SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually m ore than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

11-03-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of COVID-19 Vaccine (Comirnaty) and the Risk of Liver injury

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Liver injury** associated with the use of **Comirnaty**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Comirnaty is an mRNA-based vaccine developed by Pfizer and BioNTech to prevent COVID-19 infection. [1] Drug-induced liver injury (DILI) is common and nearly all classes of medications can cause liver disease. Most cases of DILI are benign, and improve after drug withdrawal. It is important to recognize and remove the offending agent as quickly as possible to prevent the progression to chronic liver disease and/or acute liver failure. [2] The aim of this review is to evaluate the risk of Liver injury associated with the use of Comirnaty and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between Liver injury and Comirnaty use. The search conducted on January 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 149 global case-reports. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 0.8 and above (24 cases). [4] Among them, twenty-one cases were possibly linked to Comirnaty, two cases assessed as unlikely, while the remaining one case were unable to be assessed due to lack of important information.

Literature: The signal team searched the literature to find related publications linking this ADR to Comirnaty. The search showed two published studies linking liver injury to this vaccine. [5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Comirnaty and Liver injury. Health care professionals and health regulators must be aware of the potential risk in vaccine recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

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