

CIRCULAR 19 of 2023

Date: 21/07/2023

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

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

This circular is a follow-up to circular 11 of 2023, dated 30th May 2023 and updated circular 14 of 2022 dated 16th September 2022 and serves to inform applicants, manufacturers and principals that MCAZ **may** charge fees for re-registrations (marketing authorisation renewals) of medicines with effect from 18th September 2023. The proposed re-registration fee is separate from registration fees and will be as follows:

Date of submission for Application for Renewal	Fee per Application
September 2023 – March 2024	USD 500
April 2024 – September 2024	USD 1000
September 2024 – March 2025	USD 1500
April 2025 – September 2025	USD 2000
September 2025 – December 2027	USD 2500

The proposed fees are meant to provide resources to deal with the anticipated influx of applications as we approach the end of the 5-year period specified in circular 11 of 2023.

The following are the requirements for re-registrations:

1. The submission should be in CTD format.
2. The re-registration application should be in-line with the MCAZ guideline on products re-registrations, accessible from the MCAZ website, www.mcaz.co.zw
3. Re-registration fees as stipulated in the schedule above.
4. Post approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post approval variations should be made separately.

The Authority has received **ONLY 13** applications for re-registrations since the call for voluntary submissions for re-registration was communicated in circular 3 of 2022, dated 14th September 2022. This waiver of fees expires on the 15th of September 2023 and applicants are strongly encouraged to take advantage of this period to submit re-registration applications.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE


R. T. Rukwata (Mr.)
DIRECTOR-GENERAL