MEDIA STATEMENT

A SIGNAL OF MYOCARDITIS / PERICARDITIS ASSOCIATED WITH PFIZER-BIONTECH'S COVID-19 VACCINE, COMIRNATY (BNT162B2)

26 August 2021

The South African Health Products Regulatory Authority (SAHPRA) would like to inform you of a signal of myocarditis / pericarditis associated with Pfizer-BioNTech's Covid-19 vaccine, Comirnaty® (BNT162b2). The Pfizer/BioNTech Comirnaty® Vaccine was approved by SAHPRA in March 2021. The authorisation was done in terms of Section 21 of the Medicines and Related Substance Act, (Act 101 of 1965) as amended, a mechanism in the Medicines Act that enables emergency use access subject to certain conditions.

Comirnaty® is a vaccine for preventing coronavirus disease 2019 (COVID-19). Comirnaty® contains messenger RNA (mRNA). This mRNA contains instructions which are followed by cells in the vaccinated person's body, to make the "spike protein" that is found on the surface of the SARS-CoV-2 virus. This "spike protein" triggers an immune response in the vaccinated person. Comirnaty® does not contain the virus itself and cannot cause COVID-19. The vaccine is administered as two doses (0.3mL each) given intramuscularly, the second dose 3 to 6 weeks after the first dose.

Cases of myocarditis and pericarditis have been reported in the United States and other countries after Comirnaty® administration. These case reports were more common in adolescents and young adults, and after administration of the second vaccine dose.

Myocarditis and pericarditis are diseases that cause inflammation of the heart that can occur following infections or immune related diseases. Symptoms of myocarditis and pericarditis can vary but may include shortness of breath, palpitations, irregular heartbeats, and chest pain. The public is advised to seek medical attention if they experience any of these symptoms following vaccination with Covid-19 vaccines.

SAHPRA has identified one reported case of myocarditis in the SAHPRA safety database, however, has not identified any causal relationship between any COVID-19 vaccine and this adverse event. Investigation is ongoing to determine whether this case is coincidental or related to the vaccine.

SAHPRA continues to closely monitor the safety of the COVID-19 vaccines and further investigate these findings. SAHPRA will share further updates and information with the public as they become available.

SAHPRA strongly believes that the known benefits of COVID-19 vaccination greatly outweigh the known and potential risks of receiving the Cominaty® COVID-19 vaccine. There is no need to delay vaccination while SAHPRA continues its investigation.

You are encouraged to report all cases of myocarditis and pericarditis after Comirnaty® (COVID-19 mRNA vaccine) vaccination to SAHPRA via Med Safety App. The App can be downloaded into a smart mobile phone through google Play or App store. For more information on Med Safety App, please visit SAHPRA website.

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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.