22	**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS** **(2020-21)** **SEVENTEENTH LOK SABHA**

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

STATUS OF COVID-19 VACCINE PRODUCTION IN INDIA

TWENTY- SECOND REPORT

LOK SABHA SECRETARIAT
NEW DELHI

March, 2021/ Phalguna, 1942 (Saka)

CC&F.No.22

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Presented to Lok Sabha on 17 March 2021

Laid in Rajya Sabha on 17 March 2021

LOK SABHA SECRETARIAT

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

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2.	Sh. N.K. Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Ms Sonia Sankhla	-	Assistant Executive Officer

$Re-nominated to the Committee w.e.f. 23.12.2020.

#Nominated to the Committee w.e.f 28.12.2020 vice Shri Nandigam Suresh.

INTRODUCTION

I, the Chairperson (Acting), Standing Committee on Chemicals and Fertilizers (2020-21) having been authorised by the Committee [as per Rule 277(3) of Procedure and Conduct of Business in Lok Sabha] to present the Report on their behalf, present the Twenty-Second Report (17th Lok Sabha) on the subject 'Status of Covid-19 Vaccine Production in India' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The subject 'Status of Covid-19 Vaccine Production in India' has been selected by the Standing Committee on Chemicals and Fertilizers (2020-21) for examination and report.

3. The Report was considered and adopted by the Committee at their sitting held on 15.03.2021.

4. The Committee wish to express their thanks to the officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Ministry of Health and Family Welfare (Department of Health and Family Welfare and Department of Health Research), Ministry of Science and Technology (Department of Biotechnology), Indian Council of Medicals Research (ICMR) and Drugs Controller General of India (DCGI) for furnishing necessary written replies, views and other material / information to the Committee for the examination of the subject.

5. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of Lok Sabha Secretariat attached to the Committee.

6. For facility of reference and convenience, the observations / recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
15 March, 2021
24 Phalguna 1942 (Saka)

Uday Pratap Singh
Chairperson (Acting)
Standing Committee on
Chemicals and Fertilizers

CHAPTER -I

INTRODUCTION

Overview of Corona Virus Disease (2019)

1.1 Corona Virus Disease 2019 (COVID-19) is an infectious disease caused by a newly discovered corona virus. COVID-19 is the cause of an outbreak of respiratory illness first detected in Wuhan city of Hubei province, China. The earliest date of symptom onset was 1December 2019. On 31 December 2019, World Health Organization (WHO) was informed of cases of pneumonia of unknown etiology (unknown cause) detected in Wuhan City. A novel corona virus was identified as the causative virus by Chinese authorities on 7 January, 2020. WHO temporarily termed the new virus as novel corona-virus (2019-nCoV) on 12 January 2020 and then officially named this infectious disease as Corona Virus Disease 2019(COVID-19) on 12 February 2020. Later, the International Committee on Taxonomy of Viruses (ICTV) officially designated the virus as Severe Acute Respiratory Syndrome Corona virus 2 (**SARS-CoV-2**) based on phylogeny, taxonomy and established practice. Since COVID-19 initially emerged in China, the virus has evolved for four months and rapidly spread to other countries worldwide as a global threat. WHO finally made the assessment that COVID-19 can be characterized as a pandemic and declared the COVID-19 outbreak a pandemic on 11 March 2020. COVID-19 pandemic is amongst the largest public health crisis faced by the World that is having unprecedented negative consequences on health, economy and our social lives.

1.2 A virus is a submicroscopic infectious agent that replicates only inside the living cells of an organism. It is a small parasite that cannot reproduce by itself. Once it infects a susceptible cell, however, a virus can direct the cell machinery to produce more viruses. COVID-19 is a new strain of Corona virus that has not been previously identified in humans. Corona viruses (CoV) are a large family of viruses that can cause illness ranging from the common cold to a more severe disease such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Corona viruses are zoonotic, meaning they are transmitted between animals and people. Viral infections are either prevented by vaccines or treated by Anti Viral Drugs. Since SARS-CoV-2 is a new virus and COVID 19 which is caused by the virus is a new disease, no vaccine or anti viral drug was available for this highly infectious disease.

Pandemic

1.3 The pandemic has severely impacted health systems, economic and social progress throughout the world. COVID-19 most commonly manifests as

fever, dry cough, shortness of breath and tiredness. Most people (~80%) experience mild disease and recover without hospitalization, while around 20% may become more seriously ill. From a few thousand confirmed cases in January, the number of cases continues to grow globally. As per WHO's COVID 19 Dash Board, as on 14th December 2020, across the world 7,10,51,805 cases have been reported of which 98,84,100 cases (2nd highest number of cases reported by a country after USA) have been reported from India. Of the total cases reported, 16,08,648 deaths have been reported across the world of which 1,43,355 deaths have been reported from India. The country has responded proactively to this pandemic by multitude of measures following the principle of 'Test, Track and Treat' and we have now begun seeing the decline in number of active cases and new cases reported.

Vaccine as an important tool in controlling COVID-19

1.4 Department of Health Research in its back ground note has stated that COVID-19 being a new disease, difficult to treat with hardly any proven, therapeutic option. Fighting this pandemic requires strict non-pharmaceutical measures such as hand hygiene, use of mask and physical distancing. An effective vaccine will be an important tool in controlling this pandemic. Vaccination is a simple, safe, and effective way of protecting people against the infectious diseases caused by viruses. It uses our body's natural defences to build resistance to specific infections and makes our immune system stronger. When a person gets a vaccine, his/her immune system responds in the following manner:-

- Recognizes the invading germ, such as the virus or bacteria.
- Produces antibodies. Antibodies are proteins produced naturally by the immune system to fight disease.
- Remembers the disease and how to fight it. If a person is then exposed to the germ in the future, his/her immune system can quickly destroy it before he/she becomes unwell.

The vaccine is therefore a safe and clever way to produce an immune response in the body, without causing illness. Our immune systems are designed to remember. Once exposed to one or more doses of a vaccine, we typically remain protected against a disease for years, decades or even a lifetime. This is what makes vaccines so effective. Rather than treating a disease after it occurs, vaccines prevent the people in the first instance from getting sick.

Herd Immunity

1.5 When a person gets vaccinated against a disease, their risk of infection is also reduced – so they're also far less likely to transmit the disease to others. As more people in a community get vaccinated, fewer people remain vulnerable, and

there is less possibility for passing the pathogen to transmit from person to person. This is called “herd immunity.” “Herd immunity” exists when a high percentage of the population is vaccinated, making it difficult for infectious diseases to spread, because there are not many people who can be infected.

Research and Development of Vaccine

1.6 The Current pandemic of Covid-19 has affected the lives of millions of individuals globally. Lockdowns have created severe impact on economies of many countries. Moreover, the restrictions on travel and social distancing coupled with the uncertain therapeutic outcomes have generated great interest in the speedy development of vaccine for protection against this disease. The Global pharmaceutical and vaccine research industry including that of our country has been expeditiously working on research and development of therapies and vaccines against COVID-19. About 200 vaccine candidates on varied platforms are presently undergoing development across the globe, of which about 40 candidates are in human clinical development.

1.7 Our country is well recognized as a vaccine manufacturing hub at global level. Presently, more than 60% of world’s vaccine demand for immunization programmes is met by Indian manufacturers. In our country, both industry and academia are actively involved in vaccine development. 22 vaccine candidates are in development stage by vaccine industries either through indigenous efforts or technology transfer, Indian academia is also involved in research and development of 9 vaccine candidates, 4 vaccine candidates are being developed through repurposing of existing vaccines and 1 vaccine candidate is developed through bulk transfer/formulation method. 5 vaccine candidates are in advanced stage of development. Two vaccine candidates viz. Covishield by Serum Institute of India, Pune and COVAXIN by Bharat Biotech ltd., Hyderabad have been granted approval by Drug Controller General of India for restricted use in emergency situation.

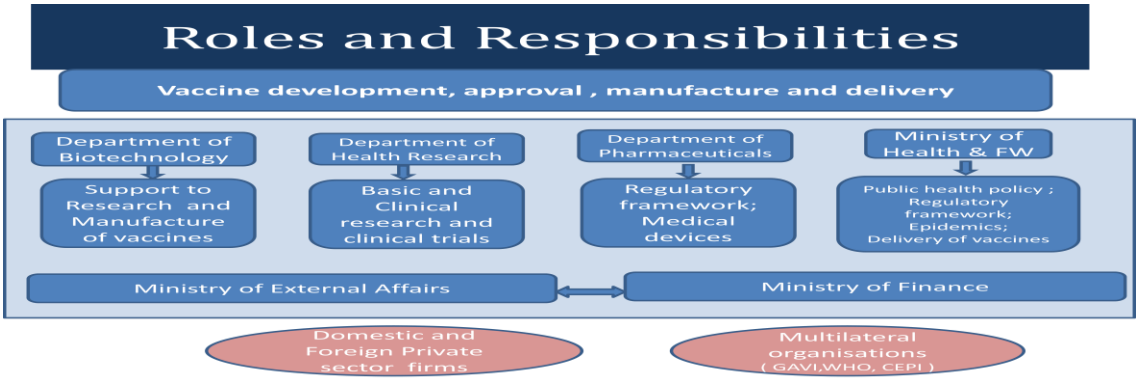
Selection of the subject “Status of COVID 19 vaccine production in India”

1.8 Based on Worldometer elaboration of the latest United Nations data, the current population of India as on 11 January, 2021 is 138,71,60,324. In this context, a preliminary exercise of mapping the Manufacturing capacity for COVID-19 vaccine candidates by leading Indian Vaccine manufacturers was undertaken. For a PAN-India coverage of the vaccine, there is a requirement for at least 100 Crore doses of the vaccine demanding huge investments. Since it is very much necessary that the people of the country are vaccinated by safe and efficacious vaccines in a time bound manner so as to create herd immunity against COVID 19 in the country, the Standing Committee on Chemicals and

Fertilizers selected the subject **"Status of COVID 19 vaccine production in India"** *for* examination and report on priority basis.

Roles and Responsibilities

1.9 The following chart shows the roles and responsibilities of various Ministries/Departments of the Government of India for vaccine development, approval, manufacture and delivery in the country**:-**



In order to coordinate the work being done by above mentioned Ministries/Departments/organizations, an apex level group called National Expert Group on Vaccine Administration For COVID-19 (NEGVAC) has been constituted by the Government of India under the chairmanship of Dr V K Paul, Member NITI Aayog, with Secretary, Health & Family Welfare as Co-chair. The following chapters deal with the subject in detail.

CHAPTER II

TECHNOLOGY, STEPS AND PROCESSES RELATED TO VACCINE DEVELOPMENT AND APPROVAL

A. Different technologies of vaccine development

2.1 In reply to a query of the Committee about the different technologies being used in development of vaccines, the Department of Bio technology (DBT) in its reply has stated that most of the candidate vaccines follow the mechanisms elaborated below, for killing or inactivating or destroying COVID 19 virus:

(i) **Inactivated vaccine** — The vaccine preparation consists of whole virus which is inactivated / killed using chemicals. Administration of the same induces production of protective antibodies in the individuals.

(ii) **Subunit vaccine** — A portion of the virus that is important for immunity, like the spike protein of COVID-19, is used to in vaccine preparation, so as to induce immunity.

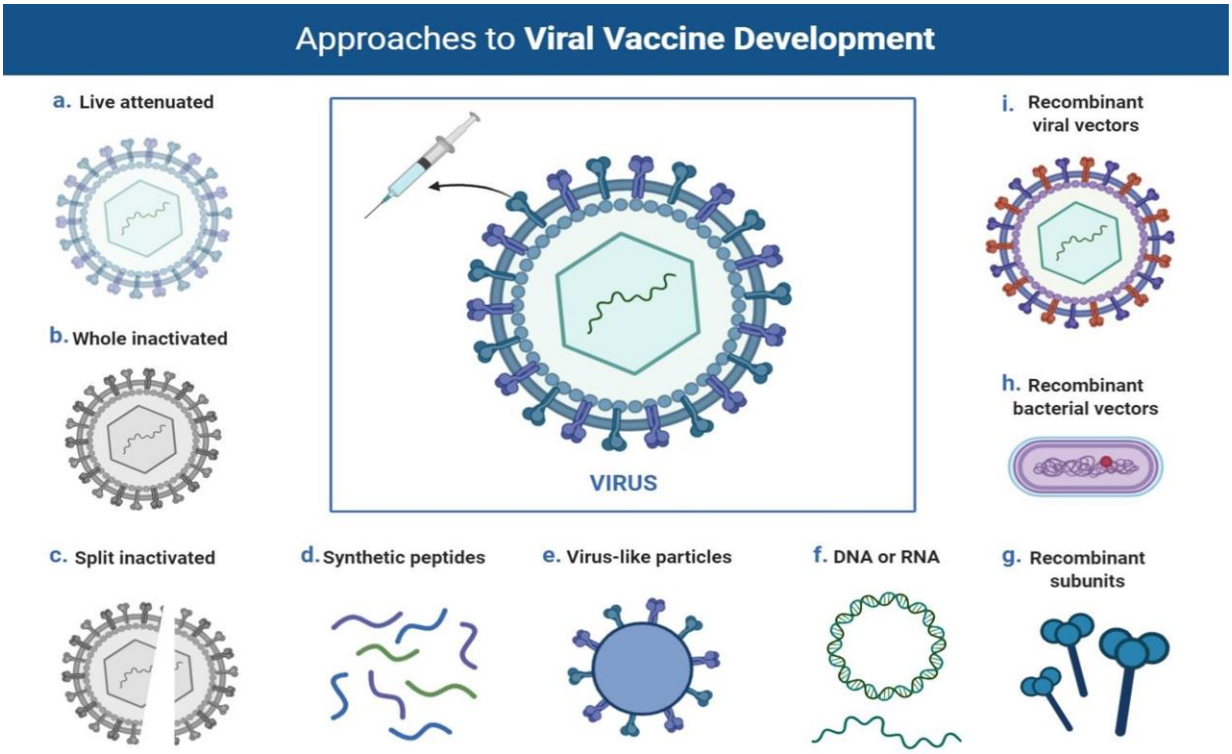
(iii) **Replicating viral vector vaccine** — In this case, a virus that does not cause disease in people (called a vector virus) is engineered to encode the coronavirus spike protein. Administration of the vaccine causes the vector virus to multiply and generate the spike protein, thus inducing a protective immune response.

(iv) **Non-replicating viral vector vaccine** —Similar to replicating viral vector vaccines, the vector virus is engineered to encode the coronavirus spike protein, but the vector virus does not reproduce in the vaccine recipient. However, it can generate the spike protein of coronavirus that could induce immunity.

(v) **DNA vaccine** — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine.

(vi) **mRNA vaccine** — In this approach, the vaccine preparation contains messenger RNA, or mRNA for the Spike protein. mRNA is processed in cells to make proteins. Administration of the vaccine preparation thus causes production of spike protein and subsequent generation of a protective immune response.

2.2 In regard to the above, the Secretary, DBT in her power point presentation during informal discussion with the Chairperson and Members of the Committee showed the following slide about the vaccine strategies:-



Vaccine type	**Advantages**	**Disadvantages**
Live attenuated	• Imitation of the whole infection process • Both antibody and cellular immunity • Long lasting immunity	• Low Stability • Risk of lack of attenuation • Risk of restoring pathogenicity • Potential for over-attenuation with associated poor immunogenicity
Inactivated	• Stable • Low cost manufacturing	• Reduced immunogenicity • Reactogenicity • Short immunity

Split and subunits	• Low reactogenicity • Easily developed	• Reduced immunogenicity • Mostly antibodies rather than cellular immunity • Short immunity • Need adjuvant
Vector	• Use pathways that induce robust and durable both cellular and humoral immunity • Easily engineered • Both antibody and cellular immunity • Act as adjuvant due to a vector properties	•Efficacy decreased by pre-existing vector immunity •Vector-specific responses may limit subsequent doses
DNA/RNA	• Easily engineered	• Instability of the mRNA and manufacturing problems • Need delivery system • No one registered for human • use

2.3 The Secretary, DBT further apprised the Chairperson and Members about the advantages and disadvantages of various types of vaccines as under:-

2.4 In a written reply to a question of the Committee about the differences of the above mentioned technologies and their suitability for vaccination, Department of Biotechnology furnished the following information:-

> **"**Inactivated vaccine formulation is a proven platform and consists of whole virus that is inactivated / killed using chemicals, which upon administration would elicit production of protective antibodies in the individuals. DNA vaccine formulation consists of the gene encoding the antigen, which upon administration will produce the protein that will induce an immune response. The vaccine preparation has the advantages of easier transport and minimal cold chain facility requirements. mRNA vaccine formulation for COVID-19 consists of messenger RNA, or mRNA for the Spike protein which is processed in cells to make proteins. Administration of the vaccine preparation thus causes production of spike protein and subsequent generation of a protective immune response. Both the DNA and mRNA Vaccine candidates are relatively new vaccine

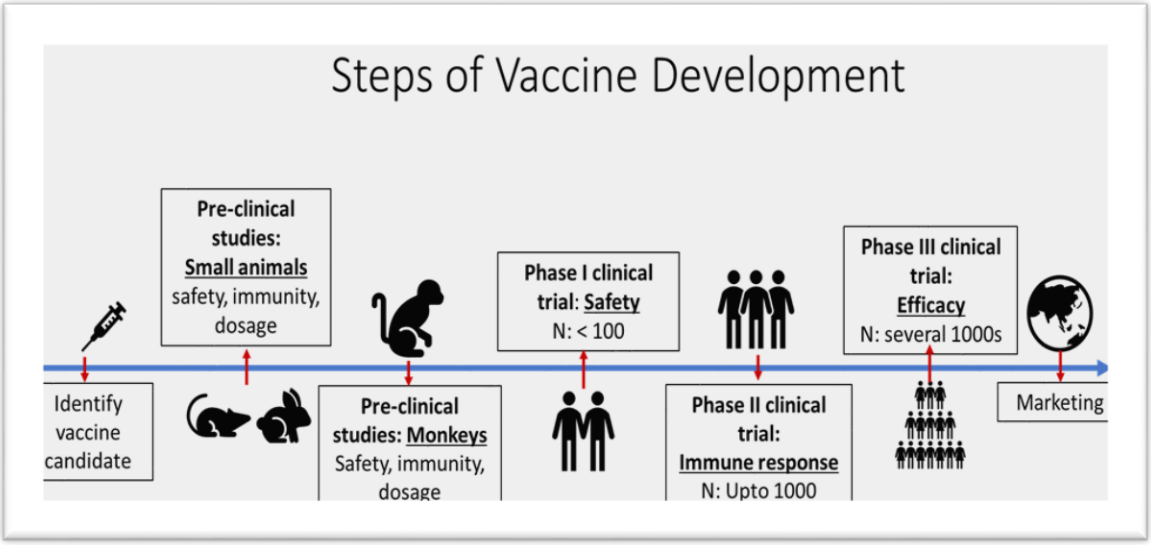
platforms. The suitability of the vaccine candidate is subject to successful demonstration of safety and efficacy in phase III clinical trials**."**

2.5 The Committee brought to the notice of the concerned Departments that there are reports that genetic vaccines like DNA vaccine and mRNA vaccine particularly the later which is a new invention may intervene directly in genetic material of the person vaccinated and alter his/her individual genes which is irreversible. In case of consequences or side effects, the vaccine receiver has to live with consequences as they cannot be cured. In this regard, the Committee enquired whether such consequences of genetic vaccines particularly mRNA is being examined by medical experts/scientists in the country so as to take a decision on using this vaccine in the country. In reply, the Department of Bio Technology has given the following reply:

"As per available knowledge the DNA and mRNA Vaccines do not integrate the DNA or mRNA of the virus into the cell nucleus of the recipient, but, instead inject part of the viral DNA/RNA into tissues to stimulate an immune response in the body. Hence, they would not intervene directly in genetic material of the person vaccinated. All matters pertaining to the ethical conduct of clinical trials, review of clinical trial data, and occurrence of adverse events during the course of the trial, are periodically reviewed by the Drug Controller General of India(DCGI)"

B. Steps in Vaccine Development

2.6 Department of Health Research (DoHR) in its background note has depicted vaccine development in the following figure:-



2.7 Further the Department of Pharmaceuticals (DoP) in its background note narrated the following steps in the vaccine development:-

i. **Manufacturing of test batches** – The batches for examination, test or analysis pre-clinical studies are manufactured.

ii **Pre-clinical studies** – The Vaccine is tested in animal studies for efficacy and safety, including challenge studies.

iii. **Clinical development**: The pre-approval clinical development includes the following phases:-

a) **Phase I clinical trial**: In this, a small group of healthy adult volunteers receive the vaccine to test for safety and immunogenicity.

b) **Phase II clinical trial**: The vaccine is given to hundreds of people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended to assess the safety and immunogenicity.

c) **Phase III clinical trial**: The vaccine is given to large number of people and tested for efficacy and safety.

iv. **Post-approval clinical assessment**- These includes assessment of Adverse Event Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) and /or Phase IV clinical trial/ post marketing surveillance under post marketing scenario.

C. Submission and Review Process of applications for vaccine production and quality testing:

2.8 The Department of Pharmaceuticals has also stated in its background note about the submission and review process of vaccine applications as follows :

i Application for conduct of clinical trial or for approval of manufacture/ import and marketing of vaccines are submitted to Central Drugs Standards Control Organization (CDSCO).

ii. All such applications are evaluated in consultation with the Subject Expert Committee (SEC) of CDSCO.

iii Application for grant of manufacturing license for vaccines after approval by CDSCO is made to the concerned State Licensing Authority (SLA). A joint inspection is carried out by experts of

Central Drugs Laboratory (CDL), officials from SLA and CDSCO. Based on the inspection report, manufacturing license is granted by SLA and countersigned by the Drug Controller General of India (DCGI).

iv In case of imported COVID-19 vaccine, importer is required to submit application to CDSCO for Import Registration Certificate and Import License.

v Every batch of vaccines for clinical trial & marketing are tested /reviewed and released by Central Drugs Laboratory, Kasauli to ensure quality.

2.9 CDSCO in its reply to a question of the Committee about its responsibilities with respect to Vaccines has stated that it is its responsibility to grant permission to conduct clinical trials, manufacturing/import for marketing, Registration certificate and license for import etc. under the provisions of Drugs and Cosmetics Act, 1940, New Drugs and Clinical Trials Rules (NDCT), 2019 and Drugs and Cosmetics Rules, 1945.(CDSCO reply to Qn 1(a))

Drug Regulation Division of Ministry of Health and Family Welfare in its background note has stated that It is important that adequate data on quality, safety, immunogenicity and efficacy is generated before approval of any vaccine to ensure the safety and effectiveness of the vaccine. Vaccines are required to be characterized and manufactured in compliance with the Good Manufacturing Practices (GMP).Manufacturing processes of every vaccine are validated, defined and controlled adequately to ensure batch to batch consistency. In regard to the above submission of the Drug Regulation Division, the Committee desired to know whether any steps have been made to manufacture COVID 19 vaccines as per WHO-GMP quality standards. In its reply, CDSCO has stated as follows**:-**

> "To manufacture and market Vaccines in the country, the applicant has to comply with the provisions under Drugs and Cosmetics Act, 1940, New Drugs and Clinical Trials Rules (NDCT), 2019 and Drugs and Cosmetics Rules, 1945. There is no requirement to comply with WHO GMP standards".

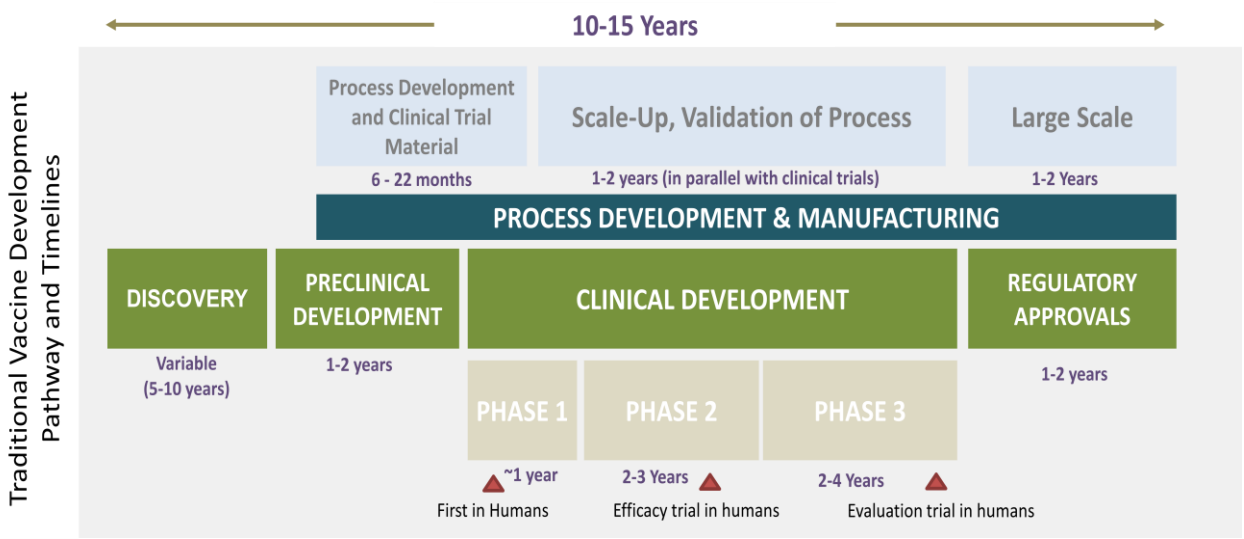
D. Fast track trial of vaccine candidates in extraordinary circumstances

2.10 The availability of a safe and efficacious vaccine for COVID-19 is crucial in effective control of the pandemic. A vaccine for an infectious disease has never before been produced in less than several years and no vaccine exists for preventing a corona virus infection in humans. The pace at which vaccines are being developed both internationally and in the country is unprecedented.

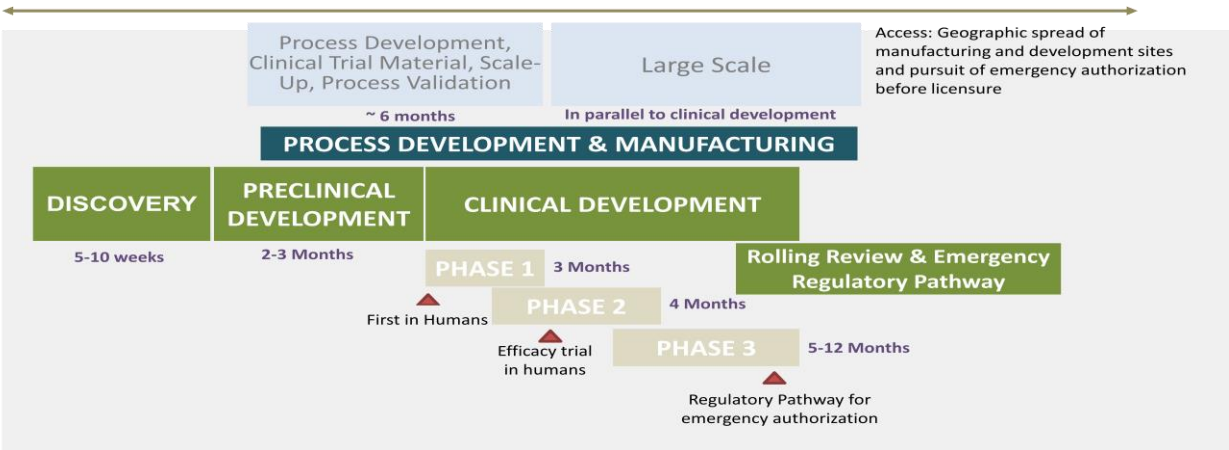
2.11 In normal circumstances, vaccine development takes close to 10 years for any infectious disease. But presently extra-ordinary measures are being taken to fast-track the development and production of COVID-19 vaccine without compromising the rigor of science and safety and efficacy measures. The steps which are helping in the fast-tracking process are fruitful collaboration between organizations and companies, conducting the required studies in parallel rather than sequentially as are usually done, planning for next phase while the earlier one is being completed and streamlining the processes of application and approvals.

2.12 In normal vaccine development each step is performed in sequence. In order to accelerate COVID-19 vaccine development, steps are done in parallel. In case of accelerated development, assessment of Adverse Event Following Immunization (AEFI) and Adverse Events of Special Interest (AESI)/Phase IV trial /post-marketing surveillance for side effects are critical.

Vaccine Development Pathway : Traditional Timelines



Vaccine Development Pathway : Accelerated Timelines



E. Measures for tackling post vaccination side effects

2.13 When the Committee enquired about the measures in place for tackling vaccine based side effects to some patients after vaccination during post approval period, CDSCO in its reply stated as follows:-

> **"**Post marketing, the Manufacturer is required to submit periodic safety update reports to CDSCO which contain the details of the adverse effects reported and assess these adverse effects if they are related to the vaccine to take necessary remedial measures. In case of vaccines supply through national immunization programme, these adverse effects are captured and appropriate measures are taken by the AEFI Secretariat under Immunisation division of Ministry of Health and Family Welfare."

CHAPTER-III

COVID-19 VACCINE RESEARCH AND DEVELOPMENT AND PRODUCTION STATUS IN INDIA INCLUDING INTERNATIONAL PARTNERSHIPS

A. Efforts for vaccine development in India by Department of Biotechnology, Ministry of Science & Technology

(a) Nodal Department for vaccine development in India

3.1 In India, the Department of Biotechnology (DBT) along with Indian Council of Medical Research (ICMR), Department of Health Research (DHR) is supporting vaccine development and manufacturing activities through both national efforts and international partnerships. At the national level, DBT has been identified as the Nodal Department by the PMO constituted Task Force, to consolidate efforts for vaccine development in India.

(b) Request for Proposal (RFP) for COVID-19 Research Consortium

3,2 On being asked about the steps taken for the development of COVID-19 vaccine in India, DBT in its written reply has stated as under:-

"Early on during the pandemic, the Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC)– a not-for-profit Public Sector Unit (PSU) of DBT, have published a "Request for Proposal (RFP) for COVID-19 Research Consortium". The RFP focused on thematic areas inclusive of development of indigenous vaccines. Presently, the Department of Biotechnology is supporting the development of nearly 12 vaccine candidates for COVID-19, by both industry and academia. Support is also being provided for development of research resources to aid vaccine development. Additionally, nearly 11 GCLP compliant clinical trial sites for quick initiation of clinical trials are also being supported and enabling regulatory guidelines were issued for expedited vaccine development. More recently, as part of the third stimulus package for Atma Nirbhar Bharat, "Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission", to be led by the Department of Biotechnology (DBT), has been launched by the Government of India. The Mission will focus on acceleration of the development of at least 5-6 COVID-19 vaccine candidates and ensure that some of these are brought closer to licensure and introduction in public health systems.

(c) Multi Pronged Strategy

3.3 In its background note, DBT has further stated that it is involved in multipronged strategy alongwith BIRAC to encourage vaccine development. Both

national efforts and international partnerships are being leveraged to support vaccine development for COVID-19. In addition, DBT is supporting companies involved in vaccine development and also strengthening the ecosystem required for vaccine development The following efforts have been made by DBT for vaccine development:-

- Through the DBT-BIRAC COVID-19 Research Consortium call, funding support has been extended to different vaccine candidates and activities to support vaccine development upto Phase I human clinical trials has been provided.
- Seed funding is being provided to early stage candidates and in candidates at advanced preclinical stages; funding support may be made available up to Phase I trials.
- Some major industry related projects being supported include Phase III trial of BCG vaccine by Serum Institute of India, mRNA vaccine (Gennova Biopharmaceuticals Ltd.), inactivated rabies vector platform (Bharat Biotech), protein subunit vaccine (Biological E Ltd.) and Vesiculo Vax Platform vaccine (Aurobindo Pharma).
- DBT is also working with the PM-Task force for supporting COVID-19 vaccine development efforts through the PM CARES fund (Prime Minister's Citizen Assistance and Relief in Emergency Situations fund).
- Additionally, the Department has set up COVID-19 Vaccine Expert Committee (VEC), including participation from Indian academia, industry, and international organizations, to provide oversight and monitoring for National COVID-19 vaccine development initiatives.

(d) National Biopharma Mission (NBM)

3.4 DBT also informed the Committee that the National Biopharma Mission (NBM) being implemented by BIRAC, has been at the forefront of supporting COVID-19 vaccine development efforts in the nation. The Steering Committee which provides oversight for all the activities being supported under the aegis of NBM, has representatives from Department of Pharmaceuticals (DoP),

Department of Health and Family Welfare and Drugs Controller General of India (DCGI).

(e) Bio safety Regulations

3.5 DBT has further informed the Committee that considering the emerging situations of spread of Coronavirus and with the understanding on requirement of rapid research and development for COVID-19, the Department has proactively taken several steps to facilitate researchers and industries involved in research on COVID-19. The following Bio safety Regulations for COVID 19 have been provided by the Review Committee on Genetic Manipulation (RCGM) and Drugs Controller General of India (DCGI):

1. Rapid Regulatory Response Mechanism- to provide expedited regulatory approvals for all diagnostics drugs and vaccines.

2. Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens- for compliance by all IBSCs and host institutions involved in research, development and handling of COVID-19 specimens.

3. A Rapid Regulatory Pathway for COVID Vaccine developed to facilitate Vaccine Trials
   Also, the Department of Biotechnology has worked with the NITI Aayog to provide Guidelines for Sharing of Bio-specimen & Data for Research on COVID-19.

(f) Mission COVID Suraksha

3.6 As a part of the Government of India's response to COVID-19 pandemic, the Department of Biotechnology (DBT), Ministry of Science and Technology, has been working with all stakeholders to address the urgent need for a COVID Vaccine. Therefore, to further accelerate these efforts DBT has launched a dedicated Mission for COVID-19 Vaccine Development Mission called "COVID Suraksha- the Indian COVID-19 Vaccine development Mission".

3.7 The goal of the Mission is to accelerate development of approximately 5-6 vaccine candidates for COVID-19 so as to ensure that within the next 12 months at least 2-4 of these are closer to licensure and introduction in market for consideration of emergency use or for licensure by regulatory authorities. The objectives of the Mission include:

1. Accelerating pre-clinical & clinical development and licensure of COVID-19 vaccine candidates that are currently in clinical stages or ready to enter clinical stage of development.

2. Establishing clinical trial sites, immunoassay laboratories, central labs and suitable facilities for animal studies, production facilities and other testing facilities to support COVID-19 vaccine development.

3. Supporting development of common harmonized protocols, trainings, data management systems, regulatory submissions, internal and external quality management systems and accreditations, to accelerate clinical development and licensure of COVID-19 vaccine candidates that have targets identified.

4. Supporting capabilities for process development, cell line development and manufacturing of GMP batches for animal toxicology studies and clinical trials.

5. Development of suitable Target Product Profile so that vaccines being introduced through the Mission have preferred characteristics applicable for India.

3.8 The Mission will be led by Department of Biotechnology and will be implemented by a dedicated Mission Implementation Unit (MIU) at Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking of DBT, as per the proposal duly approved by the Expenditure Finance Committee (EFC). Also, action has been taken for implementation and the first set of requests for Expression of Interest (REOI) have been published for clinical development of COVID-19 vaccine candidates and enhancement of capacity for COVID-19 vaccine development. Phase I of the Mission has been duly approved by the EFC for implementation at a total cost of Rs. 900 crore for a period of 12 months.

(g) Vaccine Expert Committee

3.9 COVID-19 Vaccine Expert Committee (VEC), has also been constituted by DBT, with due approval of the Competent Authority, to ensure the adoption of a holistic approach for accelerating the vaccine development efforts. The VEC has been mandated with review and evaluation of COVID-19 vaccine development projects, of both industry and academia. The VEC comprises of experts from Indian academia and science agencies.

B. Status of Vaccine development in India

(a) Efforts made by industry and academia

3.10 Nationally, nearly 30 groups, both academia and industry, are actively involved in development or collaboration or co-development and trials for COVID-19 vaccine in India. About 5 vaccine candidates are in clinical trials, which include 3 indigenously developed vaccine candidates. The details of Indian industry and

academia engaged in developing/testing of COVID-19 vaccine candidates are as follows:

I) Vaccine Development Efforts by Industry

(i) Indigenous efforts / Technology transfer

S.No.	COVID-19 Vaccine Developer / Manufacturer	Vaccine Platform	Stage of Development
1.	Serum Institute with Oxford University Astra Zeneca (ICMR)	Non- Replicating Viral Vector (ChAdOx1-S)	Clinical (Phase III)
2.	Cadila Healthcare (Zydus Cadila)	DNA Vaccine (ZyCoV-D)	Clinical (Phase III)
3.	Bharat Biotech – ICMR	Inactivated whole virion candidate vaccine (BBV152)	Clinical (Phase III)
4.	Biological E/ Collaboration	Subunit (RBD219-N1-C1)	Clinical Trial (Phase I, II)
5.	Serum Institute – Novavax	Protein Subunit Nano particle based(NVX-CoV2373)	Clinical Trial under consideration
6.	Bharat Biotech & Thomas Jefferson University, USA	Rabies vaccine platform (RABV-COV19-S1, CORORAB)	Pre-clinical
7.	Bharat Biotech and FluGen Inc& University of Wisconsin	Subunit Coroflu, an intranasal vaccine based on influenza platform(BBV150)	Pre-clinical
8.	Serum Institute with Codagenix , USA	Attenuated vaccine from Codagenix	Pre-Clinical
9.	Gennova and HDT Biotech Corporation	mRNA (HGCO19)	Pre-clinical
10.	Serum Institute with German Center for Infection Research (DZIF)	Live attenuated Recombinant measles virus-based vaccine	Pre-clinical
11.	Aurobindo Pharma Limited with Auro Vaccines	Attenuated VSV-vectored Vaccine	Pre-clinical
12.	Premas Biotech in collaboration with Akers Biosciences	Protein subunit (multi subunit) Viral proteins expressed in genetically engineered S. cerevisiae platform, D-Crypt™. (PRAK-03202)	Pre-clinical
13.	Luxmatra Innovations CCAMP, Bengaluru	mRNA vaccine -Nano-neo-mRNA platform	Pre-clinical
14.	Mynvax	Subunit (RBD of S Protein produced in insect cells)(MYNVCOV1001)	Pre-clinical
15.	Pentavalent Bio	Synthetic attenuated	Pre-clinical

	Sciences	vaccine platform for Influenza	
16.	Indian Immunologicals with Griffith University, Australia	Live attenuated with codon de-optimization	Early stage
17.	Seagull Bio Solutions	Non-replicating measles virus vector in Active Virosome Platform	Early Stage
18.	Epygen Biotech Pvt. Ltd with Dyadic, US	C1-RBD based antigen vaccine	Early Stage
19.	Panacea Biotec Ltd.	Whole inactivated virus (WIV) COVID-19 vaccine in collaboration with Refana	Early Stage
20.	Intas Pharmaceuticals Ltd.	Recombinant adeno-associated virus [rAAV] based genetic vaccine	Early Stage
21.	Reliance Life Sciences	Recombinant protein-based Covid-19 vaccine	Early Stage
22.	Bharat Biotech	Chimpanzee Adenovirus vectored vaccine	Pre clinical

ii) Bulk transfer / formulation

S.No.	COVID-19 Vaccine Developer / Manufacturer	Vaccine Platform	Stage of Development
1.	Dr Reddy's Laboratories	Non-replicating viral vector (Sputnik V)	Clinical Trial (Phase II, III)

II. Vaccine Development Efforts by Academia

S.No.	COVID-19 Vaccine Developer / Manufacturer	Vaccine Platform	Stage of Development
1.	Centre for Stem Cell Research, CMC Vellore	Spike mRNA encapsulated in lipid nano particles as a synthetic vaccine for SARS-CoV-2	Early pre-clinical
2.	Institute of Chemical Technology, Mumbai	Intranasal vaccine	Early pre-clinical
3.	IISER, Trivandrum CCMB, Hyderabad ICAR-NIHSAD, Bhopal (DEC-VAC SARS)	The project primarily focused on using S protein as a vaccine candidate	R&D project
4.	IISER, Mohali	Synthetic reconstruction of an attenuated SARS-CoV-2 virus for vaccine	R&D project

		development and a high-content inhibitor screen	
5.	Translational Health Science And Technology Institute (THSTI)	Self-amplifying RNA in a lipid nano particle	Early preclinical
6.	International Centre for Genetic Engineering and Biotechnology (ICGEB)	Recombinant subunit vaccine with hepatitis B	Early preclinical
7.	National Institute of Immunology (NII)	E. coli expressed RBD conjugated to CRM or pneumo	Early preclinical
8.	National Institute of Biomedical Genomics (NIBMG)	Baculovirus expressed virus-like particles	Early preclinical
9.	NCCS, Pune	Synthetic antigen-based vaccine	Early stage

III. Repurposing of Existing Candidates– Indian Companies

S. No.	COVID-19 Vaccine Developer / Manufacturer	Vaccine Platform	Stage of Development
1.	Serum Institute of India Pvt. Ltd., Pune	Recombinant BCG (VPM1002)	Phase III CT
2.	Cadila Pharmaceutical, Ahmedabad and National Institute of Immunology, New Delhi	MIP (*Mycobacterium indicuspraniior* Mw)Adjunct	Phase III CT
3.	ICMR- NIRT	BacilleCalmette Guerin (BCG) vaccine	Multi-centric study in elderly (> 60 years)
4.	Indian Institute of Science, Bangalore	Validating BacilleCalmetteGuarin BCG vaccine for inducing immunity to SARS-CoV-2	

B. Regulatory roles of Ministry of Health & Family Welfare in development of vaccine candidates

(a) Initiatives taken by CDSCO for improving accessibility of the vaccine

3.11 Ministry of Health & Family Welfare in their background note that the following Initiatives taken by Central Drugs Standards Control Organization (CDSCO) for improving accessibility of the vaccine:-

- CDSCO had issued a notice on 19.03.2020 that the applications pertaining to research and development of drug or vaccine for COVID-19 will be accorded high priority and will be processed on fast track basis.

- A Notice was issued on 25.03.2020 for streamlining of Lot release of consignments of imported Vaccines by port offices.

- CDSCO has published draft regulatory guidelines for development of vaccines with special consideration for COVID-19 vaccine on 21.09.2020.

- Circular has been issued on 03.04.2020 for streamlining the procedure for lot release of domestically manufactured Human vaccine.

- In order to assess the domestic availability of vials for making vaccines, meetings were held with vial manufacturers & their production capacities were assessed. It was found that in India, domestic vial manufacturers have capacity of producing 2740 million of vials per annum which are required for COVID-19 vaccine.

3.12 CDSCO has stated in a written reply to question that it has granted permission for conducting clinical trial of COVID-19 vaccines to the following manufacturers in India:

S. No.	Name of company	Phase of Clinical Trial	Study Duration	Status
1	M/s Bharat Biotech International Ltd., Hyderabad	Phase- I/II (Two trials i.e.Intramascular (IM) & Intradermal(ID) route))	IM route is 12 months & ID route is 06 months	IM route clinical trial completed. & ID route is ongoing
2	M/s Cadila Healthcare Ltd., Ahmadabad	Phase- I/II	Phase I:Approximately 15 weeks & Phase II: Approximately 34 weeks	Trial is ongoing
3	M/s Biological E limited Hyderabad	Phase- I/II	Approximately 14 months	Trial is ongoing
4	M/s. Serum Institute of India Pvt. Ltd., Pune	Phase- II/III	Approximately 7 months and 6 months of follow up	Trial is ongoing

5	M/s Bharat Biotech International Ltd., Hyderabad	Phase- III	12 months	Trial is ongoing

CDSCO has further stated that the applicants have to generate Safety, immunogenicity and efficacy data in the country as per the provisions under the Rules and submit to CDSCO for evaluation for grant of Marketing Authorization.

C. Progress made by three Vaccine Candidates which are in advanced stage

3.13 In its power point presentation on the subject, the representatives of the Ministry of health and Family Welfare showed the following slide on the progress made in three vaccine candidates which are in advanced stage**:-**

Developer	**Type**	**Name**	**Indian Manufacturer**	**Phase I**	**Phase II (ongoing)**	**Phase III (ongoing)**
Oxford, UK	Recombinant	*COVISHIELD*	Serum Institute of India Pvt. Ltd. Pune	UK (completed)	UK & South Africa	Brazil
					India	
BBIL-ICMR	Inactivated	*COVAXIN*	Bharat Biotech International Ltd. Hyderabad	India Completed	India Completed	India Approved
Cadila Healthcare	DNA	*ZCoV-D*	Cadila Healthcare Ltd. Ahemdabad	India Completed	India Ongoing	India Proposed

(a) COVAXIN Vaccine Candidate

3.14 The Department of Health Research its background note has stated as under about the development of COVAXIN which is a vaccine candidate indigenously developed in the country:-

"COVAXIN, which is a whole virion inactivated SARS CoV-2 vaccine (BBV152). This is being manufactured by Bharat Biotech in collaboration with NIV-ICMR. A well-characterized SARS-CoV-2 strain and an established vero cell (CCL-81) platform was used to produce this vaccine candidate. The seed virus (NIV 2020 -770 strain) was transferred from ICMR - NIV to Bharat Biotech. The vaccine candidate was initially tested in smaller animals like rats, rabbits and mice. Thereafter, it was tested in other bigger animals like hamsters and monkeys. After safety and immunogenicity was demonstrated in these studies, the phases of human trial were started. An adaptive, seamless phase 1, followed by phase 2 randomized, double-blind, multicenter study to evaluate the safety, reactogenicity, tolerability and immunogenicity of the whole-virion inactivated SARS-CoV-2 Vaccine (BBV152) in healthy volunteers was approved by CDSCO and registered in Clinical Trial Registry of India. This study was giving two doses of the vaccine 14 days apart in 1125 volunteers. After reviewing the findings of phase I and II studies, approval has been given for beginning the phase III trial which will be done in approximately 25,000 volunteers".

3.15 The Committee asked about the out come of Phase III trial of COVAXIN. In this regard, CDSCO in its written reply stated as follows

"CDSCO in consultation with the experts of Subject Expert Committee (SEC) has granted permission to conduct phase III clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) on 23.10.2020. As per information, M/s Bharat Biotech has started phase III clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in 21 sites across the country. The safety and immunogenicity data from phase I/II is being evaluated on continuous basis by CDSCO as and when submitted".

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(b) Covishield Vaccine Candidate

3.16 In regard to Covishield vaccine candidate, DoHR stated in its background has state as below:-

"Covishield vaccine is being tested in India by Serum Institute of India. This is a recombinant vaccine developed by Oxford University, UK. A Phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of this vaccine is underway on 1600 healthy adult volunteers".

3.17 On being asked about the progress made in testing, production and launching of this vaccine in the country and in ensuring safety and efficacy of this vaccine candidate, CDSCO in its written reply has stated that the safety data of Covishield vaccine is being evaluated on continuous basis by CDSCO as and when received. The manufacturer was granted manufacturing license to stockpile COVID-19 Vaccine with the condition the vaccine can be sold or distributed only after obtaining permission for marketing from Central Licensing Authority i.e. DCG(I**).**

(c) ZyCoV-D Vaccine Candidate

3.18 DoHR stated in its background note that ZyCoV-D is a plasmid DNA vaccine being tested by Zydus Cadila. This is newer technology and is being tested in phase I/II study. As per the status report submitted by firm on 04.12.2020, in Phase I clinical trial, a total of 48 subjects and further follow up of participating subjects is ongoing. Further, in Phase II clinical trial, a total of 1000 subjects and as per the approved clinical trial protocol, further follows up of participating subjects is ongoing. The Department of Biotechnology in their written note stated that this DNA vaccine candidate against SARS-CoV-2 being developed by Zydus Cadila, is a novel platform and has a 3-dose regimen. The formulation can be stored at 2ºC to 8ºC. Phase I Clinical Trials of the vaccine candidate showed that it is well tolerated in humans and no major safety concerns have been reported so far. Phase II Clinical Trials are ongoing and are expected to be completed in December, 2020.

(d) Latest update in ICMR website

3.19 There is a vaccine portal hosted by the ICMR website (https://vaccine.icmr.org.in) which gives updated information regarding COVID-19 vaccines and Indian initiatives in COVID-19. As per information available in this website, the following is the updated information about the above mentioned three vaccine candidates as on 10 January, 2021:-

COVAXIN: Phase III human clinical trial ongoing. DCGI approval for restricted use in emergency situation received.

COVISHIELD: Participants enrollment and vaccination of Phase II/III Human Clinical Trial completed. DCGI approval for restricted use in emergency situation received.

ZyCoV-D: Phase II human trial ongoing. DCGI approval for Phase III Human Clinical Trials received,

D. Safety and Efficacy of COVID-19 vaccines

(a) Uniformity in Safety and Efficacy of Multiple Vaccines

3.20 The Committee pointed out that considering large population size of our country, it is likely that one vaccine or vaccine manufacturer may not be able to fulfill the requirements of vaccinating entire population of the country. In the event of launching of multiple vaccines in the country, when it was asked, how does the Government proposes to ensure evenness of safety, efficacy, reactogenicity, tolerability and immunogenicity of various vaccines so as to create strong immunity against COVID 19 virus in an even manner amongst the people of various regions of the country who may receive different vaccines, CDSCO in its written comments stated as under:-

> **"**The applicant has to submit Chemistry, Manufacturing and Control (CMC), animal toxicity, safety, reactogenicity, immunogenicity and efficacy data as required under the provisions of New Drugs and Clinical Trial Rules, 2019. The data is examined by CDSCO in consultation with Subject Expert Committee (SEC) and accord approval for marketing, if found satisfactory. Further, each lot/batch of COVID-19 vaccine has to be tested & released by Central Drugs Laboratory (CDL), Kasauli before marketing in the country. The above provisions enable to ensure uniformity in the approvals granted for manufacture/import and marketing of COVID-19 vaccines in the country".

3.21 Ministry of Health & Family Welfare in its reply to the aforesaid question of the Committee has stated that one of The ToRs of The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) is 'Provide guidance on selection of COVID-19 vaccine candidates for the country. The National Expert Group will be assisted by the Standing Technical Sub-committee of National Technical Advisory Group on Immunization (NTAGI) for this purpose'. Accordingly, the NEGVAC, supported by NTAGI, will review the available scientific evidence on safety, efficacy, reactogenicity, tolerability and immunogenicity of various vaccines while making a decision for selecting a vaccine for roll-out in India. In an event of multiple vaccines being identified for roll-out in the country, adequate operational planning will be done to maximize the impact of COVID-19 vaccine on mitigating the impact of ongoing pandemic.

3.22 Further, DBT in its reply to the same question has stated that the National Technical Advisory Group on Immunisation (NTAGI) has a mandate of providing technical advice to inform decision-making on matters pertaining to immunization. A COVID-19 Working Group has been constituted under the Standing Technical Sub Committee (STSC) of the NTAGI, comprising of technical experts for reviewing the safety, efficacy, tolerability and related issues of COVID-19 vaccine candidates, so as to provide recommendations to the Government**.**

3.23 Further it was asked, whether safety and efficacy of various vaccine candidates and their suitability to the people of the country have been analyzed by the Government of India and its agencies, the Department of Biotechnology in its written reply stated, "the safety and efficacy of all the candidate vaccines is determined based on the Phase III clinical trial data, which is monitored by the DCGI periodically.

(b) Efficacy of indigenous vaccine candidates viz-a-viz foreign vaccine candidates

3.24 In reply to a question regarding indigenous vaccine candidates and their efficacy viz-a-viz foreign vaccine candidates, the Department of Biotechnology in its written reply stated as under:

> "The vaccine candidate (ChAdOx1-S), developed by Oxford University / Astra Zeneca and in-licensed to Serum Institute of India Pvt. Ltd. (SIIPL), has demonstrated an efficacy of 62-90% in the global Phase III clinical trial, depending on the dose administered. The Russian Sputnik V vaccine and the mRNA vaccine candidates of Pfizer and Moderna, have reported an efficacy of >92%, based on interim analysis of the Phase III clinical trial data. The efficacy of the indigenously developed inactivated vaccine candidate, COVAXIN, by Bharat Biotech International Ltd. (BBIL) can be determined only after completion of the administration of the second dose in the Phase III trial."

(c) Efficiency of Vaccines against various COVID 19 virus strains

3.25 On being asked about types of COVID-19 virus strains that have been reported till date in different parts of the country and how they are different from other strains reported globally**,** the Department of Biotechnology in its written reply stated as under:

> "Based on available information, so far four different lineages of SARS-CoV-2 virus have been identified across the nation with a predominance of

the A2a haplotype (20A/B/C) with D614G mutation, which is found to be emerging in almost all regions of the country. This particular haplotype has also been reported globally."

3.26 In this regard**,** further the Committee asked whether the present research by various vaccine candidates is taking place keeping in view multiple strains of COVID-19 virus so as to prevent spread of this deadly virus across the country, the Department of Biotechnology in their written reply stated, “The research efforts of the scientists are directed towards development of a broad spectrum and viable vaccine candidate against COVID-19."

E. Vaccine Manufacturing Capacity in India

(a) India’s Strength as a Vaccine Manufacturing Hub

3.27 India's strength as a Vaccine Manufacturing hub is well-recognized globally. More than 60% of Global Vaccine demand for the Immunization programmes is met by the Indian manufacturers. India’s strength in the field of vaccines lies in the manufacturing capacity of the Indian vaccine production industries, which could be potentially exploited to cater to not just India, but also to the world. Hon’ble Prime Minister has already indicated during the Vaccine Summit in London on 4th June, 2020 that the “*India not only has the capacity to contribute to the global health efforts, but also has the will to do so in a spirit of sharing and caring*”.

3.28 However, in the present scenario, where in diverse vaccine platforms are in advanced clinical stages of development and there is considerable global demand for COVID vaccines, the existing manufacturing capacities of the Indian industry would have to be ramped up. Also, there may be a requirement for setting up of additional facilities as the existing facilities may not be able to support production of the specific vaccine platforms. This is especially significant, considering India’s intent to participate in the WHO solidarity trial, whereby there is a need to manufacture potential vaccine candidates being developed indigenously and globally, for trials in India. Considering the indigenous vaccine candidates apart from other international vaccine candidates set to enter the clinical trial stage, there is a substantial requirement for production of diverse vaccine candidates.

3.29 In this context, a preliminary exercise of mapping the manufacturing capacity for COVID-19 vaccine candidates by leading Indian Vaccine manufacturers was undertaken by NEGVAC. NEGVAC has also undertaken an exercise to estimate the possible coverage and consequent requirement of vaccine in the first phase. Accordingly, the indications are that about 660 million doses of COVID-19 vaccine will be required in the first phase of vaccination program in India. However, given the uncertainties in development of natural immunity, the pattern of disease spread etc, it is quite possible that there may be

requirement for at least 1000 million doses of the vaccine demanding huge investments.

3.30 Taking into account large-scale manufacturing requirements for Phase III trials and post-licensure manufacturing, the *Mission COVID Suraksha* is proposed to be implemented by DBT. The Concept note for the Mission has already been approved by Department of Expenditure (DoE). As part of the Mission, funds would be set aside for manufacturing capacities. This will include costs for scale-up and clinical trial material generation and large scale manufacturing for commercialization. These efforts would ensure access to COVID Vaccine not only for the Indian population but also contribute to the requirement of the world.

3.31 The Secretary, Department of Pharmaceuticals while giving the power point presentation during the informal discussion held on 23.11.2020 informed the Hon'ble Chairperson and the members of the Committee who were present provided the following information about Vaccine Manufacturing Capacity in India:

> "India has strong and proven capacities in vaccine manufacturing for domestic and export markets. There are about 20 Vaccine manufacturers in India including the world's largest producer of vaccine (by number of doses).Indian vaccines are available for a number of diseases such as Influenza, TB, Hepatitis B, Tetanus, Measles etc. Indian manufacturers account for 40-70% of DPT and BCG vaccines and 90% of measles vaccine against WHO demand. The exports of vaccines from India were valued at Rs. 6500 crore in 2019-20 (which is 2/3rd of the total production)*. Covid -19 vaccine is under development globally and in India and is presently at the development and clinical trial stage.
>
> **industry estimates*

(b) Present production capacity of COVID-19 Vaccines in the country

3.32 CDSCO in their written reply to the Committee furnished the present production capacity of COVID-19 Vaccines as submitted by the manufacturers of COVID-19 vaccines:

S. No.	Name of Firm	Production Capacity (in lakhs doses /Annum)
1	M/a Serum Institute of India Pvt., Ltd., Pune	4000-5000
2	M/s Bharat Biotech International Limited, Hyderabad	1000
3	M/s Cadila Healthcare Limited, Ahmadabad	80.4

(c) License to stockpile COVID-19 vaccine

3.33 In its Background note, Drugs Regulation Section of Department of Health & Family Welfare stated that considering the emergency and unmet need, Ministry of Health & Family Welfare (MoHFW) has issued notification vide G.S.R. 1511(E) dated 18.05.2020 under Section 26B of the Drugs and Cosmetics Act,1940 providing that manufacturer can manufacture and stock any vaccine for COVID-19, which is under clinical trial, for sale or distribution after completion of clinical trial and grant of manufacturing approval by CDSCO. In accordance with the above notification, CDSCO has granted manufacturing license to the following manufacturers to manufacture & stock the COVID-19 vaccine (under clinical trial) for the purpose of making it available after successful completion of clinical trial to meet the emergency arisen due to COVID-19 pandemic:-

S.No.	Name of applicant	Production capacity (lakhs doses/Annum)
1	M/s Serum Institute, Pune (Oxford vaccine)	4000-5000
2	M/s Bharat Biotech, Hyderabad (inactivated Bulk Vaccine)	1000

F. Procurement Mechanism for COVID-19 vaccine

3.34 On being asked about the procurement mechanism for COVID-19 vaccine, the Department of Health and Family Welfare in their written reply stated as under:

> "Under the guidance of NEGVAC, the National Technical Advisory Group on Immunization (NTAGI) has recommended regarding vaccine candidates which may be available in near future subject to licensing by the DCGI and procurement will be done through company agnostic purchase agreement with vaccine manufacturers whose vaccine candidate is licensed by DCGI after ascertaining the safety and efficacy of the vaccine."

3.35 The Committee pointed that as per media reports the European Union, USA, UK, China and other countries have already entered into pre-agreements with world's leading pharmaceutical players in order to secure enough vaccine capacity for their people once it becomes available. In this regard, whether the Government of India has entered into or proposes to enter into any agreements with any vaccine manufacturer for procuring enough quantity of vaccines for the

huge population of the country and vaccination of entire population of the country, to this query the Department of Health and Family Welfare in their written note stated, "The NEGVAC is engaging with the vaccine manufacturers on a one-to-one basis to finalize the modality of securing adequate quantities of the vaccine for the beneficiaries requiring COVID-19 vaccine in a phased manner."

G. International Partnerships for Vaccine Development and Procurement

(a) Strategic engagements with global public health alliances

3.36 In the background note of Department of Pharmaceuticals it has been stated that, the Department of Biotechnology is also involved in key strategic engagements with global public health alliances to further vaccine development activities and keeping India engaged at the Global fora for COVID Vaccine development through International partnerships.

3.37 In the international arena, the Department of Biotechnology is leveraging efforts through the Ind-CEPI mission, titled- 'India Centric Epidemic Preparedness through Rapid Vaccine Development: Supporting Indian Vaccine Development. This mission being implemented as part of the Atal Jai Anusandhan Biotech Mission - Undertaking Nationally Relevant Technology Innovation (UNaTI) aimed at strengthening the development of vaccines and associated competencies/technologies for the diseases of epidemic potential in India. The strategic engagement of DBT with CEPI through Ind-CEPI will facilitate funding of proposals from Indian researchers; involved in two key engagements for COVID-19:

- CEPI's call for 'Proven vaccine technologies, applicable for large scale manufacturing, for rapid response against novel coronavirus, SARS-CoV-2' for rapid development and manufacture of proven vaccine candidates for SARS- CoV-2.
- CEPI's call on 'Centralized laboratory for measurement of immune responses elicited by SARS-CoV-2 vaccine candidates' for establishment of common protocols and provide robust assays for regulatory purposes. Under this call, the DBT-Translational Health Science and Technology Institute (THSTI) Bioassay laboratory supported under the Ind-CEPI Mission of DBT has been recognized by CEPI as one of the 06 global network of laboratories for centralized assessment of COVID- 19 Vaccines.

3.38. Also, the Department of Biotechnology, under the Indo-US Vaccine Action Programme (VAP), is facilitating access to NIH resources and expertise to enable accelerated development of COVID-19 vaccines. One of the vaccine developers being supported by DBT-BIRAC, Gennova Biopharmaceuticals Ltd.

(Pune, India), is involved in the development of a lipid encapsulated mRNA Vaccine for COVID-19 in active partnership with HDT Biotech Corporation, USA.

(b) Strengthening Clinical Trial Capacity in Neighbouring Countries:

3.39. Department of Biotechnology in partnership with Ministry of External Affairs (MEA) and Indian Missions abroad is enabling strengthening of clinical trial capacity in neighbouring countries, for facilitating Phase III trials for COVID vaccines. Two sessions have been held for over 90 participants from Afghanistan, Bhutan, Nepal, Bangladesh, Sri Lanka, Maldives and Mauritius.

(c) India's Participation in ACT and COVAX:

3.40 In the wake of the COVID-19 outbreak, the World Health Organization (WHO), along with accordant public and private global health partners, launched the Access to COVID-19 Tools (ACT) Accelerator on 24 April 2020, to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines. Considering India's focal and established role in global vaccine manufacturing, the intent for participation in the '*Vaccine Pillar'* of the ACT Accelerator (also known as COVAX), was conveyed by the Hon'ble Minister for H&FW, whereby, the vaccine manufacturing capacity of India was pledged, for making available vaccines for the world. The COVAX facility aims to get 2 billion doses of COVID vaccine by the end of 2021 and assures the participating countries for vaccine doses to cover 20% of their country's population. COVAX is co-led by Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi (The Vaccine Alliance).With nearly 29 vaccine candidates in various stages of clinical trials globally, and about 6 of them in Phase III trials, participation in the COVAX facility is beneficial in providing access to the global candidates in advanced stages, for their further utilization in the country. Also, India's pre-existing engagement strategy with CEPI and the well-established partnership with Gavi would be beneficial in meeting the COVAX targets.

3.41 In regard to the above, the Department of Health and Family Welfare in its written note to the Committee further stated that the ACT-Accelerator partners are collaborating under four pillars, one amongst which is COVAX facility led by Coalition of Epidemic Preparedness Innovations (CEPI), Gavi, the vaccine alliance and World Health Organization (WHO) that is working on Development & manufacturing of vaccines, Policy & Allocation, and Procurement & Delivery. COVAX facility aims to ensure vaccine availability through connecting pooled demand of countries with pooled supply from manufacturers. There are two type of participation in Gavi COVAX facility - one is for Self-Financing Participants (SFP) and other is for Low Income Countries (LICs) and Low and Middle Income Countries (LMICs) with Gross National Income (GNI) per capita income up to US$4000 who will get donor subsidized doses. Under Advanced Market Commitment, Gavi is supporting 92 middle & lower income countries including

India. The quantity of vaccines to be supplied from COVAX facility to India is yet to be finalized; however, advocacy with COVAX facility is ongoing to allocate India a fair share of vaccines.

3.42 The Committee asked about the details of initiatives taken by the Government of India to get the country's share of vaccines from COVAX facility, in this regard the Department of Health and Family Welfare in their written note stated as under:

> "Yes, the Government of India is constantly advocating for its fair share in the COVAX AMC supported COVID-19 vaccines at par with other AMC countries. In the Programme and Policy Committee (PPC) meeting of Gavi on 28-29 October 2020, COVAX AMC Support to India was discussed. Additional Secretary & Mission Director (National Health Mission) who represents Asia-Pacific Constituency, made a strong case to provide vaccine doses to India on pro-rata basis of population as done for rest of the AMC91 countries which is 35% of the total vaccine doses in COVAX AMC which will amount to covering 12.8% of our population. For securing these doses under COVAX Facility, we have taken parallel advocacy efforts through MEA and directly. Hon'ble HFM has written to his counterparts in UK & Australia as both countries are the members of Gavi Board and were not very supportive of India's stand as per information received from MEA (PMI Geneva). Hon'ble HFM has also written to Director General, WHO for supporting India stand in the upcoming Gavi Board is meeting in December. MEA has reached out to UNICEF headquarter in New York to solicit the support in the December Gavi Board meeting."

CHAPTER-IV

COVID-19 VACCINE ADMINISTRATION INCLUDING LOGISTICS FOR DISTRIBUTION AND DELIVERY OF VACCINES

A. National Expert Group on Vaccine Administration For COVID-19 (NEGVAC)

(a) Constitution and Composition of NEGVAC

4.1 The Government of India has set up a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) on 7th August, 2020 under the chairmanship of Dr V K Paul, Member NITI Aayog, with Secretary, Health & Family Welfare as Co-chair and Secretaries of Ministries/Departments of External Affairs, Biotechnology, Health Research, Pharmaceuticals, Electronics & IT and other experts as members.

4.2 During her power point presentation during informal discussion on the subject, the Secretary, Department of Pharmaceuticals showed the following slide on the composition of NEGVAC:-

National Expert Group on Vaccine Administration for COVID 19 (NEGVAC)

- **NEGVAC has been constituted under chairpersonship of Dr. V K Paul, Member NITI Aayog and Secretary, H&FW as Co-chairperson and following members:**

Secretary, Ministry of External Affairs	Director General, ICMR
Secretary, Department of Biotechnology	Dr Randeep Guleria, Director, AIIMS
Secretary, Department of Health Research	Dr Samiran Panda, Director, National AIDS Research Institute (NARI)
Secretary, Department of Pharmaceuticals	Dr Rakesh Aggarwal, member, National Technical Advisory Group on Immunization (NTAGI) & Dean, JIPMER Puducherry
Secretary, Ministry of Electronics and Information Technology	
Director General Health Services (DGHS)	Representatives from Five State Governments (Assam, Madhya Pradesh, Maharashtra, Tamil Nadu & Uttar Pradesh)
Representative from Department of Expenditure, Ministry of Finance	

Responsibilities of NEGVAC

4.3 As per the details given in the background note of Department of Pharmaceuticals, NEGVAC is tasked with the following responsibilities :-

(i) Providing guidance on selection of COVID-19 vaccine candidates for the country and on procurement mechanism of COVID-19 vaccine, both indigenous and international ;

(ii) Responsibilities of preparing a strategy for conceptualization and implementation mechanisms for creation of a digital infrastructure for inventory management and delivery mechanism of the vaccine including tracking of vaccination process (last mile delivery) to ensure equitable and transparent delivery of vaccine ;

(iii) NEGVAC will also provide guidance on financial resources required for procurement of COVID-19 vaccine and various options of financing the same;

(iv) Selection of delivery platforms, on cold chain and associated infrastructure for roll out of COVID-19 vaccination;

(v) Vaccine safety and surveillance; creating awareness and dissemination information.

(vi) Further NEGVAC will provide guidance on the role of India in supporting its key neighbours and development partners and on leveraging domestic vaccine manufacturing capacity for meeting the national and international needs of COVID-19 vaccines.

Accordingly, the various Departments and agencies of Government are working on vaccine development with a view to enable vaccine production and vaccination in a systematic manner.

4.4 During Power point presentation on the subject, representatives of Ministry of Health & Family Welfare stated that a Standing Technical Sub-committee of National Technical Advisory Group on Immunization (NTAGI) has been constituted under NEGVAC with the following terms of references:

- Detailed planning of vaccine delivery to priority groups.
- Arranging logistics and cold chain mechanism for grass root delivery
- Instituting trained manpower for vaccine delivery.

(c) Work done by NEGVAC

4.5 The Committee was informed by the Department of Health and Family Welfare in their written note that under NEGVAC following major decisions have been taken during first ten meetings that were held after its establishment wherein decisions pertaining to various activities of COVID-19 vaccine roll-out have been taken:-

"Formation of two sub-groups for:

a. Formally engaging with vaccine manufacturers.
b. For medical supplies logistics- consumable, Vials, syringes, transportation etc.(Responsibility of Dept. of Pharmaceuticals (DoP), Dept. of Biotechnology (DBT))

- Scaling up for beneficiary identification and logistics outreach. (Responsibility of MoHFW)
- Expedite engagements on Diplomatic front for support for COVID-19 vaccine. (Responsibility of MEA, DBT and Dept. of Health Research (DHR)
- Fast tracking the commitments of finances and policy for supporting vaccine candidate and commitment of assurance supply of vaccine from Indian Manufacturers. (Responsibility of Dept. of Expenditure (DoE), DBT and MoHFW),
- ICMR to provide progress report on point of care antibody test to be provided in next meeting of the Expert group. (Responsibility of DHR)
- Engagement with neighbouring countries for provision of COVID vaccines and support on clinical trials.(Responsibility of MEA, DBT, DHR)
- Essential Health Services should not be compromised while conducting COVID vaccinations. (Responsibility of MoHFW)
- DHR and DBT to guide on potential Emergency Use Authorization scenario. (Responsibility of DHR & DBT)
- Cold Chain strengthening for COVID Vaccination and preparation for supply of syringes and other logistics. (Responsibility of MoHFW)
- Develop robust Communication Plan for the people and reach out to the opinion makers well before scaling up of vaccination. (Responsibility of MoHFW)
- Adaptation and enhancement of existing eVIN platform for real time monitoring. (Responsibility of MoHFW)
- Prioritization of Health Care Workers, Front Line Workers, elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities for COVID-19 vaccination. (Responsibility of MoHFW)

- Advance Market Commitment has to be company agnostic & framework should be applicable to even potential vaccines in future. (Responsibility of MoHFW)
- Strengthen the AEFI Committees and surveillance and factor in the training for crisis management at state/district level. (Responsibility of MoHFW)
- AYUSH doctors could be considered as vaccinators if injections administration is among their competencies. (Responsibility of MoHFW)

These decisions during the various meetings of NEGVAC are being utilized for operationalizing various aspects of roll-out of COVID-19 vaccine."

4.6 The Committee stated that the COVID-19 was recognized by the Government as a biological disaster during March 2020 under Disaster Management Act 2005 but the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) was set up on 7th August, 2020. In view of this, the Committee asked about the reasons for the delay of nearly five months in constitution of this expert group, to this the Department of Health and Family Welfare in their written reply stated as under:

> "Since, the beginning of COVID-19 pandemic, the Department of Health & Family Welfare has been proactively involved in managing the pandemic through health system strengthening measures. The roll-out of COVID-19 vaccine is one of the many measures for controlling the pandemic in the country. The constitution of NEGVAC has been done to guide the roll-out of COVID-19 vaccine in the country when the possibility of a vaccine against COVID-19 being available was seen in terms of global research and development efforts. Hence, there has been no delay in constitution of NEGVAC."

4.7 The Committee asked about the specific challenges before the NEGVAC in the fight against spread of COVID-19 and measures that are being taken or proposed to be taken to address these challenges, in this regard the Department of Health and Family Welfare in their written reply stated as under:

> "The specific challenges before the NEGVAC are identification of vaccine candidates for roll-out in the country and prioritizing the beneficiaries for the same. To address these challenges, NEGVAC is reviewing the available scientific evidence, consulting with technical experts and engaging with the vaccine manufacturers for providing guidance to the roll-out of COVID-19 vaccine in India."

(d) Role of Department of Pharmaceuticals

4.8 In this regard, the Committee asked about the role/responsibility that has been assigned to the Department of Pharmaceuticals by NEGVAC and the steps that have been taken by the Department in fulfillment of that role/responsibility. The Department of Pharmaceuticals in its written reply stated as under:

> "Secretary DoP, as member of larger group of NEGVAC is heading the Sub Group-II on logistics and distribution which is mandated to look into the effective co-ordination of logistic aspects of COVID-19 vaccination. So far eleven meetings of this Sub-Group have taken place and the group has co-ordinated the logistic aspects like syringes, cold chains, their transportation with different ministries like MoHFW, Ministry of Civil Aviation, DBT etc. The Sub-Group also reviews the co-ordination between MoHFW and various State Governments."

B. Role of Department of Health and Family Welfare

(a) Responsibilities of Ministry of Health & Family Welfare

4.9 In a written reply to a question on its responsibilities, Department of Health & Family Welfare stated that under the guidance of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), Department of Health and Family Welfare is involved in the following activities for distribution of COVID-19 vaccine and vaccination of beneficiaries:

- Development of operational guidelines including communication strategy for COVID-19 vaccination.
- Liaison with central line ministries for support in operational planning and communication strategy for COVID-19 vaccination.
- Development of Co-Win software for individualized tracking of beneficiaries and real time information on COVID-19 vaccine stocks and their storage temperatures.
- Enlisting of the beneficiaries for COVID-19 vaccination in collaboration with States/UTs and central line ministries.
- Assessment of Cold Chain Network for storage and distribution of COVID-19 vaccine and its strengthening.
- Assessment of requirement of syringes and other logistics for COVID-19 vaccination and streamlining the supplies for the same in timely manner.
- Regular monitoring of States/UTs for various activities pertaining to planning and preparedness for COVID-19 vaccination.

(b) Preparedness of Department of Health and Family Welfare for distribution/delivery chain and associated logistics infrastructure

The details of preparedness of Department of Health and Family Welfare for distribution/delivery chain and associated logistics infrastructure for COVID-19 vaccine in India are given below**:-**

(i) Prioritization of beneficiaries and their identification:

4.10 In view of the global scale of pandemic, there will be huge demand for vaccine upon its availability. Accordingly, the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has been discussing the prioritization of various groups in terms of Health Care Workers (HCWs), Front Line Workers (FLWs), elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities who could be covered first. States/UTs and central line ministries are creating the database of HCWs working in their respective health facilities/hospitals/laboratories etc. This database of HCWs will be used for vaccinating them, once the vaccine for COVID-19 is available. Similarly, databases for other priority groups are also being prepared.

4.11 In this regard, the Committee sought the details about the progress made with respect to the data base of elderly population, elderly population with co-morbidities, people living in dense localities of cities and towns, slum areas, etc. created for vaccination followed by vaccination of Health Care Workers, the Department of Health and Family Welfare in their written reply stated as under:

> "The decision on prioritization of groups for COVID-19 vaccination will be taken by NEGVAC. Presently deliberations of NEGVAC pertain to prioritization of Health Care Workers (HCWs), Front Line Workers (FLWs), elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities. The process of creation of database of HCWs and FLWs is ongoing. The decision on additional groups to be prioritized for COVID-19 vaccination will be taken based on evolving scientific evidence to maximize the impact of this drive."

4.12 Further, the Committee asked about the concrete steps that are proposed to be taken by the Government of India to ensure required quantity of COVID-19 vaccines to vaccinate the entire population of the country at the earliest and the quantum of funds required for the same, the Department of Health and Family Welfare in their written note stated as under:-

> "Initially the vaccine will be prioritized for Health Care Workers (HCWs), Front Line Workers (FLWs), elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities. For covering 3 crore HCWs and FLWs with two doses of vaccine, around 6.6 crore doses will be required which is estimated to cost around Rs 1485 crore.

However, the total fund required for vaccinating all those requiring vaccine will depend on the estimated number of total prioritized beneficiaries and the prevailing cost of vaccine. The procurement of vaccines by MoHFW will be done using domestic funds."

4.13 The Committee also asked about the proposal to vaccinate all the people residing in hot spot areas in various States/Union Territories on priority basis to contain the spread of the pandemic, the Department of Health and Family Welfare in their written reply stated, "No, presently there is no proposal to vaccinate all people residing in Hot Spot areas. The decision on including any population group is based on the objective to minimize mortality and spread of COVID-19 pandemic taking in view the available scientific evidence. There is no concrete evidence on vaccinating people residing in hot spot areas."

4.14 On the issue of covering the people in rural and remote areas on priority basis and steps that have been taken to protect the people of rural/remote areas, the Department of Health and Family Welfare in their written reply stated, "The prioritized beneficiaries in all areas will be covered for COVID-19 vaccination including rural and remote areas."

4.15 Further the Committee also asked about the proposal to vaccinate Indian population for free of cost, the Department of Health and Family Welfare in their written reply stated, "The financing mechanism for vaccinating the entire population of the country has not been finalized yet."

4.16 During the informal discussion held on 23.11.2020, a representative of Indian Council of Medical Research informed the Committee that instead of mass vaccination, the proposal is to go for smart vaccination.

To understand this, the Committee asked about the meaning of smart vaccination along with effectiveness of this approach when the country is experiencing rising cases of COVID-19 infection in various parts of the country, the Department of Health and Family Welfare in their written note stated as under:

"Smart vaccination pertains to vaccinating those individuals who are at highest risk of contracting COVID-19 infection or mortality due to COVID-19 infection. Through vaccinating such prioritized groups, maximum benefit can be achieved in mitigating the impact of the pandemic in view of limited availability of the vaccine during the initial phases."

4.17 The Committee further asked about the ability of the smart vaccination to arrest the spread of COVID-19 caused by asymptomatic cases and steps that are proposed for an effective and universal vaccination programme to eliminate COVID-19 pandemic from the country, the Department of Health and Family Welfare in their written note stated as under:

"Smart vaccination will maximize the benefit for mitigating the impact of the pandemic in view of limited availability of vaccine in initial phases. Through this approach, further reduction in number of symptomatic as well as asymptomatic cases is expected to achieve. However, vaccination as a stand-alone measure cannot curtail the pandemic and other pharmacological as well as non-pharmacological measures like physical distancing, use of masks and hand hygiene have to be practiced to reduce the number of cases of COVID-19."

(ii) Use of Information Technology Based Platform for beneficiary management and supply chain management of vaccines

4.18 Under the Universal Immunization Programme, electronic Vaccine Intelligence Network (eVIN) is being used across states/UTs for real-time information on vaccine stocks and their storage temperature. A software named Co-WIN [earlier named as COVID-19 Vaccination Beneficiary Management system (CVBMS)] has been created as an enhancement of existing electronic Vaccine Intelligence Network (eVIN) module for individualized tracking of all beneficiaries receiving COVID-19 vaccine. Presently, the States/UTs and central line ministries are uploading the database of Health Care Workers on the Co-WIN software. Use of this software will help in efficient planning of manpower, vaccines and logistics for smooth introduction of COVID-19 vaccine.The working of Co-WIN software at various levels is as follows:

- National level: national level users at MoHFW and central line ministries will be able to create users for State/UT and/or similar levels within their organization for creating the database of beneficiaries. These users will also be able to view the dashboard having information on various activities pertaining to registration of beneficiaries, their vaccination status, available stocks of vaccines and their storage temperature

- State level: State level users will be able to create users for district within their respective state for creating the database of beneficiaries. These users will also be able to view the dashboard having information on various activities pertaining to registration of beneficiaries, their vaccination status, available stocks of vaccines and their storage temperature.

- District and Local level: District level users will be able to enter details about registration of beneficiaries, create database of health facilities and vaccinators. The district level users will then do the session planning in the Co-WIN software which will allocate the registered beneficiaries to session sites and vaccinators. The local level will be

able to conduct the vaccination sessions and view vaccination status of the beneficiaries. Both District and Local level users will be able to view the progress of the vaccination drive in their catchment area. They will also be able to view vaccine stocks and storage temperature.

(iii) Planning for Cold Chain and Syringes

4.19 Vaccines are thermo-sensitive products that needs to be stored at specified temperature at all levels from manufacturer to the site of vaccine administration.In view of introduction of COVID-19 vaccine, an assessment of Cold Chain Space requirement has been carried out for the entire country on the basis of which procurement process is being initiated for Cold Chain Equipment.An estimation of requirement of syringes has also been done under the guidance of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and timely action is being initiated to align their supplies.On the issue of adequacy of the present infrastructure and logistics to provide seamless distribution of COVID-19 vaccine across the country, the Department of Health and Family Welfare in their written reply stated as under:

> "The present infrastructure and logistics are adequate to provide vaccination to Health Care Workers and Front Line Workers which are around 3 crore. An assessment of Cold Chain Infrastructure and logistics has been carried out and strengthening measures for the same are underway for seamless distribution of COVID-19 vaccine across the country for subsequently identified beneficiaries."

4.20 On being asked about the details on the Government study on the preparedness of big countries like China, USA, European Union, Brazil, Russia etc. for administering COVID vaccine supply chain and the corresponding measures being taken/proposed to be taken to manage the stupendous task of distribution/delivery of COVID Vaccines throughout the country, the Department of Health and Family Welfare in their written reply stated as under:

> "Under the guidance of NEGVAC, the Government of India is watching the fast evolving scenarios closely. The Government of India is taking all measures for best vaccine supply practice from manufacturer to session sites to manage the stupendous tasks of distribution / delivery of COVID vaccine throughout the country. Quality cold chain equipments are supplied for storage capacity augmentation. The cold chain technician and the vaccine and cold chain handler are trained regularly on the equipment maintenance and on good storage and distribution principles."

4.21 When the Committee asked about the steps that are being taken by NEGVAC on cold chain and associated infrastructure for roll out of COVID-19 vaccination, the Department of Health and Family Welfare in their written reply stated as under:

> "For the additional requirement of Cold Chain Equipment, purchase orders have been placed for 3089 Deep Freezers (DF) and 8767 Ice-lined refrigerators (ILR) while UNICEF is supporting supply of 20 Walk-in Freezers (WIF), 40 Walk-in Coolers (WIC), 620 Deep Freezers and 2984 Ice-lined refrigerators. Further tenders have been floated for 18 Walk-in Freezers, 53 Walk-in Coolers, 6897 Deep Freezers and Department of Public Enterprises has been requested for 14 Walk-in Freezers, 12 Walk-in Coolers, 1869 Deep Freezers and 1866 Ice-lined refrigerators under CSR initiative. The supplies of the procured equipment to the states have begun from last week of November 2020."

4.22 With respect to the assessments that has been made about the requirement of cooled transport facility in the country for transporting vaccine according to the specific temperature requirements and steps that are being taken to meet the cooled transport requirement of various state/UTs for transporting vaccines, the Department of Health and Family Welfare in their written reply stated as under:

> "There is an established mechanism of vaccine transportation in the country from primary vaccine stores to the session sites maintaining required temperature. Manufacturers supply directly to 41 primary stores in the States/UTs/. Government Medical Stores Depot supply vaccines to 19 primary stores in the country. There are insulated vaccine vans, supplied by the Govt. of India to all States for vaccine transportation. Cold boxes and vaccine carriers are used for vaccine transportation to intermediary stores and session sites respectively. The same mechanism will also be used for COVID-19 vaccine transportation."

4.23 On the steps that are being taken for creation of requisite amount of cold chain space (both central storage capacity and peripheral storage requirement) and procurement of related equipment, syringes, etc. throughout the country, specifying about its funding mechanism between central / state / union territories and its implementation procedure in all states / union territories, the Department of Health and Family Welfare in their written reply stated as under:

> "The cold chain equipments are regularly procured to address the replacement of ageing equipment, change from CFC refrigerant to non CFC refrigerant, creation of new vaccine stores with cold chain equipment and

capacity augmentation to accommodate new vaccines under the Universal Immunization Program. Orders have been placed for procurement of cold chain equipment by M/s HLL (for MoHFW) and UNICEF (under KfW assistance). A landscape analysis was conducted by UNICEF and BMGH to identify potential private cold storage service providers and there may be engagement with the private service providers if any need arises."

4.24 The Department of Health and Family Welfare has furnished State/UT wise information about present status of availability of cold chain space (both central storage capacity and peripheral storage requirements) and related equipments and shortfall assessed in cold chain space and related equipments which is as under:-

"The requirement of Cold Chain equipments as per Gap analysis for COVID-19 vaccination program and availability of Cold Chain Equipment in the Country is given under in tabular form:-

Requirement of Cold Chain Equipment as per Gap Analysis for COVID-19 Vaccination Program				
S.N.	State/UT	WIC*	ILR(L)&	ILR(S)&
1	Andaman & Nicobar Islands		3	
2	Andhra Pradesh	3	102	
3	Arunachal Pradesh		2	
4	Assam	1	90	
5	Bihar		444	183
6	Chandigarh		7	
7	Chhattisgarh		74	
8	Dadara& Nagar Haveli		3	
9	Daman & Diu		2	4
10	Delhi	1	76	11
11	Goa		9	
12	Gujarat	1	190	
13	Haryana		87	6
14	Himachal Pradesh		27	
15	Jammu and Kashmir		43	
16	Jharkhand	1	101	28
17	Karnataka	2	240	
18	Kerala	1	106	
19	Lakshadweep			
20	Madhya Pradesh		121	4
21	Maharashtra	5	460	
22	Manipur		10	
23	Meghalaya		7	
24	Mizoram			
25	Nagaland		8	

26	Odisha		55	
27	Puducherry		2	1
28	Punjab		104	
29	Rajasthan	3	85	
30	Sikkim			
31	Tamil Nadu		289	13
32	Telangana	1	112	6
33	Tripura		9	
34	Uttar Pradesh	4	742	314
35	Uttarakhand		20	
36	West Bengal	5	194	
Total		**28**	**3824**	**570**

Note: * WIC is Walk-in Cooler; [&] ILR is Ice-lined Refrigerators, (L)for large and (S) for Small

Availability of Cold Chain Equipment in the Country							
S.No.	**Name of State**	**ILR (L)**	**ILR (S)**	**DF (L)[#]**	**DF (S) [#]**	**WIC**	**WIF[^]**
1	Andaman & Nicobar Islands	22	31	29	27	1	0
2	Andhra Pradesh	121	2257	244	1907	9	6
3	Arunachal Pradesh	62	189	35	191	2	0
4	Assam	276	912	222	810	5	2
5	Bihar	614	1040	382	550	19	4
6	Chandigarh	13	56	10	48	1	0
7	Chhattisgarh	265	644	230	786	5	2
8	Dadara& Nagar Haveli	13	17	4	29	0	0
9	Daman & Diu	7	19	1	15	0	0
10	Delhi	156	664	34	445	1	0
11	Goa	25	51	4	56	1	0
12	Gujarat	902	1700	605	1861	9	2
13	Haryana	172	917	46	842	16	5
14	Himachal Pradesh	69	497	24	556	5	1
15	Jammu and kashmir	119	919	65	769	5	1
16	Jharkhand	261	423	201	498	5	3
17	Karnataka	389	3375	266	3214	9	5
18	Kerala	169	1941	68	1769	6	1
19	Lakshadweep	4	22	3	12	0	0
20	Madhya Pradesh	817	1531	482	1706	12	5
21	Maharashtra	850	3583	740	3471	22	13
22	Manipur	20	92	12	93	2	0
23	Meghalaya	21	184	31	198	3	0
24	Mizoram	40	89	21	87	1	0
25	Nagaland	30	93	24	101	1	0
26	Odisha	365	1434	223	1491	13	2
27	Puducherry	21	56	19	57	0	0
28	Punjab	167	983	155	887	6	3
29	Rajasthan	609	2920	403	3073	14	3

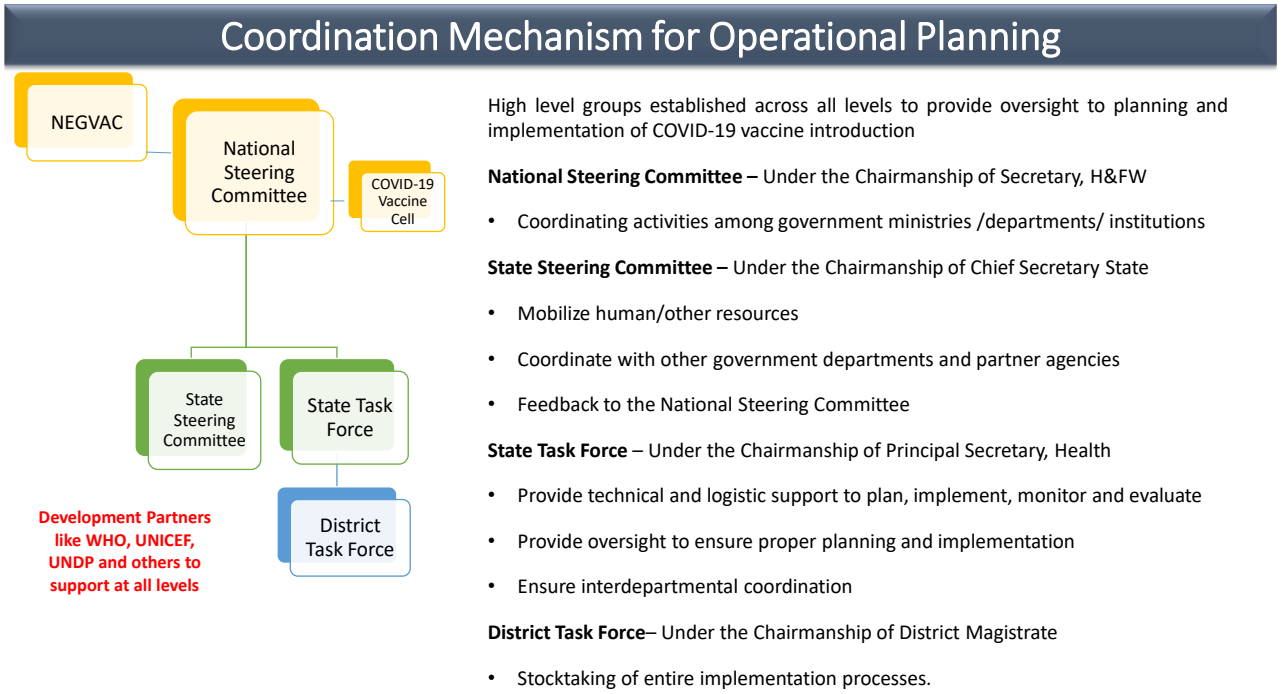
30	Sikkim	13	94	6	82	0	0
31	Tamil Nadu	365	2430	460	2232	20	6
32	Telangana	186	1012	208	927	7	3
33	Tripura	62	129	37	180	2	1
34	Uttar Pradesh	1442	2149	1108	2965	30	10
35	Uttarakhand	133	566	107	502	5	1
36	West Bengal	512	2071	242	1697	23	8
	Grand Total	**9312**	**35090**	**6751**	**34134**	**260**	**87**

Note: ^ WIF is Walk-in Freezers; # DF is Deep Freezer, (L) for Large and (S) for Small

(iv) Operational Planning

4.25 Under guidance of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), operational guidelines are also being formulated to guide the states and districts on various aspects of COVID-19 vaccine introduction like capacity building of human resources, micro-planning of sessions, planning for other logistics, vaccine distribution, communication planning etc.

4.26 The states have also been communicated to create State Steering Committee, State Task Force and District Task Force for oversight on planning and implementation of various activities and ensuring inter-departmental coordination with all the departments and mobilization of resources. In this regard, the representatives of the Ministry of Health and Family Welfare showed the following slide during informal discussion with the Hon'ble Chairperson and Members of the Committee on 23/11/2020:-



4.27 The Committee also asked about the States/UTs that have created State Steering Committee, State Task Force and District Task Force for oversight on storage and distribution of vaccine and the details of the States/UTs which have responded positively, the Department of Health and Family Welfare in their written reply stated as under:

> "Yes, the States/UTs have created State Steering Committee, State Task Force and District Task Force for oversight on storage and distribution of vaccine. As on 10th December 2020, State Steering Committees have been formed and meetings held in all the States/UTs, State Task Forces have been formed in all the States/UTs and meetings held in 32 States/UTs, District Task Forces have been formed in 735 districts/urban areas and their meetings have been held in 553 districts/urban areas. The States/UTs are advised during all interactions to proactively hold the meetings of above mentioned committees and task forces."

4.28 The Committee further asked about the effective measures that are being taken by the Government of India in coordination with all states/union territories to ensure optimum preparation on various aspects like capacity building of human resources, micro-planning of sessions, planning for other logistics, vaccine distribution/delivery chain, communication planning etc. with respect to COVID-19 vaccination programme so as to ensure that each and every citizen of the country gets vaccination at the earliest, the Department of Health and Family Welfare in its written reply stated as under:

> "Government of India, in coordination with states is regularly reviewing the preparedness on various aspects like capacity building of human resources, micro-planning of sessions, planning for other logistics, vaccine distribution/delivery chain, communication planning etc. with respect to COVID-19 vaccination programme. For this purpose multi-level coordination mechanism has been established in form of State Steering Committee chaired by Chief Secretary, State Task Force chaired by Principal Secretary (H&FW), District Task Force chaired by District Magistrate and Block Task Force chaired by Sub-Divisional Magistrate/*Tehsildaar*/Block Development Officer have been established across all levels for convergence of all stakeholders, review of progress and providing guidance to the preparatory steps and implementation of COVID-19 vaccine roll-out."

4.29 In regard to its preparedness as part of operational planning , Ministry of Health & Family Welfare in its written reply stated, “Virtual orientation of senior officials and development partners across the states/UTs has been done on

Operational and Communication planning for COVID-19 vaccination. Further, a virtual National Training of Trainers has been conducted for Programme Managers across the States who will be managing the entire process of roll-out of COVID-19 vaccine. These training will be cascaded down to districts and sub-districts for capacity building of all stakeholders who will be involved in the roll-out of COVID-19 vaccine".

4.30 The Committee asked whether WHO or any other international organization has prepared /issued any guidelines for safe storage transportation and distribution of COVID-19 vaccine from manufacturing facility to the vaccination point and the steps that are being taken / proposed to be taken for following those guidelines scrupulously for the covid19 vaccination program of the country. In this regard, Immunization Division of Department of Health and Family Welfare in its reply stated as under:-

> "WHO and UNICEF continue to provide interim guidance on various aspects of COVID-19 vaccine. In continuation to this, WHO and UNICEF have issued an interim document "Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines" dated 16th November 2020 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1), where countries are advised to have standard operating procedures in place for the supply chain, training of supply chain staff, assessment of cold chain capacity and gaps for fulfillment and data management systems for recording and reporting for vaccines and cold chain. These strategies are suggested in anticipation of a COVID-19 vaccine introduction. This interim guidance assumes that the majority of the vaccines under development will need to be stored at +2 to +8 Degree Centigrade.
>
> As part of the Universal Immunization Program in India, standard operating procedures are already developed and implemented for safe storage, transportation and distribution of vaccine. Accordingly, India has undertaken the following strategies to ensure preparedness for safe storage, transportation and distribution of COVID-19 vaccines during the vaccine roll out:
>
> Capacity gap assessment of cold chain capacity at all supply chain levels with procurement of cold chain equipment initiated to implement need-based augmentation of cold chain capacity gap at all levels.
>
> Procurement, supply and installation of cold chain equipment as per assessed need. Development of the Operational Guidelines for COVID-19 vaccine roll out with standard operating procedures for cold chain and vaccine management as per the SOPs in the Vaccine and Cold Chain Handlers Module 2016 and current assumptions of the anticipated COVID-

19 vaccine. This includes guidelines for safe storage, transportation and distribution of COVID-19 vaccines.

Roll out of training based on the operational guidelines for staff likely to be involved in COVID-19 vaccine operationalization, including Vaccine Cold Chain Handlers and Cold Chain technicians, at state, district, block and field levels.

Preventive and curative maintenance of cold chain equipment through the district Cold Chain Technicians. Standard monitoring checklists in place for monitoring of cold chain points at all levels to supervise the quality of storage and transportation of vaccines. Real time monitoring of vaccine stocks at all levels of the supply chain with real time monitoring of cold chain equipment temperature to maintain storage quality through the electronic web and mobile based system integrated in CoWIN application".

4.31 Further, the Committee sought information regarding the availability of adequate strength of human resources in all states/union territories for implementation of guidelines of NEGVAC, and the course of action for such states/union territories, the Department of Health and Family Welfare in their written reply stated, "Yes, adequate strength of human resources is available in all States/UTs for COVID-19 vaccination as per the guidance from NEGVAC."

4.30 With respect to adequacy and availability of the skilled Health Care Workforce to deliver COVID-19 vaccine, the Department of Health and Family Welfare in their written reply stated as under:

"Yes, adequate skilled Health Care Workforce is available to deliver COVID-19 vaccine. However, to minimize disruption of routine health services due to COVID-19 vaccination drive, additional potential vaccinators are being identified on CO-Win software whose services may be utilized as per the need."

4.32 On the issue of adequate production capacity for Personal Protection Equipment Kits and steps taken for their adequate and timely availability in Government Hospitals across the country, the Department of Health and Family Welfare in their written reply stated as under:

"At the beginning of the COVID -19 pandemic, there were no manufactures of COVID – 19 specification PPE coveralls in India. There were only suppliers of imported PPE Coveralls. With the efforts of the Ministry of Health and Family Welfare (MoHFW) and Ministry of Textile (MoT), there are a large number of PPE coverall manufacturers, approx. 1100 in India. Further, a large number of manufacturers of PPEs are on boarded on GeM and, therefore, and sufficient quantity of quality certified Personal Protective Equipment is now available on GeM portal.

As regards to BIS certification, there are presently more than 70 BIS certified manufactures of PPE coveralls and more than 220 BIS certified manufacturers of N- 95 masks. A large number of manufactures are also in process of attaining the BIS certification. Therefore, the availability and affordability of quality certified PPE coveralls, and N-95 masks does not appear to be a constraint anymore."

OBSERVATIONS /RECOMMENDATIONS

1. Availability of Safe, Secure and Effective Vaccine for COVID 19

The Committee have noted that COVID 19 is an infectious disease caused by a newly discovered Corona virus SARS-COV 2. It was first detected in Wuhan city of Hubei province in China during December 2019. Since then the virus evolved and spread to other countries as a major health threat affecting the socio economic life of the people at the global level. World Health Organization declared the outbreak of this highly infectious disease a pandemic on 11 March 2020. The pandemic has affected our country as well. As of now, our country is the second most affected in the world after the USA in respect of number of cases. However, the Committee are satisfied to note that our country has responded proactively to this pandemic through multitude of measures including imposition of nationwide lock down, social distancing, wearing mask, maintaining hand hygiene and above all following the principle of test, track and treat so as to control the spread. As a result of strong measures taken in our country with the cooperation of the people, there is decline in number of new cases reported and the active cases across the country. As it is a new viral disease, no therapeutic solution or vaccine was available for this highly infectious disease. Since this pandemic disrupted the normal lives of the people throughout the world and gravely affected the economy of many countries, great interest has been generated among scientists across the world to invent a vaccine for this disease, About 200 vaccine candidates on varied platforms are presently undergoing development across the globe, of which about 40 candidates are in human

clinical development. It is heartening to note that nearly 30 groups, both academia and industry, are actively involved in development or collaboration or co-development and trials for COVID-19 vaccine in our country. As per the information available in the vaccine portal of Indian Council for Medical Research (ICMR), Drug Controller General of India(DGCI) has granted approval for restricted use in emergency situation for two vaccine candidates viz, Covishield which is tested and manufactured by Serum Institute of India Pvt Ltd., Pune in collaboration with Oxford University/ Astra Zeneca and COVAXIN which is manufactured indigenously by M/s Bharat Biotech Ltd., Hyderabad in collaboration with National Institute of Virology (NIV) and Indian Council for Medical Research(ICMR). As per the preliminary exercise undertaken by NEGVAC, about 66 million doses of COVID-19 vaccine will be required in the first phase of vaccination program in India. However, given the uncertainties in development of natural immunity, the pattern of disease spread etc, it is quite possible that there may be requirement for at least 100 crore doses of the vaccine demanding huge investments. According to CDSCO, current production capacity of vaccine manufacturers in the country is nearly 60.84 crore doses/annum which includes 40 to 50 crore doses/annum of Covishield vaccine, 10 crore doses/annum of Covaxin vaccine and 84 lakhs doses/annum of ZyCoV-D vaccine by Cadila Healthcare Limited, Ahmadabad which is still under Phase III Human Clinical Trials. Central Drugs Standard Control Organisation (CDSCO) has given permission for the stockpile of first two vaccines to the tune of 100 crore doses per annum. In the initial phase of vaccination, 3 Crore Health care workers and

frontline workers are likely to be covered. Currently the population of the country is about 138.7 crore. With the present production capacity in the country, it may take more than four years to meet the requirements of vaccinating whole or majority of the population in the country as every person has to be given two doses. So, there is an urgent need to ramp up the manufacturing capacity of COVID-19 vaccine for successful implementation of programme of vaccination in the country. In view of the above observations, the Committee would like to make the following recommendations:-

(i) The Government should chalk out a definite time schedule for vaccination for the whole or majority of the population in the country so as to create a strong herd immunity against COVID 19 at the earliest particularly in the wake of spreading of highly infectious UK and South African strains of COVID 19 virus.

(ii) The Government should take all the steps necessary for the large scale manufacturing of COVID 19 vaccines in the country for meeting the vaccine requirements of the country as per the time schedule.

(iii) Particular attention should be given for the implementation of "COVID Suraksha- the Indian COVID-19 Vaccine development Mission" in letter and spirit for accelerating the research and development of safe and efficacious vaccines so as to meet the vaccine needs of the country in a time bound manner and also to fulfil the demands of other countries.

(iv) Proper monitoring as well as execution mechanism be evolved to ensure the vaccination of all.

(v) Steps should also be taken for getting country's share of vaccines from WHO's COVAX facility which aims to get 2 billion doses of COVID vaccine by the end of 2021 and has assured the participating countries to deliver vaccine doses to cover upto 20% of their country's population.

(vi) Foolproof measures should be taken to ensure safety and efficacy of vaccines to be procured from both indigenous and foreign sources.

2. <u>Critical Analysis of Vaccine Candidates in Case of Parallel Studies :</u>

The Committee have noted that normally vaccine development takes close to 10 years for any infectious disease. But presently due to utmost urgency extra-ordinary measures are being taken to fast-track the development and production of COVID-19 vaccine without compromising the rigor of science, safety and efficacy measures. The steps which are helping in the fast-tracking process are fruitful collaboration between organizations and companies, conducting the required studies in parallel rather than sequentially as are usually done, planning for next phase while the earlier one is being completed and streamlining the processes of application and approvals. In normal vaccine development, each step is performed in sequence. In order to accelerate COVID-19 vaccine development, steps are being done in parallel. The Committee are sure that our scientists and the regulators would leave no stone unturned to ensure

safety and efficacy of vaccines being developed in the county even though they are following the fast track approach of parallel studies to make available vaccines to the people at the earliest. Since ours is a large country with huge population, multiple vaccines may have to be used for vaccinating the people for creating strong immunity against COVID 19 virus in an even manner amongst the people of various regions of the country who may receive different vaccines and to prevent post vaccination side effects, the Committee strongly recommend that Drugs Controller General of India(DCGI) and Central Drugs Standard Control Organization(CDSCO) will critically analyze the quality, safety, immunogenicity, efficacy and other mandatory requirements before granting approval of vaccine candidates so as to create strong immunity against COVID 19 virus in an even manner amongst the people of various regions of the country, who may receive different vaccines, without any post vaccination side effects. In case of import of vaccines, the same rigorous process should be followed before granting their approval for import into the country.

The Committee also feel that until the efficacy and safety of the COVID-19 vaccine is attained completely, it is responsibility of the Government of India to provide medical and life insurance cover to all persons vaccinated during Emergency Use Authorization phase of vaccination in case the consumers suffer post vaccination side effects.

4. <u>Restricted Emergency Use Authorization of Vaccine Candidates:</u>

The Committee note that there are three vaccine candidates in the country which are in advanced stage of development viz. COVAXIN, a whole virion inactivated SARS CoV-2 vaccine (BBV152), Covishield, a Non-Replicating Viral Vector vaccine(ChAdOx1-S) ; and ZyCoV-D, an indigenously developed DNA vaccine being tested by M/s Zydus Cadilla. While comparing the efficacy of indigenous vaccines viz-a-viz foreign vaccine candidates, the Department of Biotechnology in their written reply stated that the vaccine candidate Covishield Vaccine has demonstrated an efficacy of 62-90% in the global Phase III clinical trial, depending on the dose administered. The Russian Sputnik V vaccine and the mRNA vaccine candidates of Pfizer and Moderna, have reported an efficacy of >92%, based on interim analysis of the Phase III clinical trial data. The efficacy of the indigenously developed vaccine candidate, COVAXIN can be determined only after completion of the administration of the second dose in the Phase III trial. As per latest information available in the Vaccine Portal hosted by ICMR in its website, Drugs Controller General of India has accorded approval for restricted use of COVISHIELD after completion of Phase III Human Clinical Trial. However, DCGI has given approval for restricted use of COVAXIN in emergency situation while Phase III Human Clinical trial is still going on. The Committee note that NEGVAC Provides guidance on selection of COVID-19 vaccine candidates for the country and NEGVAC is assisted by the Standing Technical Sub-committee of National Technical Advisory Group on Immunization (NTAGI) for this purpose. Accordingly, the NEGVAC, supported by NTAGI, is responsible for reviewing the available

scientific evidence on safety, efficacy, reactogenicity, tolerability and immunogenicity of various vaccines while making a decision for selecting a vaccine for roll-out in the country. Since the safety and efficacy of any vaccine is established only after the satisfactory completion of third phase of human clinical trials, the Committee recommend that only those vaccines candidates which prove safe and efficacious after completion of their phase-III human clinical trials should be given Emergency Use Authorization by Drugs Controller General of India. Further, the Committee recommend that NEGVAC and NTAGI should carefully examine all the aspects viz. safety, efficacy, reactogenicity, tolerability and immunogenicity of various vaccine candidates before the decision on their roll out for vaccination particularly keeping in view the DCGI approval only for restricted use in emergency situation.

5. <u>Strengthening Adverse Event Following Immunization (AEFI) Processes</u>

The Committee note that in case of accelerated development of vaccine candidates, assessment of Adverse Event Following Immunization (AEFI) and Adverse Events of Special Interest (AESI)/Phase IV trial /post-marketing surveillance for side effects are critical after successful completion of Phase III Human trials. The Committee also note that in the post marketing phase, the manufacturer is required to submit periodic safety update reports to Central Drugs Standard Control Organization (CDSCO) which contain the details of the adverse effects reported and CDSCO assess these adverse effects for taking necessary remedial measures. In the cases of vaccines supplied through national

immunization programme, these adverse effects are captured and appropriate measures are taken by the Adverse Event Following Immunization (AEFI) Secretariat under Immunization Division in Ministry of Health and Family Welfare. Though the Committee understand that it is necessary to accelerate the processes of vaccine development, testing and approval processes in view of the present situation of COVID 19 pandemic, the Committee are of the firm view that it is mandatory to monitor whether there is any adverse side effects to the people who have been vaccinated. The Committee, therefore, recommend that DCGI and CDSCO should obtain from vaccine manufacturers the weekly safety reports which should contain the details of the post vaccination adverse effects/events reported and the Ministry of Health & Family Welfare/DCGI/CDCCO should initiate immediate corrective measures thereon. Since it is a mass vaccination programme initiated by the Government of India, immediate and appropriate corrective measures should be taken by the AEFI Secretariat under Immunisation division in the cases of post vaccination adverse effects/events so as to ensure safety and efficaciousness of vaccines in the country. In this regard, AEFI Secretariat should obtain weekly reports from CDSCO and vaccine manufacturers for prompt action at their end. If necessary, AEFI Secretariat in the Ministry of Health & Family Welfare may be strengthened for the purpose.

6. <u>Compliance of WHO Good Manufacturing Practices (GMP) Standards while Manufacturing Vaccines</u>

The Committee are concerned to note the different stands taken by two wings under the Ministry of Health and Family Welfare on the important matter of quality of vaccines. Drug Regulation Division of the Ministry of

Health and Family Welfare in its submission to the Committee stated that vaccines are required to be characterized and manufactured in compliance with the Good Manufacturing Practices (GMP). Manufacturing processes of every vaccine are validated, defined and controlled adequately to ensure batch to batch consistency. In regard to the above submission of the Drug Regulation Division, the Committee desired to know whether any steps have been taken to manufacture COVID 19 vaccines as per WHO-GMP quality standards. In its reply, CDSCO has stated that the applicant has to comply with the provisions under Drugs and Cosmetics Act, 1940; New Drugs and Clinical Trials Rules (NDCT), 2019 and Drugs and Cosmetics Rules, 1945 to manufacture and market Vaccines in the country and there is no requirement to comply with WHO GMP standards. In this regard, the Committee feel that there is no doubt that it is necessary for the applicant to comply with the above mentioned law and the rules enacted therein but it is also necessary to comply with WHO GMP standards while producing vaccines. Generally all the drugs are expected to be manufactured in compliance with WHO GMP standards and the same standards may be followed for the manufacture of vaccines as well. The Committee, therefore, recommend that this matter of different perceptions about the quality standards of vaccines between Drug Regulation Division and CDSCO may be looked into and ensure that all the vaccines for COVID 19 are manufactured in accordance with WHO-GMP standards also.

7. Testing of Batches of Vaccines by Central Drug Laboratory (CDL)

The Committee note that every batch of COVID 19 vaccines for clinical trial and marketing are tested /reviewed and released by Central Drugs Laboratory, Kasauli to ensure quality of the vaccines. In this regard, it is not clear whether samples of all the batches of COVID 19 vaccines meant for vaccination programme in the country will be taken to CDL, Kaushali which is in Himachal Pradesh or they will be tested in six other Central/Regional Drugs Testing Laboratories of Central Drugs Standard Control Organization (CDSCO) functioning in Kolkata, Mumbai, Chennai, Hyderabad, Guwahati and Chandigarh as per their proximity to vaccine manufacturer. Since it is very much essential to ensure the quality of vaccines before their release for vaccination, the Committee strongly recommend that necessary arrangements should be made by CDSCO to mandatorily test the quality of every batch of vaccines either domestically manufactured or imported before releasing for vaccination. In case CDL, Kaushali is facing any difficulties in timely clearance of batches of vaccines, CDSCO may consider utilizing the services of other six laboratories under its jurisdiction.

7. Need for Timely Creation of Beneficiary Identification Data by NEGVAC:

The Committee note that the Government of India has set up a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) on 7th August, 2020 under the chairmanship of Dr V K Paul, Member NITI Aayog, with Secretary, Health & Family Welfare as Co-chair and Secretaries

of Ministries/Departments of External Affairs, Biotechnology, Health Research, Pharmaceuticals, Electronics & IT and other experts as members. One of the mandates of this Group for COVID-19 vaccine roll out is prioritization of population groups. The Committee while examining the challenges faced by NEGVAC was informed that the specific challenges before the NEGVAC are identification of vaccine candidates for roll-out in the country and prioritizing the beneficiaries for the same. In this regard, the Committee note that the, there will be huge demand for vaccine upon its availability in view of the global scale of pandemic. Accordingly, NEGVAC has been discussing the prioritization of various groups in terms of Health Care Workers (HCWs), Front Line Workers (FLWs), elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities who could be covered first. States/UTs and central line ministries are creating the database of HCWs working in their respective health facilities/hospitals/laboratories etc. This database of HCWs will be used for vaccinating them in the first phase of vaccination. Similarly, databases for other priority groups are also being prepared. The Committee note that NEGVAC is able to create only the database of about 3 crore HCWs and FLWs in the country since its creation five months ago. In this regard, the Committee feel that authentic databases of various priority groups are very much necessary for timely and successful execution of COVID-19 vaccination programme, The Committee, therefore, would like to make the following recommendations:-

(i) Creation of databases of various priority groups viz. elderly population, people with co-morbidities, women and children should

be expedited by Ministry of Health and Family Welfare in coordination with states/UTs and this work may be completed within a definite time frame. NEGVAC may coordinate this work on priority basis.

(ii) Immediate attention should be paid for timely enumeration and vaccination of elderly population (aged 50 years and above) and people aged less than 50 years with co-morbidities throughout the country for their vaccination in the second phase of vaccination as they are vulnerable for the disease and mortality.

(iii) Further HCWs and FLWs may constitute workers from both the organized and unorganized sectors. In this regard, particular care may be taken by both the Union and States/UT Governments to vaccinate the workers from private/unorganized sectors particularly the temporary/casual/contractual workers.

8. <u>Priority Vaccination of People living in Dense Localities and Hot Spot Areas</u>

The Committee note the stand taken by the Government that the decision on prioritization of additional groups such as people living in dense localities of cities and towns, slum areas, etc. for COVID-19 vaccination will be taken based on evolving scientific evidence to maximize the impact of vaccination drive. COVID 19 is an infectious disease mainly spread through the non maintenance of social distancing. In our country, there are plenty of densely populated areas in cities and towns including slum areas where social distancing norm is very difficult to be followed and those areas remain breeding grounds for COVID 19. Moreover, there are hot spot

areas where COVID 19 cases are more when compared to other areas. The Committee, therefore, recommend to NEGVAC to cover the densely populated areas in cities and towns, slum areas and hot spot areas under COVID 19 vaccination programme on priority basis to contain the spread of the disease in an effective manner.

9. <u>Smart Vaccination Programme</u>

The Committee note the proposal of the Indian Council for Medical Research that smart vaccination rather than mass vaccination is beneficial at the initial stages of vaccination programme due to limited availability of vaccines. Such smart vaccination pertains to vaccinating those individuals who are at the highest risk of contracting COVID 19 infection or mortality. Through this approach, further reduction in number of symptomatic as well as asymptomatic cases is expected to achieve. In this regard, the Committee note that the Government of India has started the first phase of COVID 19 vaccination programme for vaccinating three crore Health Care Workers who are in direct contact with COVID 19 patients and also front line workers who at the greater risk of infection due to their nature of duties. While the Committee is agreeing with the proposal that smart vaccination is beneficial at the initial stages of vaccination programme, the Committee are of the firm view that the goal of the COVID 19 vaccination programme should be universal vaccination of entire population of the country with safe and efficacious vaccines so as to create strong herd immunity in the country against COVID 19. The Committee, therefore, recommend that the Government should chalk out a definite programme for

mass vaccination of all the people in the country with safe and efficacious vaccines and execute the same in a time bound manner.

10. <u>Need for Increasing Number of Primary and Intermediary Vaccine Stores</u>

The Committee note that there is an established mechanism of vaccine transportation in the country from primary vaccine stores to the session sites for maintaining required temperature of the vaccines. Manufacturers supply directly to 41 primary stores in the States/UTs/ and the Government Medical Stores Depots supply vaccines to 19 primary stores in the country. There are insulated vaccine vans supplied by the Govt. of India to all States for vaccine transportation. Cold boxes and vaccine carriers are used for vaccine transportation to intermediary stores and session sites respectively. The same mechanism will also be used for COVID-19 vaccine transportation. In this regard, the Committee are constrained to note that there are only 60 primary stores in 29 States/ 7 UTs with nearly 741 Districts in the country. That means roughly a primary store is catering to the requirements of nearly 12 Districts in the country. This storage facility might have been sufficient for handling the existing immunization programmes which are meant for targeted groups of persons like children in case of Polio vaccine programme. But, present number of primary stores may not be sufficient for handling the COVID 19 vaccination programme as almost entire population of the country has to be vaccinated. The Committee, therefore, recommend that NEGVAC may make a comprehensive study/assessment of the number of primary stores and the number of intermediary stores required for hassle free storage and distribution of COVID 19 vaccines and take immediate necessary steps for

the creation of requisite infrastructure to increase the number of primary and intermediary stores as required by the States/Union Territories. Necessary allocation of funds for the purpose may also be considered.

11. Need to Bridge the Cold Chain Equipment Gap in all 36 States/UTs

The Committee note that an assessment of Cold Chain Space requirement has been carried out for the entire country on the basis of which procurement process is being initiated for Cold Chain Equipment. In this regard, the Department of Health and Family Welfare has informed the Committee that under the guidance of NEGVAC, the Government of India is taking all measures for best vaccine supply practice from manufacturer to session sites to manage the stupendous tasks of distribution / delivery of COVID vaccine throughout the country. Quality cold chain equipment is supplied for storage capacity augmentation. The cold chain technician and the vaccine and cold chain handler are trained regularly on the equipment maintenance and on good storage and distribution principles. The Committee were also informed that for the additional requirement of Cold Chain Equipment, purchase orders have been placed for 3089 Deep Freezers (DF) and 8767 Ice-lined refrigerators (ILR) while UNICEF is supporting supply of 20 Walk-in Freezers (WIF), 40 Walk-in Coolers (WIC), 620 Deep Freezers and 2984 Ice-lined refrigerators. The supplies of the procured equipment to the states have begun from last week of November 2020. The Committee observe that total cold chain equipments that are available to 36 states/UTs include 9312 ILR (Large), 35090 ILR(Small), 6751 DF(Large), 34134 DF(Small), 260 WIC and 87 WIF. However, 28 Walk-in Coolers (WIC), 3824 Ice-lined Refrigerators (Large) and 570 Ice-lined

Refrigerators (Small) are still needed as per the cold chain equipment gap analysis done specifically for COVID-19 vaccination programme by the Ministry of Health and Family Welfare. In this regard, the Committee recommend that the Ministry of Health and Family Welfare in coordination with states/UTs should bridge these gaps in the requirements of cold chain equipments within a fixed time frame so that all 36 states/UTs possess the required number of various kinds of cold chain equipments mainly Walk in Coolers and Ice-lined Refrigerators both large and small in size for safe storage and application of the vaccines.

12. <u>Need for Pan India Consumer Awareness Programme by NEGVAC:</u>

The Committee note that Drug Controller General of India (DGCI) has granted approval for restricted use in emergency situation for two vaccine candidates viz, Covishield and Covaxin . Subsequently, the Government of India has decided to roll out the first phase of vaccination programme for the Health Care Workers and the Frontline Workers in the country. However, there are several reports in media about safety and efficacy of these vaccines particularly about COVAXIN which has been given emergency use authorization before completion of Phase III human trials. In this regard, the Committee are confident that the Government must have taken this conscious decision to roll out these two vaccines based on scientific evidence of their safety and efficacy. However, the Committee feel that it is necessary to keep the public informed about the credentials of these vaccines. The Committee, therefore, recommend that a pan India Consumer Awareness Programme needs to be launched by NEGVAC in

coordination with States/UTs to eliminate apprehensions in the minds of the people about the safety and efficacy of these vaccines.

13. <u>Need to Allocate Separate Budgetary Support for COVID-19 Vaccination Programme:</u>

The Committee note that the Government proposes to vaccinate Health Care Workers (HCWs) and Front Line Workers (FLWs) during the first phase of vaccination. For covering 3 crore HCWs and FLWs with two doses of vaccine, around 6.6 crore doses will be required which is estimated to cost around Rs 1485 crore. The procurement of vaccines by MoHFW will be done using domestic funds. However, the Department of Health and Family Welfare in their written note stated that the total fund required for vaccinating all those requiring vaccine will depend on the estimated number of total prioritized beneficiaries and the prevailing cost of vaccine. As per the statement of the Prime Minister, the entire cost of vaccinating three crore HCWs and FLWs will be borne by the Union Government. The Committee observe that for nearly 138 crore population of the country, nearly 276 crore doses of vaccine would be required and approximately Rs.68310 crore would be necessary for covering every person in the country (deduced from 138 crore multiplied by Rs. 495 crore per crore population). In regard to vaccination of entire population free of cost, the Committee note the reply of the Government that the financing mechanism for vaccinating the entire population of the country has not been finalized yet. In case the Government find it difficult to mobilize funds for vaccinating entire population free of cost, the Committee recommend that all the people belonging to lower middle class and the poor people

living in urban and rural areas including the Below Poverty Line should be given vaccination free of cost.

14. <u>Submission of Action Taken Replies to above observations/recommendations</u>

Since this subject involves more than one Central Ministries/ Departments viz. Ministry of Science and Technology (Department of Biotechnology), Ministry of Health & Family Welfare, Ministry of Chemicals & Fertilizers(Department of Pharmaceuticals) etc., the Committee desire that the respective Ministry/Department may furnish their Action Taken Replies to the above observations/recommendations to the Department of Pharmaceuticals who may compile the replies and furnish the same within the stipulated time period of three months.

New Delhi;
15 March, 2021
24 Phalguna 1942 (Saka)

Uday Pratap Singh
Chairperson (Acting)
Standing Committee on
Chemicals and Fertilizers

MINUTES OF THE FIFTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2020-21)

The Committee sat on Monday, the 15th March, 2021 from 1500 hrs. to 1545 hrs. in Committee Room No.139, Parliament House Annexe, New Delhi.

PRESENT

Shri Uday Pratap Singh, Chairperson (Acting)

MEMBERS

LOK SABHA

2. Shri Ramakant Bhargava
3. Shri Satyadev Pachauri
4. Dr. M.K. Vishnu Prasad
5. Shri Arun Kumar Sagar
6. Shri Pradeep Kumar Singh
7. Shri Indra Hang Subba
8. Shri Prabhubhai Nagarbhai Vasava

RAJYA SABHA

9. Shri G. C. Chandrashekhar
10. Dr. Anil Jain
11. Shri Ahmad Ashfaque Karim
12. Shri Jaiprakash Nishad
13. Shri Arun Singh
14. Shri A.D. Singh
15. Shri Vijay Pal Singh Tomar
16. Shri K. Vanlalvena

SECRETARIAT

1.	Shri Manoj K. Arora	-	OSD (LSS)
2.	Shri N.K Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Shri Panna Lal	-	Under Secretary

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee.

3. The Committee, thereafter, took up for consideration and adoption the following draft Report(s):

(i) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals);
(ii) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Fertilizers);
(iii) 'Demands for Grants 2021-22' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals); and
(iv) 'Status of Covid-19 Vaccine Production In India' pertaining to the Department of Pharmaceuticals.

4. After deliberations, the Committee adopted the above four Draft Report(s) unanimously without any change/amendment.

5. The Committee also authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Report(s) by the Department of Chemicals and Petrochemicals, Department of Fertilizers and Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

The Committee then adjourned.