MEDIA STATEMENT

Safety of the COVID-19 Vaccine Janssen – response to restrictions imposed in the United States

Embargo: Immediate release

Pretoria, 12 May 2022 – In both the United States and South Africa, the COVID-19 Vaccine Janssen has been approved as a single primary vaccination dose, a single booster dose at least two months after the primary vaccination dose, and as a heterologous booster dose following completion of primary vaccination with a different COVID-19 vaccine.

On 5 May 2022, the United States Food and Drug Administration (FDA) revised the approval of the COVID-19 Vaccine Janssen for use in that country with specific restrictions. In the United States, the vaccine may only be administered to individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive this vaccine because they would otherwise not receive a COVID-19 vaccine.

The FDA had noted 60 confirmed cases of a rare but life-threatening syndrome of blood clots in combination with low levels of platelets, referred to as thrombosis with thrombocytopenia syndrome (TTS). The onset of symptoms occurred approximately one to two weeks following administration of the COVID-19 Vaccine Janssen. It must be noted that this is not a new signal as it was already reported in 2021.

On 31 March 2021, SAHPRA approved the use of the COVID-19 Vaccine Janssen in individuals 18 years of age and older. The SAHPRA-approved professional information (PI) notes that the safety and efficacy of COVID-19 Vaccine Janssen have not yet been established in children and adolescents (younger than 18 years of age). SAHPRA approved the COVID-19 Vaccine Janssen booster dose on 22 December 2021, for individuals 18 years of age and older.

The risk of TTS is addressed in the approved professional information (PI) and patient information leaflet (PIL) for the COVID-19 Vaccine Janssen. The PI and PIL contraindicates the use of this vaccine in individuals with a history of TTS. Furthermore, TTS is included in the PI and PIL as a special warning and is listed as an undesirable effect.

SAHPRA has been informed of four cases of TTS in South Africa following 8 589 109 vaccinations with the COVID-19 Vaccine Janssen (including Sisonke study doses). Two cases reported from the Sisonke cohort were confirmed to be TTS and have fully recovered. The remaining two cases are still under investigation. SAHPRA will share further information with

the public as soon as the investigations are completed, and causality is assessed.

SAHPRA, in line with the World Health Organization (WHO), as well as the European Medicines Agency (EMA), has determined that the known benefits of COVID-19 Vaccine Janssen for the prevention of COVID-19 greatly outweigh the known and potential risks of receiving the vaccine. SAHPRA continues to monitor closely the efficacy against variants of concern and the safety profile of the COVID-19 Vaccine Janssen as determined in the approved risk management plan. The COVID-19 Vaccine Janssen remains effective in reducing disease severity and hospitilisation.

Healthcare professionals and the public are encouraged to report all adverse events following immunisation with COVID-19 vaccines, including the COVID-19 Vaccine Janssen, via the Med Safety App. The App can be downloaded through the Google Play or App store. For more information on reporting adverse events following immunisation, please visit the SAHPRA website (https://aefi-reporting.sahpra.org.za/index.html).

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Notes:

1. The US FDA announcement can be accessed at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.

2. The SAHPRA-approved PI and PIL for the COVID-19 Vaccine Janssen can be accessed at http://pi-pil-repository.sahpra.org.za/wp-content/uploads/2022/04/pi-approved-Covid-19-vaccine-Janssen-suspension-for-injection-ZA-English-shelf-life-extension-transverse-myelitis-april2022.pdf and http://pi-pil-repository.sahpra.org.za/wp-content/uploads/2022/04/pil-approved-Covid-19-vaccine-suspension-for-injection-ZA-English-shelf-life-extension-transverse-myelitis-april2022.pdf.

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:
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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.

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