



MEDIA RELEASE

SAHPRA's Response to the Economic Freedom Fighters (EFF) March

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25 June 2021 – The South African Health Products Regulatory Authority (SAHPRA) is an independent, science-based entity that follows strict guidelines and processes when approving health products. SAHPRA concerns itself, like other regulators across the world, with safety, quality and efficacy of health products. These essential requirements are consistently applied to all COVID-19 vaccines and therapeutics that SAHPRA has considered for use in the country.

SAHPRA cannot allow political pressure to cloud a clear science-based approach to approving health products where the safety of the public could be compromised. It will be a sad day in the country when the regulator is undermined or influenced by any party. On 25 June 2021 the EFF handed over a memorandum to the SAHPRA CEO. This will be responded to.

SAHPRA would like to emphasise the following:

- SAHPRA does not favour any applicant as alleged by the Economic Freedom Fighters (EFF)
- Allegations against the SAHPRA Board Chair, Prof Helen Rees are totally unfounded and false.

SAHPRA, as part of its mandate, focuses on the safety and well-being of the public and no vaccine can be made available until it meets these regulatory requirements. Furthermore, SAHPRA must take into account the local epidemiology, and specifically which SARS-CoV-2 variants of concern are circulating in the country. In essence, the EFF wants SAHPRA to

approve vaccines without adherence to the critical components of safety, quality and efficacy. This could compromise public safety.

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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.