MEDIA RELEASE

SAHPRA joins the Medical Device Single Audit Programme

Embargo: Immediate release

Pretoria, 04 April 2025 – The South African Health Products Regulatory Authority (SAHPRA) has joined the Medical Device Single Audit Programme (MDSAP), an international audit programme of medicines and medical device regulators aimed at improving efficiencies in the regulation of medical device manufacturers by engaging in work sharing and collaboration. SAHPRA joins MDSAP as an affiliate member, which expands its ability to monitor the manufacturing of medical devices beyond South Africa's borders.

The MDSAP membership will result in the improved regulation of medical devices and in-vitro diagnostics (IVDs) as it increases SAHPRA regulatory reach and ensures that SAHPRA can leverage the resources of other regulators that participate in the MDSAP to both audit and monitor adherence to quality standards by medical device manufacturers in several countries globally.

"SAHPRA's admission into MDSAP signals progress in our strategy to ensure the efficient application of our own resources and those of our peers globally in safeguarding the quality, efficacy and safety of medical devices and in-vitro diagnostics (IVDs) used by the South African public," says Dr Boitumelo Semete-Makokotlela, SAHPRA Chief Executive Officer.

Dr Semete-Makokotlela says that the admission to MDSAP adds to individual agreements for both monitoring and regulatory reliance that SAHPRA already has in place with several

regulators the world over, and would thus improve SAHPRA's quality assurance abilities and has the potential to increase turnaround times in reviewing and approving key medical devices manufactured elsewhere in the world.

ENDS

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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, please send your request to media@sahpra.org.za and copy Madimetja.Mashishi@sahpra.org.za.

SAHPRA will publish 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. 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/