MEDIA RELEASE

SAHPRA SUPPORTS THE PRESIDENT'S PROCLAMATION

For immediate release

Pretoria, 19 October 2019 In February 2019 the South African Health Products Regulatory Authority (SAHPRA) received reports suggesting fraudulent activity implicating a small sector of the authority and an external stakeholder. SAHPRA's acting-CEO, the Board and the Health Minister reported the allegations to the Special Investigating Unit (SIU) and therefore welcomes today's proclamation by President Cyril Ramaphosa authorising the SIU to investigate these matters.

This matter is receiving the requisite prioritisation within SAHPRA.

SAHPRA was established in 2018 replacing the Medicines Control Council and plays a critical role in South Africa's health sector. The new authority aims to create a world class health product regulatory authority and since its inception has made enormous strides towards achieving this. Professor Helen Rees, SAHPRA Board Chairperson, stated that "Core to SAHPRA's success is ethical conduct and good governance. All allegations of misconduct involving either internal or external stakeholders will be thoroughly investigated and responded to."

Ms Portia Nkambule, SAHPRA's acting-CEO added that "SAHPRA is in the process of re-building regulatory systems that improve efficiency, transparency and accountability and this includes developing appropriate communication channels for complaints including the reporting of possible unethical or criminal behaviour."

The SAHPRA Board and staff are committed to achieving SAHPRA's mandate to ensure that all health products available in South Africa are safe, effective and of good quality, and is on track to achieve this.

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About SAHPRA

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products and clinical trials in South Africa. Health products include complementary medicines, medical devices and *in vitro* diagnostics (IVDs). SAHPRA also has the responsibility of overseeing the radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act 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 South Africans:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.