IMPORTANT MEDICINE SAFETY INFORMATION

17 August 2021

Dear Healthcare Professional

COMIRNATY® (COVID-19 mRNA VACCINE) - WARNING REGARDING RARE CASES OF MYOCARDITIS AND PERICARDITIS.

Pfizer South Africa, in collaboration with the South African Health Products Regulatory Authority (SAHPRA) wish to inform you of the warning regarding rare cases of myocarditis and pericarditis reports that were noted following the use of COVID-19 mRNA vaccines, including Comirnaty® (Covid-19 mRNA vaccine).

The Professional Information (PI) of the COVID-19 mRNA vaccine will be updated to appropriately reflect the above safety information.

Summary

- **Cases of myocarditis and pericarditis have been reported rarely following vaccination with the COVID-19 mRNA Vaccines.**
- **The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men.**
- **Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the course of myocarditis and pericarditis in general.**
- **Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.**
- **Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations.**

Background on the safety concern

The COVID-19 mRNA vaccine, Comirnaty® has been authorised in South Africa under Section 21 authorisation for active immunisation to prevent COVID-19 infection caused by SARS-CoV-2, in individuals 16 years of age and older.
Myocarditis and pericarditis have been reported in association with the COVID-19 mRNA vaccines.

The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has evaluated all available data and concluded that a causal association between COVID-19 mRNA vaccines and myocarditis and pericarditis is at least a reasonable possibility.

The benefits of vaccination continue to outweigh any risks.

Up to 31 May 2021 in the European Economic Area (EEA), 145 cases of myocarditis occurred among people who received Comirnaty®. In addition, 138 cases of pericarditis occurred following the use of Comirnaty®. It is estimated that around 177 million doses of Comirnaty® have been administered in the EEA up to 31 May 2021.

Call for reporting

Healthcare professionals are reminded to report all suspected adverse events of myocarditis and pericarditis or symptoms such as, but not limited to, shortness of breath, palpitations, and chest pains, and all other adverse events to Pfizer South Africa (see contact details below) and/or 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.

Alternatively, the ADR reporting form accessible via the SAHPRA website at https://www.sahpra.org.za/wp-content/uploads/2021/04/6.04_ARF1_v5.3_April2021-addition_of_Med_Safety_App.pdf can be completed and emailed to adr@sahpra.org.za.

Additionally, reporting can be done via the eReporting link available on the SAHPRA website (www.sahpra.org.za). For more information on ADR reporting, please contact the SAHPRA vigilance unit at pvqueries@sahpra.org.za.

Table 1: Product and contact details.

COMPANY	PRODUCT	ACTIVE INGREDIENT	CONTACT DETAILS
Pfizer Laboratories (Pty) Ltd	Comirnaty®	Covid- 19 mRNA	Tel: 0860 PFIZER (0860 734937) e-mail: ZAF.AEReporting@pfizer.com

Sincerely,

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Medical Director

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Cluster Safety Lead