MEDIA RELEASE

SAHPRA's vaccine registration process and role of the SAHPRA Board

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30 August 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.

The medicines' approval process entails a rigorous process of assessment, where all information provided by the applicant is carefully evaluated by experts in their respective fields. While SAHPRA has drastically reduced our usual time frames for the registration of COVID-19 vaccines, it has not cut back on the regulatory requirements to ensure that all these health products are safe and effective. SAHPRA will not compromise on the safety of South Africans and will not endanger South African lives. In addition, SAHPRA must take into account the local epidemiology in making decisions. Specifically when it pertains to COVID-19, efficacy of vaccines against the SARS-CoV-2 variants of concern circulating in the country is critical. Applicants have to provide data wherein they demonstrate vaccine efficacy against the variants of concern to SAHPRA. Thus, a key contributor to the time frame is whether this data is readily available from the applicants or not. The calls for SAHPRA to approve vaccines without adherence to the critical components of safety, quality and efficacy could compromise public safety and these calls run contrary to the SAHPRA mandate.

SAHPRA cannot be influenced by political pressure or any other pressure. The safety of the public is the most important priority for SAHPRA. In order to ensure this, SAHPRA applies its

guidelines, regulations and rules consistently. It will be a sad day in the country when the regulator is undermined or influenced by any political party.

Furthermore, the SAHPRA Board, that is appointed by the Minister of Health, is not involved in operational matters of SAHPRA. The Board focuses on matters of Governance as per the Medicines and Related Substances Act, Act 101 of 1965. All regulatory and operational decisions are the responsibility of the SAHPRA CEO and not the SAHPRA Board. The Chairperson of the Board, Prof Helen Rees, does not act alone in terms of Board decisions, but reflects a collective decision by the entire SAHPRA Board.

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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.