GUIDELINES ON ADVERTISEMENTS OF MEDICINE.

CONTENTS

1. Introduction:

The objective of advertisement controls for health products ("HP") is to ensure that accurate and truthful information about the products is disseminated and to ensure that the advertisements and sales promotion activities do not mislead consumers or induce unnecessary purchase or consumption of the HP. This is essential in helping both the public and healthcare professionals to make informed decisions in their choice of HP.

This Guidance aims to clarify the principles of advertisement controls for Health Products set out in the National Medicines Regulatory Act ("NMRAA") and the Regulations and should be read in conjunction with the NMRAA and the Regulations.

The examples highlighted in this Guidance are not exhaustive and may be updated periodically. Anyone who advertise or cause any product to be advertised as a HP are required to comply with the NMRAA and the Regulations.

1.1 Advertisement will include all forms of advertisement in any media. The forms of media include but are not limited to: (a) Newspapers, flyers, banners and lightboxes (b) LCD (liquid crystal display)/ LED (light emitting diodes) display panels. (c) Internet advertisements including those on digital communication channels e.g. Facebook and Blogs (d) Press releases and materials used in product launch events which are not open to the general public.

Feature of the name, identity, pack shot, tagline or logo associated with the HP, with the intent or purpose of promoting the HP and its use shall be deemed as an advertisement for purpose of the NMRAA and the Regulations.

2. Definitions

"advertisement" includes any representation by any means whatsoever, for the purpose of promoting directly or indirectly the manufacture, sale or disposal of any medicine medical device or borderline product;

"medicine" means—

(a) any substance or mixture of substances manufactured, sold, offered for sale or represented for use in—

(i) the diagnosis, treatment, mitigation or prevention of disease, abnormal physical states or the symptoms thereof in man or animal; and

(ii) restoring, correcting or modifying functions of organs in man or animal;

(b) a medicine or combination of medicine ready for use and placed on the market under a special name or in a characteristic form, both patent and non-proprietary preparations;

(c) a product made out of medicinal herbal extract;

(d) nutraceutical with therapeutic claims; and

(e) vaccines and sera,

but does not include an Ayurvedic medicine or Homoeopathic medicine;

"sell" means offer, keep or expose for sale, transmit, convey or deliver for sale, for cash or credit or by way of exchange and whether by wholesale or retail and the term "sale" shall be construed accordingly;

Label

"Label" includes any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled marked, embossed or impressed on, or attached to a container of medicine, medical device or borderline product;

Labelling

"Labelling" includes the label and any written printed or graphic matter relating to and accompanying the medicine, medical device or borderline product;

Article

(a) "any medicine, medical device or borderline product;

(b) anything used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any medicine, medical device or borderline product; and

(c) any labeling or advertising material;

3. Objectives:

The objective of these guidelines is

2.1 To ensure responsible advertising in promoting the sale of medicines which can be purchased by the consumer without a medical prescription and for which medical claims are made and cosmetics.

2.2 To ensure advertising products to the consumers is conducted in a manner that promotes the quality use of products, socially responsible, and does not mislead or deceive the consumer.

2.3 To ensure that advertisements directed to the general public help them to make rational decisions on the use of products regulated by the NMRA

2.4 To ensure that the advertisements do not mislead the consumers to rely on medicines irrationally to solve physical or emotional problems

4. Legal Background

1. National Medicines Regulatory Authority Act No 5 of 2015
2. Regulation, No.38 of 1984 (Gazette No. 378/3-1985.12.02) and their amendments.

5. Administration:

Every person / organization or government Institution who intends to publish an advertisement related to medicine/Medical Device and Borderline product in the: (a) Newspapers, flyers, banners and lightboxes (b) LCD (liquid crystal display)/ LED (light emitting diodes) display panels. (c) Internet advertisements including those on digital communication channels e.g. Facebook and Blogs (d) Press releases and materials used in product launch events which are not open to the general public, Should submit the same to the approval of advertisement subcommittee under National Medicines Regulatory Authority.

6. General Principles:

6.1 The conformity of an advertisement with this code will be assessed in terms of its probable impact, taking its content as a whole, upon a reasonable person within the class of those to whom the advertisement is directed and also taking in to account its probable impact on persons within other classes to whom it is likely to be communicated. (50,55)

6.2 All advertisements of medicines shall comply with provisions laid down under the National Medicines Regulatory Authority Act No 5 of 2015 and regulations.

6.3 An advertisement of medicines.
must not **(55)**

- 6.3.1 give any false information concerning the HP or create any erroneous impression regarding the formulation, composition, specification, quality, safety, efficacy or uses of the HP.
- 6.3.2 incorrect statements, or unsubstantiated claims.
- 6.3.3 be designed to arouse unwarranted expectations of product effectiveness through the use of text, illustrations, or sound effects.
- 6.3.4 mislead directly, by implication, or through emphasis, comparisons, contrasts or omissions with regards to safety, usage and immediacy of relief.
- 6.3.5 be directed to children and shall not contain any object that attracts them including pictures of children.
- 6.3.6 have any clauses consisting direct comparisons with other advertisers, or other products,

6.4 Advertisements for

- 6.4.1 medicines shall contain their generic name and approved indications.

6.5 Advertisements shall contain one of the following statements:

- "Read label instructions carefully"
- "Always read the label"
- "Use only as directed" or words of the similar effect.

6.6 Representation relating to a HP's safety, efficacy and quality are to be furnished to and verified by the Authority prior to advertising

6.7 ensure that advertisements of HPs also comply with any relevant conditions of registration that may be imposed. For example, a HP may be approved for certain uses, but its conditions may prohibit the advertisement of these approved uses to the public.

7.0 Prohibitions.

According to the Act ;(51)

(1) No person shall advertise any medicines to the public as a treatment, prevention or cure for any of the diseases, disorders, or abnormal physical states set out in Schedule `F'.

(2) No person shall import, sell, offer for sale, or distribute any medicines.

(a) that is represented by a [1]label; or

(b) that is advertised to the public,

as a treatment, prevention or cure for any of the diseases, disorders or abnormal physical states set out in Schedule `F'.(annexure)

(3). Improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human being.

(4). Procuring the miscarriage of women.

7.2 No products which are poisons or contain poisons as specified in the PODDA can be advertised.

8. Claims:

8.1.0 An advertisement for the use of shall **not** contain any claim or statement :

a. that it is a stimulant by use of the word 'stimulant' or words of similar importance; that would make persons to believe, from the symptoms described, that they are suffering from serious ailments or that harmful consequences may result if they used;
b. that it is a universal panacea, infallible, unfailing, magical, miraculous, a certain, guaranteed or cure;
c. that it is effective in all cases of a condition;
d. that it will be immediate or instantaneous or of an exaggerated rapidly in action or the goods posses unique or absolute properties other than as permitted in writing by the NMRA
e. that it is more efficacious or safer because it occurs naturally.

9. Professional Recommendation:

An advertisement of medicines shall not contain any implication that;

9.1 It is recommended or used generally by medical practitioners, dentists, Pharmacists, nurses, dieticians or physiotherapist or by any person using a title implying that such person is so qualified or registered.

9.2 It is recommended or used by emanates from hospitals or groups or associations representing or purporting to represent any branch of medicines or the suffers from any disease.

9.3 The announcer or any person conveying a therapeutic claim is a professional worker as set out in 9.1 hereof;

9.4 The announcement is being made from the premises of a professional workers (as set out) or from a hospital, by virtue of the set background.

11.0 General Principles:

11.1 Advertisement should contain information that is reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to include medically unjustifiable use or to give rise to undue risks.

a. Standard of Mortality or Decency

Advertisements should not contain statements or visual presentation which are or likely to be contrary or offensive to the standard of mortality or decency prevailing in the Sri Lankan Society or in any way defamatory or humiliating to any segment of the public.

b. Fear or Superstition

Advertisements should not:

(a) Without justification play on fear. Advertisements should not contain 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.

(b). play on superstition or exploit the superstitious. In this context, words like magical, miracle, miraculous, sanity, heavenly, or presentations of or reference to mythical objects or supernatural beings or powers should not be allowed.

(c). Directly or by implication exploit the religious requirement / beliefs of any community.

a. *Selection of Actors*

Popular TV Film stars, National & International sport personnel should not be used in advertisements.

d. *Acts of Violence or Illegal Activities*

Advertisements should not contain anything, which might lead or lend support to acts of violence, or criminal or illegal activity nor should they appear to condone such acts or activities.

e. Dangerous Practices or Disregard for Safety

Advertisements should not, without justifiable reason, 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. Age limit for children should be in par with similar regulations that exists for advertisements in the country.

f. Disparagement (Discredit)

Advertisements should not:

(a) Contain any statement which either expressly or by implication disparages either the medical profession or the value of professional attention and treatment or another product.

(b) Unfairly attack or discredit other products, advertisers or advertisements directly or by implications.

g. Children or Young People

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

11.2 Misleading Statement:

Advertisements should not contain any statement, or visual presentation which directly or by implication, omission, ambiguity or claim, is likely to mislead the consumer about any product or advertise, in particular with regards to;

a. The trade and/or generic description.

b. Official or other recognition of approval or certification

11.2.1 Substantiation

All descriptions, claims and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation and should be held ready for immediate production to the TAC/ Advertising subcommittee on demand.

11.2.2 Tests, Trials, Research

Reference expressly or by implication to test, trials, research and the like may only be used if they are fully substantiated. References to tests or trials conducted in a named hospital, clinic, institute, laboratory or college or by named professional or official organization are permissible only if authorized and approved by the authority of the Institution or Organization concerned and found acceptable by the Advertising subcommittee.

- Advertisements should not;

a. contain any medical statements or reverences to clinical or other trials or tests which cannot be substantiated by an authoritative evidence acceptable by Advertising subcommittee.

b. misuse research results or quotation from technical and scientific literature or conference, workshop, seminar, etc.

Statistics should not be so presented as to imply that they have a greater validity than is the case. Scientific terms should not be used to make claims which appear to have a scientific basis they do not possess. If the applicant wish to make any scientific claims they should provide all relevant publications to the advertisement sub committee when seeking approval.

11.2.3 Name of product or Brand Name

a. Advertisement of a product with a name containing the term “Doctor” or “Dr” is not acceptable.

11.3 General Claims

11.3.1 Hyperbole:

Hyperbole should not be used in Medicine Advertisements unless such hyperbole is used to attract attention to the advertisement and is not used or implied in the advertisements as a claim or inference to the superiority or superlative status of the product advertised.

Advertisement should not:

a. contains a copy which is exaggerated by reason of the improper use of words, phrases or methods of presentation

e.g. the use of the words fabulous, fantastic, Superior, Extremely, Unique, Ideal, etc.

b. contains any false claim, direct or indirect, that a product is natural, nature’s remedy’ or the like.

c. Lead consumers to over-estimate the value of a product whether by exaggeration or through unrealistic comparisons.

11.3.2. Use of certain words or phrases

The use of the following words or phrases in the advertisement of a product is not acceptable.

a. safe

b. Magic, magical, miracle, miraculous

c. Remedy, cure

d. Non-toxic

The Advertising subcommittee reserve the right to disallow any other words or phrases which in its opinion is misleading, improper or not factual.

11.3.3 Specific Claims:

11.3.4 Sexual Weakness, Ageing, Loss of Virility

Advertisement should not suggest or imply that any product offered therein will;

a. promote sexual virility or be effective in treating sexual weakness, loss of virility or habits associated with sexual excess or indulgence, or any ailment, illness or disease associated with such habits.

b. retard, control or treat premature ageing

c. retard, control or reverse the process of ageing

11.3.5 Loss of Hair, Baldness etc.

No advertisement should contain any claim or implication that

a. baldness can be prevented

b. hair loss or thinning of the hair can be arrested or reversed

c. hair growth can be stimulated or improved.

11.3.6 Control of Dandruff

Advertisements for a product or treatment offered for the control of dandruff should not contain any claim or implication that the condition can be permanently prevented. Nor should such advertisement contain any exaggerated claim or implication as to its effectiveness.

11.3.7 Vitamins:

a. No advertisement should explicitly state that good health is likely to be endangered solely because people do not supplement their diets with vitamins.

b. Advertisements should not contain any unqualified claims that vitamins will give complete protection against or treatment of viral infections, or unqualified statement that the medical profession supports such claims.

c. The functional claims regarding the benefits of key vitamins & minerals as laid out in Appendix II shall be acceptable in advertisements, provided the formulation contain 'acceptable' levels of the said nutrients

11.3.8 Diseases or conditions of the Human Body

Advertisements should not refer to any product which can be used to prevent, diagnose or treat disease or conditions of the human body as listed in Appendix1.

11.3.7 Special Cautionary Statements:

The Medicine Advertisements Board may require cautionary statements to be included in the advertisement.

11.3.7.1 Advertisement of;

a. products containing alcohol for its pharmacological effect or as solvent should state the percentage content of such alcohols as follows;

"This preparation contains X% alcohol"

Methanol or methyl alcohol should not be present in products to be taken internally.

b. product containing aspirin should include the following cautionary statement:

"Not to be taken by children below 12 years old" or other relevant cautionary statement.

c. products for the relief of fever, cough and pain should include the following statement;

"If symptoms persist, please consult your doctor" or "Take on physician advice"

d. medical self-diagnostic appliances such as blood-pressure measuring watch, etc should include the following statement:

"The user is advised to consult his/her doctor when interpreting the reading"

11.3.8. Competition/ Free Gift, Free Offer, Premium, etc

11.3.8.1 Advertisements should not:

a. encourages, directly or indirectly, indiscriminate, unnecessary or excessive use of products.

b. contains any reference, directly or indirectly to any prize competition, free gift, premium, discount, exchange scheme or any other similar scheme.

c. offer or describe any product as free or available free for trial as an incentive

d. contain any reference to the free offer of a product with the purchase of a similar or other product.

11.3.9 Mail order/ Information by correspondence

a. Advertisements should not contain any offer to diagnose, prevent or treat any diseases or conditions of the human body or symptoms of ill-health by correspondence not invite information in order to advise on diagnosis, prevention or treatment by correspondence.

b. Advertisements should not invite or induce viewers and readers to directly obtain from the advertiser information about products for the diagnosis, prevention or treatment by correspondence.

3. Direct sale from Manufacturer, Wholesaler or Representative

a. An advertisement that encourages direct sale of a medical product to the individual from the manufacturer, distributor or representative is not acceptable.

12. Handling of Applications:

12.1 Every person desirous of registering or seeks approval of advertisement shall submit an application in that behalf to NMRA before the 10th day of every month. (See appendix I)

(1). The application should be handed over with a hard copy of the particular advertisement and a CD containing visual or audio text (if already made) or copy of script with storyboard for TV commercials,

(II) for radio commercials, copy of script to include sound –effect description,

(III) Copy of following documents

a. Certificate of product registration
b. Approved indications of use (where applicable)
c. Copy of any research / surveys/ data quoted references in the advertisement (further references to be provided if requested).
d. Copy of documentation supporting professional recommendations and testimonials (Further reference to be provided if requested)

12.1 On receipt of the application serial No will be given and this number should be quoted for further clarifications thereafter.

12.2 Advertisement subcommittee will evaluate the advertisement and submit recommendations to CEO of NMRA.

12.4 If the approval is granted, the Advertisement Approval Number (ANN/..) allocated to each approved material of advertisement.

12.5 All approved advertisements must display the current approval number designated to that advertisement when publishing on every mass media.

13. Certificate of Permission:

Each and every advertisement approved by sub committee on advertisement will be granted a certificate of permission to advertise in mass media (Appendix 2)

The certificate is granted after approval of the advertisement provided that no changes can be made without prior approval from the NMRA

14. Validation period of the certificate:

The certificate of permission shall be in force for a period of two year from the date of issue unless earlier suspended or cancelled.

15. Restricted Advertising:

Use of certain words or phrases or any word /phrase that would imply such

a. safe
b. Magic, magical, miracle, miraculous
c. No toxic effects
d. Fast, prompt, quick
e. Remedy, cure

15.1 All promotion in regard to smoking in mass media to be banned

15.2 All promotional signboards that had been supplied by companies to various nursing homes, pharmacies, practitioners, etc will not be allowed.

15.3 The baby, adult & nurses or any form of medical facility or any medical personel pictures in a poster or advertisement are not recommended.

15.4 The price comparisons in the advertisements are not allowed.

15.5 Containing picture of family is not allowed.

16. Appeals and complaints mechanisms:

In the event of an advertisement not gaining approval, a request to review the decision could be submitted to CEO/NMRA

The request must be made within 10days of after notice of the decision.

17. Charge for the Advertisements:

Processing fee for advertisement is US$1000 + VAT

17. Appendices

Appendix I

Application for Advertising of Drugs/ Devices/ Borderline Products:

Office use only Application No: ……

Application for Advertising of Medicines, Medical devices and Borderline products

1. Name of the Applicant :

2. Address :

3. Generic Name of the medicine,
medical device and borderline product:

4. Brand Name :

6. Manufacturer's Name & Address :

7. Dossier No :

8.Registration Certificate No. :
(Copy should be attached)

10. Title of the advertisement :

11. Type of the Advertisement :
TV/Radio/News Paper/ Poster/ any other
(8 copies should be submitted)

The following documentation must be supplied:

Checklist

( ) Copy of appropriate regulatory documentation is attached:

( ) Certificate of product registration

( ) Label (enlarged for legibility)

( ) Copy of documentation supporting authenticated testimonials.
Copy of any research /surveys/data mentioned in advertisement (Note-further evidence to be provided if required)

( ) Draft layout or clear description of layout.

( ) For television broadcast- copy of script with storyboard is attached (Optional)

( ) For radio – copy script with sound- effect description is attached.

( ) Copy of approval for the use of a restricted / prohibited claim (if applicable)

( ) Application fee paid and receipt attached.

Application Declaration:

I, ……..Declare that the information contained

within this application is true and correct.

Signature:…….. Date: …….

Appendix 2 :

CERTIFICATE OF PERMISSION TO ADVERTISE MEDICINES/MEDICAL DEVICES/BORDERLINE PRODUCTS & COSMETICS IN MASS MEDIA

1. Registration No: ……

2. Name of the Product (Trade & Generic) :
……

3. Title of the Advertisement

Language : ……

4. Media Intended to be published: Print/Electronic /Outdoor media
……..

5. Time: ……..

6.Name & Address of Company: ……

M/S. ……..
…….of……...
……...

is /are hereby permitted to advertise through the above mentioned media accepted in Sri Lanka or location in (place)……..

This certificate of permission is subjected to the conditions prescribed in regulations 75 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act No.27 of 1980 as amended Regulations No-722/2, July 06, 1992.

This certificate of permission shall be in force for a period of two year from the date of issue unless earlier suspended or cancelled.

Date of Issue:

……..……
National Medicines Regulatory Authority.

National Medicines Regulatory Authority.
No.120, Norris Canal Road,
Colombo