MEDIA RELEASE

SAHPRA approval of booster dosing with the Pfizer (Comirnaty®) COVID-19 vaccine

Embargo: Immediate release

Pretoria, 8 December 2021- The South African Health Products Authority (SAHPRA) initially approved the use of Pfizer's Comirnaty® COVID-19 vaccine on 16 March 2021, in terms of section 21 of the Medicines and Related Substance Act (Act 101 of 1965).

On 17 November 2021, SAHPRA received an application from Pfizer to amend the dosing schedule for the Comirnaty® COVID-19 vaccine, allowing an optional third (booster) dose. Following evaluation of the data submitted, SAHPRA has approved the following options:

- A third dose of the the Comirnaty® COVID-19 vaccine in individuals aged 18 years and older, to be administered at least 6 months after the second dose.
- A third dose of the the Comirnaty® COVID-19 vaccine in individuals aged 12 years and older who are severely immunocompromised, to be administered at least 28 days after the second dose.

The data provided only dealt with the situation of homologous boosting, where the third dose is of the same vaccine as the initial course (in this case, two doses). SAHPRA is aware of the keen interest in the efficacy and safety of heterologous boosting regimens (so-called "mix-and-match" approaches), and invites submission of supportive data in this regard.

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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.