Pharmaceutical Association of Malaysia
Persatuan Farmaseutikal Malaysia

CODE OF CONDUCT FOR NON PRESCRIPTION (OTC) PRODUCTS

PhAMA CODE OF OTC PHARMACEUTICAL PRACTICE

1. INTRODUCTION

Self medication has been the first line of defence in health care since the origin of man.

Self medication when used properly, plays an important role in the country's total health picture. Through the use of nonprescription, over the counter (OTC) medicines, appropriate self medication provides relief of symptoms and treatment of ailments and injury without the supervision of a health professional.

It is the responsibility of the pharmaceutical industry to manufacture and market OTC pharmaceutical products that are safe, effective, of good quality, reasonably priced, truthfully advertised and properly labelled.

The members of the PhAMA and ipso factor the pharmaceutical industry have a dual responsibility. They have a business responsibility to provide good quality, safe and effective OTC medicines at reasonable price and also a social responsibility to truthfully advertise and promote their products to the consumer.

This Code of the OTC Pharmaceutical Practice has been drawn up specifically to meet the Industry's business and social responsibilities. The PhAMA already has a Code of Conduct for ethical products.

The determination of the PhAMA and the pharmaceutical industry's desire for high standards are expressed in these codes on a voluntary basis.

This Code will also apply to those OTC products of non-pharmaceutical origin that are marketed with medicinal claims.

2. DEFINITION

OTC Pharmaceutical Products

Any medicinal product which is used in self medication to treat ailments, not requiring a doctor's prescription.

3. OBJECTIVES

The PhAMA, recognising its heavy responsibility to the public, wishes to achieve the following objectives through this voluntary and selfregulating Code of OTC Pharmaceutical Practice.

3.1 Ensure good quality, safe and effective OTC medicine for treatment of minor ailments are made available to the consumer.

3.2 Ensure that members recognise their social responsibility tot he consumer, the manufacturer and the trade.

3.3 Contribute expertise and co-operate with Government and non-governmental organisations, both national and international, with similar objectives.

3.4 Promote and support a steady and orderly development of OTC medicines.

3.5 Educate the consumer in the proper use of OTC products and responsible self medication.

3.6 Invite non-members to participate and accept the Code.

3.7 Co-ordinate the efforts of its members towards the realisation of these objectives.

4. GENERAL PROVISIONS APPLICABLE TO ALL MARKETING ACTIVITIES

4.1 These provisions apply to pharmaceutical products which are legally available of over the counter to the public. Notwithstanding any provisions made under the Code, all marketing activities under the Code must conform to the following legal requirements:-

i. Sale of Food & Drug Ordinance 1952
ii. Trade Description Act (1972)
iii. Price Control (Labelling by Manufacturers, Importers, Producers or Wholesalers) Order 1980
iv. Control of Drugs & Cosmetic Regulation 1984
v. Sale of Food & Drug Regulations 1952
vi. Medicines Advertisement and Sales Ordinance
vii. Medicine Advertisement Board Regulations 1976
viii. Trade Marks Act (1976) & Trade Marks Regulations 1983
ix. Any other relevant laws that may be promulgated in the future

4.2 Methods of marketing must never be such as to incite unfavourable comments and bring discredit upon the pharmaceutical industry.

4.3 Exaggerated claims should not be made and all-embracing claims and superlatives are to be avoided. The word ‘safe’ must not be used without

qualification and claims must not state categorically that a product has no side effects, toxic hazards or risk of addiction.

4.4 Disparaging references to other products of manufacturers should be avoided by design or implication.

4.5 The Code is to be applied in the spirit as well as in the letter. That an advertisement is capable of an interpretation which satisfies the Code is not an adequate criterion for its approval; the advertisement must be such that no interpretation which it might reasonably bear would contravene the Code's requirements. Consideration must be given not only to the impression created by a careful study of an advertisement, but also to the impression likely to be gained from a brief or partial exposure.

4.6 Consumers of OTC Pharmaceutical should be urged to read and follow the instructions contained in labels, cartons or package inserts.

4.7 No marketing activities shall encourage directly or indirectly indiscriminate, unnecessary or excessive use of any medicine. Advertisements implying long usage of a product are only acceptable when such use is justified.

Sales promoters

4.8 Sales promoters should provide service by answering only "simple" queries that deal with maintenance of general food health e.g., dosage, indication, information on what food to take or avoid, etc. Complex queries that deal with issues of pathophysiology and pharmacology should be referred to the pharmacist on duty.

4.9 Tags that allude to their expertise, e.g. Product Consultants, Advisers, etc. should not be allowed to be worn by promoters.

4.10 They should wear "Promoters" tags to differentiate them from pharmacists on the premises.

4.11 The Company/Brand Name should be incorporated on the tag in order to identify and penalize irresponsible claims made by individual promoters.

5. ADVERTISING

Principles

5.1 An OTC pharmaceutical should not be advertised in a manner which is likely to lead to its use by young children without parental supervision. Such advertisements should not be specifically directed towards young children.

5.2 Advertising of a carminative, sedative or stimulant OTC Pharmaceutical should refer to the temporary nature of the relief provided and should recommend the product only for occasional use.

5.3 Advertisements shall be factually true and shall not mislead. No advertisement shall contain any exaggerated claim, direct or implied.

5.4 Advertisements shall be in terms readily comprehensible to the layman and shall avoid medical or technical terminology used so as to confuse the public.

5.5 Advertisements shall be clearly distinguishable from editorial matter.

5.6 No advertisement shall in words or illustration, claim or imply the cure, as distinct from the relief of symptoms of any ailment or disease.

5.7 No advertisement shall contain any offer to diagnose, prescribe or treat personally by correspondence.

5.8 All descriptions, claims and comparisons which relate to matters of ascertainable fact shall be capable of appropriate substantiation.

5.9 References to speed of absorption, dissolution, distribution and other preliminary activity are acceptable when supported by appropriate evidence. Such evidence may not necessarily be acceptable in support of claims for enhanced speed of relief.

5.10 All comparisons shall be balanced and fair. No comparative statement may, on any reasonably interpretation, mislead consumers about the product being advertised or about any other product with which it might be compared.

5.11 A product shall not be described as unique or special unless it is significantly different from others on the market. The advertisement as a whole should clearly, indicate the quality of the product which is unique.

5.12 Advertisements shall not mislead about the novelty of a preparation. Unless the product has special attributes the description ‘new’ is generally only acceptable for a reasonable time in association with the brand to distinguish the product from other products in the market.

5.13 No advertisement shall by statement or implication suggest that a product contains some unknown active ingredients.

5.14 All advertisements should be in good taste and not intimidating so as to increase and/or induce usage.

5.15 No advertisement shall discourage the consumer from seeking medical advice.

5.16 Although it is acceptable to indicate that a product is palatable, medicinal products shall not be presented in a way which could lead to misuse or misunderstanding as to the medicinal nature of the product.

5.17 No advertisement shall bring disrepute upon the OTC pharmaceutical industry, undermine confidence in advertising, or prejudice public confidence in medicines.

5.18 No member of the Association shall use ‘subliminal advertising’ i.e. the deliberate use of visual or aural messages designed to influence people in ways of which they are not consciously aware.

Medical statements, trials and tests

5.19 Advertisements shall not refer to any ‘college’, ‘hospital’, ‘clinic’, ‘institute’, ‘laboratory’ or similar establishments unless there exists a bona fide establishment corresponding to the description used.

5.20 No advertisement shall suggest that a particular product is recommended by a member of the medical, dental, pharmaceutical or related professions. Doctors, dentists, veterinary surgeons, pharmacists, nurses, midwives, etc., should not be depicted in any illustration in such a way as to suggest professional advice or recommendation.

5.21 Claims that a particular product is medically recommended or preferred are unacceptable. Any claim that a particular type of treatment or ingredient is medically recommended or preferred shall be capable of substantiation.

5.22 Implications that a particular group or scientists supports a claim shall be avoided unless the claims are valid and capable of substantiation.

Testimonials

5.23 Testimonials shall represent the genuine views of the user and shall be no more than three years old, In editing testimonials, care shall be taken that the original meaning is not changed in any way.

5.24 Testimonials containing any material contrary to any provisions of the Code may not be used.

5.25 The writers of testimonials should not be identified as members of any of the health care professions listed in 5.20.

Competitions and Public Schemes

5.26 No member shall promote to the general public, or be associated in any prize competition which is likely to stimulate unnecessarily the use of OTC Pharmaceuticals.

5.27 No member shall promote, or be in any way associated with any schemes which are intended to encourage the sales of OTC Pharmaceuticals if they are likely to introduce any hazard to the general public or to lower the integrity of the industry.

5.28 Medicines shall not be promoted on the basis of an offer to refund money to dissatisfied users.

Distribution of Samples

5.29 No member of the Association shall distribute indiscriminately unsolicited samples of OTC Pharmaceuticals.

6. USE OF PROPRIETARY NAMES

6.1 Brand names of products of other companies must not be used unless prior consent of the proprietors has been received.

7. TRADE REPRESENTATIVES

7.1 Representatives should be thoroughly trained and be competent to provide the necessary product information.

7.2 All representative should carry out their work professionally in compliance with this Code.

8. ADMINISTRATION

8.1 This Code is kept under constant review as it will accurately reflect the highest standard of conduct within the Association.

8.2 Complaints against any member contravening the Code should be in writing. The member complained against shall be invited by the Executive Director tot he Association to explain the case.

8.3 The explanation shall be submitted to the Ethics Committee for deliberation. If it is found that a breach of the Code may have occurred, the member against whom a complaint has been made shall be invited to meet the Committee to state his case.

8.4 If the Committee after hearing the member (or after due deliberation in the event of a member declining to meet the Committee) should decide by a majority vote that a breach of the Code is evident the member shall be asked to give an undertaking in writing that the breach will cease on or before a certain date as determined by the Committee.

8.5 When a member is unwilling to give such an undertaking the Committee shall report its decision to the Board of Directors who will then consider whether or not action (which may involve the suspension of membership under Rule 10(a) or expulsion from the Association under Rule 11 of the PhAMA Rules and Constitution should be taken against the member.

8.6 If any case in which it is established under the above procedures that no contravention of the Code has occurred, a notification to this effect shall be made by the Executive Director to such interested persons or bodies as the Board of Directors may decide.

End/-