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Drug Regulatory Authority
Royal Government of Bhutan
Thimphu, Bhutan; Post Box No. 1556

Regulatory Notification

Drug Regulatory Authority (DRA) is pleased to issue a guidance document on *Emergency Use Authorization procedure and conditions for Deployment of COVID-19 Vaccines*. **This procedure is effective from 10 January 2021.**

The decision to grant the Emergency Use Authorization (EUA) of COVID-19 vaccines is contingent to fulfilling the following:

1. The COVID-19 vaccine should be listed by the WHO for Emergency Use; OR
2. The COVID-19 vaccine should be approved for emergency use by the Stringent Regulatory Authorities (SRA) as designated by the WHO (https://www.who.int/medicines/regulation/sras/en/).

In case of the **technology transfer** or '**contract manufacturing**" of the *Stringent Regulatory Authority approved vaccine* by another country's manufacturer (whose National Regulatory Authority is not listed as SRA); following documentation (in addition to what has been prescribed under EUA procedure) would apply;

i. Declaration from the manufacturer confirming the manufacture of COVID-19 vaccine is based on the technology transfer and all manufacturing processes have been validated and comparable with the vaccine approved by the Stringent Regulatory Authorities; and

ii. Declaration from the manufacturer that the composition of vaccine per dose is the same as that of the principle manufacturer regardless of the trade name.

This notification has reference to the approval accorded vide note no. DRA/D4B/06-NS/20-21 dated 10 January 2021 from Hon'ble Chairperson, Bhutan Medicines Board.

Drug Controller
Drug Regulatory Authority