MEDIA RELEASE

SAHPRA signs MOU with Egyptian Drug Authority

Embargo: Immediate release

Pretoria, 11 July 2023 - The South Africa Health Products Regulatory Authority (SAHPRA) has signed a Memorandum of Understanding (MOU) with the Egyptian Drug Authority (EDA) on 09 July at the Egyptian Embassy in Pretoria.

This MOU between SAHPRA and EDA will allow for crucial collaboration and engagement on mutual reliance for pharmaceuticals, biological products, and medical devices.

The delegations of both authorities headed by EDA Chairman, Prof. Dr Tamer Essam and SAHPRA CEO, Dr Boitumelo Semete-Makokotlela launched a comprehensive dialogue to exchange visions on a wide range of topics of mutual concern. They also discussed practical approaches to deepen bilateral relations between both countries in the field of pharmaceutical industries.

Dr Semete-Makokotlela explained that “this is the first MOU that we have signed with a national regulatory authority in Africa which shows our commitment and drive to seek collaboration and knowledge sharing with our African counterparts. Capacity-building on the continent is critical because it will ensure that we remain firmly rooted in regulatory processes”.

Prof. Dr. Essam stressed that this MoU will pave the way for setting a unified vision and coordinating effective dialogue between African countries for experience exchanging in the field of pharmaceutical industries, and this comes in accordance with the directives of the Egyptian political leadership in support of African work.

Ambassador of Egypt, H.E. Mr. Ahmed El Fadly, expressed his satisfaction with the signature of the MOU, indicating that it helps remove one main non-tariff barrier to facilitating trade between both countries in the pharmaceutical sector, consequently enhancing people to peoples’ relations. “The

onus is now on relevant business communities in both countries to make the best out of this important development," he added.

This MOU intends to a synergistic relationship where both regulators share knowledge and engage on areas of market authorisation, pharmacovigilance, Good Manufacturing Practices (GMP) and clinical trials.

Issued by:
Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Cell: 066 1202 669

E-mail: yuveng@sahpra.org.za

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 EDA:

EDA, established in 2019, is an independent public service authority that is directly affiliated with the Prime Minister, it is responsible for all the regulatory activities related to pharmaceutical, biological, veterinary, herbal, cosmetic, and pesticide products, as well as clinical trials oversight.

EDA vision states to be one of the leading drug authorities worldwide ***while EDA mission*** ensures the efficacy, quality & safety of medical products, devices & related materials through legislation and policies based on international standards in addition to increasing public awareness and accessibility of innovations.

EDA is currently a World Health Organization (WHO) Maturity Level 3 authority (vaccine producing), a member of The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), an associate member of International Coalition of Medicines Regulatory Authorities (ICMRA), a member of the International Pharmaceutical Regulators Programme (IPRP). EDA is also engaged in several collaborative activities with other National Regulatory Authorities (NRAs) in Africa and worldwide.