MEDIA RELEASE

SAHPRA has authorised access to molnupiravir

Embargo: Immediate release

Pretoria, 17 February 2022 – Until recently, the treatment options for patients with mild-to-moderate COVID-19 have been limited. New oral antiviral medicines are becoming available for the treatment of confirmed COVID-19 in adults who do not require supplemental oxygen and who are at risk of progression to severe COVID -19. One of these new medicines is molnupiravir. In a phase 2/3 clinical trial, molnupiravir was shown to reduce the risk of hospitalisation or death compared with placebo, but only when treatment was initiated within 5 days of the first symptoms of COVID-19. Molnupiravir is only indicated for use in patients aged 18 years and older.

SAHPRA has authorised, with conditions, the importation of molnupiravir 200mg capsules ("LAGEVRIO"), to be provided by MSD (Pty) Ltd, in terms of section 21 of the Medicines and Related Substances Act, 1965. This authorisation is for a limited quantity of "LAGEVRIO" and is initially limited to a period of six (6) months. Imported "LAGEVRIO" will be distributed through the usual distribution chain, and will require prescription by an authorised prescriber in accordance with the control measures applied to Schedule 4 substances.

As studies in animals have shown reproductive toxicity, "LAGEVRIO" is not recommended during pregnancy. Women of childbearing potential should use effective contraception for the duration of treatment and for 4 days after the last dose of "LAGEVRIO". MSD (Pty) Ltd shall ensure that any adverse drug reactions associated with the use of molnupiravir ("LAGEVRIO") are reported to SAHPRA.

MSD (Pty) Ltd has also submitted an application for the registration of "LAGEVRIO", for which a rolling review has commenced. SAHPRA is also reviewing applications for the use of generic products containing molnupiravir. An application for another oral antiviral for adults diagnosed with mild-to-moderate COVID-19, the co-packaged presentation of nirmatrelvir and ritonavir ("PAXLOVID"), has been submitted by Pfizer (Pty) Ltd and is under consideration at present.

"The authorisation of molnupiravir for compassionate use offers further therapy in the fight against COVID-19. SAHPRA will continue to play its part in ensuring the quality, safety and efficacy of all health products, including innovative treatments, so that the public is protected at all times," 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.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy nthabi.moloi@sahpra.org.za. Include your discussion points in your request.