News Item

SAHPRA hosts 3rd AU-3S Steering Group Meeting, new member countries welcomed

Pretoria, 14 September 2023 – The South African Health Products Regulatory Authority (SAHPRA) was the host country for a robust and engaging African Union Smart Safety Surveillance (AU3S) in-person Steering Group Meeting held on 11 – 12 September 2023 in Cape Town. AU-3S is a flagship programme of the African Union Development Agency (AUDA-NEPAD).

The meeting welcomed four new countries as members of the Steering Group, namely, the Egyptian Drug Authority, the Congolese Pharmaceutical Regulatory Authority (ACOREP), Senegal's Pharmaceutical Regulatory Agency (ARP), and the Rwanda Food and Drug Authority. The current Steering Group of national regulators authorities (NRAs) are SAHPRA, Ghana Food and Drug Authority (Ghana FDA), Ethiopian Food and Drug Authority (EFDA), Kenya's Pharmacy and Poisons Board, and Nigeria's National Agency for Food and Drug Administration (NAFDAC).

Key deliberations

There were key deliberations on the draft roadmap and recommendations from the AU-3S ad hoc Continental Safety Monitoring Platform Working Group (CWG) on seven focus areas for the ongoing programme expansion – continental (geographical and language) coverage, product scope, signal management, technology optimisation and AfriVigilance, pre-licensure safety data, stakeholder engagement and sustainability and finance. Revision of the terms of reference regarding the expansion of the steering group, and implementation of the programme since the last SG meeting were also discussed.

"This in-person engagement has allowed us, as member countries of NRAs, to make key decisions to expedite the AU-3S initiatives regarding pharmacovigilance and related systems to continue on the

path to protect patients across the continent through our safety surveillance programmes," explains Dr Boitumelo Semete-Makokotlela, SAHPRA CEO.

"This third meeting of the Steering Group has provided clear directions as to how the AU-3S programme should be scaled up so that it continues to serve the continent in ensuring the safety of patients in Africa. It is a great opportunity that African countries are now able to make decisions on safety of vaccines and other therapies based on African data", recounts Aggrey Ambali, Senior Advisor, AUDA-NEPAD.

"This meeting has set a clear direction on the further expansion of the AU-3S programme", says Mick Foy, Director of Delivery, Medicines and Healthcare Products Regulatory Agency (MHRA) UK, adding that the "MHRA have facilitated capacity strengthening and the collection and safety analysis of safety data and are committed to continuing supporting the AU-3S programme for the benefit of patient safety".

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 AU3S

The long-term goal of the African Union's Smart Safety Surveillance (AU-3S) programme is to strengthen the safety surveillance of priority medical products across the African continent. Launched in 2020 with a ~10 year time horizon, the programme is being funded by The Bill and Melinda Gates Foundation (BMGF) with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and US Food and Drug Administration (FDA) as key technical partners.

The programme aims to address limited health system and safety surveillance capacity across Africa – through efficiencies like technological innovation, pooling of resources, and work sharing. With

COVID-19 further reinforcing the need for strong African PV systems, AU-3S piloted its approach on the safety surveillance of COVID-19 vaccines in five countries. These pilot countries are Ethiopia, Ghana, Kenya, Nigeria and South Africa – altogether comprising ~35% of Africa's population. The AU-3S team works closely with the medical products National Regulatory Authorities (NRAs) and Expanded Programmes on Immunisation (EPIs) from countries involved. Currently, AU-3S is pivoting from pilot phase toward a continental safety monitoring platform with addition of more countries and product scope expansion.

About MHRA

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.

We are the regulator of medicines, medical devices and blood components for transfusion in the UK.

We put patients first in everything we do, right across the lifecycle of the products we regulate. We rigorously use science and data to inform our decisions, enable medical innovation and to make sure that medicines and healthcare products available in the UK are safe and effective.

Our responsibilities are to:

- ensure medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy (effectiveness)
- secure safe supply chain for medicines, medical devices and blood components
- promote international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- enable innovation and research and development that is beneficial to public health
- collaborate with partners in the UK and internationally to support our mission to enable the earliest access to safe medicines and medical devices and to protect public health