



## **NEWS AND UPDATES**

SAHPRA registered the Comirnaty vaccine from Pfizer Laboratories Pty (Ltd) on 25 January 2022, with conditions. SAHPRA also registered the Covid-19 Vaccine MC Pharma on 31 January 2022, with conditions.

SAHPRA is currently also evaluating a number of applications for emergency use (Section 21) and/or registration of COVID-19 vaccines. The table below shows the current status of the applications under consideration:

## COVID-19 vaccine currently in review by sahpra

Name of vaccine	Applicant	Status
Sputnik V (Sputnik V)	Dr Reddy's Laboratories (Pty) Ltd	In progress. Engagements with applicant on going regarding additional data required by the regulator.
Gam-COVID-Vac (Sputnik V)	Lamar International (Pty) Ltd	In progress. Responses received to questions raised.
Covid-19 vaccine (vero cell) inactivated (Sinopharm)	LHC Pharmaceuticals Pty (Ltd)	In progress. Responses received to questions raised.
Gam-COVID-Vac Light: Vector vaccine (Sputnik light)	Lamar International (Pty) Ltd	Review of initial submission in progress.
Covavax (Novavax)	Cipla (Pty) Ltd	Review of initial submission in progress.

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As soon as any decision has been taken on these applications, based on consideration of the available evidence of safety, quality and efficacy, SAHPRA will issue a statement in this regard. The time taken to reach finality on each application will vary and will include any time taken by the applicant to address queries posed by SAHPRA.

To date, SAHPRA has registered the Pfizer/BioNTech vaccine “Comirnaty”, the Janssen Covid-19 vaccine, the Covid-19 Vaccine MC Pharma and also authorised Sinovac’s “Coronovac” vaccine (submitted by and Curanto Pharma).

“SAHPRA is committed to prioritising all COVID-19- related health products, including vaccines. Vaccines have been proven to be effective in the fight against COVID-19. However, SAHPRA will ensure that all products, including vaccines, have undergone the requisite evaluation and assessments that meet regulatory requirements prior to being made available to the public,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.