MEDIA RELEASE

SAHPRA update on the COVID-19 Vaccine Janssen – GMP Concerns

Embargo: Immediate release

7 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 includes that the vaccine should be manufactured under conditions of Good Manufacturing Practices (GMP) as determined by SAHPRA and aligned with global best practice. The manufacturing process of a vaccine and its active pharmaceutical ingredient requires stringent quality checks to ensure that the end product meets the requisite standards.

Nearly all the vaccines used in South Africa are manufactured in other countries, and SAHPRA requires documentation that confirms the quality of these vaccines from the regulatory authority in the country of manufacture. Through an arrangement called reliance, SAHPRA has formal relationships with certain regulatory authorities that allow for the confidential exchange of information. For vaccine approvals, this allows SAHPRA to access reports produced by other regulatory agencies on inspections, testing and various other aspects of manufacturing and testing compliance. SAHPRA has such a reliance arrangement with the USFDA. In addition, SAHPRA relies on lot release testing undertaken by these partnering agencies which involves reviewing manufacturing documentation and performing certain quality tests to ensure compliance with the approved and registered requirements.

A concern was identified by the FDA, relating to non-compliance to GMP at the Emergent plant in Baltimore, USA, during the manufacturing of some active pharmaceutical ingredient

used in the Janssen Covid-19 vaccine. The non-compliant batch has been rejected; however, the incident has led to the investigation of four more batches by the US FDA, and SAHPRA is awaiting reports from the US FDA on whether or not these other batches were manufactured according to GMP standards and if the batches are contaminated. Until the FDA has shared these reports, SAHPRA has insufficient information to approve specific batches of the Janssen COVID-19 vaccine.

"SAHPRA is in continuous discussion with the USFDA to ensure that this matter is resolved speedily. SAHPRA will take all the necessary steps to ensure that the vaccines that are administered to South Africans meet all the requisite stringent standards so that the health and well being of all who live in South Africa are not 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.