Ministry of Health and Family Welfare

Centre fast tracks Emergency Approvals for foreign produced COVID-19 Vaccines that have been granted EUA in other countries to Expand the Basket of Vaccines for Domestic Use and Hasten the Pace and Coverage of Vaccination

Posted On: 13 APR 2021 1:11PM by PIB Delhi

India is following a comprehensive approach to tackle COVID-19 pandemic in a proactive and pre-emptive manner. In this context, as early as May 2020, India constituted a Task Force headed by Principal Scientific Advisor to encourage R&D for vaccine manufacture & constituted in August 2020 an Expert Group headed by Member, NITI to assist in roll out of the Covid vaccination programme. It was because of these strategies that India became the first country to have two "Made in India" Covid vaccines for domestic vaccination drive.

Vaccination is one of the critical pillars of COVID control and management strategy adopted by the Centre. Presently two vaccines i.e. Covaxin by Bharat Biotech International Limited (BBIL) and Covishield by Serum Institute of

India (SII), have received Emergency Use Authorization (EUA) from the National Regulator (Drugs Controller General of India).

The matter of augmenting the Basket of Vaccines available for fighting the pandemic as well as to accelerate the pace & coverage of domestic vaccination programme was discussed in the 23rd meeting of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) held on 11th April 2021, chaired by Dr. V K Paul, Member (Health), Niti Aayog.

The NEGVAC, after comprehensive deliberation, recommended that vaccines for COVID-19, which have been developed & are being manufactured in foreign countries and which have been granted emergency approval for restricted use by USFDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO(Emergency Use Listing) may be granted emergency use 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 Second Schedule of the New Drugs & Clinical Trials Rules 2019.

Further, the first 100 beneficiaries of such foreign vaccines shall be assessed for seven days for safety outcomes before it is rolled out for further immunization programme within the country.

The Union Government, after due consideration, has accepted the recommendation of NEGVAC.

This decision will facilitate quicker access to such foreign vaccines by India & 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 for domestic.

*****

MV