MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 3 of 2022

Date: 17/02/2022

To: ALL CURRENT AND PROSPECTIVE, LOCAL AND EXTERNAL, APPLICANTS, MANUFACTURERS AND PRINCIPALS FOR REGISTRATION OF MEDICINES

RE: CLARIFICATION OF CONDITIONS FOR MEDICINES REGISTRATION REQUIREMENTS AND SUBSEQUENT EXPANSION OF REGISTRATION CERTIFICATE, SECTION 15 FORMAT ANNEXURE.

This circular serves to inform all applicants, manufacturers, and principals, that the Medicines Control Authority of Zimbabwe clarified the conditions for medicines registration and subsequently expanded section 15 of the registration certificate, i.e. "Conditions for registration imposed by the Authority", as an annexure that is meant to capture more information on the medicines registration conditions requirements. The annexure shall include information on:

General conditions of registration

Subject to:

1. Compliance with labelling requirements.
2. Mandatory Reporting of Individual Case Safety Reports(ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects;
3. Applicant, manufacturer and/or market authorization holder (MAH) is required to have a functional Pharmacovigilance system in place for their medical products;
4. Applicant, manufacturer and/or MAH is required to designate a responsible person for Pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the MAH;
5. Compliance with any request by the Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise;
6. Renewal of market authorisation every five (5) years on condition of demonstration of quality, safety and efficacy.

Product specific conditions of registration

- API manufacturer(s).
- Approved batch size(s).
- Written commitment(s) by the FPP manufacturer.
- Approved label.
- Risk management plan.

NB: Please note that the MCAZ registration conditions stated above are also part of the legal provisions for existence of a national vigilance systems based on requirements for sections 33(2) (iii), 33(3) and 29 (1) (b) 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 Immunization (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 clarification 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 the circular that is 15th February 2022.

These changes were necessitated by further clarification of medicines registration conditions requirements in line with MASCA Chapter 15:03 including additional compliance with critical international good regulatory best practices to ensure that effective, quality, and safe medicines are available to the public. We thank you for your usual co-operation in regulatory compliance and promoting patient safety.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. Rukwata (Mr.)
ACTING DIRECTOR-GENERAL