MEDIA RELEASE

SAHPRA attains ISO 9001 Certification as confirmation of its robust quality management processes

Embargo: Immediate Release

Pretoria, 29 May 2024 – The South African Health Products Regulatory Authority (SAHPRA) has attained its ISO 9001:2015 certification following a rigorous audit by the South African Bureau of Standards (SABS), a milestone that serves as a testament to the implementation of an effective and robust organisation-wide Quality Management System (QMS). A fully functioning QMS is core to achieving quality objectives that ensure that health products in South Africa meet statutory and regulatory standards of quality, safety, and efficacy.

Earlier this year, SAHPRA underwent a voluntary independent certification audit conducted by the SABS to test the implementation of SAHPRA's Quality Management System against the ISO 9001 standard, a globally recognised standard for quality management systems developed by the International Organisation for Standardisation (ISO). SAHPRA is now aligned with the Regional Strategy for the Regulation of Medicinal Products which provides that all member states must have national regulatory authorities for medicines that are functional and with systems of quality management by year 2025.

This international certification confirms SAHPRA's position among global peers as a provider of globally acceptable regulatory services that are in compliance with or exceed the ISO 9001 international standard on quality management.

"Reaching this ISO 9001 is an important achievement and is indeed a source of pride for SAHPRA, but it also inspires us to sustain our position as a world-class African health products regulator and to ensure continuous improvement in the interest of public health," says SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

"The South African Bureau of Standards (SABS) is proud to hand over certification to SAHPRA for meeting the requirements of quality management, as stipulated in ISO 9001. In terms of its management systems and processes for quality management, the company is 'SABS Approved'. We encourage all state owned institutions to emulate this achievement and we wish SAHPRA all the best as it continues on its quality journey," says Lungelo Ntobongwana, Acting CEO of the SABS.

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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.

Notes to Editors:

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

SAHPRA will post this media release via its our 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. 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/