Botswana Medicines Regulatory Authority

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Date of Approval (DD/MM//YY)

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Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
Whole Document	Document number changed from BOMRA/ER/PV/P03/G01 to BOMRA/PCT/P02/G01 because the function has moved from Department of Product Evaluation and Registration to the Department of Pharmacovigilance and Control of Clinical Trials	2	Dr. P. Gurumurthy	28/05/2020
Whole Document	The guidelines have been expanded to include more information on products. It covers different advertising methods and offer detail explanation of a wide range of scenarios. The guideline also include Advertising Fees	2	Dr. P. Gurumurthy	28/05/2020

1 Purpose

The intention and purpose of these guidelines is to facilitate applicants when coming up with advertisement and promotion materials for medical products in Botswana.

Note: Section 46 Sub-Section 1-4 of the Medicines and Related Substance Act of 2013 and Regulation 53 of the Medicines and Related Substances Regulations, provide for the control of advertising and promotion of medicines. Applicants are encouraged to familiarize themselves with this document and the above laws before initiating the process.

2 Scope

2.1 The document provides guidance to requirements for the advertising and promotion of medical products including medicines, complementary medicines, medical devices, cosmetics, and veterinary medicines in Botswana.

2.2 The scope of the guidelines relates to all medicines, complementary medicines and related substances registered under the Medicines and Related Substance Act of 2013. Advertising and promotional material that are subject to the guidelines include:

a) Aerial promotions such as on hot air balloons
b) Booklets
c) Cinema commercials
d) Consumer leaflets
e) Direct mail materials
f) Internet materials, including press releases intended for internet publication
g) On-pack statements
h) Outdoor advertising, including billboards, advertisements on wall fences and motor vehicles
i) Point of sale materials
j) Posters
k) Print advertisements
l) Promotional aids including those used for direct selling activities
m) Sales promotions
n) Telephone help lines
o) Television and radio commercials
p) Sports, art and other sponsorships
q) Social media

2.3 Legal labelling requirements and package inserts are required to comply with the provisions of the regulations on labelling of medicines, herbal medicines and related substances.

3 Definitions and Abbreviations

3.1 Definitions

For the purpose of this guideline, the following definitions shall apply:

3.1.1 Advertisement - includes a representation by any means for the purpose of promoting, directly or indirectly, the sale, distribution and/or use of a Product as defined hereunder; as well as any acts or methods to have the product information seen or known by the public.

3.1.2 Advertising - means the publicity of goods and description of products; this includes any form of notices in circulars, handouts, label wrappers, catalogue and price lists, newspaper, magazines and many other documents made orally or otherwise or by means of projected light, sound recording, radio, presenter mentions, television, billboards, mobile vans, social media and writings.

3.1.3 Advertisement or promotion- are used interchangeably and include any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any medicinal product. It encompasses written or spoken words and refers to all informational and persuasive activities by stakeholders, the effect of which is intended to induce and encourage the prescription or supply, purchase and/or use of medicines by means of highlighting qualities of medicines (product claims). Point of sale material, information leaflet, booklets and other promotional material which include specific product claims, and which are supplied separately from the product may also be considered "advertisement". Words forming part of a soundtrack or video recording are within the definition of advertisement as is a spoken word.

3.1.4 Authority - means the Botswana Medicines Regulatory Authority (BOMRA), established under the Medicines and Related Substance Act 2013.

3.1.5 Related substance - shall include cosmetics and surgical sundries, medical devices, condoms and blood products.

3.1.6 Health Claims - include any statement suggestion or implication in labelling or advertising that a product has a specific health benefit but not medicinal claims.

3.1.7 Medicinal Claims - are those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions

3.1.8 Medicine - means any substance intended for human or veterinary use, presented in its finished dosage form, that is subject to control by the Authority and includes medicinal product, pharmaceutical product, herbal medicines, veterinary medicine and related substances.

3.1.9 Complementary Medicine - means any medicinal product that contains, as active ingredients, aerial or underground parts of plants, other plant materials or combinations thereof, whether in a crude state or as plant preparations and includes herbal medicines which contain natural, organic or inorganic active ingredients and are processed or packaged in such a manner that they appear like medicines under the western system but does not include medicines containing plant material combined with chemically defined active substances, or chemically defined isolated constituents of plants.

3.1.10 Medical device - means an instrument or apparatus including components, parts and accessories of it manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptom of it in man or animal.

3.1.11 Label- means any tag, brand, and mark, pictorial or other descriptive matter written, printed, stenciled, marked, embossed or impressed on or attached to a container of any product.

3.1.12 Promotion - to make a product, service or business known to a target audience by the use of different channels, including communicating with them and influencing their decision to patronize the product, service or business.

3.1.13 Sales - includes sale by wholesale or retail, or to import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or to authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange, supply or to dispose of to a person whether for a consideration or otherwise.

3.1.14 Product - means medicine, medicinal product, pharmaceutical product, herbal medicines, veterinary medicine or related substances.

3.1.15 Product Information - the approved product information for health professionals and the public as approved by the Authority.

3.1.16 Product License - an official document issued by the Authority for the purpose of the marketing or free distribution of a product

3.1.17 Registration - any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on the market.

3.2 Abbreviations

3.2.1 BOMRA - Botswana Medicines Regulatory Authority

3.2.2 NCE - New Chemical Entity

3.2.3 PV Officer - Pharmacovigilance Officer

3.2.4 VMP's - Veterinary Medicine Products

4 Guidelines

4.1 GENERAL PRINCIPLES

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.

4.1.1 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.

4.1.2 Standards of Promotion

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

4.1.2.2 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.

4.1.2.3 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, of high ethical standards and be in good taste.

4.1.3 Products Allowed To Be Advertised

a) Only products that are registered with Botswana Medicines Regulatory Authority (BOMRA) can be advertised.

b) Schedule i, ii and iii medicines shall not be advertised to the public.

c) Product indication that does not contravene with Section 46, Sub-Section 1-4 of the Medicines and Related Substance Act of 2013.

4.1.4 Prohibited Claims

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

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

i. Diseases or defects of the kidney
ii. Diseases or defects of the heart
iii. Diabetes
iv. Epilepsy or fits
v. Paralysis
vi. Tuberculosis
vii. Asthma
viii. Leprosy
ix. Cancer
x. Deafness
xi. Drug addiction
xii. Hernia or rupture
xiii. Diseases of the eye
xiv. Hypertension
xv. Mental
xvi. Infertility
xvii. Frigidity
xviii. Impairment of the sexual function or impotency
xix. Venereal disease STDs including HIV
xx. Nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse.
xxi. Practicing contraception among human beings

xxii. Improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings

*The list is not exhaustive, and it can be modified from time to time.

4.1.5 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.

4.1.6 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.

4.1.7 Denigration and Disparagement

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

4.1.7.2 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.

4.1.7.3 However, comparisons of products from the same registration holder is allowed if substantiated.

4.1.8 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.

4.1.9 Substantiation

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

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

4.1.10 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.

4.1.11 Advertising on the Internet

a) The name, address and contact number of the advertiser must also be clearly stated in the page.

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

c) 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.

4.2 SOCIAL RESPONSIBILITY

4.2.1 Impressions of Professional Advice or Endorsement

4.2.1.1 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, e.g., the use of white coat, stethoscope, healthcare professional environment / any expression that provides undue authority that the product is recommended by a healthcare professional.

4.2.1.2 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.

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

4.2.1.4 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.

4.2.2 User Testimonials

4.2.2.1 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.

4.2.2.2 Advertisement with a testimonial must be stated with a statement:

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

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

a) Name

b) ID/ Passport number

c) Signature

d) Contact number

4.2.3 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 produced upon demand.

4.2.4 Tests, Trials and Research References

a) 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.

b) 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.

c) 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.

d) 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.

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

4.2.5 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 BOMRA;

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 than 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".

4.2.6 Encouragement of Unnecessary Purchase or Indiscriminate Use

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

b) 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.

4.2.7 Healthy Lifestyle Advice

a) Advertising should not undermine healthy lifestyle advice or health promoting behaviour such as exercise, healthy eating or smoking cessation.

b) Similarly, advertising must also not promote behaviours which are damaging to health (e.g. alcoholism, unhealthy diets, sedentary lifestyle or smoking).

4.2.8 Hyperboles

a) 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.

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

4.2.9 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.

4.2.10 Self-medication

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

a) It is unacceptable to encourage long-term use of products and to encourage consumers to discontinue the use of prescribed medicines.

4.2.11 Unwarranted Anxiety

a) 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.

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

4.3 THERAPEUTIC CLAIMS

4.3.1 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 BOMRA.

4.3.2 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 BOMRA for inclusion in the package insert of the medicine.

4.3.3 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 4.1.4 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.

4.3.1 Functional Claims

Such claims are only allowed for claim of ingredient in product as approved by the BoMRA during Registration of the product.

4.3.2 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 BoMRA in the product indication.

4.3.3 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 BOMRA in the product indication

4.3.4 Claims Relating to Immunity against Specific Disease(s)

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

4.3.5 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 BOMRA in the product indication.

4.3.6 Claims Concerning Weight Management Products

a) 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.

b) 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.

4.4 PRODUCT-RELATED CLAIMS

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.

4.4.1 'Before' and 'After' Claims

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

b) 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.

4.4.2 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.

4.4.3 Complementary Claims

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

4.4.4 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.

4.4.5 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.

4.5 ADVERTISEMENTS AIMED AT PREGNANT WOMEN

4.5.1 Pregnant or Lactating Women

a) 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.

b) 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.

c) Advertisements that promote the use of a medicine during pregnancy are only acceptable when such use is approved by BoMRA. 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.

4.6 MANDATORY STATEMENT AND WARNING OR CAUTIONARY STATEMENTS

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

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

4.6.1 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."*

4.6.2 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."

4.7 ADVERTISING COSMETICS

Registered/cleared cosmetics may be advertised without seeking prior approval, however, must not bear any medical claims. For content guidance see clause 4.1.1 above.

4.8 ADVERTISING VETERINARY MEDICINAL PRODUCTS (VMPs)

All advertising materials for VMPs must be submitted to BOMRA for approval. For content guidance. Clauses 4.1.1 and 4.1.2 apply.

4.9 HOW TO SUBMIT ADVERTISING/PROMOTIONAL MATERIAL

4.9.1 Complete the Service Request Form, ***BOMRA-QM-P09-F01***.

4.9.2 Submit the completed Service Request Form to the Finance and Administration office so that a Proforma Invoice is raised. Make payment for the Advertising material to obtain Proof of Payment.

4.9.3 Submit Advertising material, cover letter and Proof of Payment at Records Unit.

4.9.4 The cover letter should clearly state the name(s) of the product(s), registration number(s) and the type of advertisement being submitted for assessment.

4.10 FEES

The following fees shall apply according to the MRSA Regulation 2019

	(BOTSWANA PULA)
Application for approval of advertisement or promotional material per product.	Print media - 500 Electronic media -1000

5. RESPONSIBILITIES

5.1 PV Officers - Communicating guidelines to stakeholders and implementation of the guidelines.

5.2 Director, Pharmacovigilance and Control of Clinical Trials - Overall effective implementation of the guidelines and review of the guidelines when necessary.