



MEDIA RELEASE

UPDATE ON COVID-19 HEALTH PRODUCTS: SAHPRA registers the Covovax COVID-19 vaccine from Cipla (Pty) Ltd and additional indication of use of COVID-19 vaccine MC Pharma from MC Pharma (Pty) Ltd in the age group 3 -17 years.

Embargo: Immediate release

Pretoria, 28 September 2022 – SAHPRA registered a COVID-19 vaccine: the Covovax vaccine submitted by Cipla (Pty) Ltd on 16 August 2022.

Furthermore, SAHPRA approved the additional indication of the use of the COVID-19 vaccine MC Pharma in the age group 3 to 17 years on 16 September 2022.

Both vaccines have been registered in terms of Section 15 of the *Medicines and Related Substance Act (Act 101 of 1965 as amended)*, with conditions. This means that these products are not under Emergency Use Authorisation but have a full registration.

Covovax Vaccine

Covovax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. Covovax is administered intramuscularly as a course of two doses of 0,5 ml each. It is recommended to administer the second dose three weeks after the first dose. It is also recommended that individuals who receive a first dose of Covovax, complete the vaccination course with Covovax.

This authorisation is based on acceptable safety, quality and efficacy data submitted by Cipla (Pty) Ltd to SAHPRA as a rolling submission. The authorisation is, however, subject to a number of conditions which includes that the vaccine is supplied and administered in accordance with the National COVID-19 vaccination programme 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 adverse effects of the Covovax vaccine, as outlined in the clinical trial evidence submitted by the applicant, were usually mild or moderate and cleared within a few days of vaccination. Very common adverse events reported were injection site pain, injection site tenderness, fatigue, malaise headache, myalgia, arthralgia, and nausea. Very rare cases of decreased appetite, diarrhoea, chills, dizziness and somnolence have been observed following vaccination with Covovax.

COVID-19 Vaccine MC Pharma

The COVID-19 Vaccine MC Pharma is an inactivated Vero Cell vaccine, indicated for immunisation against SARS-CoV-2 in those aged 3-17 years and older. Initially developed by the Beijing Institute of Biological Products Co. (Ltd), this product has also been referred to as the Sinopharm/BIBP vaccine indicated for immunisation against SARS-CoV-2. The COVID-19 Vaccine MC Pharma is administered as two doses by intramuscular injection at an interval of 2-4 weeks and each dose is 0.5ml.

This authorisation of the 3-17 years use is based on acceptable safety, quality and efficacy data submitted by MC Pharma Pty (Ltd) to SAHPRA as a variation to the already registered MC Pharma (Pty) Ltd.

“The registration of these vaccines is a vast stride in vaccine registration as SAHPRA plays its role 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 all vaccines to ensure that the South African 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:

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A podcast will be recorded and posted on the home page. Scroll down 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.

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - <https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/>