GUIDELINE ON ADVERTISING OF MEDICINES AND MEDICINAL PRODUCTS TO GENERAL PUBLIC

Approved by Medicine Advertisements Board in MAB 3/2015
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PART 1

PREAMBLE

The 'Guideline on Advertising of Medicines and Medicinal Products to General Public' is referred to throughout as 'the Guideline'.

INTRODUCTION

1.0 GENERAL INTRODUCTION

This Guideline is intended to complement the provisions of the Medicines (Advertisement & Sale) Act 1956 and the Medicine Advertisements Board Regulation 1976.

1.1 Advertisements give notice and public information with the intent to draw attention and inform. As such they attract consumers to buy products or services and have a direct impact on business. Thus advertisers should be guided by the principles not to take undue advantage whilst laws and regulations are in place to ensure that advertisements contain a high standard of information and the contents are proper and reliable.

1.2 Medicines and medicinal products have potential for beneficial as well as harmful effects and may cause serious problems if not used correctly. All advertising and promotion of medicines and medicinal products must therefore be responsible, ethical and done in a professional manner, as well as be of the highest standard, to ensure their safe and proper use, both in self-medication and where medical supervision is required.

1.3 Advertising is understood to encompass written or spoken words, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medicinal products, generally by highlighting product claims.

1.4 The Medicine Advertisements Board (MAB) may add to, delete from or amend the Guideline from time to time by order.

1.5 Advertisements that fall under this Guideline also must comply with any other laws and regulations or guidelines of this country.

PART 2

SCOPE AND DEFINITIONS

2.0 SCOPE

This Guideline applies to all advertising of medicines and medicinal products aimed at general public.

It does not apply to the advertising of medicines and medicinal products to:

a) Members of a local or public authority
b) Members of the governing body of a public hospital
c) Registered medical practitioners
d) Registered dentists
e) Registered nurses and midwives
f) Registered pharmacists, chemists and wholesalers and retailers of poisons licensed under the Poisons Ordinance 1952, or the corresponding laws in force in Sabah or Sarawak, as the case may be, to sell poisons listed in Part I of the Poisons List:
g) Person undergoing training with a view to becoming registered medical practitioners, registered dentist, registered nurses or registered pharmacists or chemists.

It does not apply to advertising of medicines and medicinal products for animal use.

It shall not apply to any advertisement published by the Federal Government or any State Government or any local or public authority, or by the governing body of a public hospital or by any person authorized to publish such advertisement by the Minister.

2.1 DEFINITIONS

Advertisements include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound which includes but not limited to:

- advertising on electronic ordering system
- aerial promotion such as hot air balloon and/or blimps
- aisle, ceiling, floor advertising and other sign
- articles or advertorials in journals, magazines and newspapers
- brand reminders
- branded material relating to product sponsorship
- bulletins and newsletters
- calendars
- catalogues
- consumer brochures, booklets, leaflets, pamphlets and broadsheets
- consumers promoters
- counter-top advertising
- cinema, television and radio/audio commercials
- direct mail materials
- directories
- display packs, giant mock-up boxes
- gondola end advertising
- indoor displays such as at airport, washroom, shopping centre
- light box advertising
- online advertising
- outdoor displays such as billboards, banners, bunting and posters
- point of sale materials
- sports, art and other sponsorship
- talk shows

- vehicle wrappers
- video recordings
- website and other internet materials including brand home pages and banner advertising

and any other form or means of advertising

PART 3

AUTHORITY

3.1 Authority

The Medicine Advertisements Board (MAB) may, at its discretion, issue or refuse to issue any approval for advertisements of registered product to be publicised or may cancel any approval which was previously issued.

The MAB reserves the right to delete from any advertisements, acts which could bring about undesirable thoughts and impression to the viewers.

Changes to the Guidelines may be made from time to time by the MAB without giving prior notice.

3.2 Appeal

Any person aggrieved by any decision of the Board may appeal to the Minister whose decision shall be final.

3.3 Validity of the Certificate of Approval

The certificate of approval from MAB is valid for three calendar years unless otherwise specified.

3.4 Amendment of the Approved Format

Request for amendments or changes of approved advertisement formats by MAB:

i. Requests for amendments must be submitted within 2 months from the date of approval by MAB. After 2 months the applicant has to send in a new application for approval

ii. Request for amendments may be allowed upon the discretion of the MAB on a case by case basis.

iii. Amendments are allowed **ONCE** only

iv. All amendments must obtain approval from MAB **unless stated otherwise**.

v. Amendments of the following do not require MAB approval. However, the applicant is required to write in to inform MAB on the amendments made.

- Pricing
- Validity period
- Company name, logo, address, email address, telephone and fax numbers
- Format layout (the content must be exactly the same as approved by MAB)
- Approved URL for domain name (website)
- New product label as approved by Drug Control Authority (DCA)

3.5 Language

Advertisement that contains languages other than Chinese or Tamil need to be supported with translation, either in Bahasa Malaysia or English which has been endorsed by the relevant Embassy / High Commission.

PART 4

GENERAL PRINCIPLES

4.0 INTRODUCTION

This part explains the general principles related to advertising practices. Advertisers have a responsibility to ensure that advertising of medicines and medicinal does not in any way put patient and consumer safety at risk.

4.1 General

Advertisements should contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date, be capable of substantiation and in good taste. They should not contain any misleading or unverifiable information either directly or by implication that is likely to induce unjustifiable medical use or to give rise to undue risks.

It is important that advertisements do not abuse the trust or exploit lack of knowledge among the general public. Advertisements should not lead to self-diagnosis or inappropriate treatment of potentially serious diseases.

4.2 Standards of Promotion

An advertisement must present information which is factually correct and not exaggerated. Advertisements should take into account peoples' legitimate desire for information and must encourage the correct and proper use of a medicine or medicinal product and should not be misleading.

An advertisement shall be taken to be false or misleading if it falsely describes the medicine or medicinal product, or it is likely to mislead as to the nature or quality of the

product of that description or as to their uses or effects, or any reference to a false or misleading representation.

Claims made should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity. Promotional material should be accurate, objective, high ethical standards and be in good taste.

4.3 Products Allowed To Be Advertised

Advertising to the public is only allowed for product which is registered with Drug Control Authority (DCA).

No approval shall be given for Poisons as specified in the First Schedule of Poisons Act 1952 unless exempted as per Appendix 1;

- Gums, lozenges and patches indicated for nicotine replacement therapy may be advertised with approval from the MAB.

- New Chemical Entities (NCE), only for products which comply with the following criteria may be advertised **ONCE** through press releases:
    i. New drugs which are available in Malaysia for the first time or within 18 months after being marketed / launched and no other similar drug available in Malaysia;
    ii. New combinations of active pharmaceutical ingredients or;
    iii. New approved indications

4.4 Prohibited Claims

Advertisement should not contain any claims either directly or indirectly referring to:-

a) the prevention, treatment, alleviation, cure or diagnosis of diseases and conditions as listed below:-

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. Diseases 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.

(b) Practicing contraception among human beings;

(c) Improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings;

(d) Procuring the miscarriage of women.

4.5 Acts of Violence or Illegal Activities

Advertisements should not contain any statements or visual presentations which might lead to or support acts of violence, criminal or illegal activity or appear to condone such acts or activities.

4.6 Dangerous Practices or Disregard for Safety

Advertisements should not, without justification, show or refer to dangerous practices or manifest a disregard for safety. Special care should be taken in advertisements directed towards or depicting children or young people.

4.7 Standard of Morality or Decency

Advertisements should not contain statements or visual presentations which is, or likely to be interpreted to be contrary or offensive to the standard of morality or decency prevailing in the Malaysian society or in any way defamatory or humiliating to any segment of the public.

4.8 Denigration and Disparagement

The products, advertisers or advertisements of other companies should not be disparaged either directly or by implication.

Advertisements should not:

a) contain any statement(s) which either explicitly or by implication disparages the medical profession; or the value of professional attention and treatment; or another product;
b) discredit or unfairly attack other products, advertisers or advertisements directly or by implication.
(c) However, comparisons of products from the same registration holder is allowed if substantiated

4.9 Misleading Statements

Advertisements should not contain any statement or visual presentation which, whether directly or by implication, is likely to mislead the consumer about any product.

4.10 Substantiation

Advertisements should not exploit the ignorance and credulity of the public by including scientific data that the general public cannot comprehend, verify, or validate.

All claims, descriptions, and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation.

Advertisements containing statistical claims should be supported by Malaysian data unless not available.

4.11 Trust, Fear or Superstition

Advertisements should not:

a) be framed as to abuse the trust of the consumer or exploit his lack of experience or knowledge;
b) play on fear by containing any statement or illustration likely to induce fear on the part of the viewer or listener that he is suffering, or may, without diagnosis or treatment, suffer or suffer more severely, from diseases or conditions of the human body;
c) play on superstition or exploit the superstitious;
d) directly, or by implication, exploit the religious requirement(s) or belief(s) of any community.

4.12 Halal Logo / Statement

All medicines or medicinal products which already have Halal certification may publish the logo on the advertisement.

The Halal logo must be certified by JAKIM or other body recognized by JAKIM.

Advertisers are not allowed to misuse the phrase “HALAL” or any statement/pictorial relating to Islamic religion, which includes the use of the verses of the Quran in their advertisement for the purpose of misleading the consumers.

4.13 Advertisement of Health Product

Approved advertisement by MAB shall not be advertised in the same space as with product advertisement which does not require MAB’s approval, such as food, medical device and cosmetic products.

In a situation where medicine is advertised together with other health products, care must be taken to avoid misleading where border can be made clearly to distinguish advertisement has been approved by MAB and advertisement which does not require MAB’s approval.

4.14 Advertising on the Internet

KKLIU number must be clearly displayed on every page which has been approved by MAB. **The name, address and contact number of the advertiser must also been clearly stated in the page.**

In a situation where medicine is advertised together with other health products, care must be taken to avoid misleading so that it clearly distinguish advertisement has been approved by MAB and advertisement which does not require MAB’s approval.

Websites containing advertisements or information which nature and content are directed at health professionals must be access restricted and clearly labelled as intended for health professionals.

PART 5

SOCIAL-RESPONSIBILITY

5.0 INTRODUCTION

Advertisements should be prepared with and observe a high standard of social responsibility to consumers and to the society. This part aims to provide explanations on what is deemed as 'socially responsible' advertising practices.

5.1 Celebrity Endorsement

Advertisements may include a recommendation or endorsement by a person who, because of their status as a celebrity, encourage the general public to use a medicine or medicinal product but they must be responsible and accountable to the advertisement.

Such advertisements should not, whether directly or by implication, mislead the consumer about the product advertised

The definition of a celebrity taken in this Guideline is an actual person who is very well-known in public life and who, because of their celebrity status, could encourage the consumption of a medicinal product.

Advertisement with a celebrity endorsement must be stated with a statement:

"The effect of the product may vary among individuals".

5.2 Impressions of Professional Advice or Endorsement

Advertisements should not:-

(a) Have any visual and/or audio presentation of doctors, dentists, pharmacists, scientists, nurses and other paramedics, etc., which give the impression of professional or scientific advice, recommendation or endorsement; or

(b) Contain statements giving the impression of professional by scientific advice, endorsement or recommendation made by associations or persons who appear in the advertisements and who are presented either directly or by implication, as being qualified to give such advice, endorsement or recommendation eg the use of white coat, stethoscope, healthcare professional environment / any expression that provides undue authority that the product is recommended by a healthcare professional

Endorsement by professional bodies may be allowed with the consent from the respective professional bodies. Authorization from said bodies should be given in writing and produced upon demand.

Advertisement shall not refer to a 'college', 'hospital', 'laboratory' or similar establishment.

It is important to note that registered healthcare professionals are governed by ethics of the relevant statutory body that grants the respective registration and personal involvement in such promotion may lead to a breach of ethics.

5.3 User Testimonials

Advertisement may include testimonials but the individual who give the testimony must be genuinely exist and responsible as well as accountable to the advertisement and its testimonials must refer to indications approved.

Advertisement with a testimonial must be stated with a statement:

"The effect of the product may vary among individuals".

Advertisement containing testimonials by general public must be supported by a consent letter of testimony. The consent letter must include the following:

1) Name
2) IC/ Passport No
3) Signature
4) Contact No

5.4. Claims and Evidence

Claims must be based on an up to date evaluation (e.g. the most recent available data) of all evidence and must reflect this evidence accurately and clearly including the reference of this substantiating scientific evidence. All claims should be capable of substantiation either by reference to approved labelling or by scientific evidence from properly conducted investigations. Such evidence should be readily available and reproduced upon demand.

5.5 Tests, Trials and Research References

Reference to tests or trials conducted in a named hospital, clinic, institute, laboratory or college or by a named professional or official organisation is permissible only if authorised and approved by the authority of the organisation or institution concerned.

Research results, reference to or quotes from technical and scientific literature of conference, workshop, seminar etc. should not be misused. Statistics should not be presented to imply that they have a greater validity than is the case. Scientific term(s) or jargon that is irrelevant should not be used to make claims that appear to have a scientific basis which they do not possess.

Graphs, tables and pictorial representations should only be included if they are relevant to the claims or comparisons being made. They must not mislead with the use of incomplete or unusual scales, or suppressed zeros.

A graph can be adapted provided it is clear and its true meaning is not distorted. If a graph has been adapted from a paper, it must be stated so.

If an original table is not produced in its entirety, the adaptations should not mislead and must be clearly demonstrated.

5.6 Comparative Advertising

Comparative claims should:

a) be made on a factual and fair basis and is capable of substantiation. The intent and connotation of the advertisement should be to inform and not to discredit, disparage, degrade, or attack competitors, competing products or services directly or by implication;

b) be unambiguous, clearly understandable and should not mislead by distortion, undue emphasis or omissions;

c) be used for honest comparison purposes and not simply to upgrade by association;

d) be made clear what comparison(s) is being made;

e) not make unjustifiable use of the name or initials of any firm, company or institution nor take advantage of the goodwill attached to the trade name or symbol of another firm or its product(s) or the goodwill acquired by its advertising campaign;

f) not explicitly identify the competitive product, whether by name, brand, name, company, or any form of identification that clearly exposes the identity of the competition;

g) not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the DCA

h) not involve the selection of a subject matter of a comparison as to confer an artificial advantage upon the advertiser or so as to suggest that a better bargain is offered that is actually the case;

i) where appropriate, be supported by documentary evidence that is easily understood;

j) when referring to a competitive test, such tests should have been conducted by an independent and objective body. The test must be supportive of all claims made in the advertisements that are based on the test;

k) should never use or draw on partial results or stress insignificant results to mislead the consumer to draw an improper conclusion;

l) should not involve the use of 'baseless' hanging comparatives which merely claim that a product is e.g. "longer-acting", "quicker" or "stronger".

5.7 Encouragement of Unnecessary Purchase or Indiscriminate Use

Advertisements should not directly or indirectly encourage indiscriminate, unnecessary, or excessive use of the advertised product.

No advertisement should state or imply that good health is likely to be jeopardised solely because there is lack of dietary supplementation with vitamins. Vitamins should not be advertised in any manner that they are a substitute for a balanced diet.

5.8 Healthy Lifestyle Advice

Advertising should not undermine healthy lifestyle advice or health promoting behaviour such as exercise, healthy eating or smoking cessation. Similarly, advertising must also not promote behaviours which are damaging to health (e.g. alcoholism, unhealthy diets, sedentary lifestyle or smoking).

5.9 Hyperboles

Superlatives and hyperboles cannot be used to imply or claim or infer the superiority of the advertised product. The general public should not be led to over-estimate the value of a product whether by exaggeration or unrealistic comparisons or statements.

The characteristics of the product should not be exaggerated by improper use of words, phrases or methods of presentation. The MAB reserves the right to disallow any words or phrases which in its opinion is misleading, improper or not factual.

Superlative descriptors, words, and phrases which are not permissible are as specified in **Appendix 3.**

5.10 Self-Diagnosis

Advertisements should be cautious when describing a range of symptoms that may be similar to conditions other than those for which the product is indicated for, resulting in consumers making a wrongful self-diagnosis.

5.11 Self-medication

Advertising of self-medication shall not suggest that a product is a food, cosmetic or other than non-medicinal products. The advertising shall make clear that it is medicines.

Advertisements should also not suggest that it is acceptable to self-medicate when consumers may require consultation from health professionals. It should encourage individual to share information with the pharmacists or health care practitioner so that they can ensure the medicine will be suitable for the intended user.

It is also unacceptable to encourage long-term use of products indicated for self-limiting conditions in advertisements.

Advertising should not encourage consumers to discontinue the use of prescribed medicines.

5.12 Unwarranted Anxiety

Advertising should not induce unwarranted anxiety among consumers about their condition by suggesting that the condition is of greater severity than is actually the case.

Similarly, advertising should also not suggest that the condition will deteriorate if the consumer does not use the product or brand featured.

PART 6

THERAPEUTIC CLAIMS

6.0 INTRODUCTION

There should not be any words, phrases or illustrations in advertisements which claim or imply the cure of any ailment, illness or disease other than from the relief of its symptoms unless approved by the MAB.

In the case of an advertisement for a medicinal product, no specific reference shall be made to the specific properties of any individual ingredients unless a reference of this nature has been approved by the DCA for inclusion in the package insert of the medicine.

These Guidelines define 'therapeutic claims' as:

a) Treatment or prevention of diseases or conditions of human beings other than those which are prohibited under section 4.4 above.
b) Diagnosing disease or ascertaining the existence, degree, extent of a physiological condition.
c) Altering the shape, structure, composition, or size of the human body.
d) Otherwise preventing or interfering with the normal physiological function, whether permanently or temporarily, and whether by way of terminating, reducing, postponing, increasing or accelerating that function.

6.1 Functional Claims

Such claims are only allowed for claim of ingredient in product as approved by the DCA as specified in Drug Registration Guidance Document.

6.2 Claims Relating to Anti-aging

Advertisements should not suggest or imply a product will control, retard or reverse the physiological processes associated with ageing or premature ageing unless approved by the DCA in the product indication.

6.3 Claims Concerning the Brain, Memory and Concentration

Claims relating to 'improvement or enhancement of brain or memory functions', 'improving mental performance, IQ or intelligence' or 'prolonging, improving or enhancing concentration' are not acceptable unless approved by the DCA in the product indication

6.4 Claims Relating to Immunity against Specific Disease(s)

Advertisements should not claim to provide immunity against specific diseases unless approved by the DCA in the product indication.

6.5 Claims Relating to Stress

Advertisements should not purport the use of a particular product is needed to prevent or reduce the stress of modern living unless approved by DCA in the product indication.

6.6 Claims Relating to Performance in Sports and Studies

Advertisements should not imply that consumption of a particular product can improve performance in sports and studies unless approved by DCA in the product indication.

6.7 Claims Concerning Weight Management Products

Advertisements for products indicated for weight loss, reduction or management must have an appropriate balance between claims of product effectiveness and references to healthy diets and physical activity. There should not be claims that a product offers quick weight loss results or physiological thermogenic (fat-burning) activity.

Misleading claims on eating such as ‘Eat as much as you like’ should not be advertised. There should be an emphasis on a well-balanced diet plan and exercise as required under the “Warning and Cautionary Statements” section of these Guidelines.

PART 7

PRODUCT-RELATED CLAIMS

7.0 INTRODUCTION

These would cover product information other than those associated with therapeutic claims and include the following. Whilst it is acceptable to make flavour claims, advertising shall not emphasise the sensory aspects of a medicinal product, such as a flavour (eg. delicious, tasty) or cosmetic (eg. beautify, whitening) attributes to the extent that consumers may believe that the product is a food, cosmetic or other non-medicinal product.

7.1 'Before' and 'After' Claims

Advertisements should not contain improper, exaggerated or misleading claims or visuals to represent changes in the human body.

Care should be given to ensure that all claims used are related to the approved product indication and the degree of severity for which the product is indicated. The claims should not depict a more serious or chronic condition. For example, images of liver cirrhosis should not be used in advertisements of products indicated for general support of liver function.

A declaration of the originality of the claim(s) should be held ready for immediate production upon request to the MAB.

7.2 Claims Relating to Product Origin

There should not be over-emphasis to highlight the manufacturer or foreign country of origin in promoting the efficacy of a product.

7.3 Herbal Claims

Advertisements should not suggest that a product is herbal unless comply with the approved label by DCA.

7.4 Natural Claims

Advertisements should not suggest that the efficacy or safety of a product is due to the fact that it is natural nor claim that a product is 'natural' unless all of its components are naturally occurring.

However, the following categories would be considered acceptable:

a) If the active ingredient is natural, the claim must be confined to that ingredient.
b) Where only one of the ingredients is natural, the claim must be limited to that ingredient e.g. 'contains natural ingredient X'
c) Products that have a natural mode of action i.e. an action that mimics a physiological mechanism of the body e.g. bulk-laxatives. These products may claim 'acts naturally' or 'works naturally'.
d) 'Organic' claims should be supported by substantiation from relevant certifying bodies.

7.5 Product Availability / Novelty Claims

Advertisements relating to novelty of the advertised product should not be misleading.

The word "new" should not be used to describe any product or presentation which has been registered in Malaysia for more than 18 months. The word "new" is applicable to products with different registration number (MAL), for example: new formulation, new dosage form, new strength.

However, if the product is not new, then the advertisement should specify which aspect of the product is new, such as new look, new pack size, new packaging etc. Such claims can only be made up to 18 months from the date of change approved by the DCA. Advertisement shall not mislead about the novelty of preparation.

7.6 Safety Claims

Claims pertaining to product safety should not imply, whether directly or indirectly that the product is not associated with or free from any side effects. Phrases such as “No side effects”, “No harmful effects”, “No toxic or adverse effects” are disallowed.

Products containing natural ingredients should not suggest that the safety or efficacy of the product is due to the fact that it is natural.

Any statement related to side effects should be specific and based on data approved by the DCA or published data to which references are given. The term “placebo-like” in relation to safety or side effects in general is considered to be misleading as it implies that there are no drug associated side effects, when no medicine or medicinal product is completely risk free.

7.7 Specific Pharmacokinetic Related Claims

Claims of effectiveness relating to speed of action, absorption, dissolution, distribution, or other pharmacokinetic particulars are only acceptable if substantiated by evidence **or is indicated in the approved label.** Dosage instructions for once-a-day dosing do not necessarily mean that a claim of 24-hour relief is acceptable.

a) ‘All-day relief’ claims are taken to mean that the advertised effect lasts up for at least 10 hours during the day.
b) ‘All-night relief’ claims are taken to mean that the advertised effect lasts up for at least 8 hours during the night.
c) ‘Fast’ claims are taken to mean that the advertised effect takes place within about 30 minutes.

d) ‘Immediate’ or ‘Instant’ claims are taken to mean that the advertised effect takes place within about 10 seconds.

e) ‘Long-acting or sustained release’ claims are allowed only for products with a sustained released formulation.

f) ’24 hour relief’ is taken to mean that the advertised effect lasts up to 24 hours.

PART 8

ADVERTISEMENTS AIMED AT SPECIFIC POPULATIONS

8.1 Pregnant or Lactating Women

Advertisements should not suggest or recommend any medicinal products, with the exception of some vitamin and mineral supplements, for use by pregnant or lactating women.

Advertisements should not convey a message that it is routine practice for pregnant women to take medicines or medicinal products; and that the unborn baby's development would be affected if these products were not taken.

Advertisements that promote the use of a medicine during pregnancy are only acceptable when such use is approved by the DCA. Where there is suggestion for use of a product in pregnancy, all advertisements must encourage a cautious approach before use and include a statement that women should consult their healthcare professional before use.

8.2 Others

Advertisements addressed or portrayed to children or young people, or aging population which likely to be seen by them, should not contain anything, whether in illustration or otherwise, which might result in harming them physically, mentally, morally; or which exploits their credulity, their lack of experience or their natural sense of loyalty.

For example, images depicting children handling medicines or medicinal products without supervision.

PART 9

MANDATORY STATEMENT AND WARNING OR CAUTIONARY STATEMENTS

9.0 INTRODUCTION

Each advertisement must include approved registration number by the DCA anywhere on the advertisement in a clear manner and a statement:

"This is a medicine / supplement / traditional product advertisement"

(Select where appropriate)

For an audio advertisement, it is sufficient to mention:

"This is a medicine advertisement approved by the Medicine Advertisements Board"

Cautionary statements are required for particular classes of products as listed below and for all the required statements, words conveying the same meaning may be used.

9.1 Nicotine Replacement Therapy Products

Advertisements for gums, lozenges and patches indicated for nicotine replacement therapy should contain the warning statement:

"This product is not suitable for children. Do not use this product if you have serious heart disease, are pregnant or breast feeding. Not to be used by non-smokers. Consult your healthcare professional before use."

9.2 Weight Loss Products

Products for weight loss or weight reduction should include the following statement:

"This should be taken with a balanced diet and regular exercise."

PART 10

OTHER PROMOTIONAL ACTIVITIES

10.1 Advertorials and others

Any advertisements that involve promoting a pharmaceutical product with health claims in the form of advertorial or other forms of written material can be approved so long it is in line with indication approved by DCA.

Furthermore the MAB realises the importance of dissemination of health-related research to the general public. Hence advertorials which describe the historical use or current research of herbal ingredients or vitamins (such as ginseng, garlic, *tongkat ali*, vitamin C etc.) **without reference to the registered pharmaceutical product** may therefore be used **without approval from MAB subject to the followings:**

a) The product brand name, pictorial representation or any reference to the product website should not be included as this would be considered as indirect advertisement of the product.
b) There should also be certain statements or disclaimers in these advertorials that the consumer should seek appropriate professional healthcare advice.
c) Any advertisements featuring registered products containing the active generic ingredients mentioned in the advertorials or others should not be tied in with these advertorials, and thus should not be placed on the same page or facing page, to comply with this requirement.

10.2 Disease Awareness and Health Education Campaigns

Campaigns providing information, promoting awareness and educating the public about health, diseases and their management are encouraged. The primary purpose must be to increase awareness of a disease (or diseases) and to provide educational information on that disease and its management. The focus should be on health and disease

education, and where to get appropriate advice. It should not promote the use of a particular medicinal product. The product brand name, pictorial representation or any reference to the product website should not be included. The source(s) of the information material should be identified.

For the product to remain outside the definition of an advertisement, care must be taken to ensure that the information provided does not make product claims. Use of brand names, restricting the range of management options described, drawing attention to the use of specific medicines can be considered promotional in nature.

The emphasis of the material should be on the condition and its recognition rather than on treatment options. The appropriate treatment for each disease is for the health care professional to decide in consultation with the patient.

10.3 Press Releases for Product Launches

Press releases for announcements of product launches can be made with the condition that the information provided must be factual and comply with the requirements set in this Guideline.

New Chemical Entities (NCE)

Press releases for New Chemical Entities (NCE) are allowed **ONCE** only for products which comply with the following criteria:

i. New drugs which are available in Malaysia for the first time or within 18 months after being marketed / launched and no other similar drug available in Malaysia;
ii. New combinations of active pharmaceutical ingredients or;
iii. New approved indications

This should not be used as a mechanism to promote medicines to the general public and the information provided must be factual, providing the context in which the medicine will be used and the population for which it has been licensed.

It is helpful to set the product and any relevant results in the context of alternative treatments and of current practices for the treatment of the indicated condition, provided there is no disparagement of other products used for the same conditions.

The use of brand names should be kept to a minimum and the tone and content of the press release must be factual and not sensationalized. Where statements from healthcare professionals are included these should be balanced and informative.

Particular care should be taken by the company in providing information in response to direct approaches from the media where a company has little or no control over the final production and which could result in the promotion of New Chemical Entities (NCE) to the general public.

The validity period is **6 months** from the date of approval.

10.4 Contests and Competitions

Contests and competitions linked to a brand, product and company (without mention of specific claims) would be acceptable and do not require approval.

10.5 Sponsorship

Sponsorship linked to a brand, product and company (without mention of specific claims) would be acceptable and do not require approval.

10.6 Free Gift

Advertisement of products which includes free gift is allowed. Free gift cannot be the same as the product advertised, traditional or any pharmaceutical products. Examples of free gift allowed are pen, mug, calculator etc.

The value of the free gift is not allowed to be mentioned in the advertisement.

10.7 Product & Pricing Advertisement

MAB approval is not required if the advertisement is for **price lists** that contain **ONLY** the **picture** [of which the product image is less than 4cm x 5cm] and **price** of the products. It is mandatory to print the **DCA registration** number of the products.

10.8 Point of Sale Material

Point of Sale is defined as "A registered premise at which goods are retailed physically. This excludes the sale of goods through the Internet (Electronic retailing)".

(a) Giant Box -

Giant boxes do not require MAB approval. However the box must be:

i. An exact replica (not size but shape and content) as the packaging approved by the DCA
ii. Can only be hanged / displayed in the pharmacy

(b) Exemption -

Advertisement at the point of sale is exempted from MAB's approval subject to the following conditions:

i. The advertisement is not attached to the product, its label or any other approved packaging material
ii. No product claims or benefits are allowed to be mentioned
iii. Only a reference on the discount / free offer of the registered product made with the purchase of any registered product is allowed.

10.9 Advertisement by Way of Talk Show

i. Only complete script will be accepted i.e. no addition can be made to the script upon approval
ii. No caller segment is allowed

10.10 Exemption

Any advertisements that contain **ONLY** product brand and/or company name and/or logo do not require approval from the MAB.

PART 11

APPENDICES

1. List of Poisons products which may be advertised to the public
2. Diseases and conditions not allowed in advertisements aimed at the public unless approved by the MAB
3. Terms not allowed in advertisements

APPENDIX 1

List of Poisons products which may be advertised to the public

1. Gums, lozenges and patches indicated for nicotine replacement therapy

2. New Chemical Entities (NCE), only for products which comply with the following criteria:
   i. New drugs which are available in Malaysia for the first time or within 18 months after being marketed / launched and no other similar drug available in Malaysia;
   ii. New combinations of active pharmaceutical ingredients or;
   iii. New approved indications

THE ABOVE LIST ARE NOT EXHAUSTIVE AND MAY BE SUBJECT TO CHANGE

APPENDIX 2

Diseases and conditions not allowed in advertisements aimed at the public unless approved by the MAB

(a) Prevention, diagnosis or treatment of the diseases and condition of human beings as specified in the Schedule to The Medicines (Advertisement & Sale) Act 1956 (Revised – 1983) ; The list is reproduced as follows:-

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. Diseases 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.

(b) Practicing contraception among human beings:

(c) Improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings:

(d) Procuring the miscarriage of women.

APPENDIX 3

Superlatives descriptors, words or phrases not allowed in advertisements:

1. Anti-aging
2. Anti-stress
3. Any percentage *(unless substantiated)*
4. Aphrodisiac
5. Arousal
6. Complete cure
7. Effective *(for traditional and supplements)*
8. Enhancement of sexual organs
9. Excellent
10. Fabulous, Fantastic
11. Guaranteed
12. Hormone releaser
13. Ideal
14. Instant cure
15. Libido
16. Longevity
17. Miraculously, miracle, magic, magical
18. Mythical
19. No. 1 *(unless substantiated)*
20. No side effect
21. Perpetual youth
22. Potent
23. Powerful
24. Saintly, heavenly
25. Sensational relief
26. Sexual powers
27. Superior
28. The ‘best’, ‘only’, ‘most’
29. Unique
30. Wonders
31. World’s best
32. Any other superlatives, words or phrases which are synonymous to the above

THE ABOVE LIST ARE NOT EXHAUSTIVE AND MAY BE SUBJECT TO CHANGE