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REF: B/279/35/25/2022

## CIRCULAR 25 of 2022

Date: 3 March 2023

To: All applicants

### **RE: NOTIFICATION OF ISSUANCE OF REVISED REGISTRATION CERTIFICATES FOR VARIATIONS AT RE-REGISTRATION**

This circular serves to inform applicants, manufacturers and principals of the revised procedure for issuing revised registration certificates for variations at re-registration. The requirement for re-registrations was communicated in the MCAZ circular 3 of 2022 (point 6) dated 17 February 2022. As a result of this change, MCAZ will no longer issue a revised registration certificate every time an applicant submits a variation that affects the registration certificate. With effect from the 1st of January 2023, registration certificates will only be revised upon re-registration if there are variations to the product that affect the information on the registration certificate.

During the period between the approval of the variation and the re-registration date, the applicant shall attach the variation **approval** letter to the originally issued registration certificate as evidence that the changes have been approved, for example import/export permit applications.

As per the Guideline on Renewal of Product Registrations communicated in the MCAZ circular 14 of 2022 dated 16 September 2022, when applying for re-registration the applicant will be requested to submit a consolidated listing of all the amendments made to the product. This list of amendments along with the variation approval letter(s) and QIS will be used to update the information in the registration certificate.

Yours faithfully,

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**

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R. T. RUKWATA (Mr)  
**DIRECTOR-GENERAL**