PUBLIC NOTICE

Date: June 2026

STAKEHOLDER NOTICE: IMPLEMENTATION OF THE HUMAN MEDICINES ASSESSMENT BACKLOG CLEARANCE PLAN

The Botswana Medicines Regulatory Authority (BoMRA) wishes to inform all applicants and Marketing Authorisation Holders (MAHs) that it has commenced implementation of a comprehensive Human Medicines Assessment Backlog Clearance Plan aimed at restoring regulatory timelines and improving access to medicines.

Background

Over the past several years, BoMRA has experienced a significant increase in the number of applications received for registration and lifecycle management of human medicines. This increase, together with the transition from manual to electronic submissions and the expansion of regulatory functions, has resulted in an assessment backlog affecting:

- New Marketing Authorisation Applications;
- Variation Applications; and
- Renewal Applications.

BoMRA acknowledges the inconvenience these delays have caused and appreciates the patience and continued cooperation of stakeholders.

Backlog Clearance Programme

The Authority has developed a structured, risk-based backlog clearance programme that will be implemented over the next 12 months. Dedicated assessment teams have been established to accelerate review of pending applications while ensuring that scientific standards for quality, safety and efficacy are maintained.

The planned completion timelines are as follows:

Application Category	Target Completion
New Applications Backlog	January 2027
Variation Applications received in 2022	August 2026
Variation Applications received in 2023	October 2026
Variation Applications received in 2024–2025 (BRIMS submissions)	January 2027
Renewal Application backlog	January 2027

Plot 112, International Finance Park, Gaborone
Private Bag 2, Gaborone Station, Botswana
+267 373 1727/20 Toll Free : 0800 600 216
info@bomra.co.bw
Botswana Medicines Regulatory Authority
www.bomra.co.bw

BoMRA will continue processing priority public health applications alongside the backlog clearance programme where appropriate.

Requested from Applicants

- To facilitate timely completion of assessments, applicants are requested to:
- Respond promptly to requests for additional information within the stipulated timelines, including cGMP requirements.
- Ensure all future submissions are complete and compliant with BoMRA requirements.
- Ensure contact details remain current to facilitate communication.
- Utilise reliance and recognition pathways where applicable, applications to be accompanied by the necessary documents as evidence.
- Monitor application status through the Botswana Integrated Regulatory Information Management System (BRIMS), where applicable.

Other Considered Efficiencies

In parallel with the backlog clearance programme, BoMRA is implementing several process improvements to prevent future backlogs, including:

- Combined screening and scientific assessment;
- Greater utilisation of reliance and recognition pathways;
- Risk-based regulatory approaches;
- Enhanced electronic workflow management through BRIMS;
- Increased technical assessment capacity; and
- Continuous monitoring of regulatory performance.

Our Commitment

BoMRA remains committed to transparent engagement with stakeholders and will provide periodic updates on progress made against the backlog clearance plan.

We thank all applicants and Marketing Authorisation Holders for their continued cooperation as we work together to improve regulatory efficiency and facilitate timely access to safe, quality and efficacious medicines for the people of Botswana.

Correspondence

Stakeholders are encouraged to do the following:

- All Stakeholders should ensure continued compliance to GMP requirements as outlined
- Actively share existing approvals/registrations from other Authorities that BoMRA recognizes such as the WHO Listed Authorities (WLAs), Tanzania, Zambia, South Africa, Zimbabwe and Namibia. These may be emailed directly to **kmothabane@bomra.co.bw** and copied to **bkgosietsile@bomra.co.bw**