

MEDIA RELEASE

SAHPRA registers Paxlovid, an anti-viral medicine for COVID-19

Embargo: Immediate release

Pretoria, 30 January 2023 – The South African Health Products Regulatory Authority (SAHPRA) has registered Paxlovid, an anti-viral medicine manufactured by Pfizer, to treat COVID-19.

Paxlovid, which contains Nirmatrelvir (150mg) and Ritonavir (100mg), is a medicine that is used for the treatment of mild to moderate COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.

Paxlovid consists of tablets for a 5-day oral treatment regimen, with morning and evening doses. Expected side-effects include hypersensitivity reactions, diarrhoea, vomiting, and altered taste.

A shelf-life of twelve (12) months is approved for Paxlovid when stored at or below 25 °C.

"SAHPRA is committed to fast tracking the registration of all health products that are of an urgent nature such as HIV-AIDS, Cancer, and COVID-19. AS COVID-19 is a looming threat, the registration of Paxlovid heralds a welcome signal in the fight against this pandemic," 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 don 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.