

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

**LOK SABHA  
UNSTARRED QUESTION NO. 909  
TO BE ANSWERED ON 23<sup>RD</sup> JULY, 2021**

**VACCINES APPROVED FOR USE IN INDIA**

**909. SHRI UTTAM KUMAR REDDY NALAMADA:  
SHRI RANJEETSINGH HINDURAO NAIK NIMBALKAR:  
SHRI P.P. CHAUDHARY:  
SHRI BALAK NATH:  
SHRI SUMEDHANAND SARASWATI:**

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

- (a) the details of the COVID vaccines which have been approved for use in India along with the chronological account of approval granting process followed for these vaccines;
- (b) the number and details of vaccines that are currently in the process of getting approval for use in the country along with the steps being taken by the Government to speed up the approval process for vaccines in the country;
- (c) the percentage of rural population that has got vaccination doses, State/UT-wise;
- (d) the details of orders placed, price quoted and expenditure made by the Government to procure COVID- 19 vaccines, nationally and internationally as on date;
- (e) the details chronological account of COVID vaccine supplies received by the Government and their dispatch to different states for inoculation along with the data collected post monitoring by the Government regarding inoculation carried by public or private, central sponsored or state sponsored, vaccine/dose/age/month/ State/UT-wise; and
- (f) whether the Government has studied the efficacy of various vaccines against new variants of COVID present in the country and if so, the details thereof?

**ANSWER**

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

(a): As per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organisation (CDSCO) has granted permissions to following COVID-19 vaccines for prevention of COVID-19 for restricted use in emergency situation:

**1. ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) manufactured by M/s Serum Institute of India Pvt., Ltd., Pune**

CDSCO had granted permission to M/s Serum Institute of India Pvt., Ltd. Pune to conduct Phase II/III clinical trial of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) on 02.08.2020.

Subsequently, M/s Serum had submitted its application on 06.12.2020 for grant of permission to manufacture ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant). The Subject Expert Committee (SEC) of CDSCO reviewed the proposal in its meetings dated 09.12.2020, 30.12.2020 and 01.01.2021 as well as reviewed continuously the data as and when received. The MHRA approval for AstraZeneca vaccine dated 30.12.2020 along with its conditions/restrictions was also reviewed by the committee.

The committee recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions including with various conditions/restrictions.

CDSCO accepted the recommendations of the Expert Committee and accordingly, the permission was granted to M/s Serum Institute on 03.01.2021 to manufacture ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) for restricted use in emergency situation with various conditions/restrictions.

**2. Whole Virion Inactivated Corona Virus Vaccine manufactured by M/s Bharat Biotech International Limited, Hyderabad.**

CDSCO had granted permission to M/s Bharat Biotech International Limited, Hyderabad to conduct Phase I/II clinical trial of Whole Virion Inactivated Corona Virus Vaccine on 29.06.2020 & Phase III clinical trial of on 23.10.2020.

Subsequently M/s Bharat Biotech International Limited, Hyderabad submitted its application on 07.12.2020 for grant of permission to manufacture Whole Virion Inactivated Corona Virus Vaccine. The data was reviewed by CDSCO in consultation of Subject Expert Committee (SEC) in meetings dated 09.12.2020, 30.12.2020, 01.01.2021 & 02.01.2021. The committee recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains.

Further, the firm shall continue the on-going Phase III clinical trial and submit data emerging from the trial as and when available.

CDSCO accepted the recommendations of the Expert Committee and accordingly, the permission was granted to M/s Bharat Biotech on 03.01.2021 to manufacture Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) for restricted use in emergency situation in clinical trial mode with various conditions/restrictions.

**3. Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] imported by M/s Dr. Reddy's Laboratories Ltd, Hyderabad on 12.04.2021.**

CDSCO had granted permission to M/s Dr. Reddy's Laboratories Ltd., to conduct Phase II/III clinical of Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] on 22.10.2020.

Subsequently M/s Dr. Reddy's Laboratories Ltd., had submitted application for grant of permission for import of Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] on 19.02.2021

The proposal of restricted emergency use was reviewed by CDSCO in consultation of Subject Expert Committee (SEC) including data reviewed continuously as and when received.

The committee recommended grant of permission for restricted use in emergency situations subject to various regulatory provisions.

CDSCO accepted the recommendations of the Expert Committee and accordingly, the permission was granted to M/s Dr. Reddy's Laboratories Ltd on 12.04.2021 to import Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] for restricted use in emergency situation with various conditions/restrictions.

**4. mRNA-1273 COVID-19 vaccine (Moderna) imported by M/s Cipla Limited, Mumbai.**

M/s Cipla has submitted application for grant of permission for import of mRNA-1273 COVID-19 vaccine (Moderna) in the country on 28.06.2021. CDSCO has reviewed the application and granted permission to M/s Cipla Limited, Mumbai for import of mRNA-1273 COVID-19 vaccine (Moderna) for restricted use in emergency situation on 29.06.2021 in line with guidelines in the force.

**5. Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) manufactured by M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi.**

M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi has submitted complete application for manufacturing of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk on 29.06.2021.

CDSCO has reviewed the application and granted permission for manufacture of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk to M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi in line with guidelines in force for restricted use in emergency situation on 02.07.2021.

(b): CDSCO has received 04 applications for grant of approval for restricted use in emergency situation, which are under examination & the details are as follows:

- 1. Novel Corona Virus 2019-nCoV Vaccine (Recombinant) of M/s Cadila Healthcare Ltd., Ahmedabad:**
- 2. SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine of M/s Serum Institute (Hadapsar and Manjari site):**
- 3. Gam-COVID-Vac Combined vector vaccine (Sputnik V) manufactured by M/s Hetero:**
- 4. Sputnik Light Vector vaccine of M/s Dr. Reddy's Laboratories Ltd.:**

Various steps have been taken for fast track approval of COVID-19 Vaccines, as below:

- a) A system is in place for fast track processing of application for clinical trial & approval for COVID-19 Vaccines by CDSCO.
- b) The manufacturers were encouraged to share the safety, immunogenicity and efficacy data with the regulators as and when it was generated instead of waiting for the

completion of the clinical trial, so as to enable continuous assessment/rolling review for reducing the processing time.

- c) To facilitate quick development of vaccines, manufacturing site inspections were conducted during the clinical batches development phase instead of initial development.
- d) Approvals of combined phases of clinical trials like phase I/II or phase II/III were granted in consultation with SEC to reduce the timeline of development of COVID-19 Vaccines to ensure its early availability.
- e) The meetings of the Subject Expert Committee (SEC) evaluating the applications for conduct of clinical trials and approval of new drugs pertaining to COVID-19 drugs and vaccines are being held frequently. More than 150 meetings of the Committee have been held till date since COVID-19 was declared as a pandemic.
- f) 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 license, based on inspection, for stock piling & CDL release.
- g) Further, notice was issued on 01.06.2021 on regulatory pathways for approval of COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for emergency use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) providing for exemptions from conduct of post approval parallel local bridging trials and each batch testing of the vaccine by the CDL, Kasauli subject to condition that it is approved by the National Control Laboratory of the country of origin, and released by CDL, Kasauli based on such certificate and summary lot protocol, to further expedite the approvals of imported vaccines.

(c): The location of the residence of the beneficiary is not recorded on CoWIN portal. However, between 1st April 2021 to 20th July 2021, approximately 56% of the total COVID-19 vaccine doses were administered in Rural COVID-19 Vaccination Centres (CVCs).

(d): Government of India has placed orders for supply of 100.6 crore doses up to December 2021. A total of INR 8071.09 crore have been spent on purchase of COVID-19 vaccines out of the budget outlay of Rs. 35,000 crore (as of July 2021).

(e): Till 20th July 2021, a total of 42.51 crore doses have been supplied to States/UTs through all sources of which 40.36 crore doses have been utilized during the ongoing vaccination drive.

(f): The data available so far suggest that all currently used vaccines are effective in preventing hospitalization and deaths due to COVID-19.