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SAHPRA announces results of onsite inspection at Emergent BioSolutions facility in Baltimore, Maryland

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In June 2021, SAHPRA communicated that South Africa would not accept any product or ingredients made at the Emergent BioSolutions facility in Baltimore, Maryland, until the Inspectorate conducted an onsite/remote inspection. This facility manufactures a drug substance used in some doses of the Janssen COVID-19 vaccine.

The South African Health Products Regulatory Authority in collaboration with the European Medicines Agency (EMA) and Health Canada inspected the site. EMA and SAHPRA participated remotely while Health Canada performed the inspection of Emergent BioSolutions facility in Baltimore, Maryland on-site. All three regulators found the facility to be compliant with Good Manufacturing Practices (GMPs).

SAHPRA, EMA and Health Canada's compliant rating means Janssen will be able to import its vaccine into South Africa, Europe and Canada that was made with the drug substance manufactured at the Emergent BioSolutions facility.

SAHPRA, EMA and Health Canada is communicating with Janssen in the respective countries to confirm which lots of their COVID-19 vaccine is planned to enter the countries in the coming months. Only vaccine lots that meet these requirements will be released onto the South African and related markets.