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

LOK SABHA
UNSTARRED QUESTION NO. 3989
TO BE ANSWERED ON 19TH MARCH, 2021

COVID VACCINES IN THE PIPELINE

3989. SHRI BALASHOWRY VALLABHANENI:
SHRI MARGANI BHARAT:

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

(a) the details of Covid vaccines that are in the pipeline and are in phase I, II and III trials;

(b) the time by which the above vaccines are likely to enter into market;

(c) whether it is also true that Bharat Biotech is also developing intranasal Covid vaccine; and

(d) if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health & Family Welfare has granted permission to conduct clinical trials of COVID-19 vaccines to various Manufacturers/Importers in the country. The details along with trials, stage-wise are as under:

Phase I clinical trial:

1. M/s Bharat Biotech International Limited, Hyderabad for Intranasal Adenoviral vector COVID-19 vaccine (BBV154).

Phase I/II clinical trial:

2. M/s Bharat Biotech International Limited, Hyderabad for Inactivated Corona Virus Vaccine (Intradermal Route)
3. M/s Biological E Limited, Hyderabad for Receptor Binding Domain of SARS-CoV-2
4. M/s Gennova Biopharmaceuticals Limited, Pune for mRNA Vaccine for Injection (COVID-19)

Phase II/ III clinical trial:

5. M/s Dr. Reddy's Laboratories Limited, Hyderabad for Gam-COVID-Vac combined vector vaccine
6. M/s Serum Institute of India Pvt. Ltd., Pune for COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine.

Phase III clinical trial:

7. M/s Cadila Healthcare Ltd., Ahmedabad for DNA based Corona Virus Vaccine

Further, 14 COVID-19 vaccines of various technology platforms are under preclinical development stage in the country.

The approval of COVID-19 vaccine for manufacturing/marketing is based on the submission of adequate data including Chemistry, Manufacturing and Control (CMC), non-clinical (animal studies) data, clinical trial data as per provisions of New Drugs and Clinical Trials (ND & CT) Rules, 2019 and outcomes of evaluation of the same in consultation with Subject Expert Committee (SEC). The detailed guidelines and requirements for approval of clinical trial or New Drugs are specified in Second Schedule of the ND & CT Rules, 2019.

(c) & (d): CDSCO in consultation with Subject Expert Committee (SEC), has granted permission on 12.02.2021 to M/s Bharat Biotech International Limited for conduct of Phase-I clinical trial of Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154) for Intranasal route of administration.