MEDIA RELEASE

SAHPRA approval of second/booster dose of the COVID-19 vaccine Janssen

Embargo: Immediate release

Pretoria, 23 December 2021- The South African Health Products Authority (SAHPRA) initially registered the COVID-19 Vaccine Janssen, with conditions on 30 March 2021, in terms of section 15 of the Medicines and Related Substance Act (Act 101 of 1965).

On 10 December 2021, SAHPRA received an application from Janssen to amend the dosing schedule for the COVID-19 Vaccine Janssen (Ad26.COV2.S), allowing for 2nd dose at least 2 months after primary vaccination and the use of Ad26.COV2.S for heterologous booster immunisation following completion of primary vaccination with an approved mRNA COVID- 19 vaccine. SAHPRA reviewed the safety and efficacy data provided and has subsequently approved the COVID-19 Vaccines Janssen 2nd dose/booster dose as follows:

a. A second dose of 0.5 mL of COVID-19 Vaccine Janssen may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older
b. A booster dose of the COVID-19 Vaccine Janssen (0.5 mL) may be administered as a heterologous booster dose following completion of primary vaccination with an approved mRNA COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorised for a booster dose of the vaccine used for primary vaccination.

Issued by:

Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Ms Nthabi Moloi

Cell: 082 407 8854

E-mail: nthabi.moloi@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.