BOMRA ushers in new era of safer medical products with landmark regulatory reform

BOMRA
MEDICINES REGULATORY AUTHORITY
Promoting access to safe medicines

The Botswana Medicines Regulatory Authority (BOMRA) is taking decisive steps to modernize the nation's medical products landscape through the implementation of the Medicines and Related Substances Act, 2025. In a recent stakeholder engagement forum, BOMRA convened key industry players to introduce and discuss the new regulatory framework and draft regulations designed to enhance collaboration, regulatory clarity, and the safety, quality, and availability of medical products across Botswana.

This vital forum brought together a diverse cross-section of the healthcare ecosystem: market authorization holders, local technical representatives, health facilities, professional associations, retailers, importers, manufacturers, distributors, wholesalers, and others. The focus was on the draft General Regulations alongside Fees, Levies, and Penalties Regulations; both still in draft form and open for stakeholder input. BOMRA is committed to ensuring these regulations reflect practical realities and collective expertise.

In his opening remarks, BOMRA Chief Executive Officer Dr. Seima Dijeng underscored the Authority's core mission: to safeguard the safety, efficacy, and quality of all regulated medical products in Botswana. BOMRA oversees human and veterinary medicines, biologicals, vaccines, medical devices, in-vitro diagnostics, and cosmetics through robust product evaluation, registration, licensing, enforcement, pharmacovigilance, and clinical trials.

The impetus behind this legislative overhaul stems from a pressing need to modernize Botswana's regulatory system, strengthen enforcement, accommodate emerging medical products, and align national standards with regional and global best practices. The 2025 Act, passed by Parliament in December 2025, significantly broadens the regulatory framework - from 69 sections to 125, and from 13 parts to 23 - reflecting the complex demands of today's healthcare environment.

The updated framework now encompasses additional product categories, including medical devices, in-vitro diagnostics, blood products, traditional and complementary medicines, food and related substances, cosmetics, and cannabis products. It also introduces new regulatory mechanisms such as reliance on decisions by trusted authorities, mutual recognition agreements, mandatory lot release for high-risk products, haemovigilance, and a tailored authorization framework for online sales.

Acting Chief Regulatory Officer Dr. Partha Sarathi Gurumuthy emphasized that the Act establishes the foundation for regulation, but the real work lies in the subsidiary legislation that dictates the practicalities of product registration, premises licensing, importation, clinical research, and post-market responsibilities. He invited stakeholders to provide candid feedback, noting that early input is far easier to incorporate than issues discovered post-implementation.

Legal and Corporate Secretary Nonofo Thipe clarified the distinctions between the Act, regulations, and guidelines: the Act sets out the broad legal principles; regulations define operational requirements; and guidelines offer technical details that can be updated swiftly to keep pace with evolving needs.

BOMRA Legal Officer Ms. Tinky Peter, who introduced the draft General Regulations at the stakeholder forum, offered a clear and detailed explanation of how the proposed framework will work in practice.

Peter outlined that these regulations are designed to put the Medicines and Related Substances Act, 2025 into action. They set out specific requirements for medicines, medical devices, and related products—from the moment they're manufactured or imported, all the way through distribution and patient use.

One of the main rules is that all regulated products must be registered before they can be sold, imported, or dispensed in Botswana. This registration will ensure that products meet strict standards for quality, safety, and effectiveness, tightening control over what enters the local market.

The regulations also clamp down on the people and businesses handling these products. Manufacturers, wholesalers, pharmacies, and importers will need to secure the right licenses and meet set standards. BOMRA will keep its inspection powers to check that these operators are following the rules.

Peter emphasized that regulation doesn't stop once a medicine or device is approved. The framework includes post-market surveillance, giving BOMRA the ability to monitor products after they hit the market and to act swiftly if any safety or quality issues arise.

If a product is found to be harmful, defective, or unsafe, BOMRA can initiate actions such as recalls. The regulations also set rules for advertising, ensuring companies provide accurate, honest information to the public.

A big focus is also on cracking down against falsified, expired, and unregistered products. The framework lays out penalties for breaking the rules, while also offering a fair appeal process for those affected by regulatory decisions.

Beyond enforcement, the proposed regulations aim to support local manufacturing and boost Botswana's standing within regional and international medicines regulatory systems. By aligning the country's standards with recognized global benchmarks, BOMRA hopes to build trust in the local market and offer clearer guidance for the industry.

Importantly, the shift to this new system won't disrupt current operations. Peter assured that existing registrations and licenses will remain valid, ensuring smooth continuity for businesses and uninterrupted access to medicines and regulated products.

A hallmark of the new law is the expansion of enforcement powers. Inspectors will gain wider authority to inspect premises, collect samples, seize non-compliant products, and, in urgent cases, close facilities posing immediate health risks. At the same time, the law safeguards due process by requiring inspector identification, limiting powers, mandating warrants for forced entry, and providing clear avenues for appeal.

The introduction of a statutory Appeals Committee further strengthens the system by offering regulated parties a formal channel to contest regulatory decisions. Ultimately, BOMRA's reforms aim to protect consumers, improve access to quality-assured medical products, and foster a business environment that supports growth and innovation.

BOMRA is also working toward enhancing its regulatory maturity, with the World Health Organization's Global Benchmarking Tool Level 3 set as a strategic milestone. This consultation marks a crucial step to ensure Botswana's regulatory framework is not only robust on paper but practical, transparent, and responsive to the real-world dynamics of the medical products industry.

Through these reforms, BOMRA reaffirms its commitment to a safer, healthier Botswana; one where innovation and regulation go hand in hand to serve the public good.

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PRESENTATION ABOUT MRSA 2025 NEW ACT- MR NONOFO THIPE
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ANSWERING SOME QUESTIONS FROM STAKEHOLDERS

BOMRA CEO DR SEIMA DIJENG AND
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STAKEHOLDERS