SAHPRA Statement

Update:

Pretoria, 31 March 2022 – SAHPRA has assigned a non-compliant rating to the Emergent BioSolutions COVID-19 facility based on new data received. This was following a collaborative inspection which was conducted both onsite and via remote inspection. This means that SAHPRA will not accept any drug products or drug substance manufactured at this facility until another Good Manufacturing Practice (GMP) inspection is completed, and the facility meets GMP requirements. None of the Janssen COVID-19 vaccines available in South Africa contain ingredients made at this facility.

Issued by:

Dr Boitumelo Semete

CEO

Boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Mobile: 066 1202 669

E-mail: yuveng@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.