PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

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GUIDANCE ON ADVERTISMENT OF MEDICINES AND ALLIED SUBSTANCES

1- INTRODUCTION

Advertisement and promotion of medicines and allied substances which include traditional medicines and nutritional supplements with health benefits remains an important means of creating awareness and disseminating information to the public and healthcare professionals. It also provides a means of updating all on the latest advances and availability of medicines and allied substances.

Advertisements and promotions can also, if not carried out correctly, pass the wrong information and in turn affect the health of the consumer. Unethical advertisements and advertisements that are based on false claims also affect the lives of the consumers.

Over the past years there has been an increase in the number of advertisements and promotions across all media in Malawi. However, there has also been an increase in the advertisement of allied substances which include traditional medicines and nutritional supplements with otherwise little safety, quality and efficacy-related data. This poses a great threat to the safety of the consumers.

This guidance document has therefore been developed to provide information on the current minimum requirements for authorization to advertise and promote medicines and allied substances in Malawi. The guidance document stipulates, among other things, elements of advertisement and promotion, restrictions therein, basic requirements and the application procedures for obtaining approval to advertise and promote. This guiding document should be read together with the Pharmacy and Medicines Regulatory Authority Act No 9 of 2019.

2- SCOPE

This guidance document is applicable to advertisement and promotion of conventional medicines, traditional medicinal products and food supplements with health benefits. Advertisement of the practice of medicine, either conventional and traditional, is not regulated by Pharmacy and Medicines Regulatory Authority. In view of this, this guidance document does not cover advertisement and promotion of the practice of either conventional and traditional medicine.

3- MINIMUM REQUIREMENTS FOR AN ADVERTING MATERIAL

3.1 As provided for in the Pharmacy and Medicines Regulatory Authority Act No 9 of 2019, advertisement of prescription only medicines (POM) is prohibited. Applicants should therefore not submit application for advertisement of POM

3.2 The following are minimum requirements which should be considered when developing advertisements for medicines, traditional medicines and nutritional supplements:

3.1.1 The content of promotional materials must be unbiased, accurate, informative, up to date, in good taste and consistent.

3.1.2 Advertisement/promotional material should not contain misleading or unverifiable statements or omissions regarding quality, safety, and efficacy or value which is likely to induce unjustifiable product use or to give rise to undue risks;

3.1.3 The advertising or promotional materials for medicines, allied substances or nutritional supplements with health benefits should not advertise the following diseases of public interest:

3.1.3.1 Alcoholism
3.1.3.2 Appendicitis
3.1.3.3 Arteriosclerosis
3.1.3.4 Cardiovascular diseases including hypertension
3.1.3.5 Cataract
3.1.3.6 Diabetes
3.1.3.7 Hernia
3.1.3.8 Kidney stones
3.1.3.9 Pneumonia
3.1.3.10 Prostate gland disorder
3.1.3.11 Epilepsy
3.1.3.12 Gallstones
3.1.3.13 Gangrene
3.1.3.14 Glaucoma
3.1.3.15 Tuberculosis
3.1.3.16 HIV/AIDS
3.1.3.17 Cancer
3.1.3.18 Malaria
3.1.3.19 Sexually transmitted diseases
3.1.3.20 Any other disease that the Minister responsible may specify

4- APPLICATION PROCESS

3.1 The applicant should submit completed application form and attach adverting material and evidence of payment of prescribed fees as provided in the Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2019.

3.2 The Pharmacy and Medicines Regulatory Authority will evaluate the application and provide response within fourteen days

3.3 An authorization in the form of a letter will be issued by the Authority if it meets minimum requirements as prescribed in these guidelines

3.4 The Authority will issue a rejection letter and reasons thereof if the application does not meet requirements.

3.5 Upon receipt of a letter in 3.4, the applicant may address issued raised and resubmit an amended advertising material for review by the Authority.

3.6 If the resubmitted material meets the requirements an authorization in the form of a letter will be issued by the Authority

Annex 1: APPLICATION FORM FOR ADVERTISEMENT OF MEDICINE OR ALLIED SUBSTANCES

FORM 8 ADVT

PHARMACY AND MEDICINES REGULATORY AUTHORITY

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APPLICATION FOR ADVERTISEMENT OF MEDICINES OR ALLIED SUBSTANCES

1. Particulars of Applicant:

(1) Name of applicant ……

(2) Physical address/location……

(3) Postal address ……
……

(4) E-mail address……

(5) Full name and title of signatory……
……

2. Description of Advertisement:

(1) Type of activity (ies) for which application is made
(Example launch, advertisement, talk-show, exhibition,)
……

(2) Type of material (s) to be used (Attach 2 samples)
(Example: posters, literature, bags, calendars, audio, video)
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(3) Medicine or allied substance name ……

(4) Language of the publication or advert……

(6) Intended target group
(Example: Healthcare professionals, general public)
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(5) Date of application…… Signature ……

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3. **For Official Use Only**

(1) Fees payable……

(2) Receipt No…… Date……

(3) PMRA entry No……

(4) Application and samples received by (name)……
Signature…… Date……