PRESS BRIEF

The Drug Regulatory Authority (DRA) on 21 January 2021 granted Emergency Use Authorization for **Covishield™** manufactured by Serum Institute of India. The authorization was based on recommendation of the Drugs Technical Advisory Committee (DTAC) and approval of Hon'ble Chairperson, Bhutan Medicines Board. DRA has reviewed the data of the National Regulatory Authority for AstraZeneca/Oxford vaccine and **Covishield™**; and the documents received from Serum Institute of India. **Covishield™** is manufactured through 'technology transfer' from Oxford/AstraZeneca approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA). **Covishield™** is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older excluding pregnant women and breastfeeding mothers. DRA, in collaboration with the Ministry of Health will continue monitoring the performance of the vaccine in Bhutan including any adverse events following immunization.

This is the first Covid-19 vaccine to be approved for emergency use in the country. As per the international practices and WHO, Emergency Use Authorization for new vaccines are granted when proven that the known and potential benefits outweigh the known and potential risks of the vaccine during emergency situations posed by the pandemic.