Guideline for Advertisement of Medicinal Products

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Post Marketing Control Division
Drug Regulatory Authority

Drug Regulatory Authority,
Royal Government of Bhutan
P.O Box 1556
Thimphu, Bhutan

List of Contributors

We would like to acknowledge following officials for their contributions in developing this guideline:

1. Mr. Wangdi Gyeltshen, Drug Controller, Drug Regulatory Authority (DRA)
2. Ms. Ngawang Dema, Chief Regulatory Officer, Registration Division, DRA
3. Mr. Kunzang Dorji, Offtg. Chief Regulatory Officer, Inspection Division, DRA
4. Mr. Jigme Tenzin, Offtg. Chief Regulatory Officer, PMCD, DRA
5. Ms. Jambay Wangmo, Sr. Regulatory Officer, DRA
6. Mr. Tashi Dhendrup, Regulatory Officer, Inspection Division, DRA
7. Ms. Chenco Om, Deputy Chief Legal Officer, Bhutan InfoComm and Media Authority

Compilation and Editing

1. Mr. Dawa Tshering, Sr. Regulatory Officer, PMCD, DRA

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Contents

1. Introduction

Medical products have potential for benefits as well as harmful effects and may cause serious problems if not used correctly. All advertising and promotion of medical products must therefore be responsible, ethical and conducted in a professional manner, as well as be of the highest standard, to ensure their safe and proper use. Advertising encompasses written or spoken words, and any pictorial representation or design, used or appearing to be used to promote the sale of medical products, generally by highlighting product claims.

Advertising of medical products must encourage people to use the products appropriately in accordance with the existing medical information. It should not otherwise induce people to use the products unnecessarily exposing them to health risk and economic losses.

As per 234 of the Bhutan Medicines Rules & Regulation 2019, any advertisements of medical products are required to have prior approval from the Drug Regulatory Authority. Chapter XIII of the Regulation provides a basic framework for control of advertisements of medical products in the country. This guideline provides the requirements on the conduct of advertisements and sales promotion activities for medical products and is intended to complement the provisions prescribed under the Act and Regulations. It outlines general requirements, procedures, definitions and forms to be used while submitting an application.

This guideline was developed in consultation with relevant stakeholders from Bhutan InfoComm and Media Authority, Media Council of Bhutan and Department of Information and Media, Ministry of Information and Communications.

2. Scope

2. 1 This Guideline shall be applicable to all advertisement of medical products aimed at the general public.

2. 2 This shall NOT apply to the advertisement of medical products to the following cohorts:

- 2.2.1 Management of healthcare facilities;
- 2.2.2 Health Professionals registered with Bhutan Medical and Health Council;
- 2.2.3 Animal Health Professionals; and
- 2.2.4 Person undergoing training with a view to becoming registered medical practitioners, registered dentist, registered nurses or registered pharmacists.

3. Objectives:

3.1 To provide clear mechanisms and procedures for advertisements of medical products.

4. Normative Reference

4.1 The following documents, in whole or in part, are normatively referenced in this guideline and are indispensable for its application.

- 4.1.1 The Medicines Act of the Kingdom of Bhutan 2003.
- 4.1.2 Bhutan Medicines Rules and Regulation 2019.
- 4.1.3 Blood and Blood Products Regulation of Bhutan 2016.

5. Definitions:

5.1 **Advertisements:** it refers to any representations conveyed by any means whatsoever for the purpose of promoting directly or indirectly the sale or distribution of any medical products through any medium.

5.2 **Authority**: it refers to the Drug Regulatory Authority.

5.3 **Medicinal Products**: shall refer to

- 5.3.1 All substances intended for internal or external use for human or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of disease of any disorder in human or animals including vaccines and biologicals;
- 5.3.2 Such substances intended to affect the functioning of any structure found in the human and animal body;
- 5.3.3 Any other substance or device declared by the Board to be a medical product or a medicine or a drug and this may belong either to modern or (allopathic) or traditional system of medicine;
- 5.3.4 Active Pharmaceutical Ingredients; and
- 5.3.5 Health supplements.

5.4 **Sales Promotion:** it refers to any medical advertisements in the form of a sales campaign (including door-to-door sales and price discounts), an exhibition, a competition or any other activity meant to introduce, publicize or raise the profile, or public awareness or visibility, of the medical product.

6. General Principles

6.1 As per section 27 of the Act and section 234 of the Bhutan Medicines Rules and Regulation 2019, any advertisements of medical products are required to have prior approval from the Drug Regulatory Authority.

6.2 As per section 9(7) of the Regulation, the Authority reserves the right to amend any advertisements and sales promotions or activities which could bring about undesirable thoughts and impressions to the viewers.

6.3 Only those products registered with the Authority shall be allowed for advertisement.

6.4 Advertisement of any medical products, principally based exclusively on longstanding use, shall not contain phrases such as “clinically proven” or “effective in”.

6.5 Certificates or documents issued by the Authority shall not be reproduced to promote the sale or distribution of medical products.

6.6 In the interest of public safety, the Authority may reject an application for advertisements of medical products or may cancel any approval which was previously issued.

6.7 Advertisement shall take into account peoples’ legitimate desire for information and must encourage the correct and proper use of a medical product and should not be misleading.

6.8 Advertisement shall be taken to be false or misleading if it falsely describes the medical 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.

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

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

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

6.12 Advertisements shall not abuse the trust or exploit lack of knowledge among the general public.

6.13 Advertisement shall not lead to self-diagnosis or inappropriate treatment of potentially serious diseases.

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

6.15 While advertising a medical product for its benefits, it shall also explicitly include the associated side effects, contraindications or precautions. The advertisement shall contain both risk and benefit of the products.

6.16 The Authority reserves the right to disallow any words or phrases which in its opinion is misleading, improper or not factual.

7. Specific Requirements

7.1 Advertisements shall contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date, and capable of substantiation. 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.

7.2 Advertisement shall present information which is factually correct and not exaggerated.

7.3 Any advertisements of health supplements directed to the general public shall not claim, indicate or suggest, whether directly or indirectly, will prevent, alleviate or cure any disease or condition as listed in Annexure 1 of this guideline.

7.4 Advertisement shall not contain any statement which either explicitly or by implication disparages the medical profession; or the value of professional attention and treatment; or other products.

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

7.6 Advertising shall not undermine healthy lifestyle advice or health promoting behavior such as exercise, healthy eating or smoking cessation.

7.7 Advertising shall also not promote behaviors which are damaging to health (e.g. alcoholism, unhealthy diets, sedentary lifestyle or smoking).

7.8 Advertisement shall not contain any visual and/or audio contents of doctors, dentists, pharmacists, scientists, nurses and other paramedics, etc., which give the impression of professional or scientific advice, recommendation or endorsement.

7.9 Advertisement shall not 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 e.g. the use of white coat, stethoscope, healthcare professional environment or any expression that provides undue authority that the product is recommended by a healthcare professional.

7.10 No advertisements shall state or imply that good health is likely to be jeopardized solely because there is lack of dietary supplementation with vitamins.

7.11 Health supplements shall not be advertised in any manner that they are a substitute for a balanced diet or medicines.

7.12 Superlatives and hyperboles stated in Annexure 2 shall not be used to imply or claim or infer the superiority of the advertised product.

7.13 The general public shall not be led to overestimate the value of a product whether by exaggeration or unrealistic comparisons or statements.

7.14 The characteristics of the product shall not be exaggerated by improper use of words, phrases or methods of presentation.

8. Types of Advertisement

8.1 Celebrity Endorsement

8.1.1 Celebrity endorsements or recommendations may be advertised but they must be responsible and accountable to the advertisement.

8.1.2 Advertisement with a celebrity endorsement must be stated with a statement: "*The effect of the product may vary among individuals".*

8.2 Advertisements by audio-visual and print materials

8.2.1 Application for advertisement by audio-visual and print materials shall be accompanied with complete script or draft. No changes should be made to the script after the approval.

8.3 Disease Awareness and Health Education Campaigns

8.3.1 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 medical 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.

8.3.2 The emphasis of the material shall 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.

8.4 Contests and Competitions

8.4.1 Sponsorship of contests and competitions linked to a brand, product and company (without mention of specific claims) may be acceptable and may not require approval.

8.5 User Testimonials

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

8.5.2 Advertisements with a testimonial shall be stated with a statement: "The effect of the product may vary among individuals".

8.5.3 Advertisements containing testimonials by the general public shall be supported by a consent letter of testimony.

8.6 Medical Representative

8.6.1 Only medical representatives authorized by the Authority shall be allowed to carry out promotion of medical products on behalf of manufacturers and distributors. The

manufacturer and the distributor will be responsible for the statement and activities of their medical representative.

8.6.2 Medical representatives involved in promotion shall have firm scientific knowledge about the products they promote.

8.6.3 Medical representatives shall notify the Authority and submit their CV along with an accountability statement from the manufacturer or distributor prior to promotion activity.

9. Specific Prohibitions

Advertisement shall not:

9.1 Suggest or imply that a product will control, retard or reverse the physiological processes associated with ageing or premature ageing unless approved by the Authority in the product indication.

9.2 Falsely cause to understand that it is an aphrodisiac, abortifacient, strong emmenagogue or for birth control.

9.3 Promote prescription medicines including Narcotics and Psychotropic medicines.

9.4 Mention claims relating to 'improvement or enhancement of brain or memory functions', 'improving mental performance, IQ or intelligence' or 'prolonging, improving or enhancing concentration', unless indication is approved by the Authority.

9.5 Claim to provide immunity against specific diseases unless indication is approved by the Authority.

9.6 Claim that the use of a particular product is needed to prevent or reduce the stress of modern living unless indication is approved by Authority.

9.7 Imply that consumption of a particular product can improve performance in sports and studies unless indication is approved by Authority.

9.8 Claim that a product offers quick weight loss results or physiological thermogenic (fat-burning) activity.

9.9 Promote misleading claims on eating such as 'Eat as much as you like'. There should be an emphasis on a well-balanced diet plan and exercise wherever applicable.

9.10 Contain improper, exaggerated or misleading claims or visuals to represent changes in the human body.

9.11 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.

9.12 Overemphasize to highlight the manufacturer or foreign country of origin in promoting the efficacy of a product.

9.13 Claim that the product is herbal unless approved by the Authority after assessment of relevant evidence.

9.14 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:

- If the active ingredient is natural, the claim must be confined to that ingredient.
- Where only one of the ingredients is natural, the claim must be limited to that ingredient e.g. 'contains natural ingredient X'

9.15 Misuse novelty status of the advertised product. Use the word "new" only to products with different registration numbers, for example: new formulation, new dosage form, new strength. However, if the product is not new, then the advertisements should specify which aspect of the product is new, such as new look, new pack size, new packaging, etc.

9.16 Directly or indirectly claim that the product is not associated with or free from any side effects.

9.17 Make claims of effectiveness relating to speed of action, absorption, dissolution, distribution, or other pharmacokinetic particulars unless substantiated by evidence or is indicated in the approved label.

9.18 Compare medical products with food, cosmetic or other non-medical products.

9.19 Promote self-medication or in any way discourage the public from seeking advice from healthcare professionals.

9.20 Encourage long-term use of products indicated for self-limiting conditions in advertisements.

9.21 Encourage consumers to discontinue the use of prescribed medicines.

9.22 Induce unwarranted anxiety among consumers about their condition by suggesting that the condition is of greater severity than is actually the case.

9.23 Suggest that the condition will deteriorate if the consumer does not use the product or brand featured.

9.24 Make reference to tests or trials conducted in a named hospital, clinic, institute, laboratory or college or by a named professional or official organization.

9.25 Use research results, reference to or quotes from technical and scientific literature of conference, workshop, seminar etc.

9.26 Use statistical data to imply that they have a greater validity than is the case.

9.27 Use scientific terms or jargon that is irrelevant to make claims that appear to have a scientific basis which they do not possess.

9.28 Contain any claim or statement suggesting that the medical product advertised is magical or infallible or the results from taking it are guaranteed and extraordinary.

9.29 Be aimed principally or exclusively at children.

10. Exemption

Approval for advertisement is not required in following cases:

10.1 Product catalogues and price lists; provided that they do not include any medical claims about the product.

10.2 Statement on the product label and information leaflet accompanying product registered by the Authority.

10.3 Advertisement of location of premises or availability of products registered with the Authority.

10.4 Discount or free offer of the registered product made with the purchase of any registered product.

11. Procedure for Advertisement Clearance

11. 1 The applicant shall apply for advertisement clearance using form BMRR XVII-CAM in Annexure 3 stating the details of the advertisement.

11. 2 The Authority shall assess the application and communicate the outcomes of the assessment within five working days from the date of receipt of application.

11. 3 If the application fulfils the set conditions, the Authority shall issue the advertisement clearance in the prescribed format as in Annexure 4.

11. 4 If the application is rejected, the Authority will provide the reasons for refusal in writing.

12. Documents Required for Advertisement Clearance

Following documents should be submitted along with the application for clearance for advertisement of medicinal products (BMRR XVII-CAM).

12. 1 Indications;

12. 2 Major precautions (if any);

12. 3 Contraindications and warnings (if any);

12. 4 Side Effects (if any);

12. 5 Content of the advertisement (such as script, draft designs, pictures); and

12. 6 Evidence to substantiate claims where applicable.

13. Variations of Advertisement Clearance

The applicant should seek prior approval before making any modification to the approved advertisement.

14. Offences and penalties

Any person who violates the provision of this Guidelines shall be liable to penalty as per the Rules and Regulations.

15. Complaints

Complaint relating to an advertisement of a medical product shall be made to the Drug Regulatory Authority by e-mail at dra@dra.gov.bt or by telephone at +975-2-337074/337075.

Unauthorized advertisement/ promotional activities of medical products on any media by an individual or firm shall be reported by the Authority or competent Agency(s) to the Media Council of Bhutan, who shall accordingly remove from the media.

16. Reference

16. 1 Health Sciences Authority, Singapore. (2019). *Guide on advertisements and sales promotion of medicinal products* (pp. 4-18).

16. 2 Tanzania Food and Drugs Authority. (2015). Guidelines for control of promotion and advertisement of medicines, medical devices and cosmetics in Tanzania (pp. 6-31).

16. 3 World Health Organization. (1985). *Criteria for Medicinal Drug Promotion* (p. 43).

Annexure 1: Prohibited Diseases and Conditions in Advertisements

1. Appendicitis.
2. Arteriosclerosis.
3. Blindness
4. Blood poisoning.
5. Bright's disease.
6. Cancer.
7. Cataract.
8. Deafness.
9. Diabetes.
10. Diseases and disorders of the brain.
11. Diseases and disorders of the optical system.
12. Diseases and disorders of the uterus.
13. Disorders of menstrual flow.
14. Disorders of the nervous system.
15. Disorders of the prostatic gland.
16. Dropsy.
17. Epilepsy.
18. Female diseases (in general)
19. Fevers (in general).
20. Fits.
21. Forms and structure of the female bust.
22. Gallstones, kidney stones and bladder stones.
23. Gangrene.
24. Glaucoma.
25. Goitre
26. Heart diseases.
27. High or low blood pressure.
28. Hydrocele.
29. Hysteria.
30. Infantile paralysis.
31. Insanity.
32. Leprosy.
33. Leucoderma.
34. Lockjaw.
35. Locomotor ataxia.
36. Lupus.
37. Nervous debility.
38. Obesity.
39. Paralysis.
40. Plague.
41. Pleurisy.
42. Pneumonia.
43. Rheumatism.
44. Ruptures.
45. Sexual impotence.
46. Smallpox.
47. Stature of persons.
48. Sterility in women.
49. Trachoma.
50. Tuberculosis.
51. Tumours.
52. Typhoid fever.
53. Ulcers of gastrointestinal tracts.
54. Venereal diseases, including syphilis, gonorrhea, soft cancer, venereal granuloma and lymphoma granuloma.

Annexure 2: Prohibited superlatives descriptors, words or phrases 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.

Annexure 3

Form: BMRR XVII-CAM

APPLICATION FOR CLEARANCE FOR ADVERTISEMENT OF MEDICINAL PRODUCTS

Applicant particulars

Name of the applicant: ……...
Address: ……...**E-mail:** ……...
Contact number: ……..

Product particulars

Product category (please tick the appropriate box)

□ Human allopathic medicine □ Veterinary medicine □ Herbal medicine
□ Traditional medicine □ Health supplements

Product Name(s): ……..
Registration Number: ……..
Market Authorization Holder: …….
Type of Advertisement: …….

Type of material: (please tick the appropriate box)

□ Poster □ Leaflet □ Cinema □ Outdoor/ Billboard □ In/ On Public Transport
□ Magazines/ Newspaper □ Literature □ Audio □ Visual
□ Other, please specify …….

This application shall be accompanied by:
(Please tick the appropriate box)

□ A copy of proposed advert (Script, audio tape, video etc.)
□ A copy of any research or studies to substantiate product claim or benefits (if applicable)
□ Statement of accountability from celebrity in case of celebrity endorsement
□ Letter of concern for user testimonials

Declaration of applicant

□ I hereby declare that the documents submitted above/all information provided is true and correct to the best of my knowledge and belief, and I shall be liable for any consequences if any information provided is proved to be false or misleading.

□ If my application is granted authorization, I shall abide by the provisions of Medicines Act and Medicines Regulations and any other standards set by the Authority.

Signature: Date:

Annexure 4: Format for Advertisement Clearance

Regulation No:239

Advertisement Clearance

M/s……..is hereby authorized to advertise this medicinal product with following contents:

Name of the Medical Product:

Content of the Advertisement:

Terms and conditions:

1. The applicant shall not alter the contents of the advertisement or the meaning of the advertisement once approved for its purpose. Prior approval from the Authority should be obtained for any changes or modification made therein.
2. Breach of conditions shall be liable to regulatory actions as per the provisions of Medicines Act and Bhutan Medicines Rules and Regulations.

This clearance is granted vide application dated (dd/mm/yyyy) of M/s……

Date:……..

Drug Controller

Annexure 5: Checklist for Preparing Application for Clearance of Advertisement.

SN	Requirement	Yes	Remarks
1	Application Form BMRR XVII-CAM		
2	Content of Advertisement (script/ draft pamphlets/posters etc.)		
3	Referred Annexure 1 of this guideline and ensured that the content of advertisement does not contain any prohibited diseases/ conditions.		
3	Referred Annexure 2 of this guideline and ensured that the content of advertisement does not contain any prohibited superlatives descriptors, words or phrases in advertisements.		
4	Evidence to substantiate claims (where applicable).		

We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence.

Drug Regulatory Authority
Royal Government of Bhutan
Phone: 337074.337075, Fax: 33580, P.O 1556
Email: dra@dra.gov.bt Website: www.dra.gov.bt