MEDIA RELEASE

SAHPRA update on Vaccine Approvals

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21 June 2021 – The South African Health Products Regulatory Authority (SAHPRA) is an independent health products regulatory authority, governed by national legislation, whose mandate is to ensure the safety, quality and efficacy of health products available in South Africa. These essential requirements have been similarly applied to all COVID-19 vaccines and therapeutics that SAHPRA has considered for use in the country.

The normal process for the evaluation of a vaccine, necessitates that all the required information regarding product safety, efficacy and quality be provided at the time of submission. In other words, all the clinical trial data for safety and efficacy from phase one to three should be provided together with manufacturing information of the product quality. The assessment is then conducted considering all information provided. In the context of the pandemic, SAHPRA has fast tracked all COVID product reviews and like other countries, has approved products on an emergency use basis with product specific requirements for ongoing monitoring.

In an effort to respond to the pandemic, SAHPRA introduced another mechanism to facilitate review of COVID-19 applications, which is the rolling review process. The rolling review is a mechanism that facilitates the submission of data as it becomes available. Whilst reviews can commence earlier with a rolling submission, it is important to note that some very important efficacy, quality and safety information is sometimes outstanding and would require review for consideration of such products for public use. Therefore, Pharmaceutical companies can submit applications indicating a plan of when they will be submitting their data, i.e outline when the next rolling submission sequence is available for review.

When an applicant submits their respective dossiers, SAHPRA works closely with the applicant in evaluating the data. Technical, subject matter experts within SAHPRA and external members who are appointed by the CEO, comprise the team that evaluates these applications. SAHPRA also works closely with other regulators across the world as well as with the World Health Organisation (WHO) in assessing the quality, safety and efficacy of health products, and in this case, COVID-19 vaccines.

Thus far, SAHPRA has approved the AstraZeneca, Pfizer and the J&J vaccines. SAHPRA has also received applications for Coronavac (Manufactured by Sinovac) and the Sputnik V (Manufactured by the Gamaleya Research Institute) vaccines. The evaluation of the Coronovac application is at a very advanced stage. Furthermore, reports recently made available by the WHO that articulate the basis for the Emergency Use Listing for Coronavac are being considered. The Sputnik V application is a rolling review. Thus, as data becomes available to the applicant it is submitted to SAHPRA.

SAHPRA only reviews products submitted to the regulator by a local applicant. If no application has been submitted, no regulatory review can be undertaken. In addition, SAHPRA is not responsible for commissioning or undertaking the research required to support an application. Thus, there is no SAHPRA decision on, for example, Sinopharm and Moderna vaccines which have a WHO Emergency Use Listing, as there have not been any applications for these vaccines in South Africa.

In considering whether or not a vaccine introduced into South Africa is likely to be effective, SAHPRA must take into account the local epidemiology, and specifically which SARS-CoV-2 variants are circulating in the country. All the COVID vaccines currently being used worldwide have been shown to be effective against the SARS-COV-2 variant. However, all these COVID vaccines are less effective against the SARS-CoV-2 variants of concern that have emerged in the past nine months. In South Africa's third wave, the beta variant of concern is responsible for over 95% of infections. For this reason, SAHPRA is asking vaccine applicants to provide laboratory and clinical studies supporting claims about vaccine efficacy when used in the context of the beta variant of concern. If this data are not available, SAHPRA is asking applicants to generate such data. In addition, SAHPRA is working with the expert academics to develop a national protocol to monitor the effectiveness of all vaccines introduced as part of the vaccine rollout.

"SAHPRA is committed to prioritising all COVID-19- related health products, including vaccines, as the world and South Africa grapples with ending the scourge of a pandemic of mammoth proportions. SAHPRA will not be pressured to allow the public access to any product that has not met the necessary regulatory requirements and been found to be appropriate for use in South Africa," indicates 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.