MEDIA RELEASE

SAHPRA Statement on Adverse Events Following Immunisation (AEFIs) with COVID 19 Vaccines

Embargo: Immediate Release

Pretoria, 20 August 2021

The South African Health Products Regulatory Authority (SAHPRA) has a mandate to oversee the safety, efficacy and quality of all medicines registered in South Africa, including vaccines. The National Department of Health (NDoH) Expanded Programme on Immunisation (EPI) is responsible for the COVID-19 vaccination programme, and therefore collaborates with SAHPRA to oversee vaccine safety monitoring and reporting of adverse events following immunisation (AEFIs) throughout the country. Suspected AEFIs to COVID-19 vaccines are reported by health professionals and the public to SAHPRA and the NDoH. Certain adverse events have been designated by World Health Organisation (WHO) as adverse events of special interest (AESI). AESIs need to be carefully monitored and any potential association with vaccination must be confirmed by further investigation.

Since the official national roll-out of COVID-19 vaccines commenced on 17 May 2021, SAHPRA had received 1 473 reports of AEFIs by 31 July 2021, of which most were mild, non-serious 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. Mild and non-serious AEFIs are expected to resolve within a few days after vaccination, and without any prolonged or persistent negative outcomes. Examples of these include mild headache, pain and redness at the injection site, and mild fever.

Reported serious AEFIs, including AESIs, have been found to be extremely rare for the COVID-19 vaccines. Serious AEFIs are defined those that:

- require hospitalisation or prolong an existing hospitalisation;
- may be life threatening;
- result in a congenital anomaly/birth defect; or
- result in death.

Serious AEFIs should be reported immediately by the healthcare professional(s) responsible for the patient's care. Following receipt of a report of a serious AEFI/AESI, an investigation is conducted by a multi-disciplinary team from the district or the province, preferably within 48 hours. Once all the information about the case is available, causality assessment is conducted by the National Immunisation Safety Expert Committee (NISEC); an independent ministerial advisory committee. Staff members from SAHPRA and the EPI provide secretarial support to the weekly NISEC meetings. Once completed, the NISEC assessment is shared with SAHPRA and the NDoH for further action, if necessary.

Causality assessment is a procedure used to determine the true relationship between a medicine/vaccine and the occurrence of an adverse event. The purpose of causality assessment is to determine the likelihood that the event might have been caused by the medicine/vaccine received, or occurred by chance. A coincidental adverse event is one which occurred after or at the same time as exposure to the medicine/vaccine, but which is not caused by that exposure. As causality assessment takes time to complete and requires close examination of the available evidence, reported cases may be at various stages of investigation and assessment. All necessary information about the case must be reported and available in order for causality assessment to be reliably concluded. Timeous reporting of the case is equally important to ensure thorough investigation and urgent action, if required.

In the case of a death that occurred after vaccination, the following information must be submitted, to facilitate a comprehensive causality assessment:

- An autopsy or post-mortem examination;
- Full clinical history, including any comorbidities and allergies; and
- Listing of all medicines taken prior to and at the time of the adverse event.

It may not be possible to accurately determine causality when the information provided is incomplete.

To date, investigations for 32 death cases have been completed and causality assessment concluded, of which 28 were coincidental to vaccination. This means that these deaths were not related/linked to the vaccination. 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.

The public and health professionals are encouraged to report AEFIs to the health facility delivering the vaccine, on the Med Safety App (which can be downloaded from App Stores for Android and iOS phones), or by calling the COVID-19 hotline on 0800 029 999.

SAHPRA is launching a microsite, in collaboration with the NDoH, where all information pertaining to AEFI reports received will be communicated to the public. The data on the microsite is two weeks behind and updates will be loaded on a weekly basis.

Issued by:

Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Cell: 066 1202 669

E-mail: yuveng@sahpra.org.za

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.