

## Second death linked to J&J Covid-19 vaccine confirmed

South Africa has recorded its second fatal case of Guillain-Barre syndrome (GBS) following vaccination with the Johnson & Johnson (J&J) Covid-19 jab, the South African Health Products Regulatory Authority (Sahpra) has announced.



Source: **Pixabay** 

"Causality assessment of the reported case was conducted by the National Immunisation Safety Expert Committee (Nisec) using the World Health Organisation's (WHO) methodology," the Sahpra explained.

"The case was classified as a vaccine product-related event following investigations conducted and causality assessment. 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."

In August, Sahpra confirmed the first GBS death linked to the J&J shot also known as the Janssen Covid-19 vaccine.

According to the local drug watchdog, GBS is a very rare but potentially severe neurological adverse event that is associated with the administration of various vaccines and other medicines. It can be triggered by some bacterial or viral infections including Sars-CoV-2.

Symptoms of GBS, according to the Sahpra, range from mild to severe. They 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."

In a statement, Sahpra said regulatory authorities have previously investigated reports of GBS associated with Covid-19 vaccines.

"They concluded that Janssen may increase the risk of GBS. GBS is therefore listed as a rare adverse event in the professional information (PI) for Janssen."



Claimed pioneer of mRNA technology files patent infringement lawsuit against BioNTech

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Meanwhile, according to the regulator, investigations and causality assessments of all reported severe adverse events following immunisation (AEFI) with the J&J Covid-19 vaccine and others are ongoing.

"The outcomes of these investigations and causality assessments will be shared with the public as soon as they are completed."

Sahpra said it was important to note that Covid-19 jabs 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 is strongly advised not to delay Covid-19 vaccination if eligible in terms of the national vaccination programme."

In addition, 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 here

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