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 more 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"

07-09-2023

Saudi Food and Drug Authority (SFDA) – Safety Signal of AstraZeneca Covid-19 vaccine and Risk of Pityriasis Rosea

The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of ***pityriasis rosea*** *associated with the use of* ***AstraZeneca Covid-19 vaccine****. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

The AstraZeneca ChAdOx1-S/nCoV-19 [recombinant] vaccine is a replication-deficient adenoviral vector vaccine against coronavirus disease 2019 (COVID-19). The vaccine expresses the SARS-CoV-2 spike protein gene, which instructs the host cells to produce the protein of the S-antigen unique to SARS-CoV-2, allowing the body to generate an immune response and to retain that information in memory immune cells. [1] Pityriasis rosea is a relatively common skin condition that causes a temporary rash of raised red scaly patches on the body. A single pink or red oval patch of scaly skin, called the "herald patch", usually appears at least 2 days before a more widespread rash develops. It can affect anyone, but it is more common in older children and young adults (aged 10 to 35). [2]

Methodology

Signal Detection team at the National Pharmacovigilance Center (NPC) of Saudi Food and Drug Authority (SFDA) performed a comprehensive signal review using its national database as well as the World Health Organization (WHO) database (VigiBase), to retrieve related information for assessing the causality between (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) and the risk of pityriasis rosea. [3] WHO-Uppsala Monitoring Centre (UMC) criteria have been used as standard for assessing the causality of the reported cases. [4]

Results

Case Review: The search in the local database resulted in one possible case. The number of resulted global cases for the combined vaccine/adverse drug reaction is 134 global ICSRs as of July 16th 2023. [3] The reviewers have extracted and assessed thirty cases with highest completeness score. The causality assessment resulted in 30 possible cases.

Data Mining: The disproportionality of the observed and the expected reporting rate for vaccine/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, considering the null value equal to zero. The result of (IC= 1.1) revealed a positive statistical association for the vaccine/ADR combination, which means "pityriasis rosea" with the use of "COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)" have been observed more than expected when compared to other medications available in WHO database. [3]
Literature: Upon conducting a literature search, two case reports were found. [5] [6]

Conclusion

The weighted cumulative evidences identified from causality assessment of the reported case, data mining and literature are sufficient to support a causal association between (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)) and the risk of pityriasis rosea. Health regulators and health care professionals must be aware of this potential risk and it is advisable to monitor any signs or symptoms in treated patients.

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:

1. World Health Organization (WHO), 2021. AstraZeneca ChAdOx1-S/nCoV-19 [recombinant], COVID-19 vaccine. [online] Available at: < https://www.who.int/publications/m/item/chadox1-s-recombinant-covid-19-vaccine > [Accessed 17/7/2023].]
2. NHS choices. Available at: https://www.nhs.uk/conditions/pityriasis-rosea/#:~:text=This%20rash%20is%20small%2C%20raised,but%20it%20can%20be%20itchy. (Accessed: 17 July 2023].
3. Vigilyze.who-umc.org. 2023. [online] Available at: <https://vigilyze.who-umc.org/> [Accessed 17/7/2023].
4. Uppsala Monitoring Center (UMC) (2020), The use of the WHO-UMC system for standardized case causality assessment; Available at <https://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf?ua=1> [Accessed 17/7/2023].
5. Mehta, H. et al. (2021) 'Erythema nodosum, zoster duplex and pityriasis rosea as possible cutaneous adverse effects of Oxford–AstraZeneca Covid-19 vaccine: Report of three cases from India', Journal of the European Academy of Dermatology and Venereology, 36(1). doi:10.1111/jdv.17678.
6. Leerunyakul, K., Pakornphadungsit, K. and Suchonwanit, P. (2021) 'Case report: Pityriasis rosea-like eruption following COVID-19 vaccination', Frontiers in Medicine, 8. doi:10.3389/fmed.2021.75244