

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

**LOK SABHA  
UNSTARRED QUESTION NO. 532  
TO BE ANSWERED ON 04<sup>th</sup> FEBRUARY 2022**

**COVID-19 VACCINES FOR EMERGENCY USE**

**532. SHRI SANGAM LAL GUPTA:  
MS. LOCKET CHATTERJEE:  
SHRI RAJENDRA AGRAWAL:  
SHRI P.P. CHAUDHARY:  
SHRI KESINENI SRINIVAS:**

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

- (a) The details of the COVID-19 vaccination available for emergency use in India, and the vaccines in the pipeline along with the expenditure incurred on procurement of these vaccines;
- (b) the reasons for the delay in approving more vaccines for use in India;
- (c) whether the Government is undertaking trials to understand the effects on immunological response of administering disparate vaccine doses to individuals, if so, the details thereof and if not, reasons therefor;
- (d) whether the Government is reviewing the latest research for vaccinating children below the age of 15 years, if so, the details thereof; and
- (e) whether the Government has formulated any action plan for administering the booster dose to individuals who have earlier been vaccinated with both the doses and if so, the details thereof?

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

(a) to (e) National Regulator i.e. Central Drugs Standard Control Organization (CDSCO) has granted permissions to following vaccines for restricted use in emergency situation as per the New Drugs and Clinical Trials (NDCT) Rules, 2019:

1. **COVISHIELD** of M/s Serum Institute of India Pvt. Ltd. for  $\geq 18$  years age

2. **COVAXIN** of M/s Bharat Biotech  $\geq$  12 years age
3. **ZyCovD** of Cadila Healthcare Limited for  $\geq$  12 years age
4. **SPUTNIK-V** imported by Dr. Reddy's Lab. Ltd. and manufactured by M/s Panacea Biotech and M/s Hetero Biopharma, for  $\geq$  18 years age
5. **Moderna** imported by M/s Cipla Ltd., for  $\geq$  18 years age
6. **Janssen Vaccine** imported by M/s Johnson & Johnson Pvt. Ltd and manufactured by M/s Biological E Limited, for  $\geq$  18 years age
7. **CORBEVAX** of M/s Biological E Ltd., for  $\geq$  18 years age
8. **COVOVAX** of M/s Serum Institute of India Pvt. Ltd., for  $\geq$  18 years age

The following COVID-19 vaccines are under various phases of clinical development:

1. SPUTNIK-LIGHT of M/s Dr. Reddy's Lab. Ltd (Phase III).
2. Lyophilized mRNA based COVID-19 vaccine of M/s Gennova Biopharma. Ltd. (Phase II/III).
3. Nasal vaccine of M/s Bharat Biotech (Phase III).
4. Multiple Protein/ Peptide-Based SARS-CoV-2 Vaccine of M/s Aurobindo (Phase II/III).
5. Inactivated Whole-virion virus (Intra-dermal route) of M/s Bharat Biotech (Phase I/II).
6. Inactivated Rabies vector platform Corona Virus Vaccine (rDNA-BBV151) of M/s Bharat Biotech (Phase I).
7. SARS-CoV-2 Recombinant protein subunit vaccine of M/s Reliance (Phase I).

The approval of COVID-19 vaccine by the national regulator is dependent on the safety, immunogenicity and efficacy profile of vaccine through non-clinical and clinical trial data generated and there is no delay in approval of the COVID-19 vaccines.

National Regulator i.e. Central Drugs Standard Control Organization (CDSCO) has granted permissions to following entities for conduct of clinical trials for administration of mixed vaccine regimen:

1. M/s Christian Medical College, Vellore to conduct Phase IV study with COVISHIELD and COVAXIN to compare immunogenicity of mixed vaccine regimen.

2. M/s Bharat Biotech for Phase II clinical trial to evaluate the immunogenicity and safety of BBV152 (COVAXIN) with BBV154 (Adenoviral Intranasal COVID-19 vaccine).

As per the recommendation of the National Technical Advisory Group on Immunization (NTAGI), administration of precaution dose has started from 10th January 2022 to those Health Care Workers (HCWs), Front Line Workers (FLWs) and persons aged 60 years & above with comorbidities who have received two doses of Covid-19 vaccines.

Any decision on extension of eligible beneficiaries for precaution dose and vaccination of children below 15 years of age is as per the recommendations of The National Technical Advisory Group on Immunization (NTAGI) on the basis of review of available scientific evidences.

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 31<sup>st</sup> January 2022, an expenditure of INR 27,945.14 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.

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