MEDIA RELEASE

SAHPRA registers COMIRNATY's paediatric and adult vaccines

Embargo: Immediate release

Pretoria, 22 November 2022 – The South African Health Products Regulatory Authority (SAHPRA) has registered Pfizer's COMIRNATY Ready To Use (RTU) ADULT VACCINE and Dilute To Use (DTU) PAEDIATRIC VACCINE on 15 November 2022. The RTU vaccine, as the name suggests, is a formulation that does not require reconstitution in any way. The DTU vaccine must be reconstituted and cannot be used directly.

Both vaccines have been registered in terms of Section 15 (6a) 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.

The current assigned shelf-life of the frozen vial for both vaccines is nine (9) months when stored at -90 °C to -60 °C. The thawed vial has 10 weeks storage and transportation at 2 °C to 8 °C within the nine (9) months shelf life.

COMIRNATY RTU ADULT VACCINE

The COMIRNATY RTU ADULT VACCINE is an mRNA vaccine indicated for active immunisation to prevent COVID-19 in individuals 12 years and above for this new ready to use formulation.

The RTU adult vaccine is administered intramuscularly as a primary course of two (2) doses (0,3 mL each). It is recommended to administer the second dose three (3) weeks after the first dose.

For severely immunocompromised individuals aged 12 years and older, a third primary course dose may be administered intramuscularly at least 28 days after the second dose. Please note that this formulation has not been approved for boosting at this stage.

COMIRNATY DTU PAEDIATRIC VACCINE

The COMIRNATY DTU PAEDIATRIC VACCINE is an mRNA vaccine indicated for active immunisation against SARS-CoV-2 and may contribute to protection against COVID-19 in individuals 5 - 11 years of age, that is, it is for the paediatric population.

The DTU paediatric vaccine's 10 micrograms/dose is administered intramuscularly after dilution as a primary course of two (2) doses (0,2 mL each). It is recommended to administer the second dose three (3) weeks after the first dose.

For severely immunocompromised individuals aged five (5) years and older, a third primary course dose may be administered intramuscularly at least 28 days after the second.

"These authorisations are based on acceptable safety, quality and efficacy data submitted by Pfizer Laboratories (Pty) Ltd to SAHPRA as a full 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 monitoring and conformance with pharmacovigilance activities as outlined in the approved risk management plan, including the submission of periodic safety updates", 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.