MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 20 of 2025

Date: 1st July 2025

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: CALL FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION THROUGH THE EXPEDITED REVIEW PATHWAY FOR VETERINARY MEDICINAL PRODUCTS: PHASE II

The Medicines Control Authority of Zimbabwe (MCAZ) invites interested applicants to submit applications for registration of veterinary medicinal products through the expedited review pathway, effective **14th July to 15th August 2025**. The products must be registered in countries that have Authorities that have been **listed by WHO (WLA)** and those approved in **South Africa** by the South Africa Health Products Regulatory Authority (SAHPRA) through Medicines and Related Substances Act (Act No. 101 of 1965) and the Department of Agriculture, Land Reform, and Rural Development (DALRRD) through Fertilizers, Farm Feeds, Seeds and Remedies Act 36 of 1947 including those approved by NRAs with **ML3** and **ML4** status. This move aims to enhance efficiency and responsiveness to the growing demand for wider treatment options for veterinary medicinal products using the MCAZ Policy on Reliance: QPM-09-Rev2_April-2024-MCAZ-Reliance-Policy.pdf.

The Authority believes that increasing more treatment options for safe, efficacious and high-quality veterinary vaccines, pharmaceutical products and acaricides is essential in ensuring food safety, animal health and public health. MCAZ invites submission of **thirty (30)** applications which will be processed within 90 days MCAZ time through this pathway.

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

WLA, ML4, ML3 and SAHPRA approved products

1. Cover letter or Expression of Interest (EoI) clearly stating your intention to have the product(s) reviewed through the **expedited** registration pathway.
2. **Proof** of **marketing authorisation** issued by the competent authority in a WLA, ML4, ML3 country or SAHPRA.
3. Complete registration dossier in CTD format for WLA, ML4, ML3 and SAHPRA approved products
4. Proof of compliance with good manufacturing practices (cGMP) including website where cGMP status is verifiable, where applicable
5. Prefilled MCAZ registration certificate template
6. Two (2) samples of the veterinary medicine

Department of Agriculture, Land Reform, and Rural Development (DALRRD) approved products

1. Cover letter or Expression of Interest (EoI) clearly stating your intention to have the product(s) reviewed through the **expedited** registration pathway.
2. **Proof** of **marketing authorisation** issued by the competent authority in South Africa, DALRRD
3. Complete registration dossier submitted (scientific evidence demonstrating safety, quality, efficacy, and impact on food-producing animals (maximum residue limits) for Act 36 registered products) and accepted by DALRRD
4. Commitment that the applicant will submit an **updated dossier** in the **CTD** format at the anniversary of the registration or at the lapse of the renewal period or expiry of the 5 year registration period whichever comes first
5. Commitment that the applicant will agree to a **cGMP inspection** by MCAZ **before, during** or **post registration** of the veterinary medicinal product.
6. Proof of compliance with good manufacturing practices (cGMP) including website where cGMP status is verifiable, where applicable
7. Pre-filled MCAZ registration certificate template
8. Two (2) samples of the veterinary medicine

The Authority will levy the following fees for the expedited review pathway:

Application for registration of a veterinary medicine in case of expedited review of -	**Fees (USD)**
A new chemical entity	$3 000
A generic veterinary medicine	$2 500
A line extension of a veterinary medicine	$1 500

This regulatory reliance approach aims to streamline the registration process and increase access to quality, safe, and efficacious veterinary medicines.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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