MEDIA RELEASE

SAHPRA registers the COVID-19 vaccine, Coronavac

Embargo: Immediate release

Pretoria, 24 June 2022 – The South African Health Products and Regulatory Authority (SAHPRA) registered the COVID-19 vaccine, Coronavac, on 14 June 2022, with conditions**.** The registration was done in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965.

The Coronavac is an inactivated SARS-CoV-2 virus (CZo2 strain) indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18-59 years of age. A single dose of 0,5 ml contains 600SU (3µg) of inactivated SARS-COV-2 virus produced in Vero cells. The Coronavac is administered by intramuscular injection as two doses between 14-28 days apart from the initial dose.

This authorisation is based on acceptable safety, quality and efficacy data submitted by CURANTO PHARMA (PTY) LTD to SAHPRA as a rolling submission over the period March 2021 to June 2022. The authorisation is, however, subject to a number of conditions which includes that the vaccine is supplied and administered in accordance with the National Department of Health (NDoH) COVID-19 vaccination plan and applicable guidelines. Further conditions 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 Coronavac, as outlined in the clinical trial evidence submitted by the applicant, were usually mild or moderate and cleared within a few of days after vaccination. The most common side effects reported were pain at the injection site, headache, tiredness, muscle pain and nausea.

The current assigned shelf-life of the vaccine is twenty-four months when stored at acceptable for the final product in a vial or prefilled syringe, when stored at +2-8°C and protected from light.

Issued by:

Dr Boitumelo Semete

CEO

Email: 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.