MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/35/08/2025

CIRCULAR 8 OF 2025

Date: 7th March 2025

TO: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: CALL FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF HUMAN ALLOPATHIC MEDICINES THROUGH THE EXPEDITED REVIEW PATHWAY: PHASE I OF 2025

This circular is a follow-up to **Circular 17 of 2024** issued on the 31st of August 2024 and Circular **20 of 2024** issued on the 11th October 2024, on the implementation of the reliance framework through the recognition of human allopathic medicines registered by SAHPRA, as per the MCAZ-SAHPRA Memorandum of Understanding (MoU) signed on January 12, 2024 through two pilot phases. Following the successful implementation of the unilateral reliance framework for products registered by SAHPRA in pilot phases I and II in 2024 under expedited review pathway, the Authority has expanded the scope to include applications approved by countries that the Authority has signed MoU with i.e., Botswana, Belarus, Egypt, Ghana, Iran, Nigeria, Rwanda, Senegal, South Africa and Senegal in addition to those approved by Authorities that attained World Health Organisation (WHO) Maturity level three and four (**ML 3 & 4**) and those that have been **listed by WHO (WLA)** to submit applications under this pathway.

The Authority further invites interested applicants to submit applications for registration of human allopathic medicines through the expedited review pathway, effective **10th March to 11th April 2025.** During this phase the Authority will continue to **recognize medical products approved by National Regulatory Authorities (NRA) listed above** using the MCAZ Reliance Framework and the World Health Organization (WHO) guidelines on good reliance practices (GRelP). MCAZ invites the submission of fifty **(50)** applications that will be assessed through this pathway. The Authority will process these applications within 90 days of MCAZ time.

The following are the requirements for registration through the expedited pathway:

1. Expression of interest comprising a list of products intended for the expedited review registration pathway
2. Complete registration dossier in CTD format

3. Proof of registration in the form of a registration certificate issued by the NRA
4. Proof of compliance with current good manufacturing practices (cGMP) issued by NRA within the last 12 months including the website where cGMP is verifiable, if applicable
5. Prefilled MCAZ Registration certificate template
6. Two (2) samples for registration
7. Proof that the product is being marketed in the country it is registered by the NRA

The MCAZ will levy the following fees in line with the Authority fees schedule:

Ref. Fee Schedule	**Application for a registration of a medicine in case of expedited review of -**	**Fees (USD)**
7 (d) (i)	a new chemical entity	$4 500
7 (d) (ii)	a generic medicine	$4 000
7 (d) (iii)	a line extension of a medicine	$3 000

The Authority will use the above fees to provide for resources to deal with the anticipated influx of the applications for registration that will be submitted during the phase I stage of implementation of this framework.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. Rukwata (Mr.)
DIRECTOR GENERAL
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