

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 1846
TO BE ANSWERED ON 14th DECEMBER 2021**

**SHELF LIFE OF COVID-19 VACCINE AND BOOSTER DOSE OF COVID-19
VACCINE**

1846. DR. KANIMOZHI NVN SOMU:

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

- (a) whether Government has studied the shelf life of COVID-19 vaccines and its active period among the vaccinated persons;
- (b) if so, the details thereof and Government's stand on production and distribution as well as the administration of booster doses;
- (c) the effective steps taken by Government to ensure adequate production and supply of COVID-19 vaccines and booster doses in the country; and
- (d) the total expenses incurred and funds allocated and disbursed in this regard?

ANSWER

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

(a) to (d) The National Regulator i.e. Central Drugs Standard Control Organization, has approved the shelf life of 9 months for Covishield vaccine and for Covaxin vaccine it is 12 months from the date of manufacture. The COVID-19 vaccines have been developed very recently, therefore scientific evidence is still evolving globally regarding the duration of protection.

The National Technical Advisory Group on Immunization (NTAGI) and National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) are deliberating and considering scientific evidences related to justification for booster dose.

Government of India has taken many steps to augment the domestic manufacturing capacity of COVID-19 vaccines. Under '*Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission*', is implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of Department of Biotechnology (DBT), efforts have been made to strengthen COVID-19 vaccine manufacturing capabilities of Indian industry, so as to ensure optimal vaccine production. In this regard, augmentation of manufacturing

facilities was supported at Bharat Biotech International Limited (BBIL) and Indian Immunologicals Limited (IIL), Hyderabad, Indian Immunologicals Limited (IIL), supported under the Mission, has achieved a production capacity of about 20 lakh doses/month equivalent Drug Substance (DS) of COVAXIN®. The validation of the BBIL facility at Malur, Bengaluru is complete and production of Drug Substance (DS) started in August 2021. Further, support for facility augmentation at Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL), Bulandshahr; and Haffkine Biopharmaceutical Corporation Ltd (HBPCL), Mumbai; for COVAXIN® production has been envisaged. An amount of Rs. 260 Cr. has been allocated to support facility up-gradation for augmented COVAXIN® production, out of which, an amount of Rs. 27.25 Cr. has been disbursed so far. Additionally, Department of Bio Technology (DBT) along with the Public Sector Unit (PSU) Biotechnology Industry Research Assistance Council (BIRAC), is facilitating expert advisory support for facility up-gradation at Gujarat COVID Vaccine Consortium (GCVC), for augmented production of COVAXIN®.

In the current financial year i.e. 2021-22, INR 35,000 crore has been budgeted for implementation of COVID-19 Vaccination Programme. As on 09th December 2021, an expenditure of INR 19,675.46 crore has been incurred against this allocation which has been utilized for procurement of COVID-19 vaccine for free of cost supply to State/UTs.
