

# SAFETY ALERT

## Covid-19 Vaccines Safety Signal

Covid-19 disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been a global pandemic for almost the past 2 years. The pandemic has caused a lot of mortalities, morbidities and has affected global economies. Developing vaccines and mass roll out became a priority to reduce the severity of Covid-19 impact globally. Botswana listed 7 Covid-19 vaccines for emergency use to prevent severe disease, hospitalisation, mortality, and decreased morbidity. Botswana Medicines regulatory authority (BoMRA) is constantly monitoring safety of Covid-19 vaccines used in Botswana. Here we describe 3 cases of a new safety signal identified through global data base of Adverse Events Following Immunisation (AEFIs) to Covid-19 vaccines.

## Adult-onset Still's Disease (AOSD) and Covid-19 Vaccines

AOSD is a very rare systemic inflammatory condition of unknown origin (Fautrel, 2008). It is classically characterized by the following 4 main symptoms: fever  $\geq 39$  °C, arthralgia or arthritis, skin rash and hyperleukocytosis ( $\geq 10,000$  cells/mm<sup>3</sup>) with neutrophils  $\geq 80\%$ . It is potentially life threatening (Gopalarathinam et al., 2016). 19 individual case safety reports (ICSRs) of AOSD have been identified on the World Health Organization (WHO) global database associated with Covid-19 vaccines. It must be noted that the incidence of occurrence is not statistically significant compared to incidence of occurrence of AOSD associated with the use of other medicinal products. 12 ICSRs were associated with AstraZaneca Covid-19 vaccines, 5 with Pfizer-BioNTech COVID-19 vaccine and 2 with Moderna Covid-19 vaccine. The cases occurred mostly after the first doses and median- time of on set is 10.5 days after vaccination. AOSD is found to be predominant in adults aged 21-68 years and average age of 49 years. The signal suggests possible causal relationship of AOSD and Covid-19 vaccines. However, further investigational studies are needed to establish if AOSD is a vaccine related AEFI.

For more information see the references below.

## References

- Fautrel, B., 2008. Adult-onset Still disease. *Best Practice & Research Clinical Rheumatology*, 22(5), pp.773-792.
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📍 Plot 112, International Finance Park, Gaborone  
✉ Private Bag 2, Gaborone Station, Botswana  
☎ +267 373 1727/20  
☎ Toll Free : 0800 600 216  
✉ info@bomra.co.bw  
f Botswana Medicines Regulatory Authority  
🌐 [www.bomra.co.bw](http://www.bomra.co.bw)

