MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, The Gambia. Tel.no. +220 4380632, www.mca.gm

GUIDELINE FOR ADVERTISEMENT OF MEDICINES AND RELATED PRODUCTS

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1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of medicines and related products in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act") by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

1.1.2. Part II, Section 4, sub-section (l) of the Act requires that the Agency shall control advertisements of medicines and related products and Section 21 requires that advertisement of a medicine or related product for the general public has to be approved by the Agency.

1.1.3. The Medicines and Related Products Regulations, 2019 ("Regulations") details the legal requirements and stipulates that a person shall not advertise or carry out any promotional activities for a medicine or a related product for the general public or health professionals, unless the advertisement or promotional activity has been approved by the Agency.

1.1.4. The Agency charges non-refundable application fee as indicated in the MCA Fee Schedule.

1.1.5. Applicants are required to familiarise themselves with this document and the above stated law before applying for advertisement for a medicine or related product.

1.2 INTERPRETATION AND ABBREVIATIONS

The interpretation of terms provided in the Act and Regulations apply to this guideline, unless further defined in this guideline.

Advertisement includes any form of advertisement whether publication, or by display of any notice or by means of a catalogue, price list, letter, whether circular or addressed to a particular person or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or online media or any other means of communication to promote the prescription, supply, sale or consumption of medicines or related products.
It also includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicines or related products.

1.3 PURPOSE

1.3.1. In pursuance of the law this document provides guidance to persons promoting medicines or related products for human or veterinary use in The Gambia.

1.3.2. The control of advertisement and promotional activities by the Agency ensures that information provided is unbiased and not false or misleading.

1.4 SCOPE

1.4.1. This guideline applies to medicines and related products as defined in the Act and Regulations.

1.4.2. It applies to advertisement of medicines or related products for the general

public and for persons qualified to prescribe or supply them.

1.4.3. This document also applies to visits by sales representatives and sponsorship of promotional meetings or scientific congresses addressed to persons qualified to prescribe or supply medicines or related products.

1.4.4. It does not apply to correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicine or related product.

1.4.5. This guideline does also not apply to factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims.

2 GENERAL REQUIREMENTS

2.1. Any advertisement for a medicine or related product shall comply with the requirements set out in the Regulations.

2.2. Any advertisement or promotional activity of a medicine or related product must be approved by the MCA.

2.3. Advertisement or promotional activities for medicines will only be approved if the medicines are registered with the Agency, unless exempted by the Agency.

2.4. The non-refundable fee is due at the time of submission of the application to the Agency.

2.5. All parts of the advertising of a medicine or related product must comply with the particulars listed in the approved professional information or summary of product characteristics, the patient information leaflet or equivalent and the labelling.

2.6. The advertising shall encourage the rational use of the medicine or related product by presenting it objectively and without exaggerating its properties, and the advertisement shall not be false or misleading.

3 REQUIREMENTS FOR ADVERTISING TO THE GENERAL PUBLIC

3.1. Medicines and related products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical or veterinary practitioner or dentist, such as over the counter medicines, herbal medicines, cosmetics, homeopathic medicines, medical devices and household chemical substances as listed in Schedule 1 (Over The Counter (OTC) Medicines including Nutritional Supplements), 4 (Herbal Medicines), 7 (Cosmetics), 8 (Homoeopathic Medicines), 9 (Medical Devices) and 10 (Household Chemical Substances) of the Regulations.

3.2. Medicines or related products which are available on medical prescription only, controlled drugs or other medicines that contain psychotropic or narcotic substances as listed in Schedule 2 (Pharmacy Medicines), 3 (Prescription Only Medicines), 5 (Veterinary Medicines), and 6 (Diagnostic Products/Agents) of the Regulations shall not be advertised to the general public.

3.3. Advertisements for the general public shall not mention indications such as tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer, chronic insomnia, diabetes and other metabolic illnesses.

3.4. No person shall directly distribute medicines to the public for promotional purposes; the Agency may, however, authorise such distribution in special cases for other purposes.

3.5. The restrictions on advertising do not apply to campaigns carried out by or under the supervision of the Gambian Government.

3.6. All advertising to the general public of a medicine or related product shall be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicine or related product.

3.7. The advertising of a medicine to the general public shall not contain any material which:

- gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicine or related product;
- suggests that the health of the consumer can be enhanced by taking the medicine;
- suggests that the health of the consumer could be affected by not taking the medicine;
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicine;
- suggests that the medicine is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicine is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicine on the human body or parts thereof; or
- mentions that the medicine has been granted a marketing authorisation.

4 REQUIREMENTS FOR ADVERTISING TO HEALTH PROFESSIONALS

4.1. Any advertising of a medicine to persons qualified to prescribe or supply such products shall include essential information compatible with the approved professional information or summary of product characteristics and the supply classification of the medicine.

4.2. All the information contained in the documentation relating to a medicine or related product which is transmitted as part of the promotion of that product

shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine or related product concerned.

4.3. Where medicines or related products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy, and the persons shall not solicit or accept any inducement.

4.4. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and only upon approval by MCA.

5 APPLICATION FOR ADVERTISEMENT AND PROMOTION

5.1. A person or company intending to advertise or promote a medicine or related product shall submit a sample of the product, the product information and all material anticipated to be used (e.g. text, visual information, audio information, etc.) including a sample of the text/wording/pictographs/pictures of advertisement to the Agency.

5.2. The Agency will respond within one (1) month of receipt of the application and, at its discretion, approve, request changes or refuse approval of the advertisement or promotional activity. The Agency may cancel any approval which was previously issued.

5.3. The letter of approval is valid for one (1) year unless otherwise specified.

6 FINAL PROVISIONS

6.1. This guideline is the first version published by the MCA and will become effective on 25 June 2020.

6.2. This guideline will be reviewed within 3 years of becoming effective.

7 DOCUMENTS NEEDED FOR THIS GUIDELINE

Document No	**Title** (as referenced on the document)
MCA-F-306/01	Application for Advertisement - Form

8 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- MCA Fee Schedule

9 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change:**
1	20 June 2020	New document
2	25 June 2020	Editorial changes