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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Relation Office)

FDA Bhawan, Kotla Road
New Delhi, 110002
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NOTICE

Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL)

In light of COVID-19 pandemic, in order to tackle the emergency situation by increasing the availability of safe and effective vaccines, in pursuance of recommendations of 23rd meeting of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) held on 11th April 2021 and subsequent communication of the Ministry of Health and Family Welfare (MoHFW) dated 14.03.2021 for consideration and initiation of appropriate action by the DCG(I) on the recommendations which are as under :-

"The consensus of members of NEGVAC was that foreign produced vaccines for Covid-19, which have been granted emergency approval for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) may be granted Emergency Approval in India mandating the requirement of post approval parallel bridging clinical trial in place of conduct of local clinical trial as per the provisions prescribed under the Second Schedule of the New Drugs and Clinical Trial Rules, 2019. Further, the first 100 beneficiaries of such vaccines shall be assessed for 7 days for safety outcomes, before it is rolled out for further immunization programme. This will facilitate imports, including bulk importation, fill- finish capacity, etc. which will help to expedite vaccine manufacturing capacity and vaccine availability for domestic use to significantly increase base and coverage of vaccination."

it has been decided that for such applications, DCGI will issue permission for Restricted Use in Emergency situation with, inter-alia, the following conditions:

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

It has also been decided to follow the procedure as given below for processing of such applications:

- Application as per rules under Drugs and Cosmetics Act, 1940 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).
- Applicant can submit application for approval of COVID-19 Vaccines for restricted use in emergency situation in India through SUGAM online portal along with requisite fees & requisite documents in Common Technical Documents (CTD) format provided in Guidance for Industry including:
 - Details of drug substance, drug product, chemistry manufacturing control (CMC) data,
 - Analytical data, certificate of analysis,
 - Preclinical & clinical data,
 - Regulatory approvals in other countries in relevant section,
 - Good Manufacturing Practices (GMP) Certificate of Pharmaceutical Product (COPP) as per WHO guidelines,
 - Package insert, Fact sheet, SmPC proposed for India.
- CDSCO will process such applications for Restricted Use in Emergency Situation on highest priority through expedited review/accelerated approval process as per provisions of New Drugs and Clinical Trial Rules, 2019 and DCG(I) will consider and take a decision within 03 working days from date of submission of complete application by the applicant.
- Further, the foreign manufacturer proposing to import the vaccine into India may apply along with bridging trial protocol, application for import registration certificate and application for import license, along with application for permission for Restricted Use in Emergency situation for facilitating the process.
- After approval of Restricted Use in Emergency situation, CDSCO will process applications for Registration Certificate (registration of overseas manufacturing site and product (in this case COVID-19 vaccine) and Import License, within 3 working days from the date of approval of Restricted Use in Emergency Situation.
- Once the Registration Certificate and Import License are granted, as per the existing protocol of CDSCO, the applicant will be required to get every batch of the vaccine tested / released at Central Drugs Laboratory (CDL), Kasauli before it can be used as per the guidelines prescribed under National Covid-19 vaccination program.
- The applicant will use COVID-19 vaccine, after receipt of CDL approval, initially only on 100 beneficiaries and submit the safety data to CDSCO.

- CDSCO will review the safety data submitted by the applicant, and once found satisfactory, will authorize the applicant to use the vaccine .
- CDSCO will approve the bridging trial protocol in consultation with Subject Expert Committee (SEC) within 7 days of the receipt of the proposal.
- 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.
- After the receipt of the bridging trial results, the DCGI will review the permission granted for Restricted Use in Emergency situation.
- The Covid vaccines already approved by the DCGI for restricted use in emergency situation in India, and proposed to be fill finished at a site within the country different from the manufacturing site, by receiving bulk of the approved vaccine, will also be approved by CDSCO based on inspection & CDL release.
- Additionally, if such a vaccine is manufactured in India from basic drug substance stage to the fill-finish stage, it will also be given manufacturing license, based on inspection, for stock piling & CDL release.

V. G. Somani

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

All stake holders through CDSCO website.