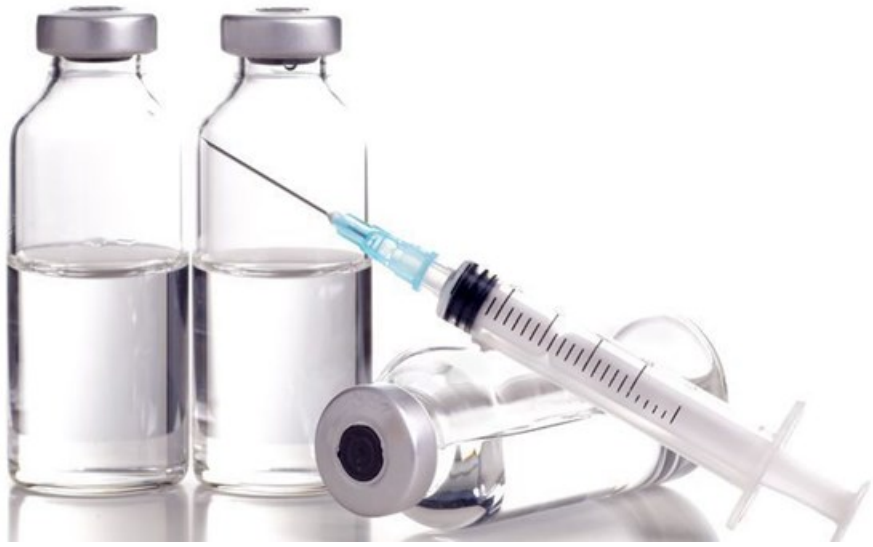
Sahpra finds deaths are not Covid-19 vaccine-related

The South African Health Products Regulatory Authority's (Sahpra) says that the investigation in deaths allegedly after the person received the Covid-19 shot found that most of them were not related or linked to the vaccination.



Source: 123rf.com

“To date, investigations for 32 death cases have been completed and causality assessment concluded, of which 28 were coincidental to vaccination,” the drug watchdog says.

“Four cases are unfortunately unclassifiable because there was either no information available about the case or the information was completely inadequate. Hence, causality assessment could not be conducted or concluded,” it says.

Sahpra defines a coincidental adverse event as one that occurred after or at the same time as exposure to medicine or vaccine, but which is not caused by that exposure.

In the case of a death that occurred after a person receives their jab, certain information should be submitted to conduct a comprehensive causality assessment.

This includes an autopsy or post-mortem examination, full clinical history, including any comorbidities and allergies, and all medicines that are taken before and at the time of the adverse event.

“It may not be possible to accurately determine causality when the information provided is incomplete,” the statement read, adding that timeous reporting is equally important to ensure a thorough investigation.

Adverse events following immunisation

Meanwhile, as of 31 July 2021, Sahpra said it received 1,473 reports of adverse events following immunisation (AEFI) since the start of the national vaccination rollout programme.

According to the drug watchdog, most of these were mild and already listed in the internationally approved product information.

“These reports account for a 0.02% reporting rate of the almost 7.1-million doses of Covid-19 vaccines administered in South Africa by then.”

Sahpra said mild and non-serious AEFI usually resolves within a few days after vaccination and without any prolonged negative outcomes.

These may include mild headache, pain and redness at the injection site, and mild fever.

Adverse events of special interest

Meanwhile, the World Health Organisation (WHO) has designated certain unexpected medical problems as adverse events of special interest (AESI), SAHPRA said.

The US Food and Drug Administration (FDA) defines AESI, serious or not, as an event of scientific and medical concern specific to the sponsor’s product or programme, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate.

According to Sahpra, reported serious AEFI, including AESI, is extremely rare for the Covid-19 vaccines.

Serious AEFI is those side effects that require hospitalisation, may be life-threatening, result in a congenital anomaly, birth defect, or even death.

“Serious AEFI should be reported immediately by the healthcare professional responsible for the patient’s care,” Sahpra says.

In addition, once all the information about the case is available, the National Immunisation Safety Expert Committee (NISEC), which is an independent ministerial advisory committee, conducts a causality assessment.

Staff members from Sahpra and the Health Department’s Expanded Programme on Immunisation (EPI), responsible for the COVID-19 vaccination programme, will then provide secretarial support to the weekly National Immunisation Safety Expert Committee (NISEC) meetings.

“Once completed, the NISEC assessment is shared with Sahpra and the department for further action, if necessary.”