MEDIA RELEASE

SAHPRA update COVID-19 Vaccine Janssen – FDA Developments

Embargo: Immediate release

13 June 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 authorisation is, however, subject to a number of conditions which include that the vaccine should be manufactured under conditions of Good Manufacturing Practices (GMP) as determined by SAHPRA and aligned with global best practice.

A concern was identified by the USFDA, relating to non-compliance with GMP at the Emergent plant in Baltimore, USA, during the manufacturing of drug substance which is used in the manufacture of theCovid-19 vaccine Janssen.

Subsequently, on 11 June 2021, the USFDA authorised two batches of drug substance produced from the Emergent site and further determined that several other batches are not suitable for use. SAHPRA reviewed the data provided by the FDA and has made a decision not to release vaccine produced using the drug substance batches that were not suitable.

However, there are approximately 300 000 doses from batches that have been cleared by the USFDA that meet the requirements and will subsequently be released and shipped to South Africa.

“SAHPRA focuses on the quality, safety and efficacy of all health products, including COVID-19 vaccines and will ensure that the safety and well-being of South Africans will not be compromised in any way,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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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.