



## **SAHPRA APPROVES MPOX TEST USING AFRICAN MEDICINES REGULATORY HARMONISATION (AMRH) CONTINENTAL EUL PROCEDURE**

**Embargo: Immediate release**

**Pretoria, 27 August 2025** – The South African Health Products Regulatory Authority (SAHPRA) has approved a molecular test kit for Mpxv , Cobas MPXV, for use on the Cobas 6800/8800 Systems, within nine working days through a collaborative and harmonised review process under the African Medicines Regulatory Harmonisation (AMRH). Rapid and accurate testing is essential for early detection and to enable timely treatment, and effective containment of the virus.

SAHPRA’s Medical Device Unit, utilising both the World Health Organization (WHO) Emergency Use Listing (EUL) report and the African Medicines Regulatory Harmonisation (AMRH) Continental EUL Procedure, has successfully leveraged reliance mechanisms to facilitate the review and approval of Mpxv diagnostic tools. This approach has proven instrumental in accelerating access to critical health technologies, particularly in public health emergencies.

The emergency use approval of the Cobas MPXV for use on the Cobas 6800/8800 Systems, developed by Roche Molecular Systems, Inc. and licensed to Roche Diagnostics South Africa (Pty) Ltd, represents a critical advancement in expanding diagnostic capacity amid Mpxv outbreaks. Rapid and accurate testing is essential for early detection, timely treatment, and effective containment of the virus.

“As part of our efforts to promote regulatory efficiency and responsiveness, SAHPRA has successfully leveraged reliance mechanisms to facilitate the review and approval of Mpxv

diagnostic tools. This marks a significant milestone in supporting regional and continental harmonisation of the regulatory processes for medical devices, including In-Vitro Diagnostics (IVDs),” says Dr Boitumelo Semete-Makokotlela, SAHPRA’s Chief Executive Officer.

For more information on the AMRH continental EUL listing publication, see here:

<https://www.nepad.org/news/public-notice-amrh-steering-committee-approves-emergency-use-listing-of-two-mpox>

**Ends**

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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](mailto:media@sahpra.org.za) and [yuveng@sahpra.org.za](mailto: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.