MEDIA RELEASE

SAHPRA perspectives on Coronavirus SARS-COV-2

Embargo: Immediate release

Pretoria, 15 May 2023 - The South Africa Health Products Regulatory Authority (SAHPRA) acknowledges and aligns itself to the statement issued by the World Health Organization (WHO) Director-General, declaring an end to the Public Health Emergency of International Concern (PHEIC) for the disease caused by the Coronavirus SARS-COV-2.

This is a welcome statement after three years of battling a pandemic of mammoth proportions that caused widespread illness and multiple fatalities.

SAHPRA played in pivotal role in supporting the National response to this Public Health Emergency. SAHPRA engaged in several partnerships with the scientific community, including other regulators, both continentally and globally, thereby ensuring that appropriate vaccines and treatments regimens were backed by sound scientific information and advice.

SAHPRA's stringent, yet responsive review pathways enable it to evaluate COVID-19-related therapeutics, vaccines, and medical devices and IVDs in record time utilising the emergence use authorisation framework. These efforts went a long way in supporting healthcare practitioners in managing disease progression, reducing hospitalisation, and reducing mortality.

Key lessons and insights for SAHPRA during this pandemic were:

1. Collaborating with a strong scientific community and regulators both locally and internationally, enabled SAHPRA to make sound and evidence-based decisions.

2. While SAHPRA was open to considering insights from various stakeholders, it was important that it remains impartial and ensures that it is not influenced by any stakeholder.
3. SAHPRA had to be agile and apply urgency in regulatory processes to accommodate the rapid pace of change in data being generated during the pandemic.
4. It was important that the regulator remained stringent in making science-based regulatory decisions to ensure the safety of the public.

SAHPRA had to engage in various programmes to inform the public and dispel burgeoning myths as the wave of fake news spread as rapidly as the pandemic itself.

Whilst there is a celebratory air as people could drop their masks and engage with each other once again, one must not let down one's guard. The coronavirus is still a health threat and there is a possibility of new variants. **We encourage the public to remain vigilant.**

"I must thank our partners and the scientific community who gave up their time selflessly to assist us in engineering a path to getting us to where we are today. The number of deaths as a consequence of this pandemic is still an indelible scar that we should not forget. I echo, the WHO Director-General, who cautions us to not drop our guard completely and to be prepared in the event that other deadly variants could change the current scenario," says SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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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.