



MEDIA RELEASE

SAHPRA and Botswana Medicines Authority partner to enhance medicines regulation in the region

Embargo: Immediate release

Pretoria, South Africa, 28 April 2024 – The South African Health Products Regulatory Authority (SAHPRA) and the Botswana Medicines Regulatory Authority (BoMRA) have signed a memorandum of understanding (MoU) that will see the two regulators partner on various areas to improve access to new medicines and therapies, the control of falsified and substandard medicines, and the sharing of best practice and regulatory information, amongst others.

The MoU between SAHPRA and BoMRA will allow the regulators to develop a cooperative partnership towards ensuring access to safe, quality, and effective health products in the respective countries.

Areas of cooperation

The partnership paves the way for the two regulators to collaborate and share information on the assessment of medicines and health products, which will result in efficiencies in the medicine approval processes in both South Africa and Botswana. This agreement also enables information sharing on the post-marketing monitoring of medicines for adverse drug reactions, resulting in more robust safety and efficacy monitoring in the interest of the health of the citizens of both countries.

The MoU also formalises joint port of entry operations between SAHPRA and BoMRA aimed at protecting the citizens of both countries from the illegal importation of unregistered, falsified and substandard medicines and health products.

SAHPRA's Chief Executive Officer, Dr Boitumelo Semete-Makokotlela, indicates that the partnership is an important milestone in building capacity within the regulators in both countries and ensuring world-class medicines and health products regulation for the benefit of citizens. "This partnership not only ensures robust intra-country post-marketing safety monitoring for health products and the sharing of data that fosters more vigorous assessments of health products; it also ensures that there is best practice sharing and capacity building that ensures that both regulators provide world-class services in their respective countries," says Dr Semete-Makokotlela.

BoMRA Acting CEO, Dr Seima Dijeng, alluded that the MoU paves the way for a concerted effort towards a shared vision between SAHPRA and BoMRA. According to Dr Dijeng, the MoU signifies not just a partnership but a demonstration of a shared vision for two National Regulatory Authorities. It is a testament to the enduring ties between our two nations, Botswana and South Africa of shared values, mutual respect and economic partnership.

Issued by:

Dr Boitumelo Semete
**CEO: South African Health Products
Regulatory Authority**
boitumelo.semete@sahpra.org.za

AND Dr Seima Dijeng
**Acting CEO: Botswana Medicines
Regulatory Authority**

For further enquiries/information contact:

SAHPRA media contact:

Madimetja Mashishi
Cell: 073 821 5994

E-mail: Madimetja.Mashishi@sahpra.org.za

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BoMRA media contact:

Israel Kgosidiile
Tel: +267 373 1720

E-mail: ikgosidiile@bomra.co.bw

About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act, 101 of 1965 (as amended), as well as the Hazardous Substances Act, 15 of 1973.

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

About BoMRA:

BoMRA derives its mandate from the Medicines and Related Substances Act (MRSA of 2013), to regulate human and veterinary medicines, medical devices, cosmetics and complementary medicines in Botswana, to ensure that they conform to the set standards of safety, quality and efficacy.

Notes to Editors:

SAHPRA will post this media release on its website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll down the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you wish to request an interview, please send your request to media@sahpra.org.za and Madimetja.Mashishi@sahpra.org.za

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - <https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/>