SAHPRA Registers Lenacapavir

Embargo: Immediate release

Pretoria, 27 October 2025 – The South African Health Products Regulatory Authority (SAHPRA) is pleased to announce the registration of Lenacapavir. Lenacapavir is an antiviral medicine that is recommended, in combination with safer sex practices, for pre-exposure prophylaxis (PrEP) to prevent HIV-1 infection in adults and adolescents weighing at least 35 kg.

An application by Gilead was submitted to SAHPRA in March 2025. The SAHPRA review process was done in collaboration with the European Medicines for All Procedure (EU-M4all). This procedure enables the European Medicines Agency (EMA), together with the participating regulatory authorities, to provide scientific opinions on high-priority medicines, such as Lenacapavir, intended for markets outside the European Union. The benefits of this pathway are to strengthen regulatory systems and accelerate access to essential medicines.

Dosage

This product, developed to prevent new HIV infections, is a six-monthly injection. There is an initiation dose of a subcutaneous injection (administered just under the skin) with tablets (taken on days 1 and 2). It is used to reduce the risk of HIV in adults and adolescents who weigh at least 35 kg, are HIV negative, and are at risk of getting HIV. Lenacapavir for PrEP should always be used in combination with safer sex practices, such as using condoms, to reduce the risk of getting other sexually transmitted infections.

“The registration of Lenacapavir is a game-changer, given the high prevalence rate of HIV in South Africa. This product is the most effective HIV prevention measure thus far,” indicated Dr Boitumelo Semete-Makokotlela, CEO: SAHPRA.

END

Issued by:

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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.

Notes to Editors:

Should you request an interview, please send your request to and copy.

SAHPRA will publish 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.