MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/35/14/2022

CIRCULAR 14 of 2022

Date: 16 September 2022

To: All applicants

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES

This circular serves to inform applicants, manufacturers and principals the implementation plan for re-registrations (marketing authorization renewals). The requirement for re-registrations was communicated in the MCAZ circular 3 of 2022 (point 6) dated 17 February 2022. With effect from 1 January 2023, product registrations for human allopathic medicines will have a validity period of five (5) years. Applications for re-registration would therefore need to be submitted every five (5) years in order to maintain the products on the MCAZ register.

The process of re-registration will be applicable to all human allopathic medicines registered by MCAZ. The process will be carried out as follows:

1. Products registered from the 1st of January 2023

With effect from 1st January 2023, all new registrations will have a validity period of 5 years from the date of registration. The validity period will be indicated on the registration certificate. An application for re-registration of the product should be submitted before the validity period of the product expires and can be submitted 3 months before the re-registration date.

2. Products registered prior to the 1st of January 2023

Registration of all products registered before 1st January 2023 will expire on the 31st of December 2027. Applications for re-registration of these products can be submitted from the 1st of January 2023 to the 31st of September 2027. A validity period of 5 years from the date of re-registration will be indicated on the registration certificate.

In both cases, applications for re-registration of the product should be submitted before registration expires. In the case where the applicant does not submit an application for re-registration 3 months after expiry, product registration will be cancelled.

The following should be considered when making an application for re-registration:

1. The submission should be made in CTD format
2. The re-registration process should be in-line with the MCAZ guideline on product re-registrations.
3. Post approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post variations should be made separately.

Please note that the re-registration process does not replace the process of annual retentions. No processing fees will be charged for re-registrations. Requests for exemptions to any of the requirements should be submitted before the re-registration dates and will be considered on a case-by-case basis.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. RUKWATA (Mr)
DIRECTOR-GENERAL