**MEDIA RELEASE**

**SAHPRA clarifies the risks and benefits of the Pfizer Comirnaty vaccine**

**Embargo: Immediate release**

**Pretoria, 11 March 2022:** The South Africa Health Products Regulatory Authority (SAHPRA) has noted that a safety report in relation to the COVID-19 Pfizer Comirnaty vaccine directed to the United States Food and Drug Administration (FDA) has been distributed on various communication platforms in South Africa. Pfizer's "COMIRNATY" vaccine is authorised for use in South Africa by SAHPRA in adults and children aged 12 years and older.

SAHPRA has a mandate to oversee the safety, efficacy and quality of all health products registered in South Africa, including vaccines. All COVID-19 vaccines authorised for use in South Africa have been evaluated for quality, safety and efficacy, and have proven to prevent serious disease and death from the COVID-19 disease.

SAHPRA monitors two types of adverse events as part of its stringent regulatory processes:

- **Adverse events following immunisation (AEFIs)**. This involves a medical event following immunisation. This will include symptoms such as fever, pain and other such ailments. This type of event has not been proven to be associated with a vaccine.
- **Adverse events of special interest (AESIs)**. Certain adverse events have been flagged by the World Health Organisation (WHO) as adverse events of special interest (AESI). AESIs need to be carefully monitored for potential association with vaccination and must be confirmed by further investigation.

Vaccine manufacturers must provide SAHPRA with risk management plans (RMPs), indicating how identified risks will be mitigated. Furthermore, safety reports are submitted to SAHPRA during the full cycle of the vaccine rollout process where vaccine safety issues are identified, monitored and assessed.

The safety report issued by Pfizer indicates all AESIs reported during the reporting period. However, not all AESIs included in the report are linked to the vaccine. As these vaccines are still new, their safety profiles are evolving and investigations are ongoing; hence the need for the continuous monitoring. Based on the latest periodically reported safety data reviewed by SAHPRA for Pfizer COVID-19 vaccines, the benefit-risk profile of this vaccine remains favourable and safe to be administered as per the roll-out schedule.

"SAHPRA ensures that all health products, including vaccines, have undergone the requisite evaluation and assessments that meet regulatory requirement prior to being made available to the public. Safety is an important concern and no product, including vaccines, will be made available to the public if there are any indications that public safety will be compromised," indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

SAHPRA will host a webinar to discuss vaccine safety and adverse events. Click here to register: https://path.zoom.us/webinar/register/WN_R8xxDvbjRmmXqVy3erG1Qg

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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.

**Notes to Editors:**

SAHPRA will post this media release on our website. Navigate to the News section on the website.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.