MEDIA STATEMENT

Update on COVID-19 Vaccine Janssen – Guillain-Barré syndrome

04 August 2022

Pretoria, 4 August 2022- On 31 March 2021, SAHPRA approved the use of the COVID-19 Vaccine Janssen for individuals 18 years of age and older as a single primary vaccination dose. COVID-19 Vaccine Janssen was later approved as a single booster dose given at least two months after the primary vaccination dose. On 22 December 2021, it was approved as a heterologous booster dose following completion of primary vaccination with a different COVID-19 vaccine. COVID-19 Vaccine Janssen is one of the vaccines provided in the national roll-out, which commenced on 17 May 2021. To date 9 135 189 doses of the COVID-19 Vaccine Janssen have been administered in South Africa.

Monitoring the safety of all health products is one of SAHPRA's key functions. In the case of vaccines, the Minister of Health has appointed a specialist committee, the National Immunisation Safety Expert Committee (NISEC), to specifically review and assess severe adverse events reported after immunisation and establish whether or not they are associated with the use of the vaccine. This is called causality assessment. SAHPRA works closely with both the National Department of Health and NISEC to ensure that all reported severe adverse events are firstly investigated by the provinces, and thereafter assessed for causality by NISEC. Against this background, SAHPRA has been informed of a fatal case of Guillain-Barré syndrome (GBS) following vaccination with COVID-19 Vaccine Janssen. Causality assessment of the reported case was conducted by the NISEC using the World Health Organization's (WHO) methodology. The case was classified as a vaccine product-related event where immunisation with the COVID-19 Vaccine Janssen was associated with the occurrence of GBS in the vaccine recipient. The events reported in the vaccine recipient were consistent with the case definition for GBS and no other likely cause of GBS was identified at the time of illness.

GBS is a very rare but severe adverse event that is associated with the administration of various vaccines and other medicines and can also be triggered by infections such as SARS-CoV-2. GBS is a rare condition affecting the body's immune system. Symptoms of GBS can vary from being mild to severe, and include muscle weakness, muscle pain, numbness, and tingling. In many cases, GBS gets better with no serious aftereffects but in some cases GBS can become serious and cause paralysis and other serious or life-threatening problems, such as breathing problems and abnormal blood pressure or heart rate. GBS-associated paralysis can require intense care with ventilatory support, which can be complicated by life-threatening infection.

Regulatory authorities have previously investigated reports of GBS associated with COVID-19 vaccines. In July 2021, the European Medicine Agency conducted a review of 108 suspected cases of GBS reported worldwide after 21 million people had received the COVID-19 Vaccine Janssen. They concluded that there is a possible increased risk and causal relationship between GBS occurrence and the COVID-19 Vaccine Janssen. GBS is therefore listed as a rare adverse event in the professional information (PI) for COVID-19 Vaccine Janssen.

Investigations and causality assessment of all severe reported adverse events following immunisation (AEFI) with the COVID-19 Vaccine Janssen and other COVID-19 vaccines is ongoing. An update on the outcome of these investigations and causality assessments will be shared with the public as they become available.

Important points to note

COVID-19 vaccines have consistently been shown to prevent severe forms of disease, hospitalisation and death. Based on the currently available evidence, SAHPRA has determined that the benefits of COVID-19 vaccination far outweigh the very low risk of severe adverse events, including GBS. The public are strongly advised not to delay COVID-19 vaccination if eligible in terms of the national vaccination programme.

SAHPRA urges the public to report any suspected adverse events following the use of all medicines and vaccines. Reporting can be done at a health facility or by downloading the Med Safety App (https://medsafety.sahpra.org.za/), which is available for Android and iOS phones, or by calling the COVID-19 hotline at 0800 029 999. More information regarding AEFI reported for the COVID-19 vaccines and how to report AEFI is available from the SAHPRA website: https://aefi-reporting.sahpra.org.za/

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965, as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

There will be a podcast available for radio shortly.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.