ZIMBABWEAN

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MEDICINES AND ALLIED SUBSTANCES CONTROL ACT
[*CHAPTER 15:03*]

Cancellation and Variation of Conditions of Registration

IT is hereby notified that the Medicines Control Authority of Zimbabwe (MCAZ) has, in terms of subsection (1)(f) of section 34 of the Medicines and Allied Substances Control Act [*Chapter 15:03*] amended the conditions of registration of medicines as follows—

A. General conditions of registration—

(a) Compliance with labelling requirements.

(b) Mandatory Reporting of Individual Case Safety Reports (ICSRs) that includes; Adverse Drug Reactions (ADRs), Adverse Events (AEs), Serious Adverse Events (SAEs) and Adverse Events Following Immunisations (AEFIs) and/or product defects.

(c) Applicant, Manufacturer and/or Market Authorization Holder (MAH) is required to have a functional Pharmacovigilance system in place for their medical products.

(d) Applicant, Manufacturer and/or MAH is required to designate a responsible person for Pharmacovigilance Qualified Persons for Pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the MAH.

(e) Compliance with any request by the Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise.

(f) Renewal of market authorisation every five (5) years on condition of demonstration of quality, safety and efficacy.

B. Product specific conditions of registration—

- Active Pharmaceutical Ingredients (API) manufacturer(s).
- Approved batch size(s).
- Written commitment(s) by the Finished Pharmaceutical Products (FPP) manufacturer.
- Approved label.
- Risk management plan.

C. Justification for variation of conditions of registration

The MCAZ registration conditions stated above are part of the legal provisions for existence of a national vigilance system based on requirements for sections 29(1)(b), 33(2)(iii), 33(3) and 34(1)(f) of the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*], MCAZ National Pharmacovigilance handbook 2016 Edition, MCAZ circular 1/2000 dated 21st March, 2000, MCAZ Pharmacovigilance Guideline for Pharmaceutical Industry MCAZ/PVCT/GL-02, Guideline for Pharmacovigilance of COVID-19 Vaccines MCAZ/PVCT/GL-03 and Zimbabwe National Adverse Events Following Immunisation (AEFIs) Guideline 2017. The use of the new format for the registration certificate will clarify all the registration conditions requirements plus product-specific information to ensure compliance, and vigilance post-registration processes. The variation of the registration conditions and subsequent new registration certificate format, with the annexure, will be implemented with immediate effect from the date of publication of this notice.

These changes were also necessitated by the need for further clarification of medicines registration conditions requirements in line with MASCA, including additional compliance with critical international good regulatory best practices to ensure that effective, quality and safe medicines are available to the public.

D. Opportunity to submit comments.

Please take note that comments on the above conditions may be submitted to the Director-General within one month of publication of this notice for consideration.