

PUBLIC NOTICE



INVITATION TO STAKEHOLDERS TO MAKE INPUT TO THE DRAFT MEDICINES AND RELATED SUBSTANCES BILL OF 2023

The Botswana Medicines Regulatory Authority (“BoMRA”) is a statutory body established under the Medicines and Related Substances Act No. 8 of 2013 (“MRSA”) with the mandate to regulate the supply chain of medicines, medical devices, and cosmetics in Botswana to ensure their quality, safety, and efficacy.

In 2018, the Authority commenced a process of amending the MRSA. The goal is to align the MRSA with international standards, being the World Health Organisation (WHO) Global Benchmarking Tool (GBT) for medicines regulators and the African Union Model Law, and to reflect the current conditions within the local market, with the aim of enhancing the quality, efficacy, and safety of medicines and related substances.

As part of this amendment process, a preliminary draft of the Medicines and Related Substances Bill of 2021 was created, which sought to repeal and re-enact, with necessary amendments, the MRSA.

To ensure that all relevant perspectives were considered, the public was invited, through a public notice, to comment on the Draft MRS Bill and stakeholder engagement sessions were conducted concurrently during which comments, concerns, and suggestions from various stakeholders were gathered. Subsequently, the Authority carefully reviewed and incorporated these valuable inputs, engaging consultants to refine the Bill resulting in the development of the Draft MRS Bill of 2023.

The Authority is now at the final stage of this process and is desirous of ensuring that comments, concerns and suggestions of all stakeholders are considered and incorporated into the MRSA.

As a stakeholder, you are invited to submit written input or comments on the Draft MRS Bill of 2023. A copy of the Draft Medicines and Related Substance Bill of 2023, a reconciliation of the changes between the Draft MRS Bill of 2021 and the Draft MRS Bill of 2023 is available on the BoMRA website (www.bomra.co.bw) together with the stakeholder comment forms for completion.

Please note that the deadline for submission of written input is **17th September 2023 at 17:00hrs.**

Once submissions are received, the Authority will carefully consider and consolidate them. Subsequently, stakeholders will be engaged in physical sessions from **18th – 22nd September 2023** according to a schedule, with details to be communicated.

Comments and requests for clarity may be sent by email to legal@bomra.co.bw or by mail or hand delivery addressed to:

**The Chief Executive Officer
Botswana Medicines Regulatory Authority
Plot 112, International Finance Park, Gaborone
Private Bag 2, Gaborone Station
Gaborone**

**Attention
Legal and Corporate Secretary
Tel No: 3731737**