

**REF:** B/279/35/17/2019

27<sup>th</sup> June 2019

To: APPLICANTS AND STAKEHOLDERS

## CIRCULAR 17/2019

### SUBMISSION OF PROMOTIONAL MATERIAL FOR APPROVAL

The Medicines Control Authority of Zimbabwe (MCAZ) would like to notify all applicants and stakeholders that all promotional material for medicines are processed by the Pharmacovigilance and Clinical Trials Division. Promotional material is defined as all informational and persuasive activities by an applicant and distributor of medicines, the effect of which is to induce the prescription, supply, purchase and/or sale of the medicine by healthcare professionals.

The Authority makes a distinction between promotional material and advertisements intended for the public. 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:

- a. appearing in any newspaper or other publication; or
- b. appearing on any television or cinema; or
- c. distributed to the members of the public; or
- d. 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.”

All samples of the promotional material should be submitted to MCAZ by the 15<sup>th</sup> of every month to enable the items to be considered during the Pharmacovigilance and Clinical Trials Committee meeting for the following month. The promotional material should contain a minimum of the following information:

#### **Fliers, Pamphlets and Posters**

1. The names of the active ingredients using either international non-proprietary names or the approved generic names of the drug
2. The brand name
3. Content of active ingredient per dosage form or regimen
4. Name of other ingredients known to cause problems, i.e., adjuvant
5. Approved therapeutic uses
6. Dosage form or regimen
7. Side effects and major adverse drug reaction
8. Precautions, contraindications, and warnings
9. Major interactions
10. Name and address of the manufacturer or distributor

11. Reference to scientific literature as appropriate

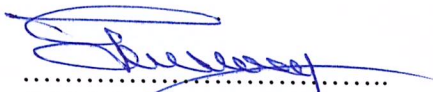
**Stationery and Any other**

1. The name of the active ingredient(s) using either international non-proprietary name (INN) or the approved generic name of the drug.
2. The brand name
3. The strength of the medicine
4. The registration number of the medicine

All promotional material should be submitted with the proof of payment of the appropriate fee.

Yours faithfully

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**



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G.N. MAHLANGU (Ms)  
**DIRECTOR-GENERAL**