



Ministry of Health and Family Welfare

# Union Government consistently and proactively working to secure and enhance the Availability of COVID Vaccines

## Liberal Enabling Environment Created by Government of India for Enhanced Vaccine Supply in the country

Posted On: 13 MAY 2021 5:41PM by PIB Delhi

There have been reports in a section of the media followed by some uninformed tweets alleging delay in licensing for Covaxin and delayed approval for technology transfer for manufacturing COVAXIN vaccine in the country.

These news reports and the content mentioned in the tweet are completely baseless and factually incorrect.

The Union Government is consistently and proactively working to secure and enhance the availability of vaccines. Government of India, in its new liberalized strategy, has made specific provisions that vaccines for COVID-19, which have been developed & are being manufactured in foreign countries and which have been granted emergency use authorization by National Regulators of United States, European Medicine Agency (EU), United kingdom, Japan or which are listed in WHO (Emergency Use Listing), will be granted emergency use approval in India. It also provides for post-approval parallel bridging clinical trial in place of conduct of prior local clinical trial as per the provisions prescribed under Second Schedule of the New Drugs & Clinical Trials Rules 2019. This is a radical departure from past allowing rapid and simplified authorization of foreign vaccines by Drugs Controller General of India (DCGI).

This will ease and facilitate the import of Covid-19 vaccines and ensure increased availability of Covid-19 vaccines in India.

The New “Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy” aims at liberalized vaccine pricing and scaling up of vaccine coverage to incentivize vaccine manufacturers to rapidly augment their production and to attract new vaccine manufacturers. It would make pricing, procurement and administration of vaccines more flexible and ensure increased vaccine production as well as wider availability of vaccines in the country

Government of India, as part of its policy to augment the domestic production of Covid-19 vaccine, has proactively encouraged Public Sector Undertakings (PSUs) as well as private companies to enter into technology transfer agreements with Indian vaccine manufacturers. Two Central Government PSUs, namely, Indian Immunologicals Ltd (IIL) and BIBCOLD have entered into a technology transfer agreement with Bharat Biotech. In addition, one State Government Undertaking, namely, Haffkine Institute, has also entered into a technology transfer agreement with Bharat Biotech. All these



technology transfer agreements have been actively promoted and assisted by Government of India. The Union Government has also extended substantial financial assistance to all the above 3 Undertakings. As a result of this proactive intervention of the Central Government, Indian Immunologicals Limited will be in a position to start production of Covaxin from September 2021, while Haffkine Institute and BIBCOL will start production of Covaxin from November 2021.

Government of India presently is also engaged in proactive dialogue with Bharat Biotech and some other PSUs, as well as private companies to execute technology transfer agreements. This would further enhance and augment the production of Covaxin in the country.

Under the new policy, 100 percent doses of imported and ready to use foreign vaccine will be available for other than Government of India channel comprising State Governments, private hospitals and hospitals of industrial establishments. The new Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy also Incentivizes in terms of prices to attract private manufacturers including offshore vaccine manufacturers to enter the country.

Government of India is proactively engaging with foreign vaccine manufacturers like Moderna, Pfizer etc., to apply for Emergency Use Authorization in India so that these vaccines can be easily imported and made available in India.

Simultaneously, Government of India along with other like-minded countries is also stressing on IPR waiver for the Covid-19 vaccines. These two interventions, taken in conjunction, will ensure easy availability of Covid -19 vaccines not only in India but globally too.

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