MEDIA RELEASE

SAHPRA registers the COVID-19 Vaccine Janssen

Embargo: Immediate release

Pretoria, 1 April 2021 – SAHPRA registered the Covid-19 Vaccine Janssen on 31 March 2021, with conditions**.** The registration was done in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965.

The Covid-19 Vaccine Janssen is an adenovirus type 26 vectored vaccine indicated for active immunisation against SARS-CoV-2. The administration of the Janssen Covid-19 Vaccine may contribute to protection against COVID-19.

"This registration signals a significant step in the fight against the COVID-19 pandemic. This authorisation is based on acceptable safety, quality and efficacy data submitted by JANSSEN PHARMACEUTICA (PTY) LTD to SAHPRA as a rolling submission over the period 11 December 2020 to 17 March 2021. The authorisation is, however, subject to a number of conditions which includes that the vaccine is supplied and administered in accordance with the NDoH COVID-19 vaccination plan and applicable guidelines. Further conditions relate to the reporting of the results of ongoing studies and conformance with pharmacovigilance activities as outlined in the approved risk management plan, including the submission of periodic safety updates" indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

The Covid-19 Vaccine Janssen is administered as a single dose by intramuscular injection to individuals 18 years and older.

The side effects of the COVID-19 Vaccine Janssen, as outlined in the clinical trial evidence submitted by the applicant, were usually mild or moderate and cleared within a few of days after vaccination. The most common side effects reported were pain at the injection site, headache, tiredness, muscle pain and nausea.

The current assigned provisional shelf-life of the vaccine is twenty-four (24) months when stored at -25°C to - 15°C. Within these 24 months, the vaccine may be stored for a three (3) month period at 2°C - 8°C. Once the vaccine has been thawed it cannot be re-frozen. The vaccine should be discarded within six hours after opening or at the end of an immunisation session, whichever comes first.

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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.