MEDIA RELEASE

SAHPRA registers two COVID-19 vaccines

Embargo: Immediate release

Pretoria, 7 February 2022 – SAHPRA registered two COVID-19 vaccines: the COMIRNATY vaccine by Pfizer Laboratories (Pty) Ltd on 25 January 2022, and the COVID-19 VACCINE MC PHARMA by MC Pharma (Pty) Ltd. on 31 January 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.

COMIRNATY vaccine

COMIRNATY is an mRNA vaccine, indicated for active immunisation to prevent COVID-19 in individuals 12 years of age and older. COMIRNATY is administered intramuscularly after dilution as a course of 2 doses (0,3 mL each). It is recommended that the second dose is administered three weeks after the initial dose.

This authorisation is based on acceptable safety, quality and efficacy data submitted by Pfizer Laboratories (Pty) Ltd to SAHPRA as a rolling submission over the period 3 February 2021 to 17 January 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 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 COMIRNATY 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. The most common adverse effects reported were pain at the injection site, headache, tiredness, muscle pain and chills. Very rare cases of myocarditis and pericarditis have been observed following vaccination with COMIRNATY. These cases have primarily

occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of these conditions following vaccination is not different from that seen with myocarditis or pericarditis from other causes.

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 18 years and older. initially developed by the Beijing Institute of Biological Products Co., Ltd, this product has also been referred to as the Sinopharm/BBIBP 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 is based on acceptable safety, quality and efficacy data submitted by MC Pharma Pty (Ltd) to SAHPRA as a rolling submission over the period 23 July 2021 to 22 December 2021. 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. 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 COVID-19 VACCINE MC PHARMA, as outlined in the clinical trial evidence submitted by the applicant, were usually mild or moderate and cleared within a few days of vaccination. The most common adverse effects reported were pain at the injection site, headache, tiredness, muscle pain and nausea.

“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:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

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)

Please also note that all queries related to the rollout of these vaccines should be addressed with the National Department of Health (NDoH)