



## **SAHPRA and the Pfizer/Biontech Comirnaty Vaccine Section 21**

**Embargo: Immediate release**

**Pretoria, 16 March 2021** – SAHPRA has approved the Section 21 application for Pfizer/Biontech Comirnaty Vaccine. This approval is subject to conducting a post Section 21 authorisation efficacy and safety surveillance of Comirnaty vaccine in South Africa (including efficacy against the SARS-CoV2 B.1.351 lineage).

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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.