Sahpra approves J&J vaccine with conditions

The South African Health Products Regulatory Authority (Sahpra) has registered the Covid-19 Johnson & Johnson vaccine in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965, with conditions.

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“This registration signals a significant step in the fight against the Covid-19 pandemic,” said Sahpra CEO, Dr Boitumelo Semete-Makokotlela.

The authorisation is based on acceptable safety, quality and efficacy data submitted by Janssen Pharmaceutica (Johnson & Johnson) to Sahpra as a rolling submission between 11 December 2020 and 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 National Department of Health 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,” she says.

The vaccine is administered as a single dose by intramuscular injection to individuals 18 years and older.

According to Sahpra, the side effects as outlined in the clinical trial evidence submitted by the applicant were usually mild

or moderate and cleared within a few 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 24 months when stored at minus 25 to minus 15 degrees Celsius.

“Within these 24 months, the vaccine may be stored for a three-month period at 2 to 8 degrees Celsius. 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.” –