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

RAJYA SABHA
UNSTARRED QUESTION NO.1036
TO BE ANSWERED ON 20TH SEPTEMBER, 2020

DEVELOPMENT OF COVID-19 VACCINES

1036: SHRI MALLIKARJUN KHARGE:

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

(a) how many vaccines for COVID-19 are being currently developed in India;

(b) how many of those are being developed by private companies and how many are being done by Government;

(c) at what stage of development are they currently in;

(d) by when will a vaccine for COVID-19 be available to the general public;

(e) the steps being taken by Government to ensure that proper clinical trials and procedures are being followed in the development of these vaccines; and

(f) the other alternative solutions to the COVID-19 pandemic that are being explored by Government?

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

(a) to (e): Central Drugs Standard Control Organisation (CDSCO) has informed that it has granted test license permission for manufacture of COVID-19 Vaccine for preclinical test, examination and analysis to the following manufacturers in India:

1. M/s Serum Institute of India Pvt., Ltd., Pune
2. Ms. Cadila Healthcare Ltd., Ahmadabad
3. M/s Bharat Biotech International Ltd., Hyderabad
4. Biological E Ltd., Hyderabad
5. M/s Reliance Life Sciences Pvt Ltd., Mumbai
6. M/s Aurbindo Pharma Limited, Hyderabad
7. M/s Gennova Biopharmaceuticals Limited, Pune

The Indian Council of Medical Research (ICMR), an autonomous organisation under the Department of Health Research, has informed that it is facilitating the following studies related to COVID-19 vaccines:

(i) An inactivated whole virion candidate vaccine (BBV152) for SARS-CoV-2 has been developed by Bharat Biotech International Ltd (BBIL) using the virus isolate (NIV-2020-770) provided by ICMR-National Institute of Virology (NIV), Pune. Characterization of the vaccine candidate has been undertaken at ICMR-NIV followed by safety and tolerability studies in small animals like rats, mice and rabbits. Status of clinical trials is as follows:

- Phase I clinical trials alongwith parallel studies in hamsters and rhesus macaques have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.

- Phase II clinical trials are ongoing.

(ii) A DNA vaccine (ZyCov-D) has been developed by Cadila Healthcare Ltd. Pre- clincial toxicity studies were conducted in small animals: mice, rats, rabbits and guinea pigs. The vaccine has been found to be safe and immunogenic. Cadila has partnered with ICMR for conduct of parallel pre-clinical studies in rhesus macaques. Status of clinical trials is as follows:

- Phase I clinical trials have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II clinical trials are ongoing.

(iii) Serum Institute of India (SII) and ICMR have partnered for clinical development of two global vaccine candidates:

- ChAdOx1-S, which is a non- replicating viral vector vaccine developed by University of Oxford/AstraZeneca. This vaccine is undergoing phase III clinical trials in Brazil. Phase II/III bridging studies have been initiated by ICMR at 14 clinical trial sites. ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai is the lead institution.

ICMR and SII have also partnered for clinical development of a glycoprotein subunit nanoparticle adjuvanted vaccine developed by Novavax from USA. The trial will be initiated in second half of October after the vaccine is manufactured by SII. The trial is led by ICMR-National AIDS Research Institute (NARI), Pune.

As per details provided by Department of Biotechnology (DBT)/Department of Science and Technology (DST), more than 30 vaccine candidates have been supported which are in different stages of development.

While the Govt. and Industry are trying their best to make available a safe and effective vaccine for COVID-19 at the earliest, it is difficult to comment on the exact timelines in view of various complex pathways involved in vaccine development.

(f): ICMR has informed that COVID-19 pandemic can be effectively contained with community engagement and awareness of use of mask, social distancing and hand hygiene practices.

Ministry of AYUSH has also taken following steps with regard to COVID-19 pandemic:

(i) Issued an advisory on 29.01.2020 on how to protect oneself from COVID and how to stay healthy. Ministry has also written a letter dated 06.03.2020 to all Chief Secretaries of States / Union territories with more specific suggestions on augmentation of General Immunity of people and about possible AYUSH intervention. Ministry has also issued self-care guidelines on 31.03.2020 for preventive health measures and boosting immunity with special reference to respiratory health.

(ii) Issued Gazette notification dated 21.04.2020 for undertaking research on COVID-19 through Ayurveda, Siddha, Unani and Homeopathy including prophylactic measures, intervention during the quarantine, asymptomatic and symptomatic cases of COVID-19. Public Health Research, Survey, Lab Based Research etc to generate evidence.

(iii) Forming of an Inter-disciplinary AYUSH R&D Task Force. Task Force has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases through thorough review and consultative process of experts of high repute from different organizations across the country for studying four different interventions viz. Ashwagandha, Yashtimadhu, Guduchi + Pippali and a poly herbal formulation (AYUSH-64). Ayush Sanjivani mobile app developed by Ministry of AYUSH has been also launched to generate data on acceptance and usage of AYUSH advocacies and measures among the population and its impact in prevention of COVID-19 targeting 05 million population.