

CIRCULAR NO. 11 of 2023

Date: 30 May 2023

To: All applicants

RE: FOLLOW-UP PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES

This Circular is a follow up to Circular 14 of 22 published on the 16th of September 2022 which communicated the introduction of re-registration of products and the implementation plan for re-registration of products by the Medicines Control Authority of Zimbabwe (MCAZ).

1. Applicants should note the following:
 - i. For products which were registered prior to 2023 which had no re-registration period specified, the 5-year re-registration period indicated in the previous circulars remains valid.
 - ii. It is worth noting that MCAZ **may** consider levying an application fee on re-registrations from 16th September 2023 (Q4) of 2023, at the anniversary of circular 14 of 2022, and further that fee may be **SUBSTANTIALLY** reviewed upwards biannually to provide for more resources to deal with anticipated influx of applications as we get to the end of the 5-year period. Applicants who submit applications before the third quarter of 2023 will not have this fee levied on their re-registration applications.
 - iii. Re-registrations for products which have been re-registered or renewed in other countries in the Southern African Development Community (SADC) region within the last 24 months will be abridged based on acceptance in the respective SADC countries, however a fee may be applicable as indicated above. This fee may however be lower than for scenario 1(ii) above.
2. The following should be considered when making an application for re-registration:
 - i. The submission should be made in CTD format.
 - ii. The re-registration process should be in-line with the draft MCAZ guideline on re-registrations which can be found on the MCAZ website.
 - iii. 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.

Please note that the re-registration process does not replace the process of annual retentions. 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.

The Authority strongly encourages applicants to take advantage of the waiver of fees which expires on the 15th of September 2023. The Authority further encourages earlier submissions as this will allow us more time to deal with any requests for exemptions.

This will become progressively more difficult as we get to the deadline. The Authority will be sending out regular statistics on these issues. From September 2022 to date, the Authority has only processed one (1) application. This means that generally **ALL** applicants except for one have not headed to the Authority's call for voluntary submissions and all the concessions that they come with. **It is extremely important to reiterate that the closer we get to the deadline, the more expensive and difficult this process is going to become.**

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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R. T. RUKWATA (Mr)
DIRECTOR-GENERAL