



SAHPRA Accepted as a Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Embargo: Immediate release

Pretoria, 1 December 2025 – The South African Health Products Regulatory Authority (SAHPRA) has officially been accepted as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), following an ICH assessment of compliance with requirements for membership, including a formal presentation outlining SAHPRA’s interest, progress, and milestones in implementing ICH principles.

The ICH is a unique global body that brings together regulatory authorities and the pharmaceutical industry to align scientific and technical standards for the registration of medicines. Since its establishment in 1990, it has evolved to support an increasingly globalised pharmaceutical environment. Its mission is to promote

worldwide harmonisation to ensure that safe, effective, and high-quality medicines are developed and registered efficiently. This harmonisation is achieved through the development of ICH Guidelines, which are formulated through scientific consensus between regulators and industry experts. Successful adoption relies heavily on regulators' commitment to implement these final Guidelines within their national systems.

The ICH Assembly met in person on 18-19 November 2025 in Singapore, in parallel with meetings of 12 Working Groups and preceded by meetings of the ICH Management Committee (MC) and the MedDRA Steering Committee (SC).

“ICH is delighted to welcome NAFDAC, Nigeria, and SAHPRA, South Africa, as new ICH Members, in addition to two new Observers: DIGEMAPS, Dominican Republic, and Philippine FDA, Philippines, bringing ICH to a total of 25 Members and 41 Observers.”

Welcoming SAHPRA's membership, CEO Dr Boitumelo Semete-Makokotlela said:

“This is a significant milestone for the South African Health Products Regulatory Authority. Membership of the ICH strengthens our commitment to the three pillars of safety, quality, and efficacy, while ensuring that our processes remain resource-efficient. This

development allows SAHPRA to benchmark its regulatory practices against global best practice for the benefit of all people living in South Africa.”



Ms Silverani Padayachee, Senior Manager, Pharmaceutical Evaluation Management (SAHPRA) flanked by Chair of ICH Assembly Ms. Lenita Lindström (left) and Vice Chair Dr. Gabriela Zenhäusern (right).

ENDS

Issued by:

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Notes to Editors:

SAHPRA will post this media release on its website. Navigate to the News section on the website.

Should you wish to request an interview, please send your request to media@sahpra.org.za and yuveng@sahpra.org.za

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/>

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.