MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 4 of 2024

Date: 04/02/2024

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES - EXTENSION OF RE-REGISTRATION FEE WAIVER

This circular is a follow-up to circular 21, 19 and 11 of 2023, dated 15th September, 15th July and 30th May 2023 respectively, on the implementation of re-registrations (marketing authorization renewals). The Authority has, after consultation with key stakeholders, further extended the waiver to levy fees for applications for re-registrations to the 30th of April 2024.

To date, the Authority has received over six hundred **(600)** applications for re-registration since the call for voluntary submissions was issued in Circular 3 of 2022, dated September 14, 2022. However, it has been noted that some applications for re-registrations are grossly deficient and fall short of the requirements stipulated in the MCAZ Guideline on product re-registrations. Such applications will be rejected after the assessment process, however the concerned products will continue having marketing authorisation rights until the 31st December 2027. The Authority strongly encourages its applicants, principals and manufacturers to take advantage of this additional time to submit **complete** re-registration applications to avoid disappointments.

With effect from 1st May 2024, the Authority will levy fees for new applications for re-registration and those **incomplete** re-registration applications already received as stipulated in item 7(a)(x) of the MCAZ Fees Schedule. Those applicants, principals and manufacturers who know that they have submitted incomplete applications are advised to take advantage of the extended waiver of fees and regularize before the 1st May 2024 deadline.

The following are the requirements for re-registrations:

1. The submission should be in CTD format
2. The re-registration should be in-line with the MCAZ Guidelines on products re-registrations, accessible from the MCAZ website, https://www.mcaz.co.zw/human-medicines-guidelines
3. Post approval variations to the product dossiers will not be accepted at the time of re-registration. Applications for post approval variations should be made separately.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R.T. Rukwata (Mr)
DIRECTOR-GENERAL