Foreword

Guidelines relating to Advertising and Promotion of Medicines directly to consumers in Zambia

The Pharmaceutical Act (No. 14) of 2004 requires that medicinal products intended to be marketed in Zambia meet acceptable standards of quality, safety and efficacy and be assessed to have been manufactured in facilities which comply with current Good Manufacturing Practices (cGMP).

One of the means for ensuring that medicinal products meet the required standards of quality, safety and efficacy is by conducting product specific pre-marketing assessments to determine whether the product should be registered.

These guidelines have been prepared to provide information to applicants who intend to advertise and promote medicinal products for use in Zambia.

This document has been developed by the Pharmaceutical Regulatory Authority (PRA) to provide guidance to applicants on the content and format of the advertisements and promotion in respect of products to be advertised and promoted. These guidelines also indicate the order of the material to be submitted and the minimum requirements for advertising and promotion of medicine.

Compliance to these guidelines will facilitate advertising and promotion of medicines in an ethical manner that is not intended to mislead the public.

It is therefore my sincere hope that these guidelines will provide the necessary information in preparing and advertisements and promotion of medicinal products in Zambia.

Finally, I wish to urge our esteemed readers and applicants to read this first edition of guidelines carefully and make as many suggestions as possible so that we have a version of the guidelines that are commensurate with current practices.

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Acknowledgements

The Ministry of Health (MoH) and the Pharmaceutical Regulatory Authority (PRA) wish to acknowledge the immense contributions of individuals and originations that constituted the Technical Working Group in developing these guidelines. The principal contributors for this guidance document were:

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The MoH and PRA would further like to thank the World Health Organisation (WHO) for providing financial and technical support to the development of these guidelines.

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Introduction

These guidelines constitute general principles for ethical standards relating to advertising and promotion of medicines. Generally, these guidelines should be applied to medicines in the categories of prescription and non-prescription modes of distribution, including herbal medicines as appropriate, and to any other product promoted as a medicine or for medicinal purposes. The guidelines are meant to be used by people in all walks of life, by governments, pharmaceutical industry (manufacturers, wholesalers and retailers), the promotion industry (advertising agencies, market research organisations), health professionals involved in prescription, dispensing, supply and distribution of medicines, universities and other teaching institutions, professional associations, patients’ and consumer groups and the media including professional media such as publishers and editors of medical journals and related publications. All these are encouraged to use these guidelines as appropriate to their spheres of competence, activity and responsibility and at the same time endeavour to develop their own sets of ethical standards in their own field relating to promotion of medicines. All companies, organisations or individuals supplying medicines, herbal medicines and related substances in Zambia are subject to registration by the Pharmaceutical Regulatory Authority.

All advertising must be consistent and comply with the Pharmaceutical Act No. 14 of 2004 and regulations made thereunder.
Definitions and Interpretations

In these guidelines, unless the context otherwise requires-

advertisement, 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 sound track or video recording are within the definition of advertisement as is a spoken word.

allied or related substance
shall include cosmetics, disinfectants, food supplements, feed additives, medical and surgical sundries, medical devices, condoms and blood products.

authority
means the Pharmaceutical Regulatory Authority (PRA), established under section four of the Pharmaceutical Act 2004.

health claims
include any statement suggestion or implication in labelling or advertising that a product has a specific health benefit but not nutritional or medicinal claims that refer to nutrient function and recommended dietary practice

herbal 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.

**label**
means any tag, brand, and mark, pictorial or other descriptive matter written, printed stencilled, marked, embossed or impressed on or attached to a container of any product.

**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.

**medicinal claims**
are those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions

**product**
means medicine, medicinal product, pharmaceutical product, herbal medicines, veterinary medicine or related substances.

**product information**
the approved product information for health professionals and the public as approved by the Authority
product licence
an official document issued by the Authority for the purpose of the marketing or free
distribution of a product
registration
any statutory system of approval required at national level as a precondition for
introducing a pharmaceutical product on the market
Scope

The scope of the guidelines relates to all medicines, herbal medicines and related substances registered under the Pharmaceutical Act No. 14 of 2004.

Advertising and promotional material that are subject to the guidelines include:

- Aerial promotions such as on hot air balloons
- Booklets
- Cinema commercials
- Consumer leaflets
- Direct mail materials
- Internet materials, including press releases intended for internet publication
- On-pack statements
- Outdoor advertising, including billboards, advertisements on wall fences and motor vehicles
- Point of sale materials
- Posters
- Print advertisements
- Promotional aids including those used for direct selling activities
- Sales promotions
- Telephone help lines
- Television and radio commercials
- Sports, art and other sponsorships

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

1. Registration

Clause 1.1

A medicine which is registered and with a valid product licence issued by the Authority may be advertised or promoted in Zambia. However, a medicinal product which is registered as a prescription only medicine or non-prescription medicine should not be advertised or promoted without prior written authorisation from the Authority
2. Advertising and Promotion

Clause 2.1
Advertising does not include factual, accurate, informative announcements and reference material concerning registered medicines, herbal medicines and related substances and relating, for example, to adverse reaction warnings, trade catalogues and price lists provided they include no product claims, measures or trade practices relating to prices, margins or discounts.

Clause 2.2
An advertisement or promotion of a medicine shall not refer, expressly or by implication, to alleviation or cure of any disease or medical condition or disorder that is prohibited under the Public Health Act and pharmaceutical regulations as contained in the prescribed schedules.

3. Advertising Information

Clause 3.1
A written advertisement for a medicine should contain the following four mandatory elements, taking into account the media employed:

- trade/brand name or proprietary name, if any, including name(s) of the active ingredient(s) using either approved generic name or International Non-proprietary Name (INN) of medicine;
- major indication(s) for use;
- major precautions, contra-indications and warnings;
- name and address of local distributor and for a local-based manufacturer, name and address of manufacturer.

Clause 3.2
Advertising should be balanced, true and should not mislead or contain any exaggerated claims, either direct or implied.
4. Information, Claims and Comparisons

4.1 Information

4.1.1 Proprietary name of a medicine

Clause 4.1.1.1
The approved name and quantity of each active ingredient of such medicine in lettering having a minimum legibility, provided that, in the case of a medicine containing only one active ingredient, such lettering should not be less than one half the size of the largest lettering used for the said proprietary name.

Clause 4.1.1.2
In any case where a name other than the proprietary name is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisements.
All these elements must be clear, legible and clearly communicated. Failure to comply is a breach of the law.

4.2 Claims

Clause 4.2.1
Information on indications and side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. The word ‘safe’ must not be used without qualification.

Clause 4.2.2
Advertising should not suggest that the safety or efficacy of a product is due to the fact that it is natural unless this has been clinically proven to acceptable standards.

Clause 4.2.3
Advertising should not claim that a product is ‘natural’ unless all of its components/ingredients are naturally occurring..
Clause 4.2.4
Advertising should not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants.

Clause 4.2.5
Advertising of a medicine should not suggest that a product is a foodstuff, cosmetic or other non-medicinal product. Foodstuff should not be advertised as medicine or vice versa.

4.3 Comparisons

Clause 4.3.1
A comparison is not permitted in advertising or promotional material:

Clause 4.3.2
Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims.

Clause 4.3.3
The word ‘new’ must not be used to describe any product or presentation, which has been generally available for more than twelve months in the country.

5. Prohibitions or Restricted Representations

Clause 5.1
Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse.

Clause 5.2
Medicine must not be advertised to the general public if they are medicine which, though not prescription only, may not legally be advertised to the general public. This prohibition does not
apply to vaccination campaigns carried out by companies, organisations or individuals approved by the Ministry of Health or the Authority.

Clause 5.3
Advertising should not cause consumers unwarranted anxiety that they are suffering from any ailment. Nor should it imply that suffering may arise if a consumer fails to respond to the advertisement’s claim. Communication which brings fear or distress should not be used.

Clause 5.4
Advertisements should not be presented to suggest that the use of medicine will improve normal good health or vice versa.

Clause 5.5
Advertising should not offer to diagnose, advise, prescribe or treat personally by correspondence.

Clause 5.6
Advertising should not claim, or imply, that a product’s effects are guaranteed.

Clause 5.7
Advertising should use language or medical terminology that does not confuse or mislead the consumer.

Clause 5.8
Advertising should not discourage consumers from seeking medical advice.

Clause 5.9
Advertising should not suggest that the medicine has been recommended by scientists or health professionals.

Clause 5.10
Advertising should not include a recommendation by a person who, because of their celebrity status, may encourage consumers to take a medicine.
6. Specific Categories

6.1 Vitamins

Clause 6.1.1
An advertisement for vitamins should not imply that vitamin supplements:
(a) are a substitute for good nutrition or a balanced diet
(b) are in any way superior to or more beneficial than dietary nutrients or that normal health may be affected by not taking vitamin supplements

6.2 Weight management

Clause 6.2.1
Claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, can only be made in conjunction with reference to sensible lifestyle factors including a diet and exercise.

6.3 Slimming/Body image

Clause 6.3.1
Fat burning, fat and starch blocking which include direct or implied claims imply efficacy. All references should be linked, by means of an asterisk, to a clear disclaimer stating “this product has not been proven to burn fat or block starch”.

6.4 Children

Clause 6.4.1
Advertising should not be aimed principally or exclusively at children. Advertising should not show children using, or within reach of, medicine without adult supervision.
6.5 

Claims based on traditional use

Clauses 6.5.1

Indications can be based on evidence of traditional use of a substance or product, and/or on scientific evidence. Indications/claims are categorised depending on the level of claim being made.

All indications must be true, valid and not misleading, and should not lead to unsafe or inappropriate use of the product. Evidence must relate to the whole product or the same active ingredient(s) with similar dosage regimen, dose form and route of administration to the product/ingredient for which the claim is being made. Evidence must be available before claiming an intended use or indication for a product.

Claims and the levels and kinds of support must be in accordance with the Guidelines for Complementary Medicines.

7. Disparaging References

Clause 7.1

When promotional material refers to published or unpublished studies, clear and complete references must be given.

8. Suitability and Taste

Clause 8.1

Although it is acceptable to indicate that a self-medication medicine is palatable and suitable, advertising should make clear that it is a medicine

9. Disguised Promotions

Clause 9.1

Promotional material and activities must not be disguised.
Clause 9.2
Market research activities, post-marketing surveillance studies, clinical assessments and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products.

10. Provisions of Reprints and use of Quotations

Clause 10.1
Reprints of articles in journals must not be provided unsolicited unless the articles have been refereed. If a non-refereed article is requested by a consumer, a copy may be provided on written request, provided that each page is stamped with the text “non-refereed article”.

11. Certification of Promotional Material

Clause 11.1
Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been approved or certified by the Authority.

12. Compliance and Undertaking

Clause 12.1
Advertising should be clearly distinguished from editorial matter. Care must also be taken with company-sponsored reports on meetings and the like to ensure that they are not disguised promotion.

Clause 12.2
No company should offer incentives to consumers through advertising for any incentive schemes/price discounts.

Clause 12.3
Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the Authority.
Clause 12.4

Companies, organisations or individuals are responsible for information about their products that is issued by their public relations agencies.