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Health Ministry issues regulatory steps to approve foreign made COVID-19 vaccines

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DCGI will consider and take a decision within three working days from the date of submission of the complete application

The Union Health Ministry has issued the Regulatory Pathway in India for COVID-19 Vaccines approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL).

CDSCO shall prepare detailed guidelines specifying regulatory pathway for approval of foreign approved Covid vaccines based on National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) recommendations.

These guidelines have since been prepared and posted by CDSCO on its website. CDSCO will take steps to widely disseminate these guidelines to the concerned stakeholders.

Applicants for grant of approval for Restricted Use in Emergency situation may be submitted to CDSCO. Application can be

made by the foreign manufacturer through its Indian subsidiary or through its authorized agent in India (in case it does not have an Indian subsidiary).

CDSCO will process such applications for Restricted Use in Emergency Situation and DCGI will consider and take a decision within 03 working days from date of submission of complete application by the applicant.

DCGI will issue permission for Restricted Use in Emergency situation with, inter-alia, the following conditions:

- Vaccine shall be used as per the guidelines prescribed under National Covid-19 Vaccination Programme.
- First 100 beneficiaries of such vaccines shall be assessed for 7 days for safety outcomes before it is rolled out for further Vaccination program.
- Applicant shall initiate conduct of post approval bridging clinical trials within 30 days of such approval.