MEDIA RELEASE

SAHPRA registers a vaccine and provides emergency use authorisation of health products in the fight against COVID-19

Pretoria, 7 June 2022

Embargo: Immediate release

1. **The COVID-19 vaccine LHC has been registered with conditions on 24 May 2022.**

The registration of the COVID-19 vaccine LHC was done in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965. This COVID-19 vaccine (Sinopharm BIBP) is an inactivated whole virion of the originator strain of SARS-CoV-2. The vaccine is administered intramuscularly in two doses with a 21- to 28-day interval.

This authorisation is based on acceptable safety, quality and efficacy data submitted by LHC Pharmaceuticals Pty (Ltd) to SAHPRA. The registration includes conditions that relate to the reporting of the results of ongoing studies and conformance with pharmacovigilance activities as outlined in the approved risk management plan, including the submission of periodic safety updates.

The side effects of the COVID-19 vaccine LHC were usually mild or moderate and occurred within seven (7) days of vaccination. The most common side effects reported were pain at the injection site, fever, and diarrhoea.

2. **Molnupiravir generic products, Molcovir by Bliss Pharmaceuticals (Pty) Ltd and Molnupiravir 200 DRL by Dr Reddy's Laboratories (Pty) Ltd, were granted S21 authorisations on 31 May and 03 June 2022, respectively.**

SAHPRA has furthermore, granted emergency use authorisation to the generic Molnupiravir 200 mg products. This drug is authorised for the treatment of adults with mild to moderate COVID-19, who do not require supplemental oxygen and who are at risk of progression to severe COVID-19. Lastly, these adults must be within 5 days of symptom onset. It is recommended that Molnupiravir 800 mg twice daily dose for five (5) days is used for the treatment of confirmed COVID-19 in adults.

“SAHPRA will continue to play its part in ensuring the quality, safety and efficacy of all health products to ensure that the South African public is protected at all times,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Issued by:

Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Cell: 066 1202 669

E-mail: yuveng@sahpra.org.za

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.