MCAZ Medicines Control Authority of Zimbabwe

Renewal of Product Registration in Zimbabwe

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Date: 22/06/2023

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MCAZ Medicines Control Authority of Zimbabwe

Outline:

1. Introduction
2. Circular 14 of 2022 and Circular 11 of 2023
3. Product reregistration requirements
4. Fees?
5. Questions

Medicines Control Authority of Zimbabwe

Introduction:Pre WHO GBT and Post WHO GBT

Mar 2011	Nov 2012	Sep 2014	May 2019	Aug 2021	May 2023
WHO vaccine assessment of MCAZ	IDP follow up visit of MCAZ by WHO	WHO prequalification of MCAZ laboratory	Regional self-benchmarking workshop	WHO formal benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ	WHO formal [re-] benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ

- *The main objectives of the May 2023 formal benchmarking are to:*

1. Benchmark the status of the regulatory system in the areas of medicine regulation using the WHO Global Benchmarking Tool (GBT).
2. Review and document the progress with IDP implementation following the last benchmarking mission conducted in August 2021.
3. Update the IDP of MCAZ and other involved affiliated institutions, if applicable, to address existing as well as new and/or potential gaps with prioritization of recommendations for implementation of the same to continually improve the overall maturity level of the regulatory system.

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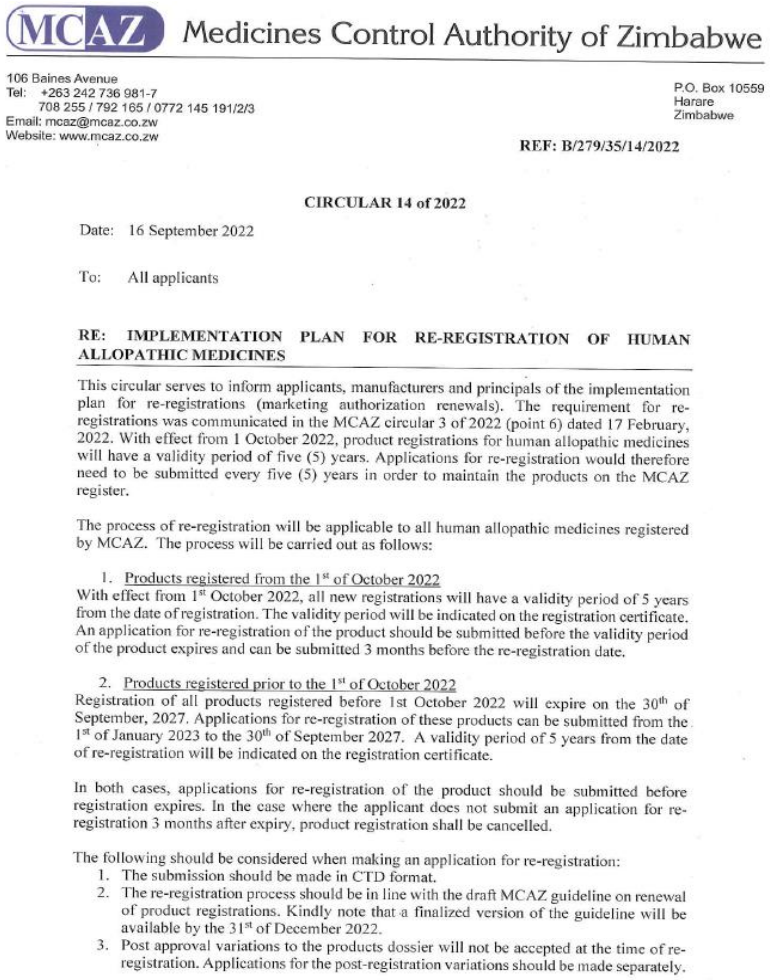
Circular 14 of 2022



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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 of 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 October 2022, 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 October 2022

With effect from 1st October 2022, 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 October 2022

Registration of all products registered before 1st October 2022 will expire on the 30th of September, 2027. Applications for re-registration of these products can be submitted from the 1st of January 2023 to the 30th 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 shall 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 draft MCAZ guideline on renewal of product registrations. Kindly note that a finalized version of the guideline will be available by the 31st of December 2022.
3. Post approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post-registration variations should be made separately.

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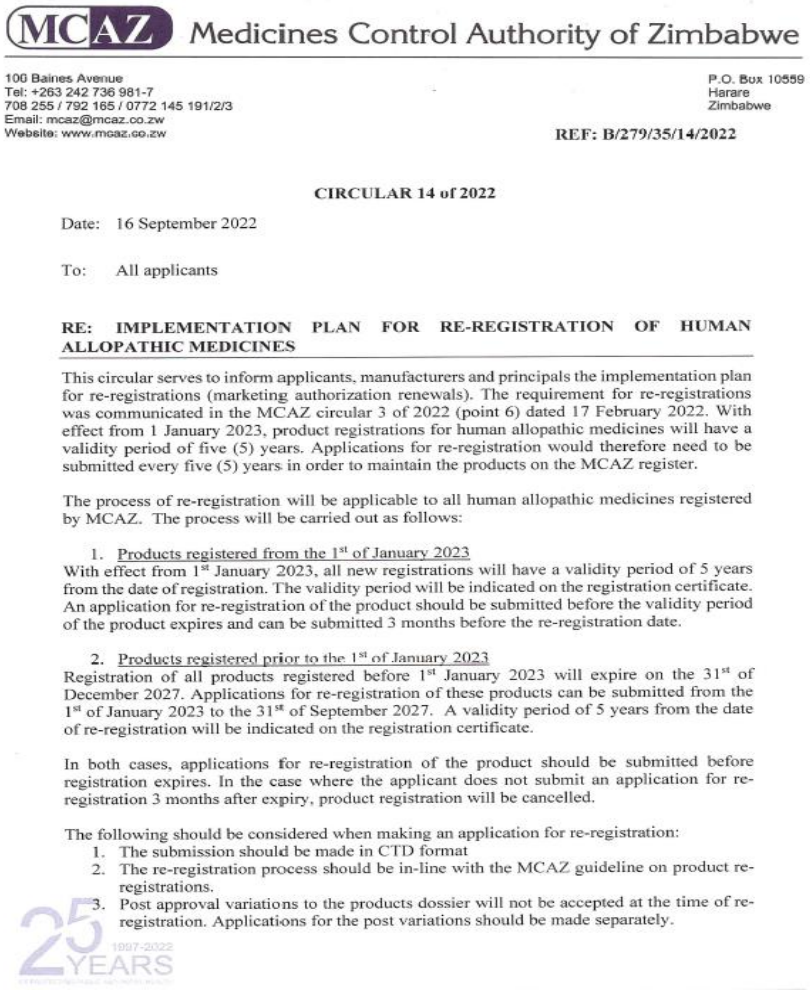
Circular 14 of 2022 – Updated



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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

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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.

25 YEARS 1997-2022

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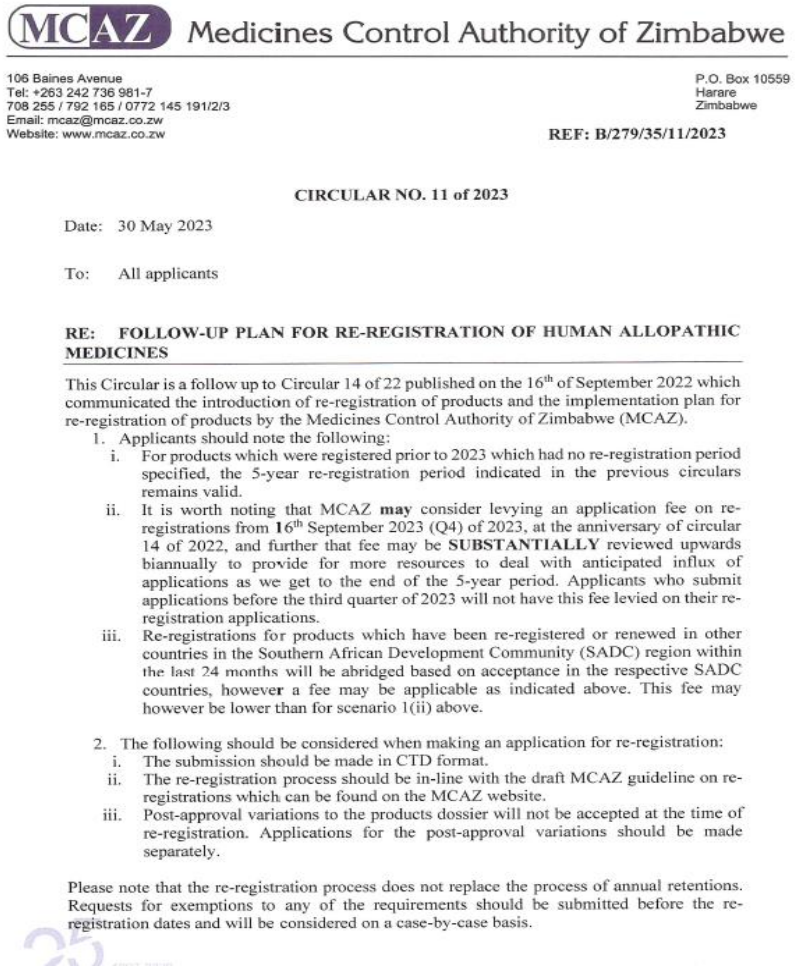
Circular 11 of 2023 – Updated



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REF: B/279/35/11/2023

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.

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Product reregistration requirements

- The Guideline on Renewal of Product Reregistrations
- Module 1 strictly hardy copy, with Module 1 – 5 as soft copy
- Application form and QIS on the MCAZ website

Product reregistration fees

- No fees charged at present
- MCAZ may levy application fees from 16/09/2023 (anniversary of circular 14 of 2022).
- Application fee may be substantially increased biannually: human resources and increase in applications

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