

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO.3045
TO BE ANSWERED ON 6th AUGUST, 2021**

COVID-19 VACCINE PRODUCTION

**3045. SHRI P.C. MOHAN:
DR. T. SUMATHY (A) THAMIZHACHI THANGAPANDIAN:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the total capacity of vaccine manufacturing/ production in the country;
- (b) the details of COVID-19 Vaccines produced in the country during the last one year;
- (c) whether the Government has taken effective steps to increase the production of COVID-19 vaccines in the country; and
- (d) if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) & (b): ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) is manufactured by M/s Serum Institute of India Pvt., Ltd., Pune, while the Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is manufactured by M/s Bharat Biotech International Limited, Hyderabad.

As communicated by the manufacturers, the monthly vaccine production capacity of Covishield is planned to be increased from 11 crore doses per month to more than 12 crore doses per month and the production capacity of Covaxin is planned to be increased from 2.5 crore doses per month to around 5.8 crore doses per month.

From 16th January, 2021 to 5th August, 2021, 44.42 crore doses of Covishield have been supplied by M/s Serum Institute of India and 6.82 crore doses of Covaxin have been supplied by M/s Bharat Biotech International Limited for the National Covid Vaccination Programme.

(c) & (d): Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare has taken various steps for fast track approval of COVID-19 Vaccines, as below:

(i) A system is in place for fast track processing of application for clinical trial & approval for COVID-19

(ii) As per CDSCO notice dated 15.04.2021, the COVID Vaccines already approved by CDSCO 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 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 licensee, based on inspection, for stock piling & CDL release.

(iii) CDSCO has granted permission for manufacturing of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk to M/s Ra (biologicals) Panacea Biotech Ltd., New Delhi for restricted use in emergency situation on 02.07.2021 and manufacturing license was issued on 05.07.2021.

(iv) CDSCO has granted permission to M/s Indian Immunological Limited, Hyderabad for manufacturing of Whole Virion Inactivated Corona Virus (COVAXIN) Bulk Vaccine on 26.03.2021 for examination, test and analysis purpose.

Further, Department of Biotechnology under the Ministry of Science & Technology has launched 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of Department of Biotechnology.

Under the mission, facility augmentation of Bharat Biotech and 01 State Public Sector Enterprise and 02 Central Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; for production of Covaxin have been supported.

In addition, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat has also been facilitated.

Further, Government of India has also extended financial assistance to one of the domestic manufacturers for 'At-risk manufacturing', advance payment against the supply orders placed with M/s Serum Institute of India and M/s Bharat Biotech, and streamlining of regulatory norms for approval of vaccines.
