Union Health Ministry Issues Regulatory Pathways for foreign produced COVID-19 Vaccines

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In a radical reform measure, the Union Government on 13th April 2021 had approved a significant streamlining and fast tracking of regulatory system 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). This decision will facilitate quicker access to such foreign vaccines by India and would encourage imports including import of bulk drug material, optimal utilization of domestic fill and finish capacity etc., which will in turn provide a fillip to vaccine manufacturing capacity and total vaccine availability within the country.

The Union Government has today 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).

The Central Drugs Standards Control Organization (CDSCO) headed by DCGI has today explained that the following would be the Pathway:

i. CDSCO shall prepare detailed guidelines specifying regulatory pathway for approval of foreign approved Covid vaccines based on NEGVAC recommendations.

ii. 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.

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

iv. 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).

v. 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.

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

1. 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.

vii. Applications for Restricted Use in Emergency situation for such vaccines maybe accompanied by bridging trial protocol, application for import registration certificate and application for import license.

viii. CDSCO will process applications for Registration Certificate (registration of oversees manufacturing

site and product: in this case Covid vaccine) and Import License, within 3 working days from the date of approval of Restricted Use in Emergency Situation.

ix. As per the existing protocol of CDSCO for batch release of vaccines, each batch of the vaccine will be released by Central Drugs Laboratory(CDL), Kasauli before it can be used as per the guidelines prescribed under the National Covid-19 vaccination programme.

x. The applicant will use Covid vaccine, after receipt of CDL approval, initially only on 100 beneficiaries and submit the safety data to CDSCO.

xi. CDSCO will review the safety data submitted by the applicant, and once found satisfactory, will authorise the applicant to use the vaccine.

xii. CDSCO will approve the protocol for the bridging trial in consultation with Subject Expert Committee (SEC) within 7 days of the receipt of the proposal.

xiii. Applicant will conduct the bridging trial within the time lines specified in the approved protocol, and submit data generated in the bridging trial to CDSCO.

xiv. After the receipt of the bridging trial results, the DCGI will review the permission granted for Restricted Use in Emergency situation.

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