



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

MEDIA RELEASE

South African and Australian health product regulators to share regulatory information and expertise

Embargo: Immediate release

Pretoria, South Africa and Canberra, Australia, 7 October 2024 – The South African Health Products Regulatory Authority (SAHPRA) and the Australian Therapeutic Goods Administration (TGA) have signed a Memorandum of Understanding (MoU), which will strengthen collaboration between the two health product regulators.

The MoU builds on the existing relationship between the health products regulators to improve capabilities in the assessment of medical products and therapeutic goods and their monitoring for continued efficacy, safety and quality once they are registered.

Areas of cooperation

SAHPRA and TGA will engage in data sharing aimed at improving the regulatory functions executed by both regulators. This will particularly focus on the assessment and approval of medical products and therapeutic goods, their monitoring for continued efficacy, and the surveillance for safety and adverse reaction (event) concerns.

According to SAHPRA's Chief Executive Officer, Dr Boitumelo Semete-Makokotlela, the agreement with the TGA expands the geographical reach for both regulators' pharmacovigilance programmes and augments their internal expertise.

"This partnership enables us to rely on each other's strengths and regulatory outputs in the evaluation of health products both before they are registered and once they are approved for public use. This would improve therapeutic outcomes for the populations we exist for

and increase the robustness of our post-registration surveillance for efficacy, safety and quality,” says Dr Semete-Makokotlela.

Deputy Secretary at the Australian Government Department of Health and Aged Care and head of the TGA, Professor Anthony Lawler, said: “TGA is very pleased to have strengthened our collaborative relationship with SAHPRA with the signing of this international agreement. We look forward to working alongside our regulatory counterparts in South Africa to share important regulatory information to ensure the continued safety, quality and efficacy of therapeutic products approved for market.”

Issued by:

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products in South Africa. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control. 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 and quality. It is these three pillars that define the ethos of SAHPRA.

About TGA:

The TGA is the Australian Government's therapeutic goods regulatory agency. As part of the Department of Health and Aged Care, TGA regulates the quality, safety, efficacy, supply and advertising of medicines, medical devices, biologics, blood products and most other therapeutics. Any items that claim to have a therapeutic effect, are involved in the administration of medication, or are otherwise covered by the *Therapeutic Goods Act 1989*, the Therapeutic Goods Regulations 1990, or a ministerial order, must be approved by TGA and registered in the Australian Register of Therapeutic Goods (ARTG).

Notes to Editors:

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

A podcast will be recorded and posted on the home page. Scroll down the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you wish to request an interview, please send your request to media@sahpra.org.za and Madimetja.Mashishi@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/>