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"

12-08-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Tozinameran and the Risk of Acute respiratory distress syndrome

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

Introduction

Tozinameran is a formulation consisting of lipid nanoparticle (LNP) encapsulating a nucleoside modified messenger RNA (modRNA) encoding an optimized form of the full-length severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike glycoprotein (SP), with potential immunizing and anti-COVID-19 activities. Upon injection of Tozinameran, the LNPs bind to the plasma membrane of nearby cells and release SARS-CoV-2 SP mRNA into the cell. The mRNA is then translated by the cellular protein translation machinery to produce SARS-CoV-2 SP. This may stimulate the immune system to induce an antibody and T-cell-mediated immune response. [1] Acute respiratory distress syndrome (ARDS) is an acute, diffuse, inflammatory form of lung injury and life-threatening condition in seriously ill patients, characterized by poor oxygenation, pulmonary infiltrates, and acute onset. On a microscopic level, the disorder is associated with capillary endothelial injury and diffuse alveolar damage. [2] The aim of this review is to evaluate the risk of Acute respiratory distress syndrome associated with the use of Tozinameran 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 potential link between ARDS and Tozinameran use.

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 1135 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO Causality assessment tool on the top 30 extracted cases. [3] Among them, thirty cases resulted in possible association to Tozinameran.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (0.3) for this drug/ADR combination which reflects positive statistical association. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Tozinameran. The search identified two published studies suggesting a possible association between the vaccine and this potential risk. [4,5]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Tozinameran and Acute respiratory distress syndrome. 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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2- Gossman, W., Peniston, H.L. and Mahapatra, S. (2024). Acute respiratory distress syndrome (ARDS). [online] Nih.gov. Available at: https://www.ncbi.nlm.nih.gov/books/NBK436002/.
3- Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/
4- Wan EYF, Chui CSL, Mok AHY, Xu W, Yan VKC, Lai FTT, Li X, Wong CKH, Chan EWY, Lui DTW, Tan KCB, Hung IFN, Lam CLK, Leung GM, Wong ICK. mRNA (BNT162b2) and Inactivated (CoronaVac) COVID-19 Vaccination and Risk of Adverse Events and Acute Diabetic Complications in Patients with Type 2 Diabetes Mellitus: A Population-Based Study. Drug Saf. 2022 Dec;45(12):1477-1490. doi: 10.1007/s40264-022-01228-6. Epub 2022 Oct 2. PMID: 36184720; PMCID: PMC9527074.
5- Tozinameran: Multisystem inflammatory syndrome: case report. Reactions Weekly. 2022;1899(1):366. doi: 10.1007/s40278-022-12338-y. Epub 2022 Mar 26. PMCID: PMC8948067.