MEDIA STATEMENT

SAHPRA AUTHORISES THE CORONAVAC VACCINE WITH CONDITIONS

3 July 2021

The South African Health Products Regulatory Authority (SAHPRA) has authorised the CoronaVac COVID-19 vaccine, manufactured by Sinovac Life Sciences Co., and imported by Curanto Pharma (Pty) Ltd. The authorisation was done in terms of Section 21 of the Medicines and Related Substance Act 101 of 1965, a mechanism in the Medicines Act that enables emergency use access and also enables SAHPRA to authorise a medicine subject to certain conditions.

CoronaVac is an inactivated whole virion vaccine derived from the SARS-CoV-2 virus (CZ02 strain). Each dose contains 600 SU of inactivated SARS-CoV-2 virus as the antigen. CoronaVac is indicated for active immunisation in individuals aged between 18 and 59 years against COVID-19, the disease caused by SARS-CoV-2 virus,.

The vaccine is administered as two doses of 0,5ml, given intramuscularly, with the second dose administered between 14 and 28 days after the first dose.

This authorisation is based on the safety, quality and efficacy data submitted by Curanto Pharma (Pty) Ltd to SAHPRA between 22 March 2021 and 22 June 2021. Although the data submitted are considered acceptable at this point, the authorisation is subject to a number of conditions. Specifically, the applicant is required to submit the final results of ongoing clinical studies. SAHPRA also took account of the World Health Organization (WHO) Emergency Use Listing (EUL) report on this vaccine.

In addition, the conditions require the submission of periodic safety updates in accordance with SAHPRA guidance, and conformance with pharmacovigilance activities as outlined in the approved risk management plan. As outlined in the clinical trial evidence submitted by the applicant, most of the side effects following administration of the CoronaVac vaccine were

mild or moderate in nature, and cleared within a couple of days. The frequently-reported adverse reactions were: pain at the injection site, headache, fatigue, muscle pain, diarrhoea and nausea.

Curanto Pharma (Pty) Ltd must provide any data or information generated or which otherwise comes into their possession, which is relevant to the risk / benefit profile of the product and/or is relevant to the conditions of use. The company is also obliged to share any such information received from the manufacturers. In particular, any data on the efficacy/effectiveness of the vaccine against disease caused by emerging SARS-CoV-2 variants of concern shall be provided to the regulator.

A provisional shelf life of 24 months is approved for both the vial and prefilled syringe presentations of the product, for storage at 2 – 8°C and protected from light.

Issued by:

Dr Boitumelo Semete-Makokotlela

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Vincent Magwenya

Email: vincentm@conversationsgroup.co.za

Cell: 082 835 6315

Mbali Mokoena

Email: mbalim@conversationsgroup.co.za

Cell: 079 434 4661

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.