SMI
New Zealand
Self-Medication Industry
Association Inc.

Code of Practice

17 April 2012

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Note: Explanatory notes have been provided throughout the Code to assist with its implementation at an operational level.

PREFACE

This Code of Practice of the New Zealand Self Medication Industry Incorporated ("NZSMI") was adopted at on 2012

NZSMI is the premier body representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products in New Zealand.

NZSMI is committed to ensuring that safe and effective self-care products are readily available to all New Zealanders.

This Self Regulatory Code of Practice has two objectives:

i) to develop and sustain an environment for the practise of responsible self medication; and
ii) to promote appropriate standards of commercial conduct.

If you have concerns about the marketing or advertising practises of a member of the New Zealand Self-Medication Industry you can make a complaint to the Complaints Panel established under this Code.

For more information about how to make a complaint to the Complaints Panel of the Association contact:

Executive Director
NZSMI Inc
P O Box 6473
Auckland
New Zealand

Phone/Fax: +64 9 235 5260
www.nzsmi.org.nz

1. DEFINITIONS

In this Code of Practice:

"Advertisement" has the same meaning as assigned to that term by the Medicines Act (except that, for the purposes of this Code, labels are excluded from the definition) and "advertising" has a corresponding meaning.

"Approved Sampling Protocol" means a protocol submitted to and approved by the Executive Director which requires that the offer of a sample:

i) must only be to a competent consumer no less than 18 years old
ii) must only be made from a location where the sample would be offered for sale in the normal course of business and in accordance with the Medicines Act
iii) must only be made by a person suitably and appropriately trained and informed to answer questions about the sample that a reasonable consumer would want to know.
iv) May only be provided accompanied by the Consumer Information Leaflet for the sample

"Association" means the New Zealand Self-Medication Industry Association Incorporated.

"Code" means this Code of Practice of the Association.

"Dietary Supplements" has the meaning assigned to that term by the Dietary Supplements Regulations 1985.

"Executive Director" means the Director for the time being of the Association.

"Excessive Quantities" means a larger quantity than is sufficient to meet the reasonable needs of the consumer.

"General Sale Medicine" has the meaning assigned to that term by the Medicines Act.

"Healthcare Professional" means a person registered as a practitioner with a responsible authority (regardless of whether that person holds an Annual Practising Certificate) pursuant to the Health Practitioners Competence Assurance Act 2003.

"Item" means a consumer good offered to a consumer which is not a Therapeutic Product or a Natural Health Product.

"Medical Device" has the meaning assigned to that term by the Medicines Act.

"Medicine" has the meaning assigned to that term by the Medicines Act.

"Medsafe" means the New Zealand Medicines and Medical Devices Safety Authority; A Business Unit of the Ministry of Health.

"**Medicines Act"** means the Medicines Act 1981.

"Members" means members of the Association in any category of membership provided for in its Constitution and Rules.

"Multi-Buy Offer" means an offer to a consumer to:

i) buy two non-prescription medicines for the price of one or for a reduced price; or

ii) buy one non-prescription medicine and get another non-prescription medicine free or for a reduced price; or

iii) buy one non-prescription medicine and get a free item; or

iv) buy a combination of items which include one or more non-prescription medicines for a cheaper price than if purchased separately; or

v) any similar statement or offer.

1. Definitions *continued*

"National Launch" means:

i) the date the Therapeutic Product or Natural Health Product becomes available for sale by retail; or

ii) the date on which the Therapeutic Product becomes available for sale by retail with a new indication.

"Natural Health Product" means any complementary healthcare product being a product which is not registered as a medicine in accordance with the Medicines Act and which is sold by retail without claiming a therapeutic purpose and includes dietary supplements until the date on which the Natural Health Products Act 2011 comes into force on which date National Health Products will have the meaning assigned to that term by the Act.

"Non-Prescription Medicine" or **"OTC Medicine"** means any medicine registered in accordance with the Medicines Act as either a Restricted Medicine or a Pharmacy-Only Medicine or a General Sale Medicine as those classifications of medicines are defined in the Medicines Act.

"Pharmacist-Only Medicine" has the same meaning as that assigned to the term Restricted Medicine by the Medicines Act.

"Pharmacy-Only Medicine" has the meaning assigned to that term by the Medicines Act.

"Prize Competition" means a contest for a prize where purchase is a condition of entry.

"Product" means Therapeutic Product or Natural Health Product.

"Promotional Activities" includes any and all representations or activities concerning the attributes of a Therapeutic Product or Natural Health Product conveyed by any means whatsoever with the primary intention, either directly or indirectly, of encouraging or promoting use of that Therapeutic Product or Natural Health Product by any medium (including electronically) and in any media (including websites).

"Related Product" has the meaning assigned to that term by the Medicines Act.

"Respondent" means a Member in circumstances where the Executive Director has received a complaint about the Member.

"Restricted Medicine" has the meaning assigned to that term by the Medicines Act.

"Therapeutic Product" means any Non-Prescription Medicine, medical device or any Related Product permitted for sale by retail for self-medication without a prescription.

"Therapeutic Purpose" has the meaning assigned to that term by the Medicines Act.

2. INTRODUCTION

2.1 The World Self Medication Industry ("WSMI") has published guidelines for developing voluntary self regulatory Codes of Advertising Practice for Non-Prescription Medicines and Natural Health Products. WSMI recognises the "Ethical Criteria for Medicinal Drug Promotion" adopted by the World Health Organisation. This Code of Practice of the New Zealand Self-Medication Industry Associated Incorporated ("NZSMI") aligns with these guidelines.

2.2 This Code of Practice of NZSMI also aligns with the Code of Practice of the Australian Self Medication Industry Incorporated ("ASMI").

2.3 The standards of practice set out in this Code are to increase public awareness, informed choice and the responsible use of Therapeutic Products and Natural Health Products for self medication.

2.4 Therapeutic Products for self-medication are advertised and sold directly to the public, without a prescription. These products are intended for use by consumers to help prevent and/or treat symptoms and/or ailments. They also assist consumers in maintaining well being and enable consumers to manage their own chronic and/or recurrent conditions.

2.5 Encouraging people to participate fully in decisions affecting their healthcare coincides with a trend for consumers to desire greater autonomy and a healthier lifestyle.

2.6 The use of Therapeutic Products for responsible self medication increases the consumer's access to appropriate healthcare advice and treatment and reduces pressure on medical services.

2.7 Advertising has great potential for conveying public healthcare messages. It serves to stimulate competition and economic growth and helps contain the cost to the consumer.

2.8 Advertising must inform and educate the public on the availability, purpose, and benefits of Therapeutic Products and Natural Health Products. Advertising must contain only correct valid balanced and verified statements and claims and must not mislead directly or by implication.

2.9 This Self Regulatory Code of Practice of NZSMI has two key objectives:

2.9.1 to develop and sustain an environment for the practise of responsible self medication; and

2.9.2 to promote appropriate standards of commercial conduct.

2.10 Acceptance and observance of provisions of the Code are a condition of membership of the Association.

3. OBJECTIVES OF THE CODE

3.1 The objectives of the Code are as follows:

3.1.1 To provide members with appropriate guidance and standard setting to demonstrate the industry's commitment to a professional approach to self regulation.

3.1.2 To assist members to comply with the WSMI Guidelines.

3.1.3 To assist members to align appropriately with the ASMI Code of Practice.

3.1.4 To appropriately and clearly define standards required in the advertising and promotion of Therapeutic Products and Natural Health Products to consumers and healthcare professionals to develop and sustain an environment for the practise of responsible self medication.

3.1.5 To ensure the industry responsibly informs consumers and healthcare professionals and upholds a high standard in the communication of information.

3.1.6 To promote appropriate standards of commercial conduct.

3.1.7 To establish parameters to guide members in the conduct of their businesses particularly in matters of advertising and promotion.

PART A:

THE CODE AND ITS APPLICATION

4. Principles of Practice

4.1 No member shall engage in any practice which is likely to introduce any hazard to the consumer.

4.2 No member shall engage in any practice that brings the self-medication industry into disrepute or undermines the professionalism or standing of the self-medication industry.

4.3 Each member shall at all times ensure that they are familiar with, and comply with Acts and Regulations which pertain to the functions and operations of the self-medication industry.

4.4 Each member shall at all times ensure that they are familiar with, and comply with, the provisions of Codes issued by the New Zealand Advertising Standards Authority and Guidelines issued by Medsafe which pertain to the functions and operations of the self-medication industry.

4.5 Each member shall at all times ensure that they are familiar with and comply with the requirements of this Code and the responsibilities inherent in membership of the Association.

4.6 Each member shall collaborate with the Association to support its programmes and activities aimed at achieving quality use of Therapeutic Products.

4.7 Each member shall act at all times, in all advertising and promotional activities, in a manner which demonstrates social responsibility, to support and facilitate responsible self-medication by consumers.

4.8 Each member will assist the Association to protect against the diversion of medicines for the production of illicit substances.

EXPLANATORY NOTES TO CLAUSE 4 Principles of Practice

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5. Advertising and Promotion

5.1 General Principles

5.1.1 An advertisement for any Therapeutic Product or Natural Health Product must:

5.1.1.1 comply with the statutory and regulatory requirements and with applicable Codes of the New Zealand Advertising Standards Authority.

5.1.1.2 contain only correct valid balanced and verified statements and claims based on current knowledge and evidence.

5.1.1.3 be pre-vetted for compliance with requirements of the Therapeutic Advertising Pre-vetting System (TAPS) established by the Association of New Zealand Advertisers prior to publication and where appropriate or required bear the appropriate approval number issued.

5.1.1.4 encourage consumers to read and follow label directions.

5.1.2 An advertisement for any Therapeutic Product or Natural Health Product must not:

5.1.2.1 be likely to arouse unwarranted and/or unrealistic expectations of effectiveness.

5.1.2.2 be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases.

5.1.2.3 mislead directly or by implication or through emphasis, comparisons, contrasts or omissions.

5.1.2.4 abuse the trust, or exploit the lack of knowledge of consumers or contain language which could reasonably bring about fear or distress.

5.1.2.5 contain any matter which is likely to lead reasonable consumers to believe that they are suffering from a serious ailment or that harmful consequences may result from the Therapeutic Product or Natural Health Product not being used.

5.1.2.6 encourage inappropriate or excessive consumption or use or encourage purchases in a larger quantity than is sufficient to meet the reasonable needs of the consumer.

5.1.2.7 contain any claim, statement or implication that the Therapeutic Product or Natural Health Product is infallible, unfailing, magical, miraculous, or that it is a certain or guaranteed or sure cure.

5.1.2.8 contain any claim, statement or implication that the Therapeutic Product or Natural Health Product is effective in all cases of a condition.

5.1.2.9 contain any claim, statement or implication that the Therapeutic Product or Natural Healthcare Product is safe or that its use cannot cause harm or that it has no side effects.

5.1.2.10 be directed to minors, except under special circumstances.

5. Advertising and Promotion: General Principles *continued*

5.1.2.11 bring the self-medication industry into disrepute or undermine the professionalism or standing of the self-medication industry.

5.1.2.12 use the term “new” more than one calendar year following the National Launch of the Therapeutic Product or Natural Health Product.

5.1.2.13 imitate slogans or devices of other members in a way intended to or likely to mislead.

5.1.3 Each member is responsible for ensuring that such of its employees who are engaged in or have responsibilities relevant to or touching upon the matters covered in this Code, are appropriately trained in and understand the obligations of the Code to discharge any responsibilities of membership of the Association.

EXPLANATORY NOTES TO CLAUSE 5.1 Advertising and Promotion: General Principles

General

The contents of the Code do not duplicate or restate requirements already in place through the operation of Acts, Regulations or Codes of the New Zealand Advertising Standards Authority or Medsafe Guidelines. Therefore this Code does not restate amongst other matters, the specific requirements for advertisements for pharmacist-only medicines, pharmacy-only medicines, or general sale medicines or Natural Health Products. Neither does this Code restate the specific requirements for advertising and promotion to healthcare professionals. See also:

- *Schedule 3 List of Relevant Codes and Guidelines; and*
- *Schedule 4 Extracts of relevant Legislation*

Re clause 5.1.2.12

National Launch is defined as:

(i) the date the Therapeutic Product or Natural Health Product becomes available for sale by retail; or

(ii) the date on which the Therapeutic Product becomes available for sale by retail with a new indication.

5. Advertising and Promotion *continued*

5.2 Scientific Information

5.2.1 Any scientific information included in an advertisement must be:

5.2.1.1 valid;

5.2.1.2 reliably substantiated such substantiation to be provided by the member without delay if requested to do so;

5.2.1.3 not obsolete, presented in a manner that is accurate;

5.2.1.4 balanced and not misleading.

5.2.2 Scientific terminology must be appropriate and able to be readily understood by the consumers or healthcare professionals to whom it is directed.

5.2.3 Any research results included in an advertisement must:

5.2.3.1 include a citation of the report;

5.2.3.2 have been published in a respected and peer reviewed journal or other similar publication;

5.2.3.3 not be repeated in such a way that another meaning to that intended by the report is conveyed;

5.2.3.4 not mislead as to data made obsolete or false by subsequent findings.

EXPLANATORY NOTES TO CLAUSE 5.2 Advertising and Promotion: Scientific Information

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5. Advertising and Promotion *continued*

5.3 Comparative Advertising

5.3.1 Comparative advertisements may only be used in circumstances permitted by the Codes of the New Zealand Advertising Standards Authority.

5.3.2 Comparative advertisements must be balanced and must not be unsubstantiated or likely to mislead the reasonable consumer, either about the Therapeutic Product or Natural Health Product advertised or that with which it is compared.

5.3.3 Comparisons should be factual and reflect substantiated current scientific evidence.

5.3.4 Comparisons should not imply that the Therapeutic Product or Natural Health Product to which it is compared is harmful or ineffective.

5.3.5 Comparisons must not insult, denigrate or unfairly criticise any other Therapeutic Product or Natural Health Product.

EXPLANATORY NOTES TO CLAUSE 5.3 Advertising and Promotion: Comparative Advertising

General

(i) Clause 4.4 of this Code requires compliance with provision of Codes issued by the New Zealand Advertising Standards Authority. One such code is the Advertising Standards Authority Code for Comparative Advertising 17 July 1989.

(ii) Section 94 of the Trade Marks Act 2002 permits the use of a competitor's trademark for the purposes of comparative advertising but only if this is in accordance with honest practices in industrial or commercial matters and the use must not take unfair advantage of, or be detrimental to, the distinctive character or the repute of the trade mark.

5. Advertising and Promotion *continued*

5.4 Multi-Buy Offers and Price Promotions

5.4.1 No member shall engage in any Multi-Buy Offer or Price Promotion where such advertisement or promotion or activity is likely to encourage or persuade reasonable consumers to purchase inappropriate or excessive quantities of a Therapeutic Product.

EXPLANATORY NOTES TO CLAUSE 5.4 Advertising and Promotion: Multi-Buy Offers and Price Promotion

General

(i) Multi-Buy Offer is defined in clause 1. It means an offer to a consumer to:

a) buy two non-prescription medicines for the price of one or for a reduced price; or

b) buy one non-prescription medicine and get another non-prescription medicine free or for a reduced price; or

c) buy one non-prescription medicine and get a free item; or

d) buy a combination of items which include one or more non-prescription medicines for a cheaper price than if purchased separately; or

e) any similar statement or offer.

(ii) The restriction on Multi-Buy Offers applies only to Therapeutic Products (i.e. to non-prescription medicines and related products) and does not apply to Natural Health Products.

(iii) The restriction on Multi-Buy Offers applies to all non-prescription medicines whether they be pharmacist-only, pharmacy-only or general sales medicines

(iv) The restriction on Multi-Buy Offers does not prohibit Multi-Buy Offers if they do not encourage purchase of inappropriate therapeutic products or of excessive quantities.

(v) By way of example only, this rule:

a) would prohibit a Multi-Buy offer which included a pharmacist-only medicine.

b) would prohibit a Multi-Buy Offer which offered a consumer a total quantity of non-prescription medicine in excess of the quantity contained in the largest pack of that non-prescription medicine approved for sale pursuant to the Medicines Act

c) would not prohibit a Multi-Buy Offer where the non-prescription medicine is commonly stored by consumers for reasonable and appropriate future use.

d) would be unlikely to prohibit a Multi-Buy Offer on a Related Product as such offers would be unlikely to encourage purchase of either inappropriate or excessive quantities due to the lower risk nature of Related Products (by comparison with other Therapeutic Products).

e) would not prohibit a Multi-Buy Offer where the free item offered is of minimal value by comparison with the price of the non-prescription medicine such as bottled water, a medicine measure, tissues, a thermometer, points in a Loyalty Scheme or other similar items.

(vi) The restriction on price promotions does not preclude "everyday low price" policies.

5. Advertising and Promotion *continued*

5.5 Competitions

5.5.1 No member shall offer to a consumer any prize competition where it is a condition of entry that a Therapeutic Product is purchased.

5.5.2 No member shall offer to any healthcare professional or to any business or its employees any inducement that:

5.5.2.1 would interfere with the independence or professional obligations of a healthcare professional; or

5.5.2.2 would reasonably be considered to encourage consumers to purchase inappropriate or excessive quantities of a Therapeutic Product.

EXPLANATORY NOTES TO CLAUSE 5.5 Advertising and Promotion: Competitions

General

(i) Prize competition is defined in clause 1 as a contest for a prize where purchase is a condition of entry.

(ii) The restriction on prize competitions applies only to Therapeutic Products (i.e. to non-prescription medicines and Related Products). It does not apply to Natural Health Products.

(iii) The restriction on offers to businesses or employees applies only to schemes that encourage consumers to make inappropriate or excessive purchases and as such it is not a blanket prohibition on employee incentive schemes.

5. Advertising and Promotion *continued*

5.6 Samples

5.6.1 The supply of or an advertisement for a Therapeutic Product must not contain or offer a sample where such a sample can reasonably be considered:

5.6.1.1 to encourage inappropriate or excessive consumption or use of the Therapeutic Product by the Consumer; or

5.6.1.2 not to be in accordance with the reasonable needs of the Consumer.

EXPLANATORY NOTES TO CLAUSE 5.6 Advertising and Promotion: Samples

Re Clause 5.6.1

(i) The restriction on the offer of a sample applies to all medicines, including general sales medicines.

(ii) The offer of a sample is acceptable if it does not encourage inappropriate or excessive use and is in accordance with the reasonable needs of the consumer.

(iii) By way of example only this rule would:

a) prohibit the offer of a sample of a non-prescription medicine otherwise than in accordance with an Approved Sampling Protocol;

b) permit the offer to a competent consumer of a sensory tester devoid of any active ingredients and appropriately labelled so as not to create confusion with the Therapeutic Product or Natural Health Product otherwise being replicated.

(iv) Clause 4.3 of this Code requires compliance with Acts and Regulations which pertain to the self-medication industry. One application of Section 18 of the Medicines Act is that the offer of a sample of a pharmacy-only medicine or a pharmacist-only medicine if otherwise permitted by clause 5.6 must only be supplied from a pharmacy with a licence to operate.

(v) Approved Sampling Protocol is defined in clause 1 as a protocol submitted to and approved by the Executive Director which requires that the offer of a sample:

i) must only be to a competent consumer no less than 18 years old
ii) must only be made from a location where the sample would be offered for sale in the normal course of business and in accordance with the Medicines Act
iii) must only be made by a person suitably and appropriately trained and informed to answer questions about the sample that a reasonable consumer would want to know.
iv) May only be provided accompanied by the Consumer Information Leaflet for the sample

5. Advertising and Promotion *continued*

5.7 Testimonials, Recommendations and Endorsements

5.7.1 An advertisement which directly or by implications claims, indicates or suggests that a Therapeutic Product or Natural Health Product is recommended:

5.7.1.1 may only be used in circumstances permitted by Acts and Regulations and by the Codes of the New Zealand Advertising Standards Authority and Medsafe Guidelines.

5.7.1.2 where permitted regarding Therapeutic Products or Natural Health Products must be documented, genuine and not misleading. Exceptional cases should be presented as such, and not portrayed as typical.

5.7.1.3 must not encourage excessive or unnecessary use of Therapeutic Products or Natural Health Products.

EXPLANATORY NOTES TO CLAUSE 5.7 Advertising and Promotion: Testimonials, Recommendations and Endorsements

Re Clause 5.7.1

(i) Section 58(i)(c) of the Medicines Act places significant restrictions on the use of testimonials in advertisements for medicines and medical devices. For example an advertisement may not directly or by implication claim, indicate or suggest that a medicine or method of treatment is recommended by a healthcare professional or that it has beneficially affected the health of a particular person or class of persons whether named or unnamed and whether real or fictitious.

(ii) The provisions of this Code do not, per se, attempt to define or restrict the use of so-called celebrity endorsements. Rather the tests to be applied are:

a) Whether the testimonial is prohibited by any relevant Acts, Regulations or Codes; and

b) Whether it encourages excessive or unnecessary use.

PART B:
MANAGEMENT OF THE CODE

6. Administration of the Code

6.1 The administration of the Code shall be supervised and co-ordinated by the Executive Director.

6.2 The Executive Director will provide assistance to members to comply with the Code by providing assistance with interpretation and advice on the application of the Code.

6.3 The Executive Director shall ensure that other members and the public who have concerns about the advertising or promotion undertaken by a member are informed about the right to complain and about how to make a complaint.

6.4 The Executive Director shall ensure that the Code is reviewed annually to ensure that the Code accurately reflects current standards to appropriately support an environment for the practice of responsible self-medication and reflects appropriate standards of commercial conduct.

7. Complaint Procedure

7.1 Terms and conditions of appointment of the Complaints Panel.

7.1.1 The Executive Director will appoint a Complaints Panel to accord with the requirements of clause 7.2.1 to participate as and when necessary in the administration of the Code.

7.1.2 Members of the Complaints Panel shall hold office for one year and shall be eligible for re-appointment.

7.1.3 In addition the Executive Director may, from time to time, appoint alternate members of the Complaints Panel for consideration of a particular complaint in the event of the unavailability of a particular member or to ensure the members of the Complaints Panel for consideration of a particular complaint do not have a conflict of interest.

7.1.4 Any member of the Complaints Panel may resign at any time by advising the Executive Director in writing. However, the resigning member should complete any complaints process with which he or she is involved before the resignation becomes effective.

7.1.5 The Complaints Panel may, at its discretion, co-opt an additional member of the Complaints Panel to provide specialist expertise or advice in which case such individual shall act as a non-voting observer.

7.2 Composition of Complaints Panel

7.2.1 The Complaints Panel for consideration of a particular complaint is to be comprised of four members and an independent Chair. The Complaints Panel shall be comprised of:

7.2.1.1 the Executive Director;

7.2.1.2 a Barrister and Solicitor with relevant experience;

7.2.1.3 a pharmacist registered with the Pharmacy Council of New Zealand and holding an Annual Practising Certificate in accordance with the Health Practitioners Competence Assurance Act 2003;

7.2.1.4 an industry representative;

7.2.1.5 a consumer representative.

7.2.2 The Chair of the Complaints Panel shall be the Barrister and Solicitor appointed in accordance with Clause 7.2.1.2.

7.3 General Guidance for Complaints Panel Members

7.3.1 Members of the Complaints Panel have a commitment to work for the greater good of the Association.

7.3.2 Members of the Complaints Panel must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest.

7.3.3 The Complaints Panel is to perform its functions with a view to ensuring that it has the confidence of members of the Association.

7.3.4 Members of the Complaints Panel undertake activities of the Complaints Panel as independent persons responsible to the Complaints Panel as a whole. Members are not appointed as representatives of particular organisations with the exception of the Executive Director.

7.3.5 If a member of the Complaints Panel considers that he/she has a conflict of interest on the complaint, the conflict of interest must be declared and the Chair will decide what that person can appropriately contribute to the consideration of that complaint.

7.3.6 Members of the Complaints Panel have a duty to act responsibly with regard to the effective and efficient administration of the Complaints Panel.

7.4 Complaint Handling Policy

7.4.1 It is the policy of the Association that all complaint procedures will be administered in accordance with the principles of natural justice.

7.4.2 The overall objective of the Complaints Panel is to contribute to the wider policy environment which develops and sustains an environment for the practice of responsible self-medication and promotes appropriate standards of commercial conduct in matters touching upon self-medication by ensuring adherence to the Code of Practice.

7.4.3 In making its decisions the Complaints Panel is expected to:

7.4.3.1 properly apply the Code in the consideration of complaints;

7.4.3.2 undertake rigorous debate and examination of the issues relating to the complaint;

7.4.3.3 make a reasoned decision in an open, fair and unbiased manner based on the principles of natural justice;

7.4.3.4 if appropriate seek further expert advice before making a final decision;

7.4.3.5 ensure that all decisions reflect an appropriate balance between protecting the rights and wellbeing of consumers and members of the Association;

7.4.3.6 make all decisions and material relating to the decision available to the Adjudicator for ruling on an Appeal when required.

7.4.4 The Executive Director may make available for the guidance of the Complaints Panel copies of previous determinations of the Complaints Panel and of the Adjudicator.

7.4.5 Prior decisions although of instructive and persuasive value are not binding on the Complaints Panel or the Adjudicator.

7.5 Confidentiality and Information Sharing

7.5.1 Members of the Complaints Panel must ensure that meetings and details of the Complaints Panel process are kept confidential.

7.5.2 Members of the Complaints Panel must not comment to members of the Association or publically on decisions made by the Complaints Panel.

7.6 Complaint Handling Procedures

7.6.1 The role of the Complaints Panel is to:

7.6.1.1 make decisions on complaints relating to the Code which are not complaints pertaining to alleged breaches of codes issued by the Advertising Standards Authority;

7.6.1.2 provide advice to the Executive Director on appropriate actions to remedy breaches of the Code;

7.6.1.3 support the objectives of the Code.

7.6.2 Subject to Clause 8.2.5 each complaint being considered by the Complaints Panel shall be determined by majority vote. Each member of the Complaints Panel, including the Chair, has one vote.

7.6.3 The complaints process is summarised in Schedule 1.

7.6.4 Subject to the provisions set out in the Code the Complaints Panel may determine its own procedures.

7.6.5 Subject to Clause 7.6.6 the Executive Director shall ensure that the determinations of the Complaints Panel are published to members which may, at the discretion of the Executive Director, be a redacted version of the Complaints Panel decision.

7.6.6 The Executive Director must not publish a decision of the Complaints Panel until the appeal period has expired with no appeal being lodged or, where an appeal is lodged, until the Adjudicator's decision has been made.

7.7 Timeline for processing complaints

7.7.1 The Executive Director must ensure that all complaints are acknowledged in writing not more than seven working days after receipt and are handled as expeditiously as possible.

7.7.2 The Executive Director must, not more than ten working days after receipt of the complaint, forward the complaint to the respondent and invite the respondent to respond to the complaint.

7.7.3 Any response which the respondent wishes to make to the complaint must be provided to the Executive Director and to the complainant not more than ten working days after receipt of the complaint from the Executive Director or within such further time as the Executive Director acting reasonably may allow.

7.7.4 If the complainant is not satisfied with the response from the respondent the complainant is to notify the Executive Director not more than twenty working days after receipt of the response that it wants the Complaints Panel to consider the complaint.

7.7.5 The Executive Director is to convene the Complaints Panel to consider the complaint. The Executive Director must ensure the matter is placed before the Complaints Panel for its consideration as expeditiously as possible.

7.7.6 The Complaints Panel is to determine the complaint and provide a reasoned decision not more than ten working days after the Complaints Panel has met.

7.7.7 The Executive Director is to provide the determination of the Complaints Panel to the parties as soon as practicable.

7.8 Fees payable for determination of a complaint

7.8.1 The Complaints Panel is to determine the appropriate contribution payable by each party to the complaint to the cost incurred by the Association due to the provision of the Complaints Panel and the directly associated complaint handling procedures incurred in consideration of that particular complaint taking into account the matters set out below:

7.8.1.1 any submissions the party may wish to make on the appropriate proportion of costs to be borne by that party.

7.8.1.2 no costs of any parties or costs incurred by the Association due to the provision of the Complaints Panel and/or the directly associated complaint handling procedures (including reasonable fees payable to the Chair and other members of the Complaints Panel) are to be a cost to the Association.

7.8.1.3 if the complainant is a Member and the Complaints Panel determines that there has been no breach of the Code, then the complainant would generally be expected to bear the cost incurred by the Association.

7.8.1.4 where the Complaints Panel determines that a breach of the Code has been established the Member in breach of the Code would generally be expected to bear the cost incurred by the Association and may, in addition, be required by the Complaints Panel to pay such proportion of the complainant's costs as the Complaints Panel shall determine is reasonable.

7.8.1.5 where the complainant is a member of the public, except where the Complaints Panel considers the complaint to have been vexatious or frivolous, no costs should lie against the complainant.

7.8.2 Fees and allowances payable to members of the Complaints Panel and to the Chair of the Complaints Panel shall be determined by the Executive Director from time to time such as to reasonably compensate members of the Complaints Panel for their time, attendances and reasonable out of pocket expenses.

8. Sanctions

8.1 Breaches

8.1.1 Where the Complaints Panel has determined that a breach of the Code has been established the Complaints Panel must consider the nature of the breach in accordance with the classification set out below.

8.1.1.1 **Minor Breach**
A breach of the Code that has no safety implications and will have no impact on the perceptions of consumers or healthcare professionals regarding the product or competitor's products.

8.1.1.2 **Moderate Breach**
A breach of the Code with no safety implications but will impact on the perceptions of consumers or healthcare professionals regarding the product or competitor's products.

8.1.1.3 **Severe Breach**
A breach of the Code that has safety implications or will have a major impact on the perceptions of consumers or healthcare professionals regarding the product or competitor's products.

8.1.1.4 **Repeat Breach**
When the same or a similar breach is repeated in the promotion:

8.1.1.4.1 of a particular product; or

8.1.1.4.2 any product of a Member which had been found to be in breach of the Code within the preceding 24 months.

8.1.2 The Complaints Panel is to consider whether or not it will impose a sanction for a breach of the Code.

8.1.3 In determining whether or not to impose a sanction and, if so, what sanction should be imposed, the Complaints Panel will consider all the circumstances including whether:

8.1.3.1 publication has ceased;

8.1.3.2 steps have been taken to withdraw the material published;

8.1.3.3 corrective statements have been made;

8.1.3.4 the breach was deliberate or inadvertent;

8.1.3.5 the member that is the subject of the complaint has previously breached the Code;

8.1.3.6 there were or are safety implications;

8.1.3.7 the perceptions of healthcare professionals or consumers have been or will be affected.

8.2 Sanctions able to be applied by the Complaints Panel

8.2.1 Undertaking to discontinue advertising

8.2.1.1 The Complaints Panel may require a member to give a written undertaking in writing to discontinue any practise which has been determined to constitute a breach of the Code. This may include without limitation a requirement for a written undertaking to cease publication and any media of an advertisement or of a particular claim.

8.2.2 Retraction and/or corrective statements

8.2.2.1 A Complaints Panel may require a member to issue retraction statements and/or corrective statements. Format, size, wording and mode of publication of such statements shall be specified by the Complaints Panel and will in general be commensurate with the advertisement which has been determined to be in breach of the Code.

8.2.3 Fines

8.2.3.1 The Complaints Panel may issue a fine and may require a member to pay a fine in accordance the Schedule of Fines contained in Schedule 2.

8.2.3.2 Such a fine payable within 20 working days of the determination by the Complaints Panel.

8.2.4 Publication

8.2.4.1 The Complaints Panel may direct the Association to publish details of the breach of the Code to all members of the Association and/or to relevant organisations and/or to the general public.

8.2.5 Suspension of Membership

By unanimous agreement:

8.2.5.1 the Complaints Panel may suspend membership of the Association for a period to be determined by the Complaints Panel.

8.2.5.2 the Complaints Panel may terminate membership of the Association.

9. Right of Appeal

9.1 Compliance with Sanctions

In the event of a member being required by a determination of the Complaints Panel to cease or withdraw a promotional activity, the member shall at once make every endeavour to comply with the determination pending any appeal against the decision pursuant to this Code. A promotional activity thus suspended shall not be recommenced before the appeal process has been concluded, nor shall any similar promotional activity be commenced during the period in question.

9.2 Appeal against determination of the Complaints Panel

9.2.1 A party dissatisfied with a determination of the Complaints Panel may provide a notice of appeal to the Executive Director.

9.2.2 The notice of appeal must be received by the Executive Director not more than ten working days after the parties have been notified of the decision of the Complaints Panel.

9.2.3 If no notice of appeal is provided in the required timeframe the Executive Director will:

9.2.3.1 initiate any sanctions imposed by the Complaints Panel; and

9.2.3.2 publish the determinations as provided by Clause 7.6.5; and

9.2.3.3 advise the Therapeutic Advertising Pre-vetting System (TAPS) of the Complaints Panel decision.

9.2.4 If a notice of appeal has been provided the Executive Director will immediately:

9.2.4.1 appoint an Adjudicator who shall be a Barrister and Solicitor with relevant experience and who shall not be a member of the Complaints Panel; and

9.2.4.2 advise the Adjudicator that the Notice of Appeal has been provided.

9.2.5 Subject to Clause 9.1 if a notice of appeal has been provided to the Executive Director no sanction recommended by the Complaints Panel will be imposed until the Adjudicator has considered the appeal.

9.3 Role of Adjudicator

The role of the Adjudicator is to:

9.3.1 Determine if what is alleged constitutes a legitimate ground for appeal; and

9.3.2 Where required, determine that appeal.

9.4 Grounds for appeal

9.4.1 The Adjudicator is to consider whether any of the grounds for an appeal are established.

9.4.2 The grounds of appeal are established where it appears that the Complaints Panel in making its decision:

9.4.2.1 did not follow a fair process based on the principles of natural justice; or

9.4.2.2 failed to take a relevant fact into consideration or took an irrelevant fact into consideration or gave a relevant fact insufficient weight; or

9.4.2.3 did not properly apply the provisions of the Code in its decision.

9.5 **Adjudication of appeal**

9.5.1 The Adjudicator will receive from the Executive Director all material relating to the Complaints Panel decision.

9.5.2 The parties may also provide additional material or submissions to the Adjudicator.

9.5.3 Any such additional submissions must be provided to the Adjudicator not more than ten working days after being invited to do so by the Adjudicator.

9.5.4 The Adjudicator will undertake a rigorous examination of the material in an open, fair and unbiased manner based on the principles of natural justice.

9.5.5 The Adjudicator will determine whether one or more of the three grounds of appeal are established.

9.5.6 If the Adjudicator determines that there are established grounds for the appeal he or she will consider and decide whether the Complaints Panel decision should be upheld, amended, quashed or referred back to the Complaints Panel for re-determination.

9.5.7 The Adjudicator must determine the appeal and provide a written decision not more than twenty working days after receipt of the Notice of Appeal, receipt of all of the material relating to the Complaints Panel decision, and receipt of any additional submissions from the parties.

9.5.8 The Adjudicator's decision is final.

9.5.9 The Executive Director shall as soon as practicable provide a copy of the Adjudicator's decision to the parties.

10. Monitoring of Advertising

10.1 **Objectives of monitoring**

To support compliance with the Code the Executive Director may monitor the advertisements or promotional material of members as and when the Executive Director sees fit.

10.2 **Aims of monitoring process**

The aims of the monitoring process are:

10.2.1 to encourage compliance with the Code through the review of advertising and promotional activities.

10.2.2 to provide comment on compliance issues for the benefit of members and the healthcare sector.

10.2.3 to provide an ongoing mechanism for the identification of trends in health matters, marketing activities or changes in technology which may indicate the need for amendments to the Code.

PART C: SCHEDULES

Schedule 1 Flow Chart of Complaints Processes

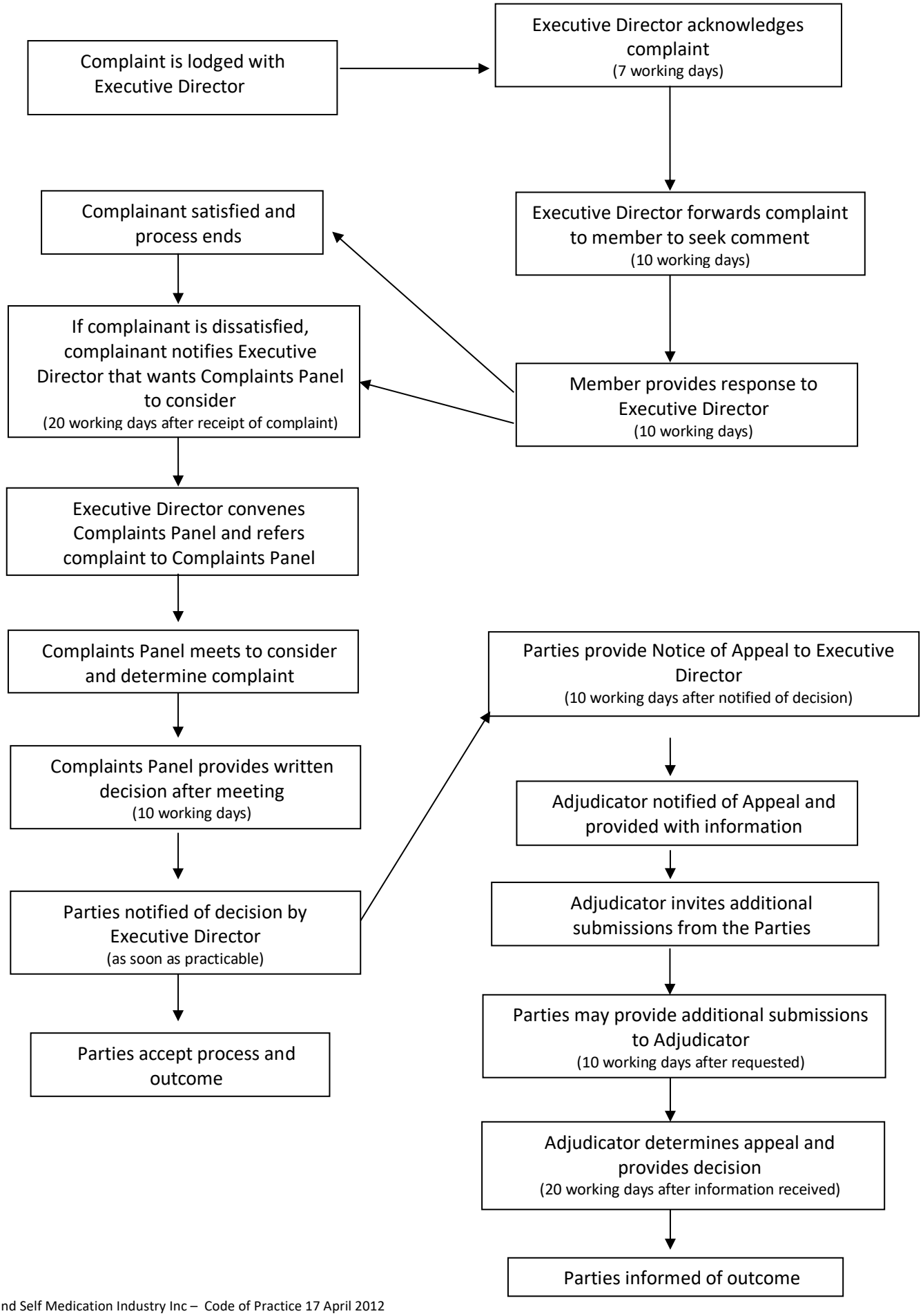
Schedule 2 Schedule of Fines

Schedule 3 Schedule of relevant Codes and Guidelines

Schedule 4 Extracts of relevant legislation

SCHEDULE 1 - FLOWCHART

The complaints process for concerns about non-compliance with the Code of Practice of the New Zealand Self Medication Industry Association Inc



SCHEDULE 2

SCHEDULE OF FINES

BREACH	FINES
Minor Breach	Nil
Moderate Breach	Maximum $5,000.00
Severe Breach	Maximum $10,000.00
Repeat Breach	Maximum $20,000.00

SCHEDULE 3

List of relevant Codes and Guidelines

- Advertising Standards Authority Codes of Practice 2010: *Therapeutic Products Advertising Code (http://www.asa.co.nz)*
- Advertising Standards Authority *Code for Comparative Advertising 17 July 1989 (http://www.asa.co.nz)*
- Australian Self Medication Industry Incorporated Code of Practice revised June 2009
- Medsafe: *Guidelines on the Regulation of Therapeutic Products in New Zealand Part 7: Advertising of Therapeutic Products Ministry of Health Edition 1.0 October 2011 (http://www.medsafe.govt.nz)*

- Joint Position Statement for the promotion of Pharmacist-Only Medicines issued by NZSMI and the Pharmaceutical Society of New Zealand Incorporated dated 25th January 2012.

SCHEDULE 4

Extracts of relevant Legislation

Medicines Act 1981 (as at 22 September 2011)

Part 2
Dealings with medicines and medical devices

Section 18 Sale of medicines by retail

(1) Except as provided in sections 25, 27, and 30 to 33, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person, sell by retail, or supply in circumstances corresponding to retail sale, or distribute by way of gift or loan or sample or in any other way,—

(a) any prescription medicine unless—

(i) the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(ii) the medicine is supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order; or

(b) any restricted medicine unless the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(c) any pharmacy-only medicine unless the medicine is sold, supplied, or distributed by—

(i) a person under the supervision of a pharmacist in a pharmacy or a hospital; or

(ii) a person who sells, supplies, or distributes the medicine in any shop described in section 51(2) and in accordance with a licence issued under Part 3.

(2) No person may sell by retail any prescription medicine otherwise than under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber.

(2A) No person may supply, in circumstances corresponding to retail sale, any prescription medicine otherwise than—

(a) under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber; or

(b) in accordance with a standing order.

(2B) Despite subsections (2) and (2A), a person may sell by retail, or supply, in circumstances corresponding to retail sale, any prescription medicine, where permitted by section 25 or section 30 or section 31 or section 69 or by regulations made under this Act.

(3) Except as may be permitted by regulations made under this Act, no person shall hawk any prescription medicine or restricted medicine or pharmacy-only medicine—

(a) from house to house; or

(b) in any public place within the meaning of section 2 of the Summary Offences Act 1981,—

otherwise than pursuant to any authority to do so expressly conferred by a licence held by him under Part 3, and in accordance with any conditions or restrictions specified in the licence.

(4) Except as may be permitted by regulations made under this Act, no person shall sell any medicine by means of an automatic vending machine or by auctioning the medicine.

(5) Every person who sells or supplies or distributes a prescription medicine in contravention of subsection (1) commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $40,000.

(6) Every person commits an offence against this Act who contravenes any of the provisions of this section (otherwise than in circumstances that constitute an offence against subsection (5)).

Part 4
Medical advertisements

Section 56 Interpretation

In this Part, unless the context otherwise requires,—

advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and **advertising** and **advertised** have corresponding meanings

medical advertisement means an advertisement relating, or likely to cause any person to believe that it relates, to any medicine or medical device or any ingredient or component thereof, or to any method of treatment

method of treatment means any method of treatment for reward undertaken, or represented to be undertaken, for a therapeutic purpose

publish means—

(a) insert in any newspaper or other periodical publication printed or published in New Zealand; or

(b) send to any person through the Post Office or otherwise; or

(c) deliver to any person or leave upon premises in the occupation of any person; or

(d) broadcast within the meaning of the Broadcasting Act 1989; or

(e) bring to the notice of the public in New Zealand in any other manner.

Section 57 Restrictions on advertisements

(1) No person shall publish or cause to be published, either on that person's own account or as the agent or employee of the person seeking to promote the sale, any medical advertisement that—

(a) directly or by implication qualifies or is contrary to any statement or other particulars required by regulations made under this Act to be marked on or attached to medicines or medical devices of the description, kind, or class, to which the medicines or medical devices advertised, or appearing to be advertised, belong or appear to belong, or on or to packages or containers enclosing medicines or medical devices of that description, kind, or class; or

(b) is prohibited by any such regulations from being marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(c) omits from the name or description of the medicines or medical devices advertised any word or words required by any such regulations to be included in the name or description marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(d) fails to make any statement required by any such regulations to be made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(e) makes any statement prohibited by any such regulations from being made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(f) is false, or is likely to mislead any other person, with regard to the nature, quality, strength, purity, composition, origin, age, uses, or effects of medicines or medical devices of that description, kind, or class or of any ingredient or component thereof; or

(g) directly or by implication states or suggests that medicines or medical devices of that description, kind, or class, cannot harm any person, or any person belonging to a particular class of persons, or is not habit-forming.

(2) For the purposes of subsection (1), any words that must be included in an advertisement in order to avoid a contravention of that subsection shall, where they appear in an advertisement published by television or otherwise in a transitory manner on a screen, be disregarded unless they are exposed in clearly legible lettering for a length of time sufficient to enable them to be read by the ordinary viewer.

(3) For the purposes of subsection (1)(f), a medical advertisement shall be deemed to be likely to mislead any person with regard to the uses or effects of medicines or medical devices of a particular description, kind, or class, or of any ingredient or component thereof, if it is likely to mislead with regard to—

(a) any purposes for which medicines or medical devices of that description, kind, or class, or any ingredient or component thereof, can be used with reasonable safety; or

(b) any purposes for which such medicines or medical devices, or any such ingredient or component, cannot be so used; or

(c) any effects that such medicines or medical devices, or any such ingredient or component, when used, or when used in any particular way referred to in the advertisement, produce or are intended to produce.

(4) Without prejudice to any liability in respect of any offence against any regulations made under this Act, every person commits an offence against this Act who contravenes any of the provisions of subsection (1).

Section 58 Further restrictions on advertisements

(1) Subject to section 60, no person shall publish, or cause or permit to be published, any medical advertisement that—

(a) directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent, alleviate, or cure any disease, or prevent, reduce, or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part 1 of Schedule 1; or

(b) directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent or cure any disease, or prevent or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part 2 of Schedule 1; or

(c) directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised—

(i) is a panacea or infallible; or

(ii) is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

(iii) has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement; or

(d) invites correspondence or the sending of hair, blood, urine, or other bodily specimens or photographs for the purposes of diagnosis or treatment concerning any disease or physiological condition.

(2) Every person commits an offence against this Act who contravenes any of the provisions of subsection (1).

(3) It shall be a good defence in a prosecution for an offence against paragraph (a) or paragraph (b) of subsection (1) if the defendant proves that the matter claimed, indicated, or suggested in the advertisement is true.

Section 59 Advertisements to contain true name of advertiser

(1) Subject to subsection (2), no person shall publish, or cause or permit to be published, any medical advertisement that does not contain a statement of the true name of the person for whom or on whose behalf the advertisement is published, and the address of that person's place of residence or business.

(2) In the case of a body corporate, it shall be sufficient compliance with subsection (1) if, instead of the address of the body corporate's place of business, the advertisement states the name of the place where the body corporate has its registered office, or, if it is not a registered company, other headquarters.

(3) Any statement that is contained in any medical advertisement and purports to set forth the name of the person for whom or on whose behalf the advertisement is published, shall, until the contrary is proved, be sufficient evidence of the name of the person for whom or on whose behalf the advertisement has been published.

(4) Nothing in this section applies to—

(a) any medical advertisement that complies with any regulations made under this Act relating to the disclosure or otherwise of the name and address of the place of residence or business of the manufacturer or seller of the medicines of the description or medical devices of the kind advertised, or the agent of either of them; or

(b) any medical advertisement relating to any description of medicines or any kind of medical devices in respect of which an exemption granted under or by virtue of this Act from the material provisions of any such regulations is for the time being in force.

(5) Every person commits an offence and is liable to a fine not exceeding $1,000 who contravenes subsection (1).

Section 60 Exemption for certain advertisements

Without limiting any power to make regulations under this Act, nothing in section 57(1)(g) or section 58 or section 59 shall apply to any medical advertisement that—

(a) is distributed only to persons referred to in section 58(1)(c)(ii); or

(b) is contained in a publication that in the ordinary course circulates solely or principally, or is distributed solely or principally, to those persons; or

(c) not being an advertisement relating to a prescription medicine, or a restricted medicine, or a pharmacy-only medicine, is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes and to persons privately consulting them.

Section 61 Misleading branding

(1) No person shall sell any medicine or medical device—

(a) that bears or has attached to it, or is enclosed in a package or container that bears or has attached to it, any false or misleading statement, word, brand, picture, label, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion, of the medicine or medical device, or of the medicine or medical device enclosed in the package or container, or of any ingredient thereof; or

(b) that has been packed, processed, or treated in a manner that is false or misleading in relation to any of the matters mentioned in paragraph (a).

(2) Every person commits an offence against this Act who contravenes subsection (1).

Section 62 Regulations relating to advertisements

(1) Without limiting section 105 but subject to subsection (2), the Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:

(a) requiring and regulating the insertion in any medical advertisement, or any particular class of medical advertisement, of such information or warning, or kind of information or warning, concerning any unwanted, incidental, or untoward effects of medicines of the description, or

of medical devices of the kind, or of the method of treatment, advertised, and such statement or kind of statement of the precautions to be taken by any user of medicines of that description, or of medical devices of that kind, or of that method of treatment, as may be prescribed:

(b) prohibiting the advertising of any specified description of medicine, or kind of medical device, or method of treatment, or of any specified class of medicine, medical device, or method of treatment, in any medical advertisement, or a particular class of medical advertisement, and prohibiting, or requiring and regulating, the mention in any medical advertisement of such matters relating to the composition, properties, nomenclature, origin, and use of medicines of the description or medical devices of the kind or the method of treatment advertised, as may be prescribed:

(c) enabling the Minister to require, after consultation with such organisations as appear to him to represent any class or classes of persons whose interests might be affected by the requirement, the insertion of particular words specified by the Minister in, or the omission of particular words or other matter so specified from, any particular medical advertisement or class of medical advertisement, and to give directions with respect to the location, size, and appearance of any such insertion and with respect to other matters incidental thereto, and providing a right of appeal in respect of any such requirement or direction:

(d) generally regulating medical advertisements or any particular class of medical advertisements, or medical advertisements relating to medicines of a particular description, or to medical devices of a particular kind, or to a particular method of treatment, or relating to particular classes of medicines, medical devices, or methods of treatment.

(2) Any regulations made under subsection (1)(a)—

(a) shall be made only on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations; and

(b) shall be designed to achieve a fair and balanced indication of the potential effects of the medicine or medical device or method of treatment advertised; and

(c) shall not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published, or the inclusion of which in the advertisement is otherwise impracticable.

Section 98 Statement by Director-General

(1) The Director-General may, for the purpose of protecting the public, publish statements relating to medicines of any description or medical devices of any kind or to any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisements, relating to medicines of any description or medical devices of any kind.

(2) Every statement published under this section shall be protected by qualified privilege.

Medicines Regulations 1984 (SR 1984/143) (as at 01 August 2011)

Part 3
Advertisements

Regulation 7 Advertisements not to claim official approval

No advertisement relating to any medicine, related product, or medical device shall contain a statement to the effect that an advisory or technical committee established under section 8 of the Act, or any member of such a committee, or any officer in the service of the Government, has approved, or has refrained from disapproving, the advertisement or any of the claims or statements made in it

Regulation 8 Advertisements for medicines

(1) Every advertisement for a prescription medicine must include—

(a) the words "Prescription medicine" or words of a similar meaning; and

(b) the name of each active ingredient; and

(c) the appropriate quantitative particulars of each active ingredient; and

(d) a statement of the purpose for which the medicine is intended to be used; and

(e) a statement that the medicine has risks and benefits; and

(f) a statement about how to find further information on the risks and benefits of the medicine.

(2) Every advertisement for a restricted medicine must include—

(a) the following statements, or statements with a similar meaning:

(i) "Available only from your pharmacist."; and

(ii) "If symptoms persist, see your doctor or health professional."; and

(iii) "Use only as directed."; and

(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:

"Always read the label."; and

(c) a statement of the purpose for which the medicine is intended to be used; and

(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

(3) Every advertisement for a pharmacy-only medicine or a general sale medicine must include—

(a) the following statements, or statements with a similar meaning:

(i) "If symptoms persist, see your doctor or health professional."; and

(ii) "Use only as directed."; and

(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:

"Always read the label."; and

(c) a statement of the purpose for which the medicine is intended to be used; and

(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

(4) Every advertisement for a medicine to be supplied by mail order, direct marketing, or via the Internet must—

(a) include the name of each active ingredient; and

(b) include the appropriate quantitative particulars of each active ingredient; and

(c) comply with the following, to the extent they are applicable:

(i) subclause (1)(a), and (d) to (f):

(ii) subclause (2)(a), (c), and (d):

(iii) subclause (3)(a), (c), and (d).

(5) A statement required by this regulation must be—

(a) clearly printed; or

(b) clearly spoken.

(6) A statement that is required by this regulation may be both clearly printed and clearly spoken.

(7) This regulation does not apply to—

(a) an advertisement for a medicine that does not refer to a therapeutic purpose:

(b) an advertisement (not being an advertisement of the kind described in subclause (4)) that is—

(i) located at the point of sale; and

(ii) positioned immediately above, below, or next to the medicine to which it relates:

(c) labels:

(d) price lists.

(8) An advertisement for a prescription, restricted, pharmacy-only, or general sale medicine that is subsequently reclassified must be treated as compliant with this regulation if—

(a) the advertisement was compliant with every applicable requirement in this regulation immediately before the medicine was reclassified; and

(b) not more than 3 months have elapsed since the medicine was reclassified.

(9) In any proceedings for an offence against section 57 of the Act, it is for the defendant to prove that subclause (8) applies.

Regulation 9 Advertisements for related products

(1) Every advertisement for a related product, other than a label or a price list, shall include a statement of the uses of the related product.

(2) Every advertisement that refers to an active ingredient of a related product by name shall state the appropriate designation of the ingredient

Regulation 10 Advertisements for medical devices

Every advertisement for a medical device, other than a label or a price list, shall include, where appropriate, the following:

(a) an accurate description of the medical device:

(b) a statement of the uses of the medical device:

(c) a statement of the appropriate precautions to be taken in the use of the medical device:

(d) a statement of any contraindications to the use of the medical device.

11 Advertisements intended for health professions

(1) This regulation applies—

(a) to advertisements intended for members of the medical, dental, pharmaceutical, and related professions; and

(b) in addition to the requirements in regulations 7, 9, and 10 (but not regulation 8).

(2) Every advertisement for a medicine must—

(a) include—

(i) the classification of the medicine; and

(ii) the name of each active ingredient; and

(iii) the appropriate quantitative particulars of each active ingredient; and

(iv) a statement of the purpose for which the medicine is intended to be used; and

(v) a statement of the appropriate precautions to be taken in the use of the medicine; and

(vi) information on the effectiveness and limitations of the medicine; and

(vii) a statement of any restriction imposed on distribution; and

(viii) the dosage regime and mode of administration, or method of use, of the medicine; and

(ix) a statement of any contraindications to the use of the medicine; and

(x) information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences; and

(xi) a statement of the known or likely poisonous effects of, or adverse reactions to, the medicine; but

(b) not include—

(i) a statement (based on the citation of a report) relating to the effectiveness or safety of the medicine that omits relevant parts of the report, or quotes from the report in such a way that another meaning to that intended by the report is conveyed; or

(ii) an unsubstantiated comparison with other medicines; or

(iii) data, previously considered valid, but made obsolete or false by subsequent findings; or

(iv) a statement of the use of the medicine, or the dosage of the medicine, that contravenes any condition of a consent given under section 20, 23, or 24 of the Act.

(3) Nothing in subclause (2)(a)(iii) or (vi) to (xi) applies to an advertisement that—

(a) is intended to provide a practitioner with details of—

(i) a major therapeutic indication of a medicine; or

(ii) the listing of a medicine in the pharmaceutical schedule (within the meaning of section 6(1) of the New Zealand Public Health and Disability Act 2000); or

(iii) a new or changed strength of a medicine; and

(b) does not enable the practitioner to reach a prescribing decision.

(4) Every advertisement for a related product or medical device must include—

(a) a statement of any restriction imposed on distribution; and

(b) the dosage regime and mode of administration, or method of use, of the related product or medical device; and

(c) information on the effectiveness and limitations of the related product or medical device.

Trade Marks Act 2002 (as at 07 October 2011)

Part 4
Legal proceedings

Section 94 No infringement for comparative advertising of registered trade mark

A registered trade mark is not infringed by the use of the registered trade mark for the purposes of comparative advertising, but any such use otherwise than in accordance with honest practices in industrial or commercial matters must be treated as infringing the registered trade mark if the use, without due cause, takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

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