SAFETY ALERT

Autoimmune hepatitis due to mRNA COVID-19 vaccines

COVID-19 disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been a global pandemic for almost 2 years now. Developing vaccines and mass roll out became a priority to reduce the severity of COVID-19 impact globally. To date, Botswana Medicines regulatory authority (BoMRA) has listed several COVID-19 vaccines for emergency use. BoMRA is mandated to monitor safety of COVID-19 vaccines used in Botswana. The authority monitors the safety of these vaccines through analysis of reported Adverse Events Following Immunisation (AEFIs), analysis of AEFIs on global database, data mining from medical literature and from the experience of other national regulatory authorities in the region and around the globe.

Recently, European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) identified a safety signal of autoimmune hepatitis which is currently under assessment. According to the report, the signal was detected through assessment of very small number of cases reported after vaccination with mRNA vaccines, Spikevax (Moderna) and Comirnaty (Pfizer) COVID-19 Vaccines from the medical literature and EudraVigilance.

As of the 15th December 2021, globally there are 249 cases of autoimmune hepatitis reported for COVID-19 vaccines. Majority of the reports came from females (65.5%). The most affected age group was 45 - 64 years. mRNA based vaccines Comirnaty and SpikeVax had most reports at 58.6% and 24.5% respectively. This was followed by AstraZeneca COVID-19 vaccine at 10.4%, then Janssen at 4.8%. 79.5% of the cases were classified as serious. Majority of the serious cases lead to or prolonged hospitalization at 60.6%.

From the literature, there has been published case reports of Autoimmune hepatitis following vaccination with both SpikeVax and Comirnaty vaccines. Majority of the cases were almost females aged between 35 and 80 years. They presented with liver-specific signs and symptoms occurring 4 to 35 days after the fist dose or 7 days post 2nd dose. The predisposing factors identified amongst the cases are pregnancy and autoimmune thyroiditis.

To date BoMRA has not received any reports of autoimmune hepatitis. Healthcare professionals are encouraged to be vigilant to identify and treat any signs and symptoms suggestive of autoimmune hepatitis.

Possible signs and symptoms of autoimmune hepatitis are but not limited to;

- **Fever**
- **Fatigue**
- **Diarrhea**
- **Jaundice**
- **Chest pain**
- **Cessation of menses**
- **Joint pain or joint swelling**
- **Abdominal pain or ascites**
- **Spider-like blood vessels in the skin**
- **Large abdomen due to large liver and spleen**

Reporting of Adverse Events Following Immunization (AEFIs)

HCPs should encourage vaccinees to visit their nearest healthcare facility if they experience any AEFIs or any discomfort after they are vaccinated. All AEFIs that healthcare workers get notified of must be reported to BoMRA.

Reporting of AEFI

AEFIs must be reported to BoMRA through EPI focal persons within your respective DHMTs.

Report all AEFI to BoMRA: **aefi@bomra.co.bw.**
WhatsApp numbers – 75846041; 75846037
AEFI Reporting Forms– You may download the forms from BoMRA website **www.bomra.co.bw.**
For any other information contact us at

Phone - Call 3731754 /66/88/ 53 / 71

For more information about the COVID-19 vaccines or any other medicine contact **BoMRA National Medicines Information Centre** at 3731788/71 or email **nmic@bomra.co.bw.**

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