Medicines Control Authority of Zimbabwe

GUIDELINES FOR ADVERTISING AND PROMOTION OF MEDICINES IN ZIMBABWE

MANUFACTURERS, APPLICANTS, WHOLESALE DEALERS AND ALL THOSE WHO INTEND TO ADVERTISE MEDICINES FOR SALE IN ZIMBABWE

1. Preamble:

These guidelines were partly derived from recommendations from the World Health Assembly (WHA 41.17) resolutions adopted at the 41st WHA of 13th May 1988 on Ethical Criteria for Medicinal Drug Promotion together with a number of policies adopted by the Authority over a number of years.

2. Scope:

These guidelines apply to all advertising material other than promotional material submitted with applications for registration of medicines.

3. Definitions:

3.1 **Authority:** The Medicines Control Authority of Zimbabwe established by Section three of the Medicines and Allied Substances Control Act [MASCA].

3.2 **Medicine:** Subject to Section seventy-five of the Medicines and Allied Substances Control Act [MASCA], means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in—

3.2.1 The diagnosis, treatment, mitigation or prevention of disease or any abnormal physical or mental state or the symptoms thereof in man or in animals; or

3.2.2 Restoring, correcting or modifying any physical, mental or organic function in man or in animals;

3.3 **Advertisement:** The Medicines and Allied Substances Control Act (Chapter 15:03) [MASCA] defines an advertisement in relation to any medicine as "any written, pictorial, visual or other descriptive matter or verbal statement or reference:

3.3.1 appearing in any newspaper or other publication; or

3.3.2 appearing on any television or cinema; or

3.3.3 distributed to the members of the public; or

3.3.4 brought to the notice of the members of the public in any manner whatsoever; which leads to the promotion of the sale of that medicine."

3.4 **Promotion:** This is defined following the WHA resolutions as all informational and persuasive activities by a manufacturers and distributor of medicines the effect of which is to induce the prescription, supply, purchase and/or sale of the medicine

4. Legal Requirements:

As stipulated in Section 65 of the Medicines and Allied Substances Control (General) Regulations, 1991, (S.I 150 of 1991).

4.1 No person is permitted to advertise any medicine without the approval of the Authority in writing.
4.2 No person is permitted to advertise or sell any medicines in connection with any bonus offer or discount to the public.
4.3 Advertising of psychotropic substances or any medicine which contains codeine or any of its salts is not permitted. (SI 256 of 1998). This includes window displays for e.g. cough and cold preparations
4.4 Advertising of medicines to the public is NOT permitted if it is in terms calculated to lead to their use for the treatment of human beings for any of the following conditions:

Alcoholism, Appendicitis, Arteriosclerosis, Cardiovascular disease, Cataract, Diabetes, Hernia, Kidney stone, Pneumonia, Prostate gland disorders, Epilepsy, Gallstones, Gangrene, Glaucoma, Hypertension, Hypotension, Infantile diarrhoea, Plague, Pleurisy, Locomotors or any other ataxia, All types of meningitis, Nephritis, Osteoarthritis, Sexually transmitted infections, Pneumoconiosis, Multiple sclerosis, Rheumatic fever, Rheumatoid arthritis, Malignant disease, Thrombosis, Tuberculosis, Poliomyelitis, Parkinson's disease.

4.5 Note that advertisements for medicines to be used in these conditions may however be permitted when they are directed at the medical or veterinary professionals. Such advertisements will still require to be approved by the Authority.
4.6 If any medicine has been registered it shall be available to the public only on the direction of a medical practitioner, dental practitioner or veterinary surgeon and no person shall advertise that medicine otherwise than:
4.6.1 in a medical, dental or veterinary or pharmaceutical journal approved by the Authority; or
4.6.2 to members of the medical, dental, veterinary or pharmaceutical profession;

5. General Requirements for Advertising

5.1 Promotional Material in all forms to physicians and health-related professionals.

Section 35 of the Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991, states that every application for the registration of a medicine shall be accompanied by detailed information of all advertising material.

It therefore follows that once a medicine is registered, any additional promotional or advertising material should be submitted to the Authority for approval as amendments to the initial application.

5.1.1 The wording and illustrations in advertisements to physicians and related health professionals should be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. The text should be fully legible.
5.1.2 It is required that advertisements should contain full product information, as defined by the approved scientific data sheet or similar document, for a given period from the date of first promotion or for the full product life. Advertisements that make a promotional claim should at least contain summary scientific information.
5.1.3 The following list, can serve as an illustration of the type of information that such advertisements should usually contain, among others:

5.1.3.1 the name of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
5.1.3.2 the brand name;
5.1.3.3 content of active ingredient(s) per dosage form or regimen;
5.1.3.4 name of other ingredients known to cause problems;
5.1.3.5 approved therapeutic uses;
5.1.3.6 dosage form or regimen;
5.1.3.7 side-effects and major adverse drug reactions;
5.1.3.8 precautions, contra-indications and warnings;
5.1.3.9 major interactions;
5.1.3.10 name and address of manufacturer or distributor;
5.1.3.11 reference to scientific literature as appropriate.

5.1.4 Where advertisements are permitted without claims (reminder advertisements), they ought to include at least the brand name, the international nonproprietary name or approved generic name, the name of each active ingredient ,and the name and address of the manufacturer or distributor for the purpose of receiving further information.

6. The General Requirements for Promotional Material

6.1 Active promotion should take place only with respect to drugs legally available in the country.
6.2 All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful informative, balanced, up-to-date, capable of substantiation and in good taste.
6.3 They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.
6.4 The word "safe" should only be used if properly qualified.
6.5 Comparison of products should be factual, fair and capable of substantiation.
6.6 Promotional material should not be designed so as to disguise its real nature.
6.7 Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements.
6.8 Promotion in the form of financial or material benefits should not be offered to or sought by health care practitioners to influence them in the prescription of drugs.
6.9 Scientific and educational activities should not be deliberately used for promotional purposes.
6.10 Promotions that require participants to acquire a certain quantity of purchase to determine qualification should exclude purchase of medicines.
6.11 Wholesale Dealers may run competitions involving medicines provided these are not directed at the end-user.

7. Advertisements in all forms to the general public

7.1 Advertisements to the general public should help people to make rational decisions on the use of medicines determined to be legally available without a prescription.
7.2 Language which brings about fear or distress should not be used.
7.3 Advertisements should be reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation and in good taste.
7.4 While they should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health.

7.5 Advertisements may claim that a medicine *can* cure, prevent, or relieve an ailment only if this can be substantiated.
7.6 Where applicable, appropriate limitations to the use of the medicine must be pointed out.
7.7 When lay language is used, the information should be consistent with the approved scientific data sheet or other legally determined scientific basis for approval.
7.8 The material to be used should comply with the conditions of registration
7.9 Unsubstantiated claims of superiority over other brands will not be permitted.
7.10 Advertisements should not be directed at children
7.11 The advertisement of **any unregistered medicine** is not permitted. This includes medicines acquired with the approval of the Authority under the provisions of section 75 of the MASCA.
7.12 As stipulated in section 65 of the SI 150 of 1991, bonus offers and discounts offered directly to the public are not permissible. The following however apply:
7.12.1 Point of sale indication of a price reduction may be permitted for medicines in the HR, HR (Vet), VMGD and P categories.
7.12.2 Indication of the selling price of medicines in the HR, HR (Vet) and VMGD categories may be permitted. Indication of a price reduction is however not permitted.

8. Acceptable Claims

The Licensing and Advertising Committee of the Authority considers all advertising material submitted for approval. The Committee meets regularly on the first Tuesday of every month.

Advertisements must be submitted at least two weeks prior to the meeting to ensure they are included on the agenda for the next meeting.

To facilitate the review process applicants are encouraged to limit the indications claimed to the following:

8.1 Those derived from data already submitted to the Authority during registration of the product that have been substantiated and approved. **NB This approval may not apply to listed medicines which have yet to be reviewed and registered.**
8.2 Those on the approved package inserts.

The Authority reserves the right to limit the claims made on advertisements directed to the public. Applicants should not use the advertisement before written approval is given. Additional material requested to substantiate any claims should be made available promptly so as to facilitate a timeous decision.

9. Submission of Advertisements to the MCAZ

The Regulatory officers are available to advice during the preparation of any material for presentation to the Licensing and Advertising Committee.

9.1 Applications to be submitted by the 20th of the month for consideration during the next meeting.
9.2 For audio or visual (television, video, cinematographic) advertisements it is required that written scripts be submitted prior to final recordings being made, in case changes are called for. On approval of the written scripts, the applicant may

then submit the video or audiotapes in the approved format. Two copies of each will be required. One copy will be retained by the Authority and the other will be returned to the applicant.

9.3 For printed material **ONE** colour copy and **NINETEEN** other good copies should be submitted. The Authority may reject any unsatisfactory copies.

9.4 The advertisements should always contain the following and any other requirements as may be deemed necessary by the Authority;

9.4.1 standard warnings where applicable. These should be of a large enough size to be easily readable on the advertisement or be read loud enough to be heard by listeners or displayed long enough to be seen by viewers respectively.

9.4.2 approved Name(s) and strength of all the active ingredient(s) per unit dose should be stated

9.4.3 Name and address of manufacturer or distributor

9.4.4 The registration number and category for distribution should be indicated (visual/written advertisements only)

9.4.5 Pictorial advertisements for the print media should include appropriate reference to published literature where relevant.

If approved/disapproved, the Authority issues an approval/ disapproval letter which is then communicated to the customer. Each approved advertisement will be issued a reference number in the following format L&A/ 80.3.1/2016 for example.

NB. **All matters pertaining fulfilment of the requirements of the application should be resolved within sixty (60) days of submitting the application. Failure to resolve any outstanding issues within the stipulated time will result in the application being refused. Should the applicant wish to pursue the matter after the stipulated sixty (60) day period, a new application will have to be submitted.**

10. Amendments to Advertisements

Should the applicant require to make any changes to the approved advertising material, these will have to go through the approval process. Note that proposed changes by the applicant also include changes to any existing and previously approved advertisement.

The decision of the Authority will be communicated in writing to the applicants within ten working days of the decision being made. An approval number will be quoted for each approval e.g. L&A/ 80.3.1/2000. Any subsequent amendments will have a different approval number.

The applicant should be able to refer to this approval number whenever any queries are raised regarding an advertisement.

11. Penalties imposed for failure to adhere to the advertising requirements

All advertisers are reminded that failure to comply with these guidelines constitutes an offense as in accordance with Section 40 of the Medicines and Allied Substances Control Act (Chapter 15:03)