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South African
Health Products
Regulatory Authority

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Media release on the approval process of Covid vaccines

Attn: All Editors
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#Head
Three more Covid vaccines being reviewed for use in South Africa

#Begins
The South African Health Products Regulatory Authority (SAHPRA) has reduced the time taken to register COVID-19 vaccines to less than three months where the required standard of data is available, while continuing to adhere to strict guidelines to ensure the safety of South Africans.

Explaining the applications process to approve COVID-19 vaccines, SAHPRA, an independent body established in terms of the Medicines and Related Substances Act, indicated that approving a new medicine usually takes 20 months, on average. In order to ensure that South Africa has all the weapons available to fight the COVID-19 pandemic, SAHPRA staff have been working around the clock and have reduced that time to less than 90 working days on average, where the required standard of data is available.

SAHPRA also announced that:

- It has so far authorised three COVID-19 vaccines: those manufactured by AstraZeneca, Pfizer and Janssen (Johnson & Johnson);
- It has not received applications for the registration of the vaccines manufactured by Moderna or Novavax;
- It has also not received any applications from Cuban manufacturers;
- The evaluation of the CoronaVac vaccine, manufactured by Sinovac, is at an advanced stage; and
- It is currently reviewing applications for one of the Sinopharm vaccines and for the Sputnik V vaccine, manufactured by the Gamaleya Research Institute.

SAHPRA emphasised that it applies the same criteria to the evaluation of all COVID-19 -vaccine applications, in order to ensure the safety of all South Africans. Every application for registration of a COVID-19 vaccine is evaluated against the same standards of safety, quality and efficacy.

Dr Boitumelo Semete-Makokotlela, SAHPRA Chief Executive Officer, stated: “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 we have drastically reduced our usual time frames for the registration of COVID-19 vaccines, we have not cut back on the checks required to ensure that they are safe and effective. We will not compromise on the safety of South Africans and we will not endanger South African lives.”

“The Sputnik V application is being processed under a rolling review process, meaning that we are processing their application as we receive the data. This vaccine is also being evaluated under Section 21, which enables us to authorise it for emergency use. SAHPRA has held numerous engagements with the representatives of the two applicants for registration of this vaccine. To date,

we have exchanged correspondence on several occasions regarding the data required for their application," says Semete-Makokotlela.

She points out that according to the regulations, SAHPRA can only evaluate an application that has been submitted by a locally licensed applicant.

"We, like the rest of South Africa, may be aware of other vaccines that are being used in other countries but unless we receive an application for its approval, we cannot register it," says Semete-Makokotlela.

She says that in addition to reviewing COVID-19 vaccines, SAHPRA has also been very busy approving other health products required for the testing and care of COVID-19 patients, such as ventilators, diagnostic tests and repurposed medicines.

"Our mandate is not only confined to medicine. It also encompasses the approval of medical devices and diagnostics tests, as well as overseeing clinical trials. Our staff has been working around the clock to ensure that we meet this mandate in the shortest possible time given the monumental challenge confronting South Africa. We have to do so with the primary objective of ensuring the safety of South Africans. We understand that lives depend on us and we hold this responsibility sacrosanct," says Semete-Makokotlela.

SAPHRA says it is deeply dismayed at recent unfounded allegations that it is dragging its heels on registering COVID-19 vaccines.

"As a regulator with integrity, which places the interests of the country it serves and its people at the forefront of its decision-making, SAHPRA is committed to acting responsibly and in accordance with its mandate at all times. SAHPRA strives to be responsive in this time of crisis, ensuring that health products are timeously and appropriately assessed and authorised. We welcome any endeavour by civil society and political parties which can constructively assist SAHPRA in meeting its mandate. We will authorise COVID-19 vaccines which meet the necessary standards of safety, quality and efficacy as soon as is possible," says Semete-Makokotlela.

#ENDS

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