COVID-19 Vaccines – Possible Risk of Menstrual Disorders

Pretoria, 02 February 2022 – To date, SAHPRA has authorised the Pfizer/BioNTech vaccine "Comirnaty", the Janssen Covid-19 vaccine, and Sinovac's "Coronavac" vaccine (submitted by Curanto Pharma). SAHPRA is currently evaluating a number of applications for emergency use (Section 21) and/or registration of COVID-19 vaccines. A national vaccine roll-out commenced on 17 May 2021 with both the Comirnaty (Pfizer-BioNTech) vaccine and COVID-19 Vaccine Janssen.

This communication serves to update members of the public regarding reports of adverse events following immunisation (AEFIs) associated with COVID-19 vaccine administration. All medicines, including vaccines, can cause side effects. In the case of vaccines, adverse events that occur after vaccine administration are known as AEFIs. An untoward event which follows immunisation does not necessarily have a causal relationship with the administration of the vaccine. It is important that the causal link between an adverse event and vaccine administration be established.

SAHPRA is aware of the menstrual disorder reports received in the vaccine safety database via the recommended channels of reporting of AEFIs for COVID-19 vaccines. A total of 90 menstrual disorder events have been received since the national roll out on 17 May 2021. Taking into account 9.85 million vaccinations carried out in the adult female population as at 07 January 2022, the event reporting rate is 0.91 per 100 000 vaccinations (9 (nine) events following 1 million vaccinations). Commonly reported menstrual disorders are heavy menstrual bleeding, pains prior to menstruation and intermenstrual bleeding while other menstrual disorders were not specified.

Studies have reported that most women may have experienced changes to their menstrual cycle owing to the COVID-19 pandemic-related factors such as behavioural changes, anxiety, and COVID-19 infections.

Other regulatory authorities have also looked into the menstrual disorder events associated with COVID-19 vaccines. The European Medicine Agency conducted a review of menstrual disorders reported worldwide and about half of the reports had past or current relevant medical or concomitant medication as an alternative explanation for menstrual disorder. The review further concluded no evidence for causal relationship for the occurrence of menstrual disorder with Comirnaty. Further research to investigate how COVID-19 vaccination can disrupt menstrual cycle is necessary.

SAHPRA and the National Department of Health are currently monitoring and investigating these events in order to determine the causal link. COVID-19 vaccines have proven to prevent severe form of disease, hospitalisation and death. Based on the current knowledge and evidence, SAHPRA strongly believes that the benefits of COVID-19 vaccination still outweighs a relatively insignificant risk (9 events per 1 million vaccinations) of possible temporary menstrual cycle disorder following vaccination.
SAHPRA will share updates or information regarding the outcome of the investigations on the AEFI Reporting Dashboard as soon as it becomes available. SAHPRA discourages any delay in COVID-19 vaccination while investigations of these events are ongoing. More information regarding AEFIs for COVID-19 vaccines is available from the SAHPRA website: https://aefi-reporting.sahpra.org.za/

We urge the public to report suspected adverse events they experience following use of all medicines and vaccines. Reporting can be done at a health facility or by downloading and reporting on the Med

Safety App, which is available for Android and iOS phones, or phone the COVID-19 hotline at 0800 029 999. More information on reporting adverse events following immunisation is available from the SAHPRA website: https://medsafety.sahpra.org.za/

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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.