JOINT MEDIA RELEASE

SAHPRA and USP Announce MOU to Advance Regulatory Oversight for Medical Products in South Africa

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SAHPRA Media Contact:
Yuveng Gounden
E-mail: yuveng@sahpra.org.za
Cell: +27 66 1202 669

USP Media Contact:
Anne Bell (she/her)
Email: adb@usp.org
Office: +1-301-998-6785
Mobile: +1-240-701-3242

Pretoria, 14 January 2022- The South African Health Products Regulatory Authority (SAHPRA) has signed a Memorandum of Understanding (MOU) with the U.S. Pharmacopeia (USP) to help expand the availability of health products, including medical devices, that are safe, efficacious, and of assured quality.

SAHPRA, the health products regulator in South Africa, is collaborating with USP, an independent, scientific non-profit organisation, to support SAHPRA's three pillars of safety, quality, and efficacy and its overall aim to achieve the World Health Organisation Maturity Level 4, designated for regulatory systems that operate at the most advanced levels of performance. These advances will help accelerate and expand access to essential health products and improve oversight of the growing local pharmaceutical and health products manufacturing industry in South Africa. To this end, SAHPRA and USP will collaborate to:

- Strengthen capacity for the adoption of risk-based approaches for regulatory inspections and post-marketing surveillance
- Strengthen quality control laboratories for medicines, biologicals, and vaccines as well as medical devices
- Collaborate on advancing regional regulatory harmonisation initiatives of strategic importance for SAHPRA and USP
- Contribute to improving public health in Africa by promoting timely access to quality-assured health products and advancing innovation.

"This MOU will ensure that SAHPRA achieves world-class standards through a firm partnership agreement with USP. In an era where COVID-19 has wreaked havoc with lives and economies, it is virtually obligatory that partnerships of this nature will strengthen our initiatives and assist us in achieving our goals and long-term vision," indicates SAHPRA Chief Executive Officer (CEO), Dr Boitumelo Semete-Makokotlela.

"SAHPRA has been a mainstay of regulatory leadership on the African continent," says Ronald T. Piervincenzi, Ph.D., USP CEO. "USP is proud to build on our longstanding programs that support quality medicines in the region. Our partnership with SAHPRA will advance regulatory leadership, particularly as South Africa emerges as a regional manufacturing hub and takes important steps toward health security and supply chain resiliency."

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 (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 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 USP

USP is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines. We are working to strengthen the global supply chain so that the medicines people rely on for health are available when needed and work as expected. USP has 16 offices across 13 countries and implements global health programs in 40+ countries worldwide.