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MEDIA STATEMENT

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HEALTH DEPART MENT WELCOME THE APPROVAL OF CORONAVAC COVID-19 VACCINE

Pretoria: Acting Minister of Health Mamoloko Kubayi has described an announcement by the South African Health Products Authority (SAHPRA) on the approval of the CoronaVac COVID-19 vaccine, manufactured by Sinovac Life Science for use in South Africa as turning point and much needed relief for the country`s vaccination rollout programme.

This authorisation with conditions, is based on the safety, quality and efficacy data submitted by the vaccine manufacturer to SAHPRA between 22 March 2021 and 22 June 2021.

Accordingly, SAHPRA has indicated that while it considered the submitted data acceptable at this point, the authorisation is subject to a number of conditions including submission by the manufacturer of the final results of ongoing clinical studies. The regulator also took account of the World Health Organization (WHO) Emergency Use Listing (EUL) report on this vaccine. Amongst the conditions, the manufacturer will provide any information that comes into its possession relating to risk conditions of use and efficacy of the product.

This approval came at the time when the government is implementing an expanded and multipronged vaccination programme to reach as many people as possible, while the infection numbers continue to increase at an alarming rate. This will enable government to initiate procurement processes to secure more vaccine .

“On behalf of the Department, I would like to express gratitude to our regulatory authority for their sense of urgency, which included reducing turnaround time to process applications for registration of medical products, COVID-19 vaccine in particular - without compromising their strict guidelines to ensure the safety of our people.

“It is an undeniable fact that SAHPRA plays a key role in the country`s response to this pandemic by ensuring that safe and efficacious vaccines are approved for use in the country,” said Minister Kubayi.

More information about this vaccine, including the level of safety and efficacy against the current dominant Delta variant in South Africa will be made public at a later stage, once a formal report has been received from SAHPRA.

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