7.3.2.6 Recommendation 6

With regard to monitoring, it was decided that monitoring by industry should be encouraged and that proactive monitoring which is accompanied by sanctions which are sufficient to promote deterrence to be considered. It is proposed that monitoring can be carried out cost-effectively under a system of co-regulation. For example, monitoring costs can be expected to be low for industries when securing information about members and their activities.

7.3.2.7 Recommendation 7

With regard to enforcement, it was decided that the existing system of enforcement, which is government regulation is replaced by a system of co-regulation. Co-regulation will ensure that both industry and the government are responsible for enforcement, but the government will have the overriding mandate. Although a system enforced self-regulation where persuasion is initially used to encourage compliances and escalating to harsh punishments when soft technique fails, was noted as an effective system of regulation, upon an analysis in the Malaysian context, the system proved to be impractical for Malaysia. The system cannot be implemented without an occurrence of high costs and large resources. Nevertheless the doors to this option are not to be shut and the option may be revived in the future.

Recommendations 2, 4 and 5 discussed above are suitable for a long term resolution. Recommendations 8 and 9 set out the short term solution to the problem of advertising of medicinal products in Malaysia.

7.3.2.8 Recommendation 8

It is recommended that as an initial step, the deficiencies in the *Medicines (Advertisement and Sale) Act 1956* (Malaysia) should be addressed. The *Medicines (Advertisement and Sale) Act 1956* (Malaysia) currently has several loopholes, which hinder adequate regulation. It has been noted, that the fine imposed under the Act for non-compliance with the Act is minimal. As seen at [3.3.1.1], the fine ranges from RM3,000.00 or less, or

imprisonment for a year, or both for first offenders, to an amount not exceeding RM5,000.00 or two years imprisonment for subsequent convictions. It is, therefore suggested that the fines which may be imposed should be increased. It is also noted that the defence set out in section 5 of *Medicines (Advertisement and Sale) Act 1956* (Malaysia) is too broad. As a result, advertisers or manufactures, who advertise medicinal products to categories of persons allowed under the law, have been able to escape liability when their advertisements are also viewed by the public. As noted at [3.3.1.1], advertisements in pamphlets and brochures, which are intended for members of the medical profession, are placed in spots where the public is able to view them. It is, therefore, suggested that an 'exception' is created in the Act, where advertisers or manufacturers can be considered liable for the advertising of medicinal products in the pamphlets and brochures. A claim could then be brought by a consumer who has been misled by advertisements found in the pamphlets and brochures. This, in essence, would ensure that advertisements of medicinal products are strictly confined to the members of the medical profession and not available to the public. Further, it has been noted that the requirement under section 6F (1) of *Medicines (Advertisement and Sale) Act 1956* (Malaysia), namely that the previous sanction of the Public Prosecutor must first be obtained before an action can be brought to court, has been argued to cause delays in the legal process. It is, therefore, suggested that this requirement be removed so as to enable actions to be processed in a speedier manner.

7.3.2.9 Recommendation 9

Consumers who have been misled by deceptive advertisements may either bring an action in court under the *Consumer Protection Act 1999* (Malaysia) or file a claim with the Tribunal for Consumer Claims. Most have preferred the Tribunal for Consumer Claim because of the cost involved with legal processes. Courts, and the cost of engaging a lawyer can cost up to RM5,000.00. Hence claims not exceeding RM25,000.00 are heard in the Tribunal for Consumer Claim. It has been noted, however, at [3.3.1.3], that claims regarding medicinal products are not within the scope of the term 'goods' and therefore fall outside the *Consumer Protection Act 1999* (Malaysia). It is, therefore, suggested that the meaning of the term 'goods' is broadened so as to include medicinal products.

7.4 LIMITATIONS AND CHALLENGES IN THE STUDY

A comparative analysis of the regulation of advertising of medicinal products in the three jurisdictions shed light on how each nation deals with the challenges posed by the regulation. It provided a perspective on how to deal with constraints and limitations found in such regulation. However, there are limitations in the study which hindered a comprehensive analysis. The study faced challenges which were ordinarily found in a comparative study.

Comparing diverse way of dealing with similar problem shows how problems can be addressed in more than one way, but identifying exact comparable measurements or yardsticks proved impossible. Even if it were possible, it was not feasible to obtain an exact yardstick. For instance, the terminology used in one country was not the exact equivalent used in another country. Terms covered either a broader or narrower scope of categories.

Furthermore, factors which had an impact on the regulation in one country did not make a similar impact in another. For example, some countries have more advanced technology than others and this contributed to a broader dissemination of information. In others, strong public interest groups challenged freedom of information. These components influenced the mechanics of the regulation of advertising of medicinal products and determining a comparable point has not been challenge free.

The thesis was mindful that each nation has a unique combination of regulatory strategies which were developed in stages and through various influences such as politics, culture and social and economic structure. These combinations pose difficulties when making an assertion that a particular factor will lead to a similar result in a different country. The thesis, however, acknowledges that these factors will have to be considered when considering reforms for the regulation of advertising of medicinal products.

A further challenge is in achieving a balance between factors. The form of regulation that is to be recommended for the regulation of advertising of medicinal products must strike a

balance between factors. It needs to be a form of regulation that is not overly burdensome to businesses, but at the same time addresses the mischief that the businesses may bring. It also needs to have a sense of balance between preventing dissemination of deceptive claims and assuring a sufficient flow of information to consumers, which may be beneficial to facilitate the making of an informed decision about their health. Striking the balance between these two extremes was not an easy task.

However, despite these limitations and challenges, an analysis on how the existing regulation of advertising of medicinal products can be improved has been given. This was possible because the key aspects of regulation which were compared provided a framework for understanding the fundamentals of regulation of advertising medicinal products, which policy makers can employ when designing the system of regulation. The study demonstrated viable and feasible recommendations so as to improve the existing system of regulation in Malaysia.

7.5 FUTURE STUDY

Future studies in this area may focus on how collaboration between countries may be achieved in the regulation of advertising of medicinal products. Effective controls over deceptive advertising appeared necessary not only in developing countries such as Malaysia, but also in developed country such as Australia and the United States. The study has shown that the three countries face varied challenges and are constrained by various limitations in regulation. One of the finding in the thesis was how similar principles influence regulation, but with different standards or controls and resources used to monitor and enforce violation makes an impact.

Collaboration between regulatory agencies in the three jurisdictions can mutually benefit the three jurisdictions in controlling the advertising of medicinal products. This is possible because of the similarities that underlie the regulation in the three jurisdictions. For example, promotional activities are controlled by government agencies and/or industries through voluntary codes of practice which are underpinned by legislation. Further, law and regulations generally emphasise the presentation of accurate information in advertisements. Where specific objectives are the same, collaboration for mutual benefit is possible and should be explored.

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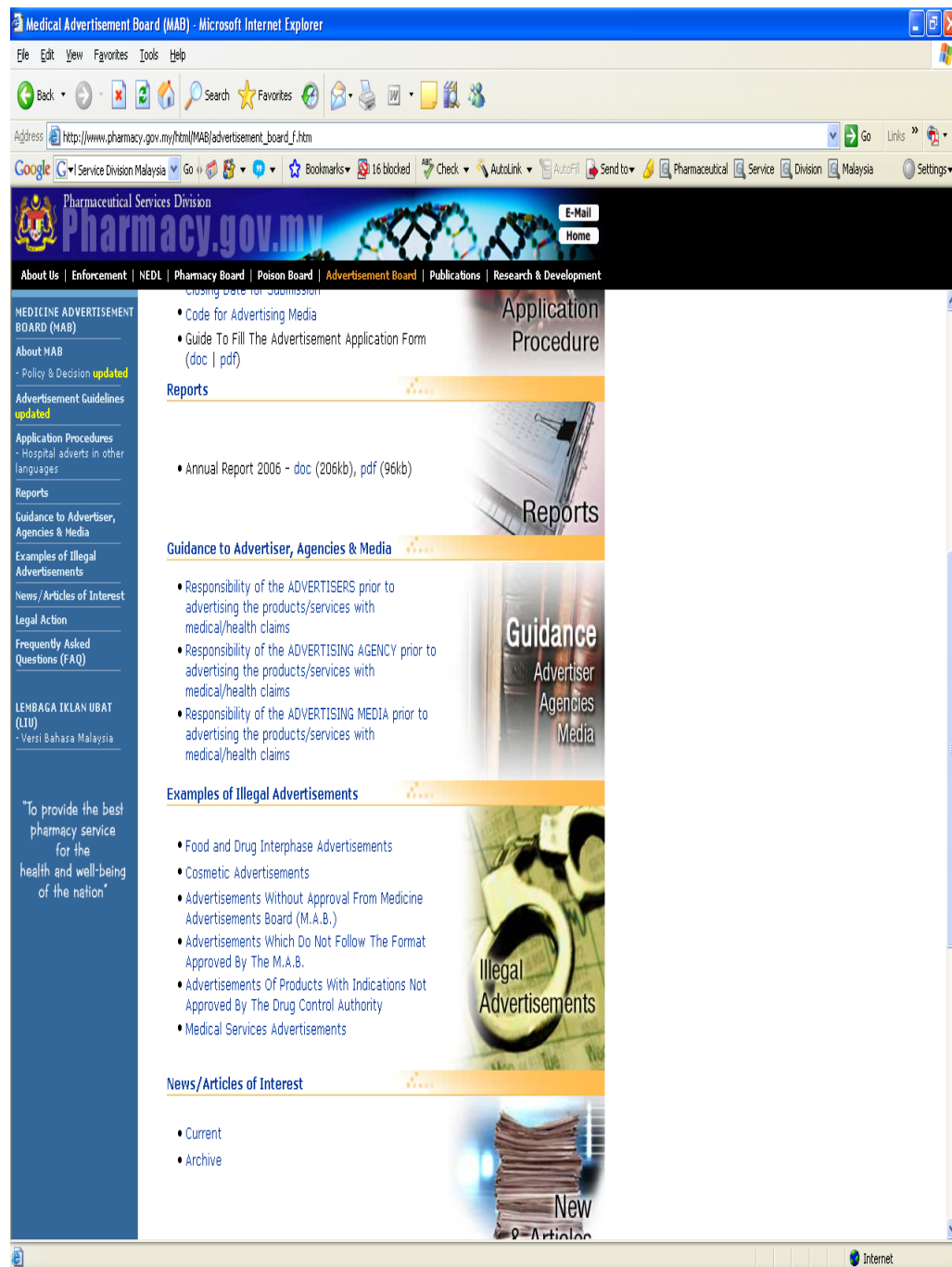
Personal Interview

Interview with 3 officers namely; (1) Yogeswary a/p V Markandoo, the Deputy Director of Pharmacy Enforcement Division; (2) Nor Aza Binti Hassan, the Assistant Deputy Director of Pharmacy Enforcement Division; and (3) Azlinda Binti Abdul Samad, the Assistant Deputy Director of Pharmacy Enforcement Division, all from the Medicine Advertisement Board, Pharmacy Enforcement Division Ministry of Health Malaysia, (personal interview, 18 May 2007).

APPENDIX

Appendix A

Official Website of Medicine Advertisement Board in 2007



Appendix B

Example of Advertisement found misleading by the Medicine Advertisement Board.

Food and Drug Interphase Advertisements

YOU CAN FEEL YOUNG AGAIN...

with
HGH BOOSTERS
Your Best Defense Against Aging

The **REJUVAMIN®** and **REJUVAMAX®** anti-aging supplement products are your best path to higher human growth hormone (HGH) levels which promote these benefits:





- ✓ Tighter, sleeker, smoother skin
- ✓ Enhanced energy levels
- ✓ Decrease in body fat without exercise
- ✓ Increase in lean body mass
- ✓ Strengthened immune system
- ✓ Deeper and sounder sleep
- ✓ Sharper memory and concentration
- ✓ Stronger bones
- ✓ Improved exercise capacity
- ✓ Higher threshold in coping with stress
- ✓ Reduced appetite
- ✓ Youthful feeling of joy in living

Rejuvamin® Bulk Pack
(125gm & 250gm)
For persons under 64kgs (140lbs)
Age: 30 - 54 years old

Rejuvamax® Bulk Pack
(175gm & 350gm)
For persons above 64kgs (140lbs)
Age: 30 years old and above
Specially recommended for persons over the age of 55.

TAKE AN ACTIVE ROLE IN FIGHTING AGING!
Not A Hormone - No Side Effects - Suitable for Vegetarian. Manufactured in USA.

Available at selected pharmacies, and:

guardian   
 apex pharmacy

Terkini

BeMuda

BIO-ORANGE

Nampak **Muda**
Rasa **Muda**
Pasti **Muda**

Produk Berasaskan :HGH-Amino Acid Complex



BeMuda berkesan untuk:

- Anti Kedut/Penuaan-Membaiki Struktur Kulit-Menghaluskan Kulit-Agen Pencerahan Kulit-Meningkatkan Tenaga-Meningkatkan Sistem Imunisasi-Menguatkan Tulang-Meningkatkan Daya Ingatan-Meningkatkan Sistem Penghadaman-Mengatasi Kesukaran Tidur-Mengatasi Masalah Rambut/Kuku/Tumit-Mengatasi Masalah Dalam Tubuh-

Ingredients / Kandungan :

L-Arginine, L-Ornithine, L-Glutamine, L-Glycine, Creatine Monohydrate, L-Carnitine, L-Lysine, L-Leucine, L-Isoleucine, L-Valine, Whey Protein, Plant Fibers, Vitamin A, Vitamin B1 (Thiamine), Vitamin B2 (Riboflavin), Vitamin B3 (Niacin), Vitamin B6 (Pyridoxine), Vitamin B9 (Folic Acid), Vitamin B12, Vitamin D, Vitamin E and Minerals.

Over 28,000 clinical studies worldwide shown that "You can turn your biological clock back by 20 years."
(Counterbalancing research by David Rudman, M.D. published in the New England Medical Journal of Medicine)

The Statement 'Over 28,000 clinical studies worldwide shown That "You Can Turn Your Biological Clock By 20 years is not true and is not permitted to be advertised if it is classified as pharmaceutical product.

The Foundation of Health

The body is designed to work perfectly so that you'll be able to enjoy the overall feeling of well-being and balance of optimum health. If yours isn't, something is in the way, like polluted, stressful environment, toxins and negative thoughts. Or, there is a deficiency, probably nutritional. While there is no easy way to optimum health, experts agree that the key contributing factor is your diet.

Supporting your health has never been easier.

GREENS TOTAL is an advanced nutrient rich superfood that contains over 70 uniquely combined ingredients of grasses, algae, antioxidants, immune builders, blood purifiers, organ tonifiers and many more which your body needs for an all-round health.

VITAMINS / MINERALS / OTHERS: Zinc, Silica, Biotin, Boron, CoQ10, Calcium, Selenium, Folic Acid, Magnesium, Molybdenum, Alpha Lipole Acid, Chromium, Picolinate, Vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, Iodine, Potassium, Phosphorus, Vanadium, Copper, Iron, Manganese

ORGANIC GRASSES: Wheat Grass, Alfalfa Grass, Barley Grass

PHYTONUTRIENTS: Soy Protein Powder (Genistein, Daidzein), Kale Powder, Carrot Powder, Cherry Powder, Tomato Powder, Spinach Powder, Tangerine Powder, Bioflavonoids, Broccoli (Lycopene, Zeaxanthin, Cryptoxanthin, Lutein, Sulforaphane, Ellagic Acid, Carotenoids, Isothiocyanates, Indole 3 Carbinol)

SUPERFOODS: Carob, Lecithin, Red Beet, Rose Hips, Royal Jelly, Oenocetanol, Acerola Berry, Jerusalem Artichoke

PROBIOTICS / POS: Lactospore, Fructo-oligosaccharides, Bifidobacterium Bifidus, Lactobacillus Bulgaricus, Lactobacillus Acidophilus

CLEANSERS/DETOXIFIERS: Burdock Root, Flax Seed Meal, Dandelion Root, Brown Rice Bean, Apple Fiber/Pectin, Oat Bran Concentrate

ADAPTOGENIC HERBS: Pau D'Arco, Fo Ti, Bilberry, Horsetail, Echinacea, Astragalus, Milk Thistle, Grape Seed, Ginger Root, Slippery Elm, Licorice Root, Ginkgo Biloba, Pycnogenol, Hawthorn Berry, Siberian Ginseng, Japanese Green Tea

POWER MUSHROOMS: Reishi, Maitake, Shiitake

DIGESTIVE ENZYMES: Lipase, Papain, Lactase, Amylase, Protease, Cellulase, Bromelain

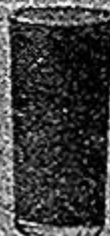
SEA ALGAE: Spirulina, Chlorella, Red Dulse, Norwegian Sea Kelp



500 GM

Over 70 health-giving nutrients in a glass of delicious GREENS TOTAL.

Take it daily and build a solid foundation of health. You'll restore your vitality, enjoy boundless energy and experience a remarkable difference in how you feel.



TISHCON
CORP.
New York, U.S.A.

Available at all leading pharmacies.

For further information please write or fax to:
PAHANG PHARMACY SDN. BHD. (100264)
31 Jalan PJS 11/1, 46150 Bandar Sunway, Selangor
Tel: 03-5633 8806 Fax: 03-5633 8495

Advertisements Without Approval From Medicine Advertisement Board (MAB)
The following are examples of advertisement for products that are registered as pharmaceutical products with the Ministry of health Malaysia however, these product failed to obtain the necessary approvals from the Medicine Advertisement Board . These advertisements were found to be in breach of s 4B of the Medicine Advertisement & Sale Act 1956. (Malaysia)

AyurSlim
The safe, weight-loss formulation!

*A weight-loss
formulation
recommended for
obese individuals*



*AyurSlim contains herbs
that may be useful to:*

- ~~Burn calories~~
- ~~Suppress appetite~~
- ~~Improve bowel frequency~~
- ~~Reduce absorption of sugar~~

Key Ingredients:
Carelia curculio, Commiphora wightii,
Cynodon sylvesteris, Terminalia chebula
and Trigonella foenum-graecum.

Himalaya
HERBALS

Himalayan Herbal Care Sdn Bhd
Tel: (05) 243 2090
Fax: (05) 243 2085
E-mail: himalaya@tm.net.my
URL: www.himalayaherbalnigoo.com

[illegible]



MEDERMA

Skin care for scars

Get rid of unsightly scars fast with Mederma, including those resulting from accidents, surgery and burns. Just apply onto scars and you'll see the visible improvement - fast!



RM **27.40**

Pharmaton[®]
Caplets
with selenium



A combination of the standardized Ginseng Extract G115 with vitamins, minerals and trace elements in film-coated tablets. Convenient, easy-to-carry blister packs, especially for those on the move!

Pharmaton Caplets 30's	RM43.00
Pharmaton Caplets 60's	RM78.00

HEALTH TIPS

How to choose your Probiotics ?

A) Human strains bacteria
Bacteria from human sources attach to cells 10 times greater than dairy bacteria. Local Malaysian human strains serve better because they are already used to the environment of the human intestinal tract and are more likely to survive and colonize. They can adapt to our chatty & spicy diet, water and weather.

B) Lactobacillus
Lactobacillus was found to have excellent tolerance to the acidic condition in the stomach. Lactobacillus had been proven to resist gastric acid and bile, adhere to mucosa of human gastrointestinal tract and fight against potential pathogens - bacteria which causes diseases.

C) Getting the best strains
A major misconception by a lot of people is that, the more types of bacteria there are will give more benefits. Actually too many strains will only cause colonization of bacteria and may disrupt normal intestinal flora. As a result, it is better to take two to five single strain products than one multi-strain product (which have little viable organisms in it at consumption time).

D) Consume after food
An increased state of acidity in the stomach can destroy probiotics. This can be a waste of time and money. After a meal, the stomach becomes less acidic and this allows bacteria a better chance of surviving. Furthermore the decreased acidity following the consumption of food enables the population of probiotics to double in size.

E) Stay viable in room temperature
Majority of the probiotics available in the market need to be refrigerated. Refrigeration can cause condensation and the resulting moisture can destroy the bacteria. With the latest state of the art "freeze dried" technology, bacteria are cultured and dried to stay dormant for more than 3 years, at room temperatures. The key to friendly bacteria's effectiveness is their ability to be viable once they enter a conducive environment. Also, they are convenient to take along when traveling.

Message brought to you by:



Be the first 50 to call us for a FREE healthy token and a FREE Probiotics™ handbook:

THC

Total Health Concept Sdn Bhd
54, Jalan SS2/72,
47300 Petaling Jaya, Selangor.
Tel: 603-7965 2799
Fax: 603-7965 2727

PRINCE[®]
gold USA

Do you know.....
Prostate cancer has been the 2nd most deadly cancer
after lung cancer among men studied in majority of
developed countries.

Care for your prostate while it is still functioning.....
Prince Gold[®] Saw Palmetto Berries Extract, containing
160mg of the highest grade Saw Palmetto Berries

Made in USA
USFDA

Extract in lipid form available,
which have been
studied to be
more tolerable in
terms of efficacy
in absorption.
It contains 85%-
95% fatty acids
and sterols in
each soft gel.

Saw Palmetto Berries is a common herb consumed by
men ensuring proper function of the prostate may it
be powder capsule or tablet form, while Prince Gold[®]
Saw Palmetto Berries Extract Soft Gel is a **lipid extract**,
which has been found to be **more tolerable** compared
to other forms of Saw Palmetto extract. Once again, we
come to answer this Age-Old question again.....

QUALITY? OR QUANTITY?



Approved Distributors:
SARANI Healthcare Supplies (Private) Ltd., Two Storey Rd., #01-000, Telok Ayer Stm, Singapore 100
SARANI Healthcare Supplies (Australia) Pty Ltd, Suite 100, 430 Pitt St, Sydney NSW 2000 Australia
Pharmaceutical Link (Pty) Ltd, 100, 430 Pitt St, Sydney NSW 2000 Australia
Pharmaceutical Link (Pty) Ltd, 100, 430 Pitt St, Sydney NSW 2000 Australia
Pharmaceutical Link (Pty) Ltd, 100, 430 Pitt St, Sydney NSW 2000 Australia

AA Network Asia Mail: (770) 431 3011 Fax: 05 7987 6000 Fax: 05 7987 6000 E-mail: aa@network.asia.net

w w w . a a n e t w o r k . i n f o

**Now available, health supplements
in 100% animal-free soft capsules.**

Announcing the latest breakthrough in health supplements, Vegicaps® I-1. The world's first soft capsules that are 100% natural, totally free of any animal or artificial ingredients. No worries of any conflict with your religious beliefs, no fear of any animal diseases.

To: Amazing Aids Sales Dept. 238 Glen St/24711, 47501, Peaslee, Idaho
Tel: (208) 468-4436 Fax: (208) 468-4437

Please send me more information on The Health Farm's Virginia's "Soft"
☐ How it is different from statins or 2 piece hard capsules
☐ What products are available
☐ Where I can buy it

Mr/Ms/Mr _____ Age _____
Address _____
Tel No: () _____ Postcode _____

Neopage® Sulf is made from specially cultured molasses and glucose-yeast consortia.

It takes 56 steps and 30 quality control procedures to make one lego® set capsule. 7
 While production is fully computerized for safety, accuracy and
 standardized design, it also guarantees each capsule is tamper
 proof and free from moisture, oxygen and microbiological
 contamination.

SAVE RM15

So get a laptop that is not only attractive but also sturdy, reliable, available and easy to use.

Because it is 100% tripropylene in liquid form, the supplement is absorbed rapidly and fully—without any waste. What you eat is what you get.

Time is short
In just the
welling of
hours, a
whole lot
happening
in the
Quarter of
1998

Look out for the ASHP logo on patient products. www.ashp.org

SAVE RM15
with every purchase of
The Health Farm
Veggie® Soft Natural
Vitamins E 200 IU,
100's color packs at
selected pharmacies



The Health Farm Vegetables® Soft supplements from E. F. Scherer, the world's largest soft gel manufacturer.

SOLARAY® Since 1973
Trusted brand, wide range and great value.

Cranberry AF Extract

Painful & burning urination



Available at all leading pharmacies and Patiala branches.

Corway (M) Sdn. Bhd. (101224-A) Your Ultimate Choice For Healthy Living! Tel: 03-7883 9100 Fax: 03-7884 1327

Matters of the Heart



In the hustle and bustle of modern living, your heart is constantly going through hard times. An unhealthy diet rich in fat, lack of exercise, stress and smoking are just some of the factors that can affect your heart health. Simple lifestyle changes such as adopting a healthy diet, getting adequate exercise and sufficient rest should be practiced so that your heart stays healthy. Taking good health supplementation can also help take care of your heart.

NEW! WaterOxy - Oxygenated Mineral Water
For extra energy, drink WaterOxy - water with oxygen!
Natural mineral water which has been infused with oxygen gives bottles under pressure to re-blink and re-energize your body. Great for anyone who needs more energy - those recovering from illness, athletes, those feeling tired. Our special oxygen infused water means that the oxygen stays in the water and is released into your body after you drink WaterOxy - Not when you open the bottle.
500 ml Only RM1.95

GET CASH REWARDS FOR EVERY EMPTY BOTTLE RETURNED TO US!
Look for the sticker on the back of the bottle.

NEW!



L-ARGININE 500MG PLUS
21st Century L-Arginine is a natural amino acid that helps to maintain heart health.
30 vegetarian capsules
Only RM21.95



CO-ENZYME Q10 30MG
It is vital to every cell in our body, especially for the heart. The heart depends on CoQ10 to meet its constant energy needs.
30 vegetarian capsules
Only RM49.95
Also available in:
50mg (30%) for only RM69.95
100mg (60%) for only RM79.95



LECITHIN OMEGA COMPLEX
Contains 5 heart healthy ingredients: Lecithin, Omega-3 Fish Oils, Vitamin E, Garlic & Onion Extract.
30 softgels
Only RM34.95




GARLIC 20,000
Garlic is renowned for its role in supporting cardiovascular health. One a day to keep your heart going!
90 softgels
Only RM22.95


21ST CENTURY
The Ultimate Team

SAFE AND NATURAL. ONLY PHARMACEUTICAL GRADE INGREDIENTS USED. AVAILABLE AT ALL LEADING PHARMACIES AND CORWAY MEDICAL HALLS. 21ST CENTURY PRODUCTS Sdn. Bhd. (101224-A) TEL: 03-7883 9100 FAX: 03-7884 1327 www.21stCentury.com.my


IS YOUR LIVER HEALTHY?




A healthy liver acts as a general cleanser and regulator of the blood. It functions as a pollution controller. One that ensures poisons are made harmless, takes out dissolved foods and filters out pollutants from your blood. It also stores useful food and nutrients to be used when the body needs them. To help you maintain a healthy liver, 21st Century has created a range of supplements specially for people concerned about their liver health.




ALCOVITE
A powerful combination of Amino Acids, B-Complex, Vitamin C, Lipotropic & Vitamin E to help maintain a healthy liver for those who drink.
30 tablets
Only RM14.95



BIG-100
Contains high strength Vitamin C with active B-Vitamins to help nourish your liver.
30 tablets
Only RM21.95



SILYMARINE
A herb that has been shown to be very good for the liver. Helps in the maintenance of a healthy liver.
30 sachets
Only RM19.95



B-COMPLEX
A special B-Vitamins formula with lipotropics, wheat germ & lecithin to help you take care of your liver.
30 capsules
Only RM18.95

SEE US AT ALL LEADING PHARMACIES AND CHINESE MEDICAL HALLS. 21ST CENTURY PRODUCTS SDN. BHD. (INCORPORATED) TEL: 403-4034 2161 FAX: 403-4034 2162

21ST CENTURY
To 21st Century

SEE US AT ALL LEADING PHARMACIES AND CHINESE MEDICAL HALLS. 21ST CENTURY PRODUCTS SDN. BHD. (INCORPORATED) TEL: 403-4034 2161 FAX: 403-4034 2162

BIO-LIFE

Healthcare as Nature intended



IMMUNE BOOSTING NUTRIENTS

MULTIBLEND PROBIOTIN
Yoghurt Capsules
Restore the balance in your gut ecology and improve digestive health and immunity. Each vegetable capsule provides 5 billion C.F.U. of live and active cultures from the major probiotics: *Lactobacillus*, *Bifidobacterium* and *Streptococcus*. Suitable for adults and children.

AB JUNIOR Yoghurt Powder
with live & active cultures
A delicious vanilla flavoured probiotic supplement for children. Contains 1 billion C.F.U. of two clinically proven strains, *Lactobacillus acidophilus* EA-3TM and *Bifidobacterium BB-12TM*. AB Junior can be taken directly or added to water or juice. Helps to ward off allergies and improve absorption of nutrients for optimal growth and development.

EVENING PRIMROSE OIL
to enhance skin and overall wellbeing
Evening Primrose Oil (EPO) is a rich source of Omega 6 fatty acids and Gamma Linolenic Acid (GLA). Available in 500mg and 1000mg vegetable based soft capsules with 100% S.O.A. Suitable for men & women of all ages.

FISH OIL 1000mg
for brain, vision and cardiovascular health
Each 1000mg vegetable based soft capsule contains pharmaceutical grade fish oil with 1000mg of Eicosapentaenoic Acid (EPA) and 300mg of Docosahexaenoic Acid (DHA). Bio-Life Fish Oil has been tested for safety, potency and quality. The ideal way to ensure optimal intake of Omega 3 fatty acids.

For advice on natural healthcare & holistic therapies, CALL CUSTOMER HEALTH ADVISORY 03-77282407 (Mon-Fri)
Available at all leading pharmacies. e-mail: health@bionlife.com.my

Below are the categories of advertisements that was publicized without adhering to the format approved by the M.A.B.

Format Yang DiluluskanFormat yang disiarkanFormat yang diluluskanFormat Yang Disiarkan

Format yang diluluskan

Kanak-kanak Aktif dan Cergas Memang Menyenangkan

Perintah dari pemerintah

Kanak-kanak yang aktif dan cergas adalah hal yang diinginkan oleh orang tua. Untuk itu, orang tua harus memastikan bahwa anak-anak mereka mendapatkan nutrisi yang cukup. Blackmores Kids adalah suplemen nutrisi yang lengkap untuk anak-anak. Dengan mengonsumsi Blackmores Kids, anak-anak akan mendapatkan nutrisi yang mereka butuhkan untuk tumbuh dan berkembang dengan sehat. Blackmores Kids adalah suplemen nutrisi yang lengkap untuk anak-anak. Dengan mengonsumsi Blackmores Kids, anak-anak akan mendapatkan nutrisi yang mereka butuhkan untuk tumbuh dan berkembang dengan sehat.

TIDAK BERTAKUT LINTAH, PERICU, ATAU PERMATA

BLACKMORES

DILULUSKAN

Format Yang Disiarkan

Active, lively kids are a joy.

Blackmores Multivitamins & Minerals For Kids ensures kids get their full supplement of nutrients daily for healthy growth.

BLACKMORES

www.blackmores.com.au

Appendix C

Compilation of Cases in breach of Medicines (Advertisement and Sale) Act 1956 by the Pharmacy Enforcement Section, Ministry of Health Malaysia.

Bil/No	Syarikat/Company	Tahun/Year	Kesalahan/Breaches	Denda/Fine
1	Yun nam Hair Cair S/B.	2004	S 4A	1,500.00
2	Rodiah Tok Kechil	2004	S 4B	1,000.00
3	Svenson S/B.	2004	S 4A	400.00
4	TRN Marketing S/B.	2005	S 4B	500.00 @ penjara 2 minggu
5	TRN marketing S/B.	2005	S 4B	500.00 @ penjara 2 minggu
6	Blue Iris Marketing S/B.	2005	S 3(1)	700.00 @ penjara 3 minggu
7	Pfizer (M) S/B.	2005	S 4B	700.00 @ penjara 3 minggu
8	Leesa Formula S/B.	2006	S 3(1)(c)	500.00 @ penjara 2 minggu
9	Organon (M) S/B.	2006	S 4B	800.00 @ penjara 2 bulan
10	Bella'Z Mutiara Marketing S/B.	2006	S 4B	700.00 @ penjara 2 bulan
11	Sendayu Tinggi S/B.	2006	S 4B	1,000.00
12	Audra Herbal S/B.	2006	S 4B	800.00 @ penjara 1 bulan
13	Liwon Marketing S/B.	2006	S 4B	900.00
14	D'Navenchee S/B.	2006	S 4B	900.00
15	Nona Rogay S/B.	2007	S 4B	800.00 @ sebulan penjara
16	Kumpulan Malay Media S/B.	2007	S 4B	700.00 @ sebulan penjara
17	Kumpulan KTH S/B.	2007	S 4B	700.00 @ sebulan penjara
18	Alice Total Health & Beauty Specialist S/B.	2007		900.00 @ 9 hari penjara
19	Herba Al -Jabbar	2008	S 4B	1,000.00
20	Million Ringgit Marketing	2007	S 3(1)(c)	700.00 @ 7 hari penjara
21	Kumpulan Malay Media S/B.	2007	S 3(1)(c)	1,500.00 @ 7 hari penjara
22	D'Navenchee Beauty S/B	2008	S 4B	2,000.00 @ 2 bulan penjara
23	Era Cekap Enterprise	2009	S 3(1)(a)	1,500.00 @ 1 bulan penjara
24	Dunia Herbs Sales & Marketing	2009	S 4B	1,500.00 @ 1 bulan penjara
25	Herbaceutical (M) S/B.	2009	S 4B	3,000.00 @ 5 bulan penjara
26	Al-Jabbar Healthcare S/B.	2009	S 3(1)(a)	4,000.00 @ 5 bulan penjara
27	Easy Excell Biz S/B.	2010	S 3(1)(c)	1,200.00 @ 2 bulan penjara

Appendix

Statistics on the Number of Cases charged under the *Medicines (Advertisement and Sale) Act 1956* for Malaysia.

Statistik Pendakwaan Untuk Kes-kes Kesalahan di Bawah Akta Ubat (Iklan dan Jualan) 1956 Untuk Seluruh Negara

Tahun/Year	Jumlah kes/No of Cases	Denda (RM)/Fine
2005	10	7,300.00
2006	11	10,250.00
2007	18	16,800.00
2008	25	27,500.00
2009	29	50,100.00
2010 (sehingga Jun)	12	19,400.00

Kesalahan yang terlibat dibawah Akta Ubat (Iklan dan Jualan) 1956 yang biasa didakwa adalah :

1. Tidak mematuhi Seksyen 3(1)(a,b,c,d)
2. Tidak mematuhi Seksyen 4A
3. Tidak mematuhi Seksyen 4B

Complied by Ghazali Mansor, Senior Principal Assistant Director, Legal Section, Pharmacy Enforcement Section, Ministry of Health Malaysia on the 3rd of December 2010.

Appendix D - A recent Internet search of websites on types of advertising claims.

Advertisements also commonly show before and after photographs of patients who had taken the product and allegedly been cured.

testimonies; in one of which there was a claim of a cure for cervical cancer,¹ **GAMAT HEALIN**
better healthy life

- Home
- Healwell
- gamolen and gamatol
- testimony of jelly
- documentary
- FAQ
- contact us

INJURED LEG CURED BY GAMAT JUICE



PUAN Halimah has suffered from diabetes for several years and ail efforts and pains were taken to cure that disease but with no encouraging results. A lot of expenses were incurred to cure the discase. It happened when she accidentally kicked a sharp object in front of her house. Her left leg toe started to swell. She consulted several traditional doctors and tried various traditional medicine without success.

Unfortunately, her left leg continued to swell further making her movements difficult and restricted. She suffered immense pain when her toe wound worsened. To reduce the pain she took pain killers bought from a nearby shop where she stays. The painkillers were temporarily effective and she was in pain again. Due to the pain she was going through, she consulted a doctor in Selama, Perak. She was advised by the doctor to amputate her toe. However, Puan Halimah had no desire to lose her toe but rather leave it as it was then to be cripple.

Puan Halimah was approached by an Awal Gamat agent who recommended her Gamat Juice. At first she had little faith in the product, as to what effect a juice could do to cure her legs. After much convincing from the agent, she decided to try the product. However, after a short period of consuming the Gamat Juice she noticed changes in her wounds. It dried up the pus on her wounds. It also reduced the swelling of the toe and other parts of her legs. Since then, she began to believe in the product and it is a must for her to consume the Gamat Juice. Smilingly, she said: "it is a must for me to consume Gamat Juice or my life is incomplete".

She also wishes to advice others who suffers the same fate to start using Gamat Juice immediately as it would be foolish not to try something new but rather lose part of their organs.

" like me, I did not believe in the product but after trying it I know of the effectiveness of the Gamat Juice. It is not because I am trying to promote the product but only trying to help others who suffer the same fate I did", said Puan Halimah.

EFFECTS OF GAMAPEPTIDE ON HUMAN SKIN

Nothing even comes close to measuring up with Gamat Oral Juice/Jelly when it comes to beauty enhancement. It helps your body to produce natural collagen to delay and reduce fine lines and improve complexing noticeably. No expensive collagen-based or anti-oxygen gels can compare. As much as external application product claims to work beneath the skin, our observations show that only Gamat Oral preparation, truly rejuvenates the skin from within.

The numerous studies carried out after consumption of Gamat Oral preparations have provided evidence of;

- i. Stimulating effect on cell renewal of the epidermis, thanks to the formation of new vessels and greater oxygen consumption, thus better cellular respiration.
- ii. Greater suppleness caused by maintaining a satisfactory degree of moisture in the skin and good elasticity due to better quality of the supporting fibers.

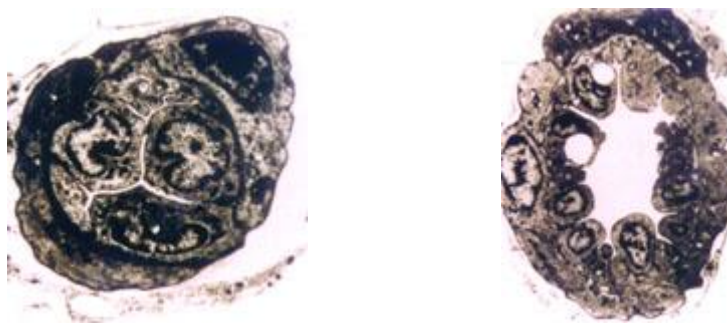
More than just enhancing the superficial condition, gamat oral preparations consumption go beyond the skin-deep layer, literally to improve the overall state of the being.

Skins.

Whether consuming it orally or applying directly onto the skin surface, the main effect of Healin Master is on blood vessels and capillaries. This substance could increase the blood flow by dilating the blood vessels and capillaries in organs, tissue and on the skin surface. By doing this it helps to nourish the organs, tissue, cells and skins with nutrient and increase the supply of oxygen. Research has shown that nourishing the skin from the inside will help maintaining a regular skin structure and in the presence of gama peptide it will rebuild damaged skin.

Cardiovascular System

Our research data have shown that following consumption of Oral Jelly for one hour, it exhibited a protective effect on cardiovascular system anaphylactic reaction. It's proven cardio tonic activity, that is increase the ability of heart to beat in addition to its vasodilator effect on coronary arteries may probably account for the observation that it could relieve chest pain in most patients. Thus, it is assumed that Healin Master oral preparations may be of benefit in those affected by circulatory disorders like high blood pressure, short of breath (dyspnea) in chained smokers and the feeling of lethargy.



Healing of wounds and suppression of inflammation

Taking Healin Master oral preparation will increase the insulin release from the pancreas. Thus causes increased utilization of glucose and oxygen. These two effects are coupled and they result in a rise in the ATP-turnover and thus in a greater provision of energy in the cell.

In deficient state with impairment of the normal function of the energy metabolism such as hypoxia (short of oxygen supply), and in states of increased energy requirement in reparation and regeneration, Healin Master oral preparation promotes the energy-dependent processes of the functional metabolism and the conservation metabolism. An increase in blood supply is seen as a secondary effect.

The levels of insulin increase in a dose-dependent manner following the intake of oral preparation. This probably accounts for the reduction in blood glucose level and the stimulation in appetite especially in the early stage of consumption.

iv. Respiratory System

One day because of excruciating pain my back and difficulty in breathing, I went to the hospital only to find that my right lung had degenerated. The doctor probed from all angles, but could not locate the cause. I was discharged after 2 days in the hospital with just some antibiotics and routine steroid treatments. The pain plagued me daily thereafter and I could hardly sleep at night. I was depressed and campus life was uninteresting because of my inability to participate in laboratory work. After taking GAMATTM plus for 3 weeks, my pain was gone and I could breathe much better. My face was smoother and rosy - much better than before GAMATTM intake. Now I look forward to campus life and every day is a new challenge (photos attached).



i) Image (x-ray)

showing the degeneration of right lungs.

ii) 3 weeks after the intake of GamatPlus.

Radio imaging shows the reappearance of blood vessels in the right lung.

Pharmacology of Gamapeptide Extract (Supreme Gamat)

Laboratory observations indicates that gamapeptide injection or ingestion though oral route produced various dose-dependent effects, including the promotion of cellular respiration (increase oxidative phosphorylation), induction of wound healing, suppression of pain, systemic anaphylactic reactions and suppression of fatigue.





1. *Promotion of Wound Healing*
The wound healing promotion was markedly stronger that of control guinea pigs with induced wounds. The recovery time was 3-fold faster than the control group.

2. *Anti-Stress Effect*
Ingestion of extract exhibited anti-anaphylactic effects when tested on systemically induced anaphylactic reactions. Guinea pigs sensitized with ovalbumin will undergo systemic anaphylactic reactions and died within 9 minutes following the challenge with and antigen. Pretreatment with Gamapeptide extract orally delayed the death for 47 minutes whilst comparatively, pretreatment with dexamethasone managed to delay time of death for only 21 minutes.

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Toxicology Acute Toxicity Studies

Lethal Oral Dose (ml/kl)

Infinity no animal (mouse) died when consume up to 100 ml/kl body weight.

Teratogenicity

Daily ingestion at 10-100 mg/kg (therapeutic effect can be obtained at 3-10 mg/kg) body weight for 14 days on day 7 and 17 of pregnancy in female Wistar rats. This substance produced to influence on fetus delivered at term or pups ages 21 days or younger.

Anaphylaxis Test


Guniea pigs or sensitized guinea-pigs were administered orally with Gamapeptide Extract and observed for occurrences of systemic anaphylactic reactions. No anaphylactic reaction was observed follwing the ingestion.

Histamine Test

Pain and itch Perception

Our studies both experimentally and clinically in patients with injuries suggest that products of "Gamat" possesses remarkable effect on suppression of pain and itch perception. When you are inflicted with pain associated with injuries, any of the product of healin Master, be it cream, gel, body, shampoo, nor facial foam, will surely relieve the pain and itch sensation.

Leng Sin - Testimonies; in one of which there was a claim of a cure for cervical cancer,²



The banner features the 'LS' logo and the text 'Leng Sian Herbal Tea' in a stylized font. Below this, it says 'An Inherited Traditional Herbal Preparation!!'. The background shows a man and a woman smiling while drinking tea at a table. There are also images of tea boxes and a tea set.


→ Testimonials

Symptoms

- Cancer
- Diabetes
- Ovarian Problem
- Thyroid

Our Products

- Herbal Tea

 **Call Us NOW !**
Tel : (6)05-808 3133

Case 1: Cervical cancer

Symptoms :Cancer

■

In August 1995, madam Choo was diagnosed with cervical cancer. She then accepted series of radiotherapy treatment. There was no improvement after radiotherapy, more over she suffered from the side effects.

On 5 September 1995, she started drinking **LS Herbal Tea** (50gm) and one bottle of Xiao Yan Bao, and she followed our advice on diet ?cutting down the intake of meat.

Madam Choo went back for check-up after 3 months on herbs. Medical report indicated that she had great improvement.

She continued drinking **LS Herbal Tea** (20gm) everyday, and taking Xiao Yan Bao occasionally (every one or two week once).

One year later she went back to the same hospital for medical check-up, doctor confirmed that she was free of cancer at that time.

² <www.lengsian.com.my>. Last visited 9 November 2010.



TAIPING MEDICAL CENTRE

Your Ref:

Our Ref:

Page No. 1
10/22/98

Date:

Dr. Lim
Consultant Surgeon

To Whom It May concern

Re: CHOO MAH

The above named first presented to me with severe anaemia in Feb 1995. Her Hb was 4.gd/dl and she had lightheadness. She had a widespread murmur too. She had had cervical cancer and completed a course of radiotherapy. She had heavy haematuria. VE shows no palpable recurrence of her tumour and she denies per rectal blood loss (radiation proctitis). She is obsessive about food restrictions and takes no chicken, eggs, seafood except a few types of fish.

Cystoscopy showed severe radiation cystitis. She has had several treatments of formalin instillation which have stopped the haematuria. She is no longer anemic and takes a normal diet. On a few occasions at cystoscopy low grade transitional cell bladder tumour has been observed. However that has clear both spontaneously and with TUR resection.

She has remained well the past one year.

Sincerely,

Dr. Lim
MB, Ch.B, FRCS (Ed) /
CONSULTANT SURGEON



Case 2: Uterus fibroid

Symptoms :Ovarian Problem

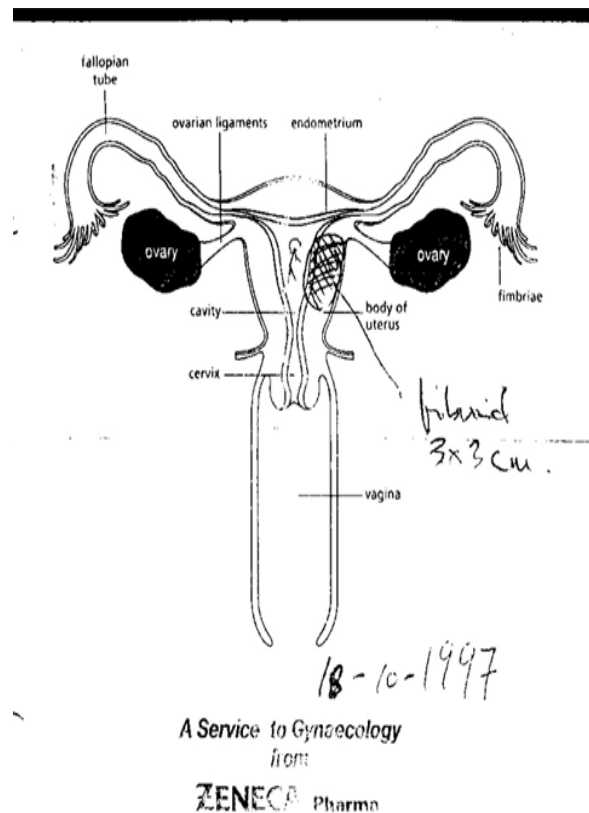
- Madam Loo (42 years old) has menstrual pain since early age. She needs to take 1 strip of menstrual panadol a day when having menstrual pain. In September 1997, she experienced heavy menstrual flow.

A 3x3cm fibroid was discovered in her ovary.

After medical consultation, she started drinking **LS Herbal Tea** (40gm) everyday.

- After drinking for 1 month, she did not have any discomfort during menstruation.
- She did not experience menstrual pain in the subsequent 2 months.

In February 1998 she went back to the same specialist center for check-up. It was confirmed that there is no more fibroid in her ovary.



Case 3: Diabetes, Heatiness

Symptoms :Diabetes



Mr. Chua who works in a farm always has headache, flu, and heatiness problems for years. He also suffers from constipation problem, every time he spends about half an hour in toilet. Moreover, he always feels breathless when he is working.

His 48-year old mother has diabetes. Both her legs are swollen (edema), and she also has frequent urination. She need to go to clinic almost every month for same reason; vomit and diarrhea due to heatiness.

Mr. Chua started drinking **LS Herbal Tea** everyday with the dosage of 50gm, boiling in 1.5 liter of water. The first boiling was given to her mother, while he took the second boiling.

Two days after he drank **LS Herbal Tea**, he felt much better when going to toilet, there was no more constipation. One week later, he experienced an overall improvement, he sweat a lot when farming, he felt very healthy. In fact, he never feel breathless and headache anymore.

Great improvement was seen in his mother's health too. Firstly, vomiting and diarrhea problem were gone, then her swollen legs started to subside. At the same time, she did not have frequent urination, only 2 to 3 times a day (day time). And her sugar level dropped to normal from 16mmol/liter.

▶ Case 4: Ovarian Fibroid

Symptoms :Ovarian Problem

Ms Lee (22 years old) always has heavy menstrual flow.

Medical check-up indicated that she had a ovarian fibroid (7 years ago, forgotten about the size). Doctor suggested to remove, but parents opposed to the operation.

She started drinking **LS Herbal Tea**. After 2 months, she went for medical check-up in Singapore, no more fibroid.

She returned to Sabah for her study after that. Went for another medical-check up, confirmed no more fibroid.

▶ Case 5: Thyroid, Female related problems

Symptoms :Thyroid



Madam Lee (43 years old) has thyroid problem Whenever she is moody, her thyroid glands would enlarge and she would feel pain. She always feels lack of energy, flu and headache.

Started drinking **LS Herbal Tea** in June 2002 (40gm a day). After 3 months, her thyroid problem subsided.

Her daughter (18 years old) has leucorrhea and pre-menstrual syndrome, she always feel lethargy and discomfort. After drinking **LS Herbal Tea** for 2 months, all her problems disappeared.

▶ Case 6: Hipoglycemia

Madam Tan used to suffer from sudden blackout. There was once she black-out and fell off from a bike while riding pillion on the road. Besides, she always fainted when working halfway, as a result, she was force to quit the job.

She tried to consult many doctors, but her condition did not improve.

After drinking **LS Herbal Tea** for about 1 month, her condition improved significantly. She continues drinking **LS Herbal Tea** , and her problem never relapse. Now, she has returned to her job. She has been drinking **LS Herbal Tea** fore more than 4 years.

Advertising claims such as that medicinal products are purely 'herbal and safe', '100% safe and effective', or '100% natural' are found.³

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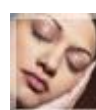
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³. Rainforestherbs at <<http://www.rainforestherbs.com/products.html>>. last visited 9 November 2010.

