

SAHPRA AUTHORISES COVISHIELD - AN ADENOVIRUS-VECTORED VACCINE FOR THE PREVENTION OF COVID-19

In an effort to enable and support the country's response in fighting the COVID-19 pandemic, SAHPRA has on 22 January 2021 granted a Section 21 authorisation to the Department of Health for COVISHIED (a covid-19 vaccine manufactured by Serum Institute of India) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The regulatory process involved a thorough and rigorous review of the data submitted to ensure that the vaccinees will receive safe, efficacious and quality-assured vaccines.

SAHPRA is currently reviewing applications for registration of the Janssen and Pfizer covid-19 vaccines. SAHPRA had pre-submission discussions with a few other manufacturers where they are able to share the readiness of data for submission.

SAHPRA has and will continue to prioritise all COVID-19 applications and will apply an expedited approach to all COVID-19 related health products, including vaccines. SAHPRA will keep the public updated on any new developments.