MEDIA RELEASE

COVID-19 Vaccine Janssen update – Third fatal case of Guillain-Barré syndrome

Embargo: Immediate release

Pretoria, 21 April 2023 – The South African Health Products Regulatory Authority (SAHPRA) issued media statements on 4 August 2022 and 12 September 2022, relating to two fatal cases of Guillain-Barré syndrome (GBS) following vaccination with COVID-19 Vaccine Janssen. SAHPRA has been informed of a third fatal case of GBS following vaccination with the same vaccine.

A causality assessment of the reported case was conducted by the National Immunisation Safety Expert Committee (NISEC) using the World Health Organization's (WHO) methodology. Following investigations, the case was classified as a vaccine product-related event. The events reported in the vaccine recipient were consistent with the case definition of GBS and no other likely cause of GBS was identified at the time of illness.

As previously communicated, GBS is a very rare but potentially severe neurological adverse event that is associated with the administration of various vaccines and other medicines and can also be triggered by some bacterial or viral infections, including SARS-CoV-2. Symptoms of GBS range from mild to severe, and may include muscle weakness, muscle pain, numbness, and tingling. In many cases, GBS resolves with no serious after-effects, but in some cases GBS can cause serious or life-threatening problems.

Regulatory authorities have previously investigated reports of GBS associated with COVID-19 vaccines. They concluded that COVID-19 Vaccine Janssen may increase the risk of GBS. 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 reported severe adverse events following

immunisation (AEFI) with all COVID-19 vaccines are ongoing. The outcomes of these investigations and causality assessments will be shared with the public as soon as they are completed.

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 AEFIs reported for the COVID-19 vaccines **and how to report an 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.

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