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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)

SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations of the Committee contained in their Twenty Second Report (Seventeenth Lok Sabha) on 'Status of Covid-19 vaccine Production in India' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

THIRTIETH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

DECEMBER, 2021 / AGRAHAYANA, 1943 (SAKA)

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Action Taken by the Government on the Observations / Recommendations of the Committee contained in their Twenty Second Report (Seventeenth Lok Sabha) on "Status of Covid-19 vaccine Production in India" of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 02.12.2021

Laid in Rajya Sabha on 02.12.2021

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2021 / AGRAHAYANA, 1943 (SAKA)

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

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS
LOK SABHA

2	Shri Maulana Badruddin Ajmal
3	Shri Deepak Baij
4	Shri Ramakant Bhargava
5	Shri Prataprao Govindrao Patil Chikhalikar
6	Shri Rajeshbhai Naranbhai Chudasama,
7	Shri Ramesh Chandappa Jigajinagi
8	Shri Pakauri Lal
9	Shri Kripanath Mallah
10	Shri Satyadev Pachauri
11	Smt Aparupa Poddar
12	Dr. M.K.Vishnu Prasad
13	Shri Atul Kumar Singh alias Atul Rai
14	Shri Arun Kumar Sagar
15	Shri M. Selvaraj
16	Shri Pradeep Kumar Singh
17	Shri Uday Pratap Singh
18	Shri Indra Hang Subba
19	Shri Prabhubhai Nagarbhai Vasava
20	Dr. Sanjeev Kumar Singari#
21	Vacant*

RAJYA SABHA

22	Shri G.C.Chandrashekhar
23	Dr. Anil Jain
24	Shri Ahmad Ashfaque Karim
25	Shri M.V. Shreyams Kumar
26	Shri Jaiprakash Nishad
27	Shri Anthiyur P. Selvarasu
28	Shri Arun Singh$
29	Shri A.D. Singh
30.	Shri Vijay Pal Singh Tomar
31.	Shri K. Vanlalvena

SECRETARIAT

1.	Shri Manoj Kumar Arora	-	Officer on Special Duty(LSS)
2.	Shri Nabin Kumar Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Shri Kulvinder Singh	-	Deputy Secretary
5.	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.
**Vacant vice* Shri Er. Bishweswar Tudu nominated MoS on 07.07.2021.

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2021-22)

Smt. Kanimozhi Karunanidhi - Chairperson

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LOK SABHA

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3. Maulana Badruddin Ajmal
4. Shri Deepak Baij
5. Shri Ramakant Bhargava
6. Shri Prataprao Patil Chikhlikar
7. Shri Rajeshbhai Naranbhai Chudasama
8. Shri Sanjay Shamrao Dhotre
9. Shri Ramesh Chandappa Jigajinagi
10. Shri Kripanath Mallah
11. Shri Vasava Prabhubhai Nagarbhai
12. Shri Satyadev Pachauri
13. Smt Aparupa Poddar (Afrin Ali)
14. Dr. M.K.Vishnu Prasad
15. Shri Arun Kumar Sagar
16. Shri M. Selvaraj
17. Dr. Sanjeev Kumar Singari
18. Shri Atul Kumar Singh
19. Shri Pradeep Kumar Singh
20. Shri Uday Pratap Singh
21. Shri Indra Hang Subba

RAJYA SABHA

22. Shri Ayodhya Rami Reddy Alla
23. Shri G.C.Chandrashekhar
24. Dr. Anil Jain
25. Shri M.V. Shreyams Kumar
26. Shri Jaiprakash Nishad
27. Shri Anthiyur P. Selvarasu
28. Shri Arun Singh
29. Shri Vijay Pal Singh Tomar
30. Shri K. Vanlalvena
31. Vacant

SECRETARIAT

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2.	Shri C. Kalyanasundaram	-	Additional Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Ms Sonia Sankhla	-	Assistant Executive Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-22) having been authorized by the Committee, do present on their behalf this Thirtieth Report on Action taken by the Government on the Observations/ Recommendations of the Committee contained in their Twenty Second Report (Seventeenth Lok Sabha) on **"**Status of Covid-19 vaccine Production in India", pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

2. The Twenty Second Report was presented to Lok Sabha and also laid in Rajya Sabha on 17th March, 2021. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) furnished their replies on 14th October, 2021 indicating action taken on the recommendations contained in that Report. The Committee at their sitting held on 16th November, 2021 considered and adopted the Draft Report.

3. An analysis of the action taken by Government on the Observations/ Recommendations contained in the Twenty Second Report (Seventeenth Lok Sabha) of the Committee is given in Appendix-II.

4. For the facility of reference and convenience Recommendations/ Observations of the Committee have been printed in thick type in the body of the Report.

New Delhi;
16 November, 2021
25 Kartika, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson
Standing Committee on
Chemicals and Fertilizers

CHAPTER I

REPORT

1.1 This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Twenty Second Report (Seventeenth Lok Sabha) of the Committee on the subject **"Status of COVID-19 vaccine production in India"** of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha and Rajya Sabha on 17.3.2021. In all, the Committee made 14 Observations / Recommendations containing 21 sub-recommendations in the Report.

1.2 Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the 22nd Report within three months from the date of presentation of the Report. The Action Taken Replies of the Government in respect of all the 14 Observations / Recommendations containing 21 sub-recommendations in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) *vide* their OM No.31026/68/2020-IFD dated 06-08-2021. These Replies have been categorized as follows:-

(i) Observations / Recommendations that have been accepted by the Government :-

Sl. Nos. 1(ii),1(iii),1(iv), 1(v), 1(vi), 2(i), 3, 4, 5, 6, 10, 11,12, 13, 14

(Total = 15)

Included in **Chapter II** of the Draft Report.

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply :-

Sl.No. 1(i), 2(ii), 7(i), 7(ii), 8, 9 (Total = 6)

Included in **Chapter III** of the Draft Report.

(iii) Observations / Recommendations in respect of which replies of the Government have not been accepted by the Committee :-

Sl.No Nil (Total = 0)

Included in Chapter **IV** of the Draft Report.

(iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:-

Sl.No. Nil (Total=0)

Included in **Chapter V** of the Draft Report.

1.3 **The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I of this Report should be furnished expeditiously.**

1.4 The Committee will now deal with action taken by the Government on all the Observations/Recommendations which still require reiteration or merit comments.

RECOMMENDATION NO 1

Availability of Safe, Secure and Effective Vaccine for COVID 19

1.5 While stressing on the need for availability of safe, secure and effective vaccine for COVID 19, the Committee made the following recommendation:-

"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 ingeniously 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

1.6 In reply to the above recommendation No.1(i) of the Committee, the Department of Pharmaceuticals has stated as under:-

"Ministry of Health and Family Welfare (MoHFW) has informed that the COVID-19 vaccination is an ongoing and dynamic process, which is being expanded to include beneficiary groups as prioritized by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). With effect from 1st May 2021, as per the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy, the State Government/UT Administration and private sector have been empowered to procure additional vaccine doses and have been given flexibility to customize to local needs and open vaccination to any age category above 18 years of age. Based on the experiences gained from 1st May 2021 and requests from States, the Guidelines for National COVID Vaccination Program were revised wherein, now GoI will procure 75% of the vaccines being produced monthly by the manufacturers in the country and these will continue to be provided free of cost to States/UTs. These doses, in turn, will be administered by the States/UTs free of cost to all citizens as per priority through Government Vaccination Centres. The private sector continues to have the option of direct procurement of 25% of monthly production of the domestic vaccine manufacturers. The price of vaccine doses for private hospitals would be declared by each vaccine manufacture and the private hospitals may charge up to a maximum of Rupees 150 per dose as service charges. Adequate quantity of COVID-19 vaccines is likely to be available for vaccination of all eligible beneficiaries aged 18 years and above, and the Government of India is committed to ensure vaccination of these beneficiaries in shortest possible time. In view of the dynamic nature of COVID-19 pandemic and evolving status of availability & type of COVID-19 vaccines, a definite time frame cannot be indicated currently for completion of vaccination. The COVID-19 vaccination drive is based on WHO's recommendations & global practices, with an aim to maximize the impact of vaccination, save lives and keep the health system intact and functioning".

1.7 In its action taken reply to recommendation No.1(ii) above, the Department of Pharmaceuticals stated as under:-

"The production capacity of the vaccines under the vaccination drive has been gradually ramped-up by the manufactures and is expected to increase further in the next couple of months. To further support the manufacturers in ramping up vaccine production, Government of India has also provided financial support of INR 1500 crore to M/s Biological E Ltd for 'at-risk manufacturing' of 30 crore doses and advance payment for 66 crore doses to be procured from M/s Serum Institute of India and M/s Bharat Biotech International Ltd. during July/Aug'21 to Dec'21. This would ease the limitation of vaccine availability over time. New vaccines (domestic as well as offshore), as and when approved by the National Regulator, will be taken up under the programme to improve vaccine availability and vaccination coverage.

Further, as stated by CDSCO, for augmentation of production capacity of COVID-19 vaccines in the country, Inter-ministerial group has been formed for providing support to COVID-19 vaccine manufacturers. The group visited following manufacturing facilities-

1. M/s Serum Institute, Hadapsar and Manjari facilities.
2. M/s Bharat Biotech, Hyderabad and Bangalore facilities.
3. M/s Indian Immunologicals (IIL), Hyderabad facility.

and provided guidance to firms to increase the production capacity and submitted the report. CDSCO is facilitating and handholding the applicants for reducing the processing time for scale up of manufacturing of approved COVID-19 vaccines through Post Approval Changes as per provisions of CDSCO guidance for industry.

Department of Biotechnology (DBT) has further stated that the Government of India is supporting vaccine development and manufacturing activities through both national efforts and international partnerships. Currently, in India, 04 vaccine candidates for COVID-19 have been approved for Emergency Use Authorization (EUA). Besides these, about 09 vaccine candidates are in clinical stage of development and 01 candidate is in advanced pre-clinical stage of development; several promising vaccine candidates are in early stages of development. Further, to address the urgent need for making available sufficient vaccine doses to meet the existing requirements, efforts have been made to support scale-up of vaccine production, under Mission COVID Suraksha. Accordingly, support for one private industry (Bharat Biotech, Hyderabad) and three public sector manufacturing facilities (Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; Bharat Immunologicals and Biologicals, Bulandshar), is being provided to make them ready with enhanced capacities to support augmented production of Covaxin, over the next 6-8 months. The Department of Biotechnology (DBT) is also facilitating technology transfer of

Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), comprising of Hester Biosciences, OmniBRx Biotechnologies Pvt Ltd, and Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat."

1.8 In reply to the above recommendation No.1 (iii)of the Committee, the Department of Pharmaceuticals replied as under:

"Department of Biotechnology has informed that to reinforce and accelerate the COVID-19 vaccine development efforts and to address the urgent need for a safe and efficacious COVID-19 vaccine, 'Mission COVID Suraksha - the Indian COVID-19 Vaccine Development Mission', was announced by the Government, as part of the Atmanirbhar Bharat 3.0 package. The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of DBT, at a total cost of Rs. 900 Cr. for 12 months. The goal of the Mission is to accelerate 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 the market for consideration by regulatory authorities and for introduction in public health systems.

Three Requests for Expression of Interest (REOI) for COVID-19 candidate vaccine development, enhancement of capacities to support COVID-19 vaccine development and conduct of human clinical trials have been issued. Four COVID-19 vaccine candidates in advanced clinical development stage and one vaccine candidate in advanced pre-clinical development, are being supported under this Mission. Additionally, 19 clinical trial sites across the nation, three immunogenicity assay laboratories and three animal challenge facilities are also being supported under the Mission. Additionally, augmentation of facilities for COVID-19 vaccine manufacturing, is also being supported under Mission COVID Suraksha.

A strong technical and financial internal due diligence is an integral part of the mission implementation process. Domain area specific Scientific Advisory Groups (SAG), have been constituted for scientific and technical due diligence of the applications received. An "Evaluation and Monitoring Committee for Technology Transfer", was constituted, to provide oversight and expert guidance and to monitor the progress of the facility augmentation to support COVID-19 Vaccine manufacturing under Mission Covid Suraksha. The ultimate focus is on bringing to the citizens of the country a safe, efficacious, affordable, and accessible COVID vaccine at the earliest and to strengthen the vaccine development ecosystem in the country for other on-going and future viral vaccine development."

Further Comments of the Committee

1.9 The Committee note that stand taken by the Government that in view of the dynamic nature of COVID-19 pandemic and evolving status of availability & type of COVID-19 vaccines, a definite time frame cannot be indicated currently for completion of vaccination process in the country. Further the Committee note that the Government has made efforts under Mission COVID Suraksha to support scale-up of vaccine production so as to address the urgent need for making available sufficient vaccine doses to meet the existing requirements of the country. Four vaccine candidates for COVID 19 have been approved for Emergency Use Authorization. Besides, 09 vaccine candidates are in clinical stage of development and one is in advanced pre-clinical stage of development. Several promising vaccine candidates are in early stages of development. The Committee also note that support for one private industry and three public sector manufacturing facilities is being provided to make them ready with enhanced capacities to support augmented production of Covaxin over the 6-8 months. Further in order to ease the vaccine availability, the Government has provided financial support of Rs 1500 crore to M/s Biological E Ltd for 'at risk manufacturing' of 30 crore doses and advance payment for 66 crore doses to be procured by M/s serum Institute of India and M/s Bharat Biotech International Ltd. during July/August 2021 to December 2021. In this regard, the Committee hope that these efforts of the Government under Mission COVID Suraksha would be continued and it will be ensured that the required quantum of safe and efficacious vaccines will be produced in the country for vaccinating all the targeted population in the country in a time bound manner. Progress made in this regard should be intimated to the committee.

1.10 Further the Committee also recommended in para 1(iv) above that "Proper monitoring as well as execution mechanism be evolved to ensure the vaccination of all. In reply to this recommendation of the Committee, the Department of Pharmaceuticals replied as under:

> "Ministry of Health and Family Welfare has informed that the regular review meetings of COVID-19 vaccination are conducted by the Ministry of Health & Family Welfare with the States/UTs to orient them on new developments, review the vaccination drive implementation & performance status and resolve queries in the shortest time frame.
> Another level of review of the vaccination drive takes place through the Empowered Group- 5 (EG- 5), constituted under the Disaster Management Act, 2005, mandated to decisively and effectively address evolving challenges in COVID-19 vaccination pertaining to vaccine procurement, manufacturing, import, logistics, daily supply, utilization and wastage monitoring. Further, National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) also reviews the programme performance on a regular basis and provides guidance on all aspects of COVID-19 vaccination. Progress under the COVID-19 vaccination drive is also reviewed by Cabinet Secretariat from time to time."

Further Comments of the Committee

1.11 The Committee note from the action taken reply furnished by the Government that the entire vaccination process is monitored at the levels of Ministry of Health and Family Welfare, Empowered Group-5 constituted under the Disaster Management Act, 2005, National Expert Group on Vaccination Administration for COVID 19(NEGVAC) and the Cabinet Secretariat. Since the entire process of procurement and supply of vaccines is being done by the Government of India, it is very much necessary to ensure timely supply of adequate quantum of vaccines to all the States/UTs according to their requirements. In this regard, the Committee would like to recommend the following :-

(i) Availability and requirement of every State and UTs should be reviewed regularly and immediate steps should be taken to resolve the issues connected with the vaccination process in individual States/UTs.

(ii) Particular attention should be paid for timely procurement and supply of requisite quantum of vaccines for meeting the requirements of all the States/UTs for administering second dose of vaccines for those who are waiting for second dose of vaccine as well as for the coverage of those who have not yet been vaccinated.

(iii) Further the data collected from the monitoring process may be utilized for evidence based policy making on fight against COVID-19 by all the concerned Departments.

1.12 The Committee further recommended in para 1(v) above that "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." In the action taken reply received from the Government of India, it has been stated as under:

> "India is an AMC eligible Country under COVAX facility to get donor supported doses of COVID-19 vaccine. India has advocated for its fair share to get COVID-19 vaccines under COVAX Facility. In December 2020 meeting, Gavi Board approved high range package of support for India, providing 20% of total AMC doses, subject to vaccine prices and available funds. Gavi COVAX through a decision letter has communicated that 97,164,000 indicative doses of AstraZeneca/SII with 35-40% in Q1 & 60-65% in Q2 will be supplied to India. Till date, Gavi COVAX has supplied 10 million doses of COVISHIELD to India through COVAX Facility. However, the remaining doses from COVAX facility are contingent upon availability of the same with COVAX."

Further Comments of the Committee

1.13 The Committee note that Gavi COVAX Advance Market Commitment (AMC), a mechanism within the COVAX facility is to ensure that 92 middle- and lower-income countries that cannot fully afford to pay for Covid-19 vaccines themselves get equal access to Covid-19 vaccines as higher-income self-financing countries. The Committee note that India is an AMC eligible country and as per GAVI board approval, India will get 20 percent of total AMC doses subject to vaccine prices and available funds. However, Gavi COVAX has so far supplied only 1 Crore

doses out of 9.71 Crore doses committed from COVAX facility but the remaining doses from COVAX facility are contingent upon availability of the same with COVAX. In this regard, the Committee recommend that the Government should pursue vigorously for getting due share of doses of COVID vaccines for the country from COVAX facility as COVAX facility has assured to cover up to 20% of the population of participating countries. Progress made in this regard may be intimated to the Committee.

1.14 The Committee further recommended in Para 1(vi) above that foolproof measures should be taken to ensure safety and efficacy of vaccines to be procured from both indigenous and foreign sources. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals replied as below:

> "Central Drugs Standard Control Organisation (CDSCO) has informed that as per the New Drugs & Clinical Trials Rules, 2019, for grant of permission to manufacture or import of a new drug including vaccines, the applicant is required to submit new drug application along with various data such as chemical and pharmaceutical information, non-clinical as well as clinical data of safety and efficacy of the drug including results from local clinical trial as specified in the Second Schedule of the said Rules. The aforesaid Rules provide the detailed requirements and guidelines for conduct of nonclinical and clinical studies and approval of new drug which include vaccines. The requirements apply to both, vaccines manufactured in the country or imported from overseas. Further, the Rules provide for grant of marketing authorization in certain special situations where relaxation, abbreviations, omission or deferment of data may be considered.
>
> CDSCO has issued regulatory pathway for approval of COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL).
>
> CDSCO has further revised the regulatory pathway on 01.06.2020, wherein the requirement to conduct post marketing bridging trial and prior approval of CDL for release of each lot of the vaccine has been done away with if the vaccine batch/lot has been certified and released by National Control Laboratory of Country of Origin. However, scrutiny and review of their Summary Lot Protocol & certificate of analysis of Batch/Lot shall be undertaken by CDL, Kasauli for Batch release as per standard procedure.
>
> Further, SOP Guidance for import of COVID-19 vaccine by private sector or any person was issued on 04.05.2021."

Further Comments of the Committee

1.15 The Committee note the above mentioned steps taken by the Government for ensuring safety and efficacy of vaccines procured from both indigenous and foreign sources. In this regard, the Committee hope that the New Drugs & Clinical Trials Rules, 2019 and the regulatory pathways/ SOP guidance issued by CDSCO are being followed due diligently while granting approvals for new vaccines launched/ to be launched in the country both from indigenous and foreign sources and that fool proof measures are being taken by the Government for ensuring safety and efficacy of COVID 19 vaccines being administered in the country.

RECOMMENDATION NO 6

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

1.16 While stressing on the need for testing of batches of vaccines by Central Drug Laboratory (CDL), the Committee had made the following recommendation:-

> "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, Kasauli 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, Kasauli is facing any difficulties in timely clearance of batches of vaccines, CDSCO may consider utilizing the services of other six laboratories under its jurisdiction."

1.17 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals replied as follows:

"Central Drugs Laboratory (CDL), Kasauli alone has huge capacity to test nearly 200 batches per month (which is far more than the number of batches being received i.e. around 50 batches by CDL Kasauli for testing on monthly basis), and there is no delay for testing and release of the COVID-19 vaccines. However, to build the capacity of India for long run, Two more laboratories namely National Institute of Biologicals (NIB), Noida and National Centre for Cell Science (NCCS), Pune have been developed and notified for testing of COVID-19 Vaccines. Further, a laboratory at National Institute of Animal health (NIAH), Hyderabad is also under development specifically for COVID-19 vaccine testing. Six (06) laboratories of CDSCO other than CDL, Kasauli are designed for testing of Drugs, Devices and Cosmetics only, and not for vaccines."

Further Comments of the Committee

1.18 The Committee note that there is no delay in testing and releasing of COVID 19 vaccines as Central Drugs Laboratory(CDL), Kasauli has huge capacity to test nearly 200 batches of vaccines per month. However, as a long term measure two more laboratories at Pune and NOIDA have been developed and notified for testing COVID 19 vaccines. One more laboratory at Hyderabad is under development. In this regard, the Committee hope that all the three new laboratories would start functioning in a time bound manner and it would be ensured that every batch of vaccines is tested and certified by CDL, Kaushali before sending the batch for vaccination. Progress made in this regard may be intimated to the Committee.

RECOMMENDATION NO 10

Need for Increasing Number of Primary and Intermediary Vaccine Stores

1.19 While stressing on the need for increasing number of primary and intermediary vaccine stores, the Committee had made the following recommendation:-

"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. "

1.20 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals replied as under:

"There are around 29,000 cold chain storage points at the State level & below catering to the requirement of COVID-19vaccines of 741 districts across 29 States and 7 UTs. This cold chain network is spread from the State till sub-District level such that the vaccines can be stored and managed across the country. Manufacturers supply vaccines directly to 41 primary stores in the States/UTs/Government Medical Stores Depots (GMSDs) while the GMSDs supply vaccines to 19 primary stores in the country.

There are around 837 District/Regional Vaccine Stores and 28,258 sub- District vaccine storage facilities. There exists a clear & established mechanism of vaccine supply from State to Divisional Stores (for large states)or State to District Stores (for smaller targeted groups of persons like children in case of states), and further to sub-district stores. The vaccines are transported through Insulated/refrigerated vaccine vans. An assessment of the Cold Chain Storage Space and transportation mechanism had been carried out prior to introduction of the COVID-19 vaccine and the same has been adequately strengthened to meet the storage requirement of COVID-19 vaccine along with Universal Immunization Programme. It is also pertinent to note that majority of the vaccines are stored at Sub-District Cold Chain Points that are co-located/nearest to the COVID-19 Vaccination Centres. The Primary Stores are usually meant for storage of Buffer Stocks and storing the vaccine supplies for albeit short duration of time. Presently, the infrastructure is adequate to handle the storage and transportation requirements for vaccination of the entire adult population of the country."

Further Comments of the Committee

1.21 The Committee note from the above action taken reply furnished by the Government that the present infrastructure is adequate to handle the storage and transportation requirements for vaccination of the entire adult population of the country. However, the children below 18 years of age are yet to be covered under the vaccination programme. Hence, the Committee recommend that Government should review continuously the requirements of cold storage facilities at state, district and sub-district levels of every State/UT and necessary steps should be taken for strengthening the infrastructure required for storage and transportation of vaccines in every state/UT in the country. Specific action taken reply in this regard should be furnished to the Committee.

RECOMMENDATION NO 12

Need for Pan India Consumer Awareness Programme by NEGVAC

1.22 While stressing on the need for Pan India Consumer Awareness Programme by NEGVAC, the Committee had made the following recommendation:-

> **"**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."

1.23 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals replied as under:

"MoHFW has informed that the COVID-19 Vaccines Communication Strategy has been developed, for implementation at the National and State level, to raise awareness about the safety, efficacy and immunogenicity of COVID-19 vaccines, build vaccine confidence, address misinformation against vaccination, address vaccine hesitancy & vaccine eagerness and promote COVID appropriate behaviour. The strategy aims to promptly disseminate factual information about the vaccines and the vaccination process through clear, consistent and transparent messaging. This is being done through multimedia platforms (print/electronic/ social media), through MoHFW website and engagement of various stakeholders, community leaders and influencers to reach out to the last mile. The strategy is based on five key pillars– viz., advocacy, capacity building, media engagement, community engagement and crisis management. For successful implementation of the strategy, several measures have been taken so far. These include capacity building of stakeholders at National and State level including State Immunization and IEC officials, Civil Society Organizations, Radio jockeys including Community Radio professionals, etc. for leveraging their networks for active campaigning to create awareness about benefits of vaccination. Aggressive advocacy to build vaccine confidence through reputed public and private sector Doctors at National level and States/UTs and through other key influencers.

A Communications National Media Rapid Response Cell has been established at MoHFW which is carrying out real-time review of news reports and disseminating content on building confidence in vaccines and to counter less than adequate informed media narrative. A special campaign against vaccine hesitancy was also launched by the Union Minister for Health and Family Welfare. The Ministry has also reached out to 22 Central line Ministries including Rural Development, Panchayati Raj, Ministry of Information and Broadcasting and MyGov etc. for engaging their field level networks to support information dissemination and social mobilization".

Other measures include, a special webpage on information pertaining to COVID 19 vaccine; national helpline number 1075 to answer queries regarding COVID-19 vaccination drive; a new pre-caller tune; dissemination of communications package comprising of posters, banners, leaflets, bilingual Frequently Asked Questions (FAQs) and fact-check videos by key experts with information on COVID 19 across States/ UTs; Panel discussions and interviews on Television; experts identified for op-eds and articles to build vaccine confidence; Digital campaign on social media platforms; articles in major National and Regional dailies etc."

Further Comments of the Committee

1.24 The Committee note that several steps have been taken by the Government to raise awareness about the safety, efficacy and immunogenicity of COVID-19 vaccines, build vaccine confidence, address misinformation against vaccination, address vaccine hesitancy & vaccine eagerness and promote COVID appropriate behaviour. Eventhough, the country reached the mile stone of 100 crore vaccinations, as on 09 November, 2021, about 74.22 Crore people received first dose of vaccine and about 34.37 crore people were administered second dose of vaccine. Out of about 134 crore population of the country of the country, about 25.41 crore are yet to be vaccinated. The Committee, therefore, recommend that the Government should continue its efforts with full vigour to create awareness and to eliminate apprehensions in the minds of the people about the safety, efficacy and immunogenicity of COVID 19 vaccines and to promote COVID appropriate behaviour among people of the country.

RECOMMENDATION NO 14

1.25 Since the subject under examination involved various Ministry/ Department /Organisations the Committee had made following recommendation:-

> "Submission of Action Taken Replies to above observations/recommendations: 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."

1.26 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals replied as under:

> "Based on the inputs received from the Ministries/Departments/Organizations concerned, action taken replies to the above observations/recommendations of the Committee have been compiled by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers."

Further Comments of the Committee

1.27 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.

CHAPTER II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION NO 1 (II)

Availability of Safe, Secure and Effective Vaccine for COVID 19

2.1 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 ingeniously 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:-

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.

REPLY OF THE GOVERNMENT

2.2 The production capacity of the vaccines under the vaccination drive has been gradually ramped-up by the manufactures and is expected to increase further in the next couple of months. To further support the manufacturers in ramping up vaccine production, Government of India has also provided financial support of INR 1500 crore to M/s Biological E Ltd for 'at-risk manufacturing' of 30 crore doses and advance payment for 66 crore doses to be procured from M/s Serum Institute of India and M/s Bharat Biotech International Ltd. during July/Aug'21 to Dec'21. This would ease the limitation of vaccine availability over time. New vaccines (domestic as well as offshore), as and when approved by the National Regulator, will be taken up under the programme to improve vaccine availability and vaccination coverage.

Further, as stated by CDSCO, for augmentation of production capacity of COVID-19 vaccines in the country, Inter-ministerial group has been formed for providing support to COVID-19 vaccine manufacturers. The group visited following manufacturing facilities-

4. M/s Serum Institute, Hadapsar and Manjari facilities.
5. M/s Bharat Biotech, Hyderabad and Bangalore facilities.
6. M/s Indian Immunologicals (IIL), Hyderabad facility.

and provided guidance to firms to increase the production capacity and submitted the report. CDSCO is facilitating and handholding the applicants for reducing the processing

time for scale up of manufacturing of approved COVID-19 vaccines through Post Approval Changes as per provisions of CDSCO guidance for industry.

Department of Biotechnology (DBT) has further stated that the Government of India is supporting vaccine development and manufacturing activities through both national efforts and international partnerships. Currently, in India, 04 vaccine candidates for COVID-19 have been approved for Emergency Use Authorization (EUA). Besides these, about 09 vaccine candidates are in clinical stage of development and 01 candidate is in advanced pre-clinical stage of development; several promising vaccine candidates are in early stages of development. Further, to address the urgent need for making available sufficient vaccine doses to meet the existing requirements, efforts have been made to support scale-up of vaccine production, under Mission COVID Suraksha. Accordingly, support for one private industry (Bharat Biotech, Hyderabad) and three public sector manufacturing facilities (Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; Bharat Immunologicals and Biologicals, Bulandshar), is being provided to make them ready with enhanced capacities to support augmented production of Covaxin, over the next 6-8 months. The Department of Biotechnology (DBT) is also facilitating technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), comprising of Hester Biosciences, OmniBRx Biotechnologies Pvt Ltd, and Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat .

RECOMMENDATION NO 1 (III)

2.3 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 fulfill the demands of other countries.

REPLY OF THE GOVERNMENT

2.4 Department of Biotechnology has informed that to reinforce and accelerate the COVID-19 vaccine development efforts and to address the urgent need for a safe and efficacious COVID-19 vaccine, 'Mission COVID Suraksha - the Indian COVID-19 Vaccine Development Mission', was announced by the Government, as part of the Atmanirbhar Bharat 3.0 package. The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of DBT, at a total cost of Rs. 900 Cr. for 12 months. The goal of the Mission is to accelerate 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 the market for consideration by regulatory authorities and for introduction in public health systems.

Three Requests for Expression of Interest (REOI) for COVID-19 candidate vaccine development, enhancement of capacities to support COVID-19 vaccine development and conduct of human clinical trials have been issued. Four COVID-19 vaccine candidates in advanced clinical development stage and one vaccine candidate in advanced pre-clinical development, are being supported under this Mission. Additionally, 19 clinical trial sites across the nation, three immunogenicity assay laboratories and three animal challenge facilities are also being supported under the Mission. Additionally, augmentation of facilities for COVID-19 vaccine manufacturing, is also being supported under Mission COVID Suraksha.

A strong technical and financial internal due diligence is an integral part of the mission implementation process. Domain area specific Scientific Advisory Groups (SAG), have been constituted for scientific and technical due diligence of the applications received. An "Evaluation and Monitoring Committee for Technology Transfer", was constituted, to provide oversight and expert guidance and to monitor the progress of the facility augmentation to support COVID-19 Vaccine manufacturing under Mission Covid Suraksha. The ultimate focus is on bringing to the citizens of the country a safe, efficacious, affordable, and accessible COVID vaccine at the earliest and to strengthen the vaccine development ecosystem in the country for other on-going and future viral vaccine development.

Comments of the Committee

(Please see Para No. 1.9 of Chapter - I of the Report)

RECOMMENDATION NO 1 (IV)

2.5 Proper monitoring as well as execution mechanism be evolved to ensure the vaccination of all.

REPLY OF THE GOVERNMENT

2.6 MoHFW has informed that the regular review meetings of COVID-19 vaccination are conducted by the Ministry of Health & Family Welfare with the States/UTs to orient them on new developments, review the vaccination drive implementation & performance status and resolve queries in the shortest time frame. Another level of review of the vaccination drive takes place through the Empowered Group- 5 (EG- 5), constituted under the Disaster Management Act, 2005, mandated to decisively and effectively address evolving challenges in COVID-19 vaccination pertaining to vaccine procurement, manufacturing, import, logistics, daily supply, utilization and wastage monitoring. Further, National Expert Group on Vaccine

Administration for COVID-19 (NEGVAC) also reviews the programme performance on a regular basis and provides guidance on all aspects of COVID-19 vaccination. Progress under the COVID-19 vaccination drive is also reviewed by Cabinet Secretariat from time to time.

Comments of the Committee

(Please see Para No. 1.11 of Chapter - I of the Report)

RECOMMENDATION NO 1 (V)

2.7 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.

REPLY OF THE GOVERNMENT

2.8 India is an AMC eligible Country under COVAX facility to get donor supported doses of COVID-19 vaccine. India has advocated for its fair share to get COVID-19 vaccines under COVAX Facility. In December 2020 meeting, Gavi Board approved high range package of support for India, providing 20% of total AMC doses, subject to vaccine prices and available funds. Gavi COVAX through a decision letter has communicated that 97,164,000 indicative doses of AstraZeneca/SII with 35-40% in Q1 & 60-65% in Q2 will be supplied to India. Till date, Gavi COVAX has supplied 10 million doses of COVISHIELD to India through COVAX Facility. However, the remaining doses from COVAX facility are contingent upon availability of the same with COVAX.

Comments of the Committee

(Please see Para No. 1.13 of Chapter - I of the Report)

RECOMMENDATION NO 1 (VI)

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

REPLY OF THE GOVERNMENT

2.10 Central Drugs Standard Control Organisation (CDSCO) has informed that as per the New Drugs & Clinical Trials Rules, 2019, for grant of permission to manufacture or

import of a new drug including vaccines, the applicant is required to submit new drug application along with various data such as chemical and pharmaceutical information, non-clinical as well as clinical data of safety and efficacy of the drug including results from local clinical trial as specified in the Second Schedule of the said Rules. The aforesaid Rules provide the detailed requirements and guidelines for conduct of nonclinical and clinical studies and approval of new drug which include vaccines. The requirements apply to both, vaccines manufactured in the country or imported from overseas. Further, the Rules provide for grant of marketing authorization in certain special situations where relaxation, abbreviations, omission or deferment of data may be considered.

CDSCO has issued regulatory pathway for approval of COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL).

CDSCO has further revised the regulatory pathway on 01.06.2020, wherein the requirement to conduct post marketing bridging trial and prior approval of CDL for release of each lot of the vaccine has been done away with if the vaccine batch/lot has been certified and released by National Control Laboratory of Country of Origin. However, scrutiny and review of their Summary Lot Protocol & certificate of analysis of Batch/Lot shall be undertaken by CDL, Kasauli for Batch release as per standard procedure.

Further, SOP Guidance for import of COVID-19 vaccine by private sector or any person was issued on 04.05.2021.

Comments of the Committee

(Please see Para No. 1.15 of Chapter - I of the Report)

RECOMMENDATION NO 2 (I)

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

2.11 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.

Reply of the Government

2.12 CDSCO accords permission to manufacture or import COVID-19 vaccines after ensuring Safety, Quality, Immunogenicity and Efficacy of Vaccines in consultation with Subject Expert Committee (SEC) comprising subject matter experts from Microbiology, Pulmonology, Immunology, Paediatrics, Internal medicine etc. and in compliance with the provisions of New Drugs and Clinical Trials Rules, 2019.

RECOMMENDATION NO 3

Restricted Emergency Use Authorization of Vaccine Candidates:

2.13 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.

REPLY OF THE GOVERNMENT

2.14 As stated by the Department of Biotechnology, the Standing Technical Sub-committee (STSC) of the National Technical Advisory Group on Immunization (NTAGI), co-chaired by Secretary, DBT; Secretary, Department of Health Research (DHR) & Director General, Indian Council of Medical research (DG, ICMR), has constituted the COVID-19 Working Group (WG), to provide evidence-based recommendation, on the use of COVID-19 vaccines. The Department of Biotechnology is involved in deliberations of the COVID-19 WG on all aspects related to programmatic implementation of COVID-19 vaccines; introduction of validated assays for robust clinical development of COVID-19 vaccines; vaccine dosage, prioritization, delivery and other logistics.

Further, CDSCO has stated that permission is accorded to manufacture or import COVID-19 vaccines after ensuring Safety, Quality, Immunogenicity and Efficacy of Vaccines in consultation with Subject Expert Committee (SEC) comprising of subject matter experts from Microbiology, Pulmonology, Immunology, Paediatrics, Internal medicine etc. and in compliance with the provisions of New Drugs and Clinical Trials Rules, 2019.

RECOMMENDATION NO 4

Strengthening Adverse Event Following Immunization (AEFI) Processes

2.15 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.

REPLY OF THE GOVERNMENT

2.16 As post marketing surveillance, the applicants are required to submit Periodic Safety Update Reports as specified in the Fifth Schedule of New Drugs and Clinical Trials Rules, 2019 for approved Vaccines every six months for the first two years after approval. For subsequent two years, the periodic safety update reports need to be submitted annually.

Further, considering COVID-19 pandemic, as per condition of the marketing authorization permission, the importer/manufacturers of approved COVID-19 vaccines are required to submit the safety data including Adverse Event Following Immunization (AEFI) & Adverse events of special interest (AESI) with due analysis every 15 days for first two months and monthly till completion of the ongoing clinical trial in the country in addition to monitoring by Adverse Event Following Immunization (AEFI) committee of MoHFW. This will ensure active monitoring of the safety data of the vaccines permitted for use in the country.

As part of Adverse Events Following Immunization (AEFI) surveillance, a feature for reporting of minor, serious and severe AEFIs occurring within 30 minutes of vaccination and also beyond 30 minutes of vaccination by vaccinators and District Immunization Officers is already a part of the Co-WIN software which manages the allocation of

sessions and appointments for vaccination and records the processes of vaccination at the session sites. After the rapid review of 498 reported serious and severe AEFIs, an advisory has been issued to states and districts for steps to be taken to identify, report, investigate and manage events such as Thrombosis and Thrombocytopenic Syndrome (TTS). Besides this, the data on serious and severe AEFIs reported following use of COVAXIN under clinical trial mode has been shared on weekly basis with DCGI/CDSCO by the Immunization Division. To strengthen the AEFI system, more technical and clinical experts (medical specialists, cardiologists, neurologists, respiratory medicine specialists, etc.) have been involved as members of AEFI committee members (at national, state and district levels) for rapid review of reported serious and severe AEFIs for trend analysis and causality assessments. The human resources at the AEFI Secretariat have been increased to manage the surge in reported AEFIs.

RECOMMENDATION NO 5

Compliance of WHO Good Manufacturing Practices (GMP) Standards while Manufacturing Vaccines

2.17 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.

REPLY OF THE GOVERNMENT

2.18 The COVID-19 vaccine manufacturers develop & manufacture their products as per Good Manufacturing Practices (GMP) requirements which are laid down in Schedule-M of Drugs and Cosmetics Rules and WHO guidelines. Therefore, quality standards are maintained as per WHO GMP Guidelines and under the provisions of Drugs & Cosmetics Rules, 1945. In this regard, WHO has recoganized CDSCO as Functional National Regulatory Authority (NRA) for vaccines after assessment the regulatory system.

RECOMMENDATION NO 6

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

2.19 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, Kasauli 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, Kasauli is facing any difficulties in timely clearance of batches of vaccines, CDSCO may consider utilizing the services of other six laboratories under its jurisdiction.

REPLY OF THE GOVERNMENT

2.20 Central Drugs Laboratory (CDL), Kasauli alone has huge capacity to test nearly 200 batches per month (which is far more than the number of batches being received i.e. around 50 batches by CDL Kasauli for testing on monthly basis), and there is no delay for testing and release of the COVID-19 vaccines. However, to build the capacity of India for long run, Two more laboratories namely National Institute of Biologicals (NIB), Noida and National Centre for Cell Science (NCCS), Pune have been developed and notified for testing of COVID-19 Vaccines. Further, a laboratory at National Institute of Animal health (NIAH), Hyderabad is also under development specifically for COVID-19 vaccine testing. Six (06) laboratories of CDSCO other than CDL, Kasauli are designed for testing of Drugs, Devices and Cosmetics only, and not for vaccines.

Comments of the Committee

(Please see Para No. 1.18 of Chapter - I of the Report)

RECOMMENDATION NO 10

Need for Increasing Number of Primary and Intermediary Vaccine Stores

2.21 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.

REPLY OF THE GOVERNMENT

2.22 There are around 29,000 cold chain storage points at the State level & below catering to the requirement of COVID-19vaccines of 741 districts across 29 States and 7 UTs. This cold chain network is spread from the State till sub-District level such that the vaccines can be stored and managed across the country. Manufacturers supply vaccines directly to 41 primary stores in the States/UTs/Government Medical Stores Depots (GMSDs) while the GMSDs supply vaccines to 19 primary stores in the country.

There are around 837 District/Regional Vaccine Stores and 28,258 sub- District vaccine storage facilities. There exists a clear & established mechanism of vaccine supply from State to Divisional Stores (for large states)or State to District Stores (for smaller

targeted groups of persons like children in case of states), and further to sub-district stores. The vaccines are transported through Insulated/refrigerated vaccine vans. An assessment of the Cold Chain Storage Space and transportation mechanism had been carried out prior to introduction of the COVID-19 vaccine and the same has been adequately strengthened to meet the storage requirement of COVID-19 vaccine along with Universal Immunization Programme. It is also pertinent to note that majority of the vaccines are stored at Sub-District Cold Chain Points that are co-located/nearest to the COVID-19 Vaccination Centres. The Primary Stores are usually meant for storage of Buffer Stocks and storing the vaccine supplies for albeit short duration of time. Presently, the infrastructure is adequate to handle the storage and transportation requirements for vaccination of the entire adult population of the country.

Comments of the Committee

(Please see Para No. 1.21 of Chapter - I of the Report)

RECOMMENDATION NO 11

<u>Need to Bridge the Cold Chain Equipment Gap in all 36 States/UTs</u>

2.23 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.

REPLY OF THE GOVERNMENT

2.24 As per the cold chain equipment gap analysis done specifically for COVID-19 vaccination programme by the Ministry of Health & Family Welfare, the storage capacity for COVID-19 vaccines has been augmented with additional supply of 8887 Ice-Lined Refrigerator (Small), 4730 Ice-Lined Refrigerator (Large), 8178 Deep Freezer (Small), 4298 Deep Freezer (Large), 106 Walk-in-Cooler and 52 Walk-in-Freezer at the various vaccine stores of all States/UTs. As a result, there is no any further gap in storing the COVID-19 vaccines.

RECOMMENDATION NO 12

Need for Pan India Consumer Awareness Programme by NEGVAC

2.25 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.

REPLY OF THE GOVERNMENT

2.26 MoHFW has informed that the COVID-19 Vaccines Communication Strategy has been developed, for implementation at the National and State level, to raise awareness about the safety, efficacy and immunogenicity of COVID-19 vaccines, build vaccine confidence, address misinformation against vaccination, address vaccine hesitancy & vaccine eagerness and promote COVID appropriate behaviour. The strategy aims to promptly disseminate factual information about the vaccines and the vaccination process through clear, consistent and transparent messaging. This is being done

through multimedia platforms (print/electronic/ social media), through MoHFW website and engagement of various stakeholders, community leaders and influencers to reach out to the last mile. The strategy is based on five key pillars– viz., advocacy, capacity building, media engagement, community engagement and crisis management. For successful implementation of the strategy, several measures have been taken so far. These include capacity building of stakeholders at National and State level including State Immunization and IEC officials, Civil Society Organizations, Radio jockeys including Community Radio professionals, etc. for leveraging their networks for active campaigning to create awareness about benefits of vaccination. Aggressive advocacy to build vaccine confidence through reputed public and private sector Doctors at National level and States/UTs and through other key influencers.

A Communications National Media Rapid Response Cell has been established at MoHFW which is carrying out real-time review of news reports and disseminating content on building confidence in vaccines and to counter less than adequate informed media narrative. A special campaign against vaccine hesitancy was also launched by the Union Minister for Health and Family Welfare. The Ministry has also reached out to 22 Central line Ministries including Rural Development, Panchayati Raj, Ministry of Information and Broadcasting and MyGov etc. for engaging their field level networks to support information dissemination and social mobilization.

Other measures include, a special webpage on information pertaining to COV ID 19 vaccine; national helpline number 1075 to answer queries regarding COVID-19 vaccination drive; a new pre-caller tune; dissemination of communications package comprising of posters, banners, leaflets, bilingual Frequently Asked Questions (FAQs) and fact-check videos by key experts with information on COVID 19 across States/ UTs; Panel discussions and interviews on Television; experts identified for op-eds and articles to build vaccine confidence; Digital campaign on social media platforms; articles in major National and Regional dallies etc.

Comments of the Committee

(Please see Para No. 1.24 of Chapter - I of the Report)

RECOMMENDATION NO 13

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

2.27 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.

REPLY OF THE GOVERNMENT

2.28 MoHFW has stated that as per the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy, the vaccination of population aged 18 years and above has been opened up from 1st May 2021 through State government/UT administration and private sector. It places more power in the hands of States to independently plan, process and execute vaccination drives according to their aspirations. It also empowers private sector & corporates to take up mass vaccination drives for various subsets of people. Govt. of India continues to support free of cost vaccination of population groups prioritized by NEGVAC, i.e. Health Care Workers (HCWs), Front Line Workers (FLWs) and population above 45 years of age at Government COVID Vaccination Centres which receive vaccine doses from Govt. of India. All the States/UTs that have started vaccination of 18+ age group are providing it free of cost to the beneficiaries through their CVCs while it'll be at a charge at private CVCs. Any person, including people from lower middle class and people below poverty line, can avail vaccination free of cost from the Government CVCs. Recently, as per the revised Guidelines for National COVID Vaccination Program, which came into effect from 21st June 2021, Government of India is procuring 75% of the vaccines being produced by the manufacturers in the country. The vaccines procured are continue to be provided free of cost to States/UTs as has been the case from the commencement of the National Vaccination Programme. These doses will be administered by the States/UTs free of cost to all citizens as per priority through Government Vaccination Centres. The price of vaccine doses for private hospitals would be declared by each vaccine manufacturer, and any subsequent changes would be notified in advance. The private hospitals may charge up to a maximum of Rupees 150 per dose as service charges. State Governments may monitor the price being so charged. All citizens irrespective of their income status are entitled to free vaccination. Those who have the ability to pay are encouraged to use private hospital's vaccination

centres. Demand of vaccines from the private hospitals is aggregated in CoWIN portal and payment of this is made directly to manufacturer by the private hospitals.

Further, in the spirit of “Lok Kalyan”, use of non-transferable Electronic Vouchers, which can be redeemed at private vaccination centers, will be encouraged, which would enable people to financially support vaccination of Economically Weaker Sections at private vaccination centres .

RECOMMENDATION NO 14

2.29 Submission of Action Taken Replies to above observations/recommendations: 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.

REPLY OF THE GOVERNMENT

2.30 Based on the inputs received from the Ministries/Departments/Organizations concerned, action taken replies to the above observations/recommendations of the Committee have been compiled by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

Comments of the Committee

(Please see Para No. 1.27 of Chapter - I of the Report)

CHAPTER – III

OBSERVATION / RECOMMENDATION WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

RECOMMENDATION NO 1 (I)

Availability of Safe, Secure and Effective Vaccine for COVID 19

3.1 **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 ingeniously 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:-

> **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.**

REPLY OF THE GOVERNMENT

3.2 Ministry of Health and Family Welfare (MoHFW) has informed that the COVID-19 vaccination is an ongoing and dynamic process, which is being expanded to include beneficiary groups as prioritized by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). With effect from 1st May 2021, as per the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy, the State Government/UT Administration and private sector have been empowered to procure additional vaccine doses and have been given flexibility to customize to local needs and open vaccination to any age category above 18 years of age. Based on the experiences gained from 1st May 2021 and requests from States, the Guidelines for National COVID Vaccination Program were revised wherein, now GoI will procure 75% of the vaccines being produced monthly by the manufacturers in the country and these will continue to be provided free of cost to States/UTs. These doses, in turn, will be administered by the States/UTs free of cost to all citizens as per priority through Government Vaccination Centres. The private sector continues to have the option of direct procurement of 25% of monthly production of the domestic vaccine manufacturers. The price of vaccine doses for private hospitals would be declared by each vaccine manufacture and the private hospitals may charge up to a maximum of Rupees 150 per dose as service charges. Adequate quantity of COVID-19 vaccines is likely to be available for vaccination of all eligible beneficiaries aged 18 years and above, and the Government of India is committed to ensure vaccination of these

beneficiaries in shortest possible time. In view of the dynamic nature of COVID-19 pandemic and evolving status of availability & type of COVID-19 vaccines, a definite time frame cannot be indicated currently for completion of vaccination. The COVID-19 vaccination drive is based on WHO's recommendations & global practices, with an aim to maximize the impact of vaccination, save lives and keep the health system intact and functioning.

RECOMMENDATION NO 2(II)

3.3 **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.**

REPLY OF THE GOVERNMENT

3.4 CDSCO accords permission to manufacture or import COVID-19 vaccines after ensuring Safety, Quality, Immunogenicity and Efficacy of Vaccines in consultation with Subject Expert Committee (SEC) comprising subject matter experts from Microbiology, Pulmonology, Immunology, Paediatrics, Internal medicine etc. and in compliance with the provisions of New Drugs and Clinical Trials Rules, 2019.

MoHFW has informed that in view of the pandemic situation when vaccines are needed to be developed and administered in record time, globally, the countries are using COVID-19 vaccines under emergency use approval. These vaccines are approved for use only after these have documented minimum acceptable level of quality, safety and efficacy prescribed by the National Regulator. Same is the case in India. In India, there is no provision of compensation for recipients of COVID-19 vaccine against any kind of side effects or medical complications that may arise due to COVID-19 inoculation. However, measures have been put in place like availability of anaphylaxis kits at each vaccination site, observation of vaccine recipients for 30 minutes at session site for any adverse events so as to take timely corrective measure and if required immediate referral to Adverse Event Following Immunization (AEFI) management centre. Also, the AEFI management of such cases are provided free of cost in Public Health Facilities. The COVID-19 vaccination is voluntary for the beneficiary and is in public health interest of the country.

RECOMMENDATION NO 7

<u>Need for Timely Creation of Beneficiary Identification Data by NEGVAC:</u>

3.5 **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 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.

REPLY OF THE GOVERNMENT

3.6 At the start of COVID-19 vaccination drive, the database was created for the prioritized groups of Health Care Workers and Front Line Workers as these are defined and organized occupation categories which were linked with & vaccinated as per their parent organization/facility . However, subsequently, with expansion of the prioritized categories, i.e., persons > 60 years from 1st March 2021, persons aged 45- 59 years with co-morbidities from 15th March 2021, all persons > 45 years of age from 1st April 2021 and most recently all persons > 18 years of age from 1st May 2021, the need for creation of a database before vaccination drive did not remain as the vaccination drive has been opened for all adults and has been made people-centric. To avail vaccination, individuals pre-register themselves on Co-WIN portal by entering certain required details or take a walk-in appointment, thereby, negating the need for creation of a database beforehand.

States/UTs were requested to create a database of Health Care Workers and Front Line Workers as these are defined and organized occupation categories which were linked & vaccinated as per their parent organization/facility.

(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.

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.

REPLY OF THE GOVERNMENT

3.7 As also mentioned above, the vaccination process has evolved over the period of time and has been made people-centric where vaccination is provided on-demand by the beneficiaries. They can choose the time and place of vaccination as per their convenience. To ensure adequate protection through 1st and 2nd dose to this population group, the Ministry of Health & Family Welfare has time and again emphasised with States/UTs on ensuring the 2nd dose to the due beneficiaries and has been conducting regular review meeting with the States/UTs to follow-up on the same.

The Health Care Workers and Front Line Workers as prioritized by NEGVAC comprised workers from both public and private sector (including temporary/casual/ contractual workers). The same was communicated to the States/UTs through virtual meetings, written communication and Operational Guidelines.

RECOMMENDATION NO 8

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

3.8 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.

REPLY OF THE GOVERNMENT

3.9 Initially, the COVID- 19 vaccination drive covered the Health Care Workers & Frontline Workers, which later opened up for all persons >45 years of age. With the introduction of the Liberalized Pricing and Accelerated National COVID- 19 Vaccination Strategy from 1st May 2021, the vaccination is open to all persons aged above 18 years irrespective of place of residence, gender or epidemiological situation of the area. This strategy cuts across all areas and has opened up vaccination opportunity to population beyond the groups initially prioritized by NEGVAC.

RECOMMENDATION NO 9

Smart Vaccination Programme

3.10 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.

REPLY OF THE GOVERNMENT

3.11 MoHFW has informed that the COVID-19 vaccination drive started on 16th January 2021. The Day 1 witnessed vaccination of the highest number of beneficiaries covered anywhere in the world on the first day. With limited manufacturing capacity and limited number of vaccine manufacturers, the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) prioritized beneficiaries for vaccination. From starting with the Health Care Workers from 16th Jan' 21, the vaccination drive has been sequentially expanded to cover Front Line Workers from 2nd Feb' 21, persons aged 60 years and above and persons aged 45 years and above with specified comorbidities from 1st March 2021. From 1st April all persons above 45 years of age were made eligible for vaccination. From 1st May all

persons above 18 years of age were made eligible depending upon the decision made by State/UT. As per Revised Guideline for National Covid Vaccination Program which came into effect from 21st June 2021 all citizen above 18 years of age are eligible for free vaccination in Government COVID vaccination centres.

Under the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy, with effect from 1st May 2021, all individuals above 18 years of age are eligible for COVID-19 vaccination as per decisions made by State/UT governments.

In the direction of universal vaccination of population of the country with safe and efficacious vaccines, GoI revised its Guidelines for National COVID Vaccination Program based on the experiences gained from 1st May 2021. Under this, GoI will procure 75% of the vaccines being produced by the manufacturers in the country and will be provided free of cost to States/UTs as has been the case from the commencement of the National Vaccination Programme. These doses will be administered by the States/UTs free of cost to all citizens as per priority through Government Vaccination Centres. It continues to engage with the private sector to provide wider options and convenience to the beneficiaries, where private sector hospitals can directly procure vaccines upto 25% of monthly production of the manufacturers. All citizens irrespective of their income status are entitled to free vaccination under the programme. Those who have the ability to pay are encouraged to use private hospital's vaccination centres. Demand of vaccines from the private hospitals is aggregated in CoWIN portal and payment of this is made directly to manufacturer by the private hospitals.

CHAPTER – IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

NIL

CHAPTER – V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

NIL

New Delhi;
16 November, 2021
25 Kartika, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers

MINUTES OF THE FIRST SITTING OF THE

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2021-22)

The Committee sat on Tuesday, the 16th November, 2021 from 1500 hrs. to 1700.hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

K. KANIMOZHI - CHAIRPERSON
MEMBERS

LOK SABHA

2. Shri Dibyendu Adhikari
3. Shri Prataprao Patil Chikhlikar
4. Shri Kripanath Mallah
5. Shri Parbhubhai Nagarbhai Vasava
6. Shri Satyadev Pachauri
7. Shri Arun Kumar Sagar
8. Shri Pradeep Kumar Singh
9. Shri Uday Pratap Singh

RAJYA SABHA

10 Shri Ayodhya Rami Reddy Alla
11 Shri G.C.Chandrashekhar
12 Dr. Anil Jain
13 Shri Anthiyur P. Selvarasu
14 Shri Arun Singh

SECRETARIAT

1. Shri N. K. Jha - Director
2. Shri C. Kalyanasundaram - Additional Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Shri Panna Lal - Under Secretary

2. At the outset, the Chairperson welcomed the Members to the newly constituted Committee and apprised them that the sitting has been convened to consider Memorandum No.1 regarding selection of subjects for examination during the year (2021-22) and also to discuss the future course of action of the Committee during the tenure.

3. The Committee then considered Memorandum No. 1 and after discussion selected the following subjects pertaining to the Ministry of Chemicals and Fertilizers for detailed examination during 2021-22:-

I. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF FERTILIZERS)

1. Nano-fertilizers for sustainable crop production and maintaining soil health.
2. Tax structure on fertilizers sector in terms of GST and import duties – analysis of the tax structure of raw material and final products and its impact

on self-sufficiency and use of fertilizers.

3. Prices, Availability and distribution of fertilizers.

II. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF CHEMICALS AND PETROCHEMICALS)

4. Vision 2024 - To establish India as a leading manufacturer of chemicals and petrochemicals.
5. Insecticides – promotion and development including safe usage - licensing regime for insecticides.
6. Disposal of toxic waste from Bhopal Gas Leak site.
7. Environmental Impact of Petrochemical products.

III. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

8. Promotion of Medical Device Industry.
9. Availability of Medicines and Medical devices for COVID Management.
10. Self sufficiency of key starting Material and intermediates.

4. The Committee then considered and adopted the following draft Action Taken Reports unanimously without any amendment/change:-

i.	XXX	XXX	XXX
ii.	XXX	XXX	XXX
iii.	XXX	XXX	XXX
iv.	XXX	XXX	XXX
v.	XXX	XXX	XXX
vi.	XXX	XXX	XXX

vii. ATR on the recommendations/ observations of the Committee contained in the Twenty Second Report on the subject “Status of COVID-19 vaccine production in India” (Department of Pharmaceuticals).

5 The Committee also authorised the Chairperson to finalize and present the Action Taken Reports to the Parliament in the ensuing session.

The Committee then adjourned.

Appendix – II

(*Vide* Para-3 of Introduction to Report)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE TWENTY SECOND REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS ON THE SUBJECT 'STATUS OF COVID-19 VACCINE PRODUCTION IN INDIA' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	21
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 1(ii),1(iii),1(iv), 1(v), 1(vi), 2(i), 3, 4, 5, 6, 10, 11,12, 13 and 14)	15
	Percentage of Total	71.0%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation No. 1(i), 2(ii), 7(i), 7(ii), 8 and 9)	06
	Percentage of Total	29.0%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation No. Nil)	Nil
	Percentage of Total	0%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (*Vide* Recommendation No. Nil)	Nil
	Percentage of Total	0%
	Total	100%