USP Welcomes Executive Delegation from the South African Health Products Regulatory Authority

August 30, 2023, Rockville, MD – USP welcomed an executive delegation of senior leadership from the South African Health Products Regulatory Authority (SAHPRA) to its Rockville headquarters, capping off a two-part visit from the regulator. During the visits, USP and SAHPRA exchanged ideas and shared perspectives, and explored areas of expanded technical collaboration.

USP and SAHPRA signed a Memorandum of Understanding in 2022 to help expand the availability of health products that are safe, efficacious, and of assured quality and support SAHPRA in its overall aim to achieve the World Health Organization Maturity Level 4, a designation reserved for regulatory systems that operate at the most advanced levels of performance. USP also supports SAHPRA in its efforts to serve as a center of regulatory excellence and expand its capacity in the areas of medical devices and biologics.

"Our partnership with USP helps leverage state-of-the-art science in quality assurance and regulatory practice and helps strengthen our ability to be responsive to today's regulatory challenges," indicates SAHPRA Chief Executive Officer (CEO), Dr Boitumelo Semete-Makokotlela. "We look forward to where this partnership will take us in the years to come."

In December 2022, the Promoting the Quality of Medicines Plus (PQM+) program, funded by the U.S. Agency for International Development and implemented by USP, held a joint workshop in partnership with SAHPRA to strengthen regulatory oversight of vaccines in the region as part of the U.S. Government's Global VAX initiative, which mobilized U.S. resources and expertise toward the global goal of vaccinating 70 percent of the population of every country against COVID-19. The workshop is one of several areas of technical assistance being provided to SAHPRA through the PQM+ program.

"We are proud of our enduring collaboration with SAHPRA," Ronald T. Piervincenzi, Ph.D., USP CEO. "Both through our MOU as well as continued partnership, we know that SAHPRA will be well positioned to continue to advance regulatory excellence not only in South Africa, but also in the region and throughout the continent."

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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 (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 18 offices across 15 countries and implements global health programs in 50+ countries worldwide.

About PQM+:
The Promoting the Quality of Medicines Plus (PQM+) Program is a five-year cooperative agreement (No. AID-7200AA19CA00025) between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs).