SAHPRA registers Covid-19 Vaccine Janssen (Ad26.COV2-S [recombinant]) with conditions

The South African Health Products Authority (SAHPRA) registered the Covid-19 Vaccine Janssen on 31 March 2021**.** The registration was done in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965, which allows SAHPRA to register a medicine subject to certain conditions.

The Covid-19 Vaccine Janssen is a monovalent, recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding a severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) Spike (S) protein indicated for active immunisation against COVID-19. Following administration of the Covid-19 Vaccine Janssen, the S glycoprotein of SARSCoV-2 is transiently expressed, stimulating both neutralising and other functional S-specific antibodies, as well as cellular immune responses directed against the S antigen, which may contribute to protection against COVID-19.

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 submission of periodic safety updates in accordance with SAHPRA guidance, the reporting of the results of ongoing studies and conformance with pharmacovigilance activities as outlined in the approved risk management plan.

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

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

The current assigned provisional shelf-life of the vaccine is 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 refrozen. The vaccine should be discarded within six hours after opening or at the end of an immunisation session, whichever comes first.