



106 Baines Avenue  
Tel: +263 242 736 981-7  
708 255 / 792 165 / 0772 145 191/2/3  
Email: [mcaz@mcaz.co.zw](mailto:mcaz@mcaz.co.zw)  
Website: [www.mcaz.co.zw](http://www.mcaz.co.zw)

P.O. Box 10559  
Harare  
Zimbabwe

REF: B/279/35/21/2023

## CIRCULAR 21 of 2023

Date: 15/09/2023

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

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

This circular is a follow-up to circular 19 and 11 of 2023, dated 20<sup>th</sup> July and 30<sup>th</sup> May 2023 respectively, on implementation of re-registrations (marketing authorisation renewals). Taking into consideration the concerns from stakeholders, the Medicines Control Authority of Zimbabwe has extended the waiver to levy fees for applications of re-registration to the 31<sup>st</sup> December 2023.

To date, the Authority has received **over 150** applications for re-registrations since the call for voluntary submissions was communicated in circular 3 of 2022, dated 14<sup>th</sup> September 2022. The Authority strongly encourages its applicants, principals and manufacturers to take advantage of this additional time to submit re-registration applications.

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 guideline on products re-registrations, accessible from the MCAZ website, [mcaz.co.zw](http://mcaz.co.zw)
3. Post approval variations to the product dossiers will not be accepted at the time of re-registration. Applications for the post approval variations should be made separately

The Authority **may** levy fees communicated in circular 19 of 2023, dated 20<sup>th</sup> July 2023 with effect from 1<sup>st</sup> January 2024.

Yours faithfully,

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**

R. T. Rukwata (Mr.)

**DIRECTOR-GENERAL**