

# Health Authorities Confirm First Vaccine-related Death in South Africa

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*The South African Health Products Regulatory Authority has confirmed that a person died of Guillain-Barré syndrome that was causally linked to receiving the Johnson & Johnson Covid-19 vaccine.*

A patient who had received the Johnson & Johnson Covid-19 vaccine has died after developing Guillain-Barré syndrome (GBS) and a prolonged hospital stay.

To protect patient confidentiality, and because it is such a rare disease, Professor Hannelie Meyer from the National Immunisation Safety Committee said no patient details, not even the province where the death occurred, will be made public.

She has confirmed that they have positively linked the cause of death to the vaccine.

“It is a very rare event,” she said. “The person presented with the symptoms shortly after vaccination and this had led to prolonged hospitalisation, mechanical ventilation and further infections.”

GBS has been identified before as a possible side-effect of the vaccine. It has also been identified as a post-infection complication of Covid-19.

On 13 July, the American Food and Drug Administration revised its fact sheets for the J&J Covid-19 vaccine to include information pertaining to an observed increased risk of GBS following vaccination.

At the time there were about 100 preliminary reports of GBS in the US related to 12.5 million doses of the J&J vaccine. Of these, 95 were serious and required hospital admission. There was one reported death.

GBS is an immune system disorder where the body’s immune cells attack the nervous

system and cause weakness and tingling in the arms and legs.

Professor Marc Blokman, who specialises in clinical pharmacology, said GBS was very rare and affected about 100,000 people worldwide every year.

“It can be mild but it can also lead to either rapid or progressive weakness and has the potential to affect the respiratory system,” he said. GBS could be caused by bacterial or viral infections and certain medicines or vaccines could predispose patients to develop the syndrome.

“We were acutely aware of it and it was part of the vigilance plan.”

He said the reported death due to the Covid-19 vaccine mirrors the situation in other countries.

“It is exceedingly rare. Very few cases are reported and even fewer are confirmed as being caused by the Covid-19 vaccine.

“We are convinced that the benefits of the vaccine still greatly outweigh adverse events.”

### See the case ‘in proportion’

The chairperson of the South African Health Products Regulatory Authority (Sahpra) board, Helen Rees, said the country would not have seen such a rare side-effect if the vaccine had not been rolled out to millions.

“We must be very careful to keep this event in proportion,” she said. “We must ask what is the risk of the disease itself?”

She said they were discussing the case with the World Health Organization and other regulators and can confirm that it was very, very rare.

Sahpra’s chief, Dr Boitumelo Semete-Makokotlela, said this was the first death confirmed to be linked to the Covid-19 vaccine.

“There is one death after nine million doses of the vaccine,” she said.

They had assessed the deaths of 160 people up to now for possibly being caused by the Covid-19 vaccine and this was the first that had not been coincidental.

She said the investigation was still ongoing in a number of other cases.

Dr Nicholas Crisp, the deputy director-general in the Health Department, said a compensation fund for people harmed by the Covid-19 vaccine has to date received 75 claims that were causally linked to the vaccine and more are under investigation.

Headaches, dizziness, fever and pain were among the most common side-effects reported, according to data gathered from Sahpra’s safety app.

Sahpra statistics show that between 17 May 2021 and 15 July 2022, 217 deaths were reported to them with claims that it was linked to the Covid-19 vaccine.

Of these, 33 were under investigation and investigation for 184 had been finalised. In 154 cases the deaths were found to be coincidental. In 88 cases the deceased had Covid-19 and in two cases they had died of complications after a breakthrough infection.

In 30 cases the deaths could not be investigated properly due to a lack of information.

Meyer said they received a number of reports for anaphylaxis, a potentially fatal allergic reaction, but on investigation it was just a “very bad reaction”.

Among the serious adverse events investigated, about 70% had been coincidental and many had been stress-related.

But for less-severe reactions patients most often reported severe headaches, with 870 having received the Pfizer jab, a two-dose vaccine, and 372 the J&J shot.

Fever as a side-effect was reported by 176 patients who received the J&J vaccine and 440 who had Pfizer’s. Pain was reported by 147 patients who received the J&J vaccine and 320 who had the Pfizer vaccine.

Close to 300 people who received the Pfizer vaccine reported nausea, as did 147 people who were jabbed with J&J’s vaccine.

A total of 360 people who received either of the Covid-19 vaccines also reported shortness of breath, while about 480 reported dizziness.

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