



MEDIA RELEASE

SAHPRA registers new long-acting HIV Pre-exposure prophylaxis

Embargo: Immediate release

Pretoria, 2 December 2022 – The South African Health Products Regulatory Authority (SAHPRA) has registered Cabotegravir (Apretude 600 mg/3ml injection), a long-acting HIV pre-exposure prophylactic.

Cabotegravir is an antiretroviral drug (ARV) that people living with HIV may use, together with other ARVs, to keep the virus in their bodies from making copies of itself. When such medicine is used to prevent HIV infection — that is, if it is taken before exposure to HIV — it is called pre-exposure prophylaxis, or PrEP and thus plays an important role in preventing HIV infection.

Apretude 600 mg/3ml injection is the first and only long-acting, injectable PrEP for reducing the risk of getting HIV. This drug is a safe and highly effective prevention option for people at substantial risk of HIV infection. HIV prevention efforts have stalled, with 1.5 million new HIV infections in 2021, as indicated by the World Health Organization (WHO). Having such options will go a long way in reducing the rate of new infections.

“SAHPRA joins the global fight against this disease. The priority review pathway followed to assess and finally register long acting Cabotegravir (CAB-LA) marks a bold step in this direction,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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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 (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.

Notes to Editors:

SAHPRA will post this media release on our 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 request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.