



 Plot 112 International Finance Park, Gaborone
 Private Bag 2 Gaborone Station, Botswana
 info@bomra.co.bw

 (+267) 373 1720
 (+267) 373 1727
 (+267) 318 6254

Ref: MRA 1/8/5 VOL II (158)

11th May 2021

ATT: All Stakeholders

**RE: INVITATION TO STAKEHOLDERS TO MAKE INPUT TO THE DRAFT
MEDICINES AND RELATED SUBSTANCE BILL OF 2021**

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 the process of amending the MRSA with the aim of ensuring alignment to the World Health Organisation Global Benchmarking Tool for medicines regulators, the African Union Model Law and to align the Act to the current conditions prevailing in the local market.

The Authority has received a Draft of the Medicines and Related Substances Bill of 2021 which seeks to repeal and re-enact, with amendments, the MRSA to adequately address the issues identified. Whilst at a preliminary stage, the Authority is desirous of ensuring that comments, concerns and suggestions of all stakeholders are considered and incorporated into the MRSA.

The Authority hereby invites you, as a stakeholder, to make written submissions on the Draft Bill, in accordance with the attached guidance note. A copy of the Draft Medicines and Related Substance Bill of 2021 is available on the BoMRA website (www.bomra.co.bw) together with the stakeholder comment forms for completion.

The deadline for submission of written input is **31st May 2021 at 17:00hrs**. Upon receipt, BoMRA will consider and consolidate all written submissions to finalise the Bill. You are further advised that the Bill is in the early stages of development and the Authority will accordingly continue to engage all stakeholders until its completion and enactment.

Board Of Directors

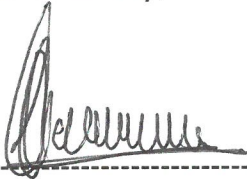
Mr Duncan Thela (Chairperson) / Dr Mbatshi Mazwiduma / Dr Tirayaone Mampane / Dr Gasetsewe Sento / Dr Gontle Moleele / Mr Kagiso Balopi
Ms. Boltho Kebabonye Bayendi / Dr Joyce Kgatlwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Letlhogile Modisa / Dr Stephen Ghanie

Comments and requests for clarity may be sent by email to nthipe@bomra.co.bw and lletshola@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

Yours faithfully,



Dr. Stephen Ghanie
Chief Executive Officer

Board Of Directors

Mr Duncan Thela (**Chairperson**) / Dr Mbatshi Mazwiduma / Dr Tiroyaone Mampane / Dr Gaseitsewe Sento / Dr Gontle Moleele / Mr Kagiso Balopi
Ms. Botho Kebabonye Bayendi / Dr Joyce Kgatlwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Letlhogile Modisa / Dr Stephen Ghanie
