

PUBLIC NOTICE

CALL FOR SUBMISSION OF DOSSIERS FOR EXPEDITED REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VMPS)

Date : 9th September 2026

The Botswana Medicines Regulatory Authority (BoMRA) invites interested principals, manufacturers and Marketing Authorisation Holders (MAHs) to submit dossiers for registration of veterinary medicinal products (VMPs) through the “reliance based” - expedited registration pathway. This initiative supports BoMRA's ongoing efforts to enhance access to quality-assured, safe and effective veterinary medicines on the Botswana market.

This pathway is guided by BoMRA's Reliance Policy, which recognises regulatory decisions of competent authorities with established regulatory systems. Applications submitted under this pathway will benefit from a streamlined evaluation process while maintaining full scientific and regulatory rigor.

Expedited Review Window's Key Information

Submission Period: 8 Sep – 7 Dec 2026

Target Registration Timeline: Compliant Applications will be concluded within four (4) calendar months from the date of submission.

Submission Method: Online via the BRIMS Self-Service Portal: <https://brims.bomra.co.bw/#/public/app-home>

Application Fees: As per the approved Fee Schedule (these are pre-configured on BRIMS)

Important Submission Requirements

Applicants are required to submit a complete Common Technical Document (CTD) dossier (Modules 1–5).

From the Pilot project and the recent submission window, BoMRA observed some inconsistencies in dossier structuring and wishes to emphasise the following:

- All information for each module must be compiled and submitted within a single, complete module.
- Applicants should desist from submitting multiple fragmented folders for the same module (e.g., submitting several separate “Module 1” folders instead of one complete Module 1).
- NB. Submissions that do not comply with the above requirements will not be accepted for scientific review.

Eligibility Criteria

A. Products with Full CTD Dossiers

- A cover letter clearly indicating the request for expedited review

- Proof of a valid Marketing Authorisation issued by an NRA recognised by BoMRA
- A complete CTD dossier (Modules 1–5)
- Completed BoMRA checklist. Applicant should indicate the section and pages of the dossier where each set of information is located.
- Evidence of cGMP compliance, including a verifiable source confirming GMP status

B. Older Products Listed in Botswana (BV-Listed) without CTD Dossier

- A cover letter clearly indicating the request for expedited review.
- Proof of a valid Marketing Authorisation from a recognised NRA.
- A complete registration dossier containing scientific data supporting quality, safety and efficacy, including information critical for registration of products intended for use in food-producing animals
- A completed BoMRA checklist. Applicant should indicate the section and pages of the dossier where each set of information is located.
- A written commitment to submit a full CTD-format dossier at the time of first renewal.
- Proof of cGMP compliance or a commitment to undergo GMP inspection by BoMRA which should be finalised at the time of the registration of the product.

Additional Information

All products that were submitted under the previous submission phases, where applicants are still addressing outstanding queries, will now be considered outside the project timelines. Applicants will still be allowed time to address the outstanding queries as is the case with the normal registration pathway.

BoMRA will continue to apply its usual scientific and regulatory standards to ensure that all registered products meet the required quality, safety and efficacy requirements. Interested applicants are encouraged to arrange for a pre-submission meeting with the VMU team to discuss their products' specific issues, to allow for submission of complete dossiers, and prevent unnecessary delays during scientific evaluation which affect overall project TAT

Contact Information

For any further enquiries or clarifications, please contact the Veterinary Medicines Registration Unit via registration.vetmeds@bomra.co.bw or call **+267 373 1760**.