**MEDIA RELEASE**

# SAHPRA will commence review of vaccine applications for registration for COVID-19

**Embargo: Immediate release**

**Pretoria, 15 December 2020 –** With the advent of COVID-19, vaccine development is a critical area of need. SAHPRA has been proactive and is prepared for the vaccine registration process. The readiness programme includes the establishment of a specialised working group, the COVID-19 Vaccine Registration Working Group (CVr WG) comprising both external and internal SAHPRA experts specialising in areas of vaccinology, manufacturing, clinical trials, epidemiology, vigilance and other specialisations informing quality, safety and efficacy of the products and this case vaccines.

SAHPRA will prioritise all COVD-19 applications and will apply an expedited approach to health products, including vaccines. For vaccines registration, the expedited process will include using approaches such as:

- Performing rolling reviews of submissions, that is reviewing data that is available and accepting ongoing data in batches for review.
- Reliance on regulatory work done by other regulators that SAHPRA aligns with
- A collaborative approach through the World Health Organisation (WHO)

SAHPRA may issue terms and conditions requiring the applicant to provide additional data confirming the elements of safety, quality and efficacy.

“SAHPRA will review the safety and efficacy of each vaccine on a case-by-case basis and will only grant approval for public use once it has met acceptable standards of quality, safety and efficacy”, indicates Dr Boitumelo Semete-Makokotlela, CEO of SAHPRA.

**Once this approval takes place the National Department of Health (NDoH) will determine access, roll out strategy and distribution.**

Vaccines can prevent disease and also have adverse effects in some individuals. SAHPRA has a mandate to monitor such adverse effects and ensure that they are recorded and managed properly so that, regulatory action can be taken. The development and authorisation of COVID-19 vaccines must be supported by toxicology and safety studies in relevant animal models in compliance with the international standards of Good Laboratory Practices (GLP). If the candidate Covid-19 vaccine is to be used in pregnant women, then developmental and reproductive toxicity studies must be conducted to better understand the risks.

Vaccines can prevent disease and also have adverse effects in some individuals. SAHPRA has a mandate to monitor such adverse effects and ensure that they are recorded and managed properly so that, should a vaccine become problematic, regulatory action can be taken to either warn the public about newly discovered adverse effects or remove the vaccine from the market in order to protect the public. SAHPRA achieves this through its Pharmacovigilance Unit. Reports of suspected adverse events following immunization can be submitted on the SAHPRA website using the link:
[https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA

The public is encouraged to report their suspected vaccine-related complaints through their healthcare provider at the healthcare facility from which the vaccination was administered to ensure that all important and relevant facts are captured on the reporting form to enable proper investigation and handling of the vaccine-related complaint.

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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.