MEDIA RELEASE

SAHPRA and the SputnikV Vaccine

Embargo: Immediate release

Pretoria, 18 February 2021 – SAHPRA has NOT received documentation for the SputnikV vaccine developed by the Gamaleya Institute in Russia as has been reported.

SAHPRA can confirm that a pre-submission meeting was held. At this stage it is work in progress.

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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.