SFDA
Safety Communication

[14 /07/2021]

Potential Risks of Myocarditis and Pericarditis Following the Use of mRNA COVID-19 Vaccines

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about the potential risks of myocarditis and pericarditis following the use of messenger RNA (mRNA) vaccines including Pfizer-BioNTech and Moderna vaccines that are used to combat coronavirus disease 2019 (COVID-19).

Myocarditis and pericarditis are inflammatory conditions of the heart. Symptoms can vary but often include breathlessness, palpitations, and chest pain. The SFDA has conducted a comprehensive evaluation of published literature and post marketing databases on the potential risks of myocarditis and pericarditis in individuals who received mRNA COVID-19 vaccines.

There have been internationally very rare reported cases of myocarditis and pericarditis following the use of the mRNA COVID-19 vaccines. The onset of symptoms typically starts within few days of vaccine administration. The available data suggests that most of these cases occurred in younger men and were mild in nature. In addition, vaccinated individuals had resolution of symptoms usually within a short period following standard treatment or rest.

Based on the available evidence, the benefits of mRNA COVID-19 vaccines in preventing COVID-19 outweigh the potential risks. The SFDA emphasizes that healthcare professionals should advise vaccinated individuals to seek immediate medical help if they experience new

onset of chest pain, shortness of breath, palpitations or arrhythmias (symptoms suggestive of myocarditis and pericarditis).

Call for reporting:

Healthcare professionals should report any suspected adverse events related to the use of COVID-19 vaccines to the National Pharmacovigilance Center via below reporting channels:

COVID Vaccine adverse event electronic reporting form:

(https://ade.sfda.gov.sa/Covid/CovidRequest)

Email: NPC.drug@sfda.gov.sa