



REPORT NO.

137

PARLIAMENT OF INDIA

RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING  
COMMITTEE ON HEALTH AND FAMILY WELFARE

ONE HUNDRED THIRTY SEVENTH REPORT

On

"VACCINE DEVELOPMENT, DISTRIBUTION MANAGEMENT AND  
MITIGATION OF PANDEMIC COVID-19"  
PERTAINING TO  
MINISTRY OF HEALTH & FAMILY WELFARE

*(Presented to the Chairman, Rajya Sabha on 12<sup>th</sup> September, 2022)*  
*(Forwarded to the Speaker, Lok Sabha on 12<sup>th</sup> September, 2022)*

*(Presented to the Rajya Sabha on 8<sup>th</sup> December, 2022)*  
*(Laid on the Table of Lok Sabha on 8<sup>th</sup> December, 2022)*



Rajya Sabha Secretariat, New Delhi  
September, 2022/Asvina, 1944 (SAKA)

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September, 2022/ Asvina, 1944 (SAKA)**

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**COMPOSITION OF THE COMMITTEE**

**(2021-22)**

**1. Prof. Ram Gopal Yadav - Chairman**

**RAJYA SABHA**

2. Dr. Anil Agrawal
3. Dr. L. Hanumanthaiah
4. *Vacant*
5. *Vacant*
6. Dr. Santanu Sen
7. Shri A. D. Singh
8. Dr. Kanimozhi NVN Somu
9. *Vacant*
10. *Vacant*

**LOK SABHA**

11. Shrimati Mangal Suresh Angadi
12. Ms. Bhavana Gawali (Patil)
13. Shri Maddila Gurumoorthy
14. Ms. Ramya Haridas
15. Dr. Chandra Sen Jadon
16. Dr. Amol Ramsing Kolhe
17. Shrimati Kavitha Malothu
18. Dr. Sanghmitra Maurya
19. Shri Arjun Lal Meena
20. Shrimati Pratima Mondal
21. Dr. Pritam Gopinath Munde
22. Shri K. Navaskani
23. Dr. Sujay Radhakrishna Vikhe Patil
24. Adv. Adoor Prakash
25. Shri Haji Fazlur Rehman
26. Dr. Rajdeep Roy
27. Dr. DNV Senthilkumar S.
28. Shri Anurag Sharma
29. Dr. Mahesh Sharma
30. Dr. Krishna Pal Singh Yadav
31. Dr. Lorho S. Pfoze

**SECRETARIAT**

- |                              |                             |
|------------------------------|-----------------------------|
| 1. Shri Mahesh Tiwari        | Joint Secretary             |
| 2. Shri Shashi Bhushan       | Director                    |
| 3. Shri Bhupendra Bhaskar    | Additional Director         |
| 4. Shri Praveen Kumar        | Deputy Secretary            |
| 5. Shrimati Harshita Shankar | Deputy Secretary            |
| 6. Shri Rajesh Kumar Sharma  | Assistant Committee Officer |
| 7. Ms. Monika Garbyal        | Assistant Committee Officer |

## PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this One-Hundred Thirty Seventh Report on the Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19.

2. The Department-related Parliamentary Standing Committee on Health and Family Welfare examined the outbreak of Pandemic Covid-19 and its management and presented its 123<sup>rd</sup> Report to the Chairman Rajya Sabha on 21<sup>st</sup> November, 2020 and presented to the Parliament on 2nd February, 2021. Taking note of the eventuality of second Covid wave in other countries, the Committee in that Report had warned the Government regarding the possibility of the increase in Covid cases and the need for upgrading the health infrastructure to tackle possible subsequent Covid wave. The Committee further presented its 130<sup>th</sup> Report on the Action taken by the Government on the Recommendations/Observations contained in the 123<sup>rd</sup> Report in the Parliament on 3<sup>rd</sup> December, 2021. The Committee in that Report recommended the Government to focus on strengthening of health infrastructure, ensuring adequate availability of beds, adequate supply of oxygen cylinders and essential medicines etc.

3. Keeping in view the continued outbreak of Pandemic Covid -19 with its mutating variants, the Committee, in its meeting held on 30<sup>th</sup> December, 2020 decided to undertake the subject "Vaccine Development, Distribution Management and Mitigation Plan of Pandemic Covid-19 for detailed examination. During the examination of the subject, the Committee heard the views of the Secretaries, Department of Health and Family Welfare and Department of Health Research in its Committee meetings held on 12th January 2021 and 10th August, 2021. The Committee also heard the views of Principal Scientific Adviser to the Government of India and AIIMS Director in the Committee meeting held on 22nd January, 2021.

4. With Omicron becoming the dominant Covid variant globally, the Committee in its meeting held on 9<sup>th</sup> December, 2021 heard the views of Secretaries, Department of Health and Family Welfare and Department of Health Research on the "Challenges posed by Omicron variant of Covid-19, the strategy adopted and measures taken to combat the same". Continuing with the examination of the subject, the Committee in its meetings held on 4<sup>th</sup> April, 2022 heard the views of the Ministry of Women and Child Development, the Department of Biotechnology, SAMA- Resource Group for Women & Health and the National Institute of Public Finance and Policy (NIPFP). In its subsequent meeting held 5<sup>th</sup> April, 2022, the Committee heard the views of Dr. Gagandeep Kang, Virologist and Microbiologist, Jan Swasthya Abhiyan and the representatives of the State Government of Maharashtra, Karnataka and Kerala on the subject "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID 19".

5. The Committee also undertook two study visits to (i) Srinagar and Chandigarh from 6<sup>th</sup> to 9<sup>th</sup> September, 2021 and (ii) to Guwahati, Bangluru and Mumbai from 25<sup>th</sup> to 29<sup>th</sup> April, 2022 and held deliberations with the representatives of the State Governments regarding the status of the vaccination drive in the respective States and the steps being taken to mitigate the onslaught & affects of the pandemic Covid-19.

6. The Committee also sought the written views of various organizations/associations and the State Governments and the Union Territories on the subject. In response to that the Committee received Memoranda from several States/UTs.

7. During the finalization of its Report, the Committee relied upon the following documents/ papers:-

- (i) Background Note on " Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19" received from following Departments/Ministries (a) Department of Health and Family Welfare, (b) Department of Health Research, (c) Department of Biotechnology, (d) Ministry of AYUSH, (e) Department of Pharmaceuticals, (f) Ministry of Panchayati Raj etc.
- (ii) Oral Evidences tendered by Secretaries, Department of Health and Family Welfare, Department of Health Research and Ministry of AYUSH;
- (iii) Oral Evidences tendered by representatives of the Department of Biotechnology, Ministry of Women & Child Development, State Governments, other stakeholders and their written submissions;
- (iv) Written submissions of various Organizations/Associations;
- (v) Replies to the questionnaires received from the Department of Health and Family Welfare, Department of Health Research and Ministry of AYUSH; and
- (vi) Other relevant documents pertaining to the subject.

8. The Report is divided into seven chapters, viz: - Chapter- I deals with the resurgence of the pandemic Covid-19; Chapter-II stipulates vaccine Research and Development; Chapter-III deals with Vaccine Procurement and Distribution; Chapter- IV covers the unfolding of the National Covid-19 Vaccination Programme; Chapter-V focuses on the views of the State Government, Other Departments/Ministries and other stakeholders; Chapter- VI enumerates the Challenges in Covid-19 Mitigation and Management; and Chapter- VII highlights how Pandemic is far from Over.

9. The Committee in its meeting held on 8<sup>th</sup> August, 2022 considered the Draft Report and adopted the same.

10. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report and also reproduced at the end of the Report at ‘Observations/Recommendations of the Committee-at a Glance’ .

11. On behalf of the Committee and on my own behalf, I extend special thanks to Secretaries and officers of the (i) Department of Health and Family Welfare and (ii) Department of Health Research for their useful inputs on the subject. I also acknowledge the contribution of the stakeholders for their deep insight and useful suggestions during the course of interactions. I further extend special appreciation to the officers & staff attached with Health & Family Welfare of the Committee Section for their tireless efforts in assimilating all relevant information and enabling the Committee in producing this magnificent Report.

**New Delhi**  
**8<sup>th</sup> August, 2022**  
**Sravana , 1944 (Saka)**

**PROF. RAM GOPAL YADAV**  
**Chairman, Department-related**  
**Parliamentary Standing Committee on**  
**Health and Family Welfare**



## ACRONYMS

ABHWCs	Ayushman Bharat Health and Wellness Centres
AB-PMJAY	Ayushman Bharat/Pradhan Mantri Jan Arogya Yojana
ASU&H	Ayurveda, Siddha, Unani and Homoeopathy
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Riga and Homeopathy
CCC	COVID Care Center
CEPI	Coalition for Epidemic Preparedness Innovations
CFR	Case Fatality Rate
CGRMS	Central Grievance Redressal Management System
CHC	Community Health Centers
CHE	Current Health Expenditure
CII	Confederation of Indian Industry
CPHC	Comprehensive Health Care
CSOs	Civil Society Organizations
CSU	Central Surveillance Unit
DBT	Department of Bio Technology
DCH	Dedicated COVID Hospital
DCHC	Dedicated COVID Health Centre
DGHS	Director General of Health Services
DHR	Department of Health Research
DLE	Direct Lab Empanelment
DSOs	Disease Surveillance Officer
DSU	District Surveillance Units
EUA	Emergency Use Authorization
GE	Genus Epidemicus
GERD	Gross domestic expenditure on R&D
GHE	Government Health Expenditure
GHSA	Global Health Security Agenda
GOI	Government of India
GoM	Group of Ministers
HBPs	Health Benefit Packages
HCQ	Hydroxychloroquine
HEM	Hospital Empanelment Module
IAPSM	Indian Association of Preventive and Social Medicine
IAS	Indian Administrative Service
ICMR	Indian Council of Medical Research
ICTV	International Committee on Taxonomy of Viruses
IDSP	Integrated Disease Surveillance Programme
IDSP	Integrated Disease Surveillance Programme
IDSP	Integrated Disease Surveillance Programme
iGOT	Integrated Government Online Training
IHIP	Integrated Health Information Platform
IHS	Indian Health Service
IJMR	Indian Journal of Medical Research
ILI	Influenza Like Illness
IPHA	Indian Public Health Association

IPHS	Indian Public Health Standard
IST	Indian Standard Time
JMG	Joint Monitoring Group
LMWH	Low Molecular Weight Heparin
MEA	Ministry of External Affairs
MERS	Middle East Respiratory Syndrome
MHA	Ministry of Home Affairs
MoHFW	Ministry of Health and Family Welfare
MRHRUs	Model Rural Health Research Units
MRUs	Multi Disciplinary Research Units
MSMEs	Micro, Small and Medium Enterprises
NAFU	National Anti-Fraud Unit
NARI	National AIDS Research Institute
NCDC	National Center for Disease Control
NDMA	National Disaster Management Authority
NEC	National Executive Committee
NHA	National Health Authority
NIV	National Institute of Virology
PHC	Primary Health Centers
PHEIC	Public Health Emergency of International Concern
PM-ASBY	Prime Minister Atma Nirbhar Swasth Bharat Yojana
PMGKY	Pradhan Mantri Garib Kalyan Yojana
PoE	Points of Entry
PPE	Personal Protective Equipment
RRTs	Rapid Response Teams
SAFUs	State Anti-Fraud Units
SARI	Severe Acute Respiratory Illness
SARS	Severe Acute Respiratory Syndrome
SDRF	State Disaster Response Fund
SHA	State Health Agencies
SII	Serum Institute of India
SOP	Standard Operating Procedure
SOPs	Standard Operating Protocols
SOR	Objects and Reasons
SSU	State Surveillance Units
STI	Science, Technology and Innovation
STWs	Standard Treatment Workflows
STGs	Standard Treatment Guidelines
TDABC	Time Driven Activity Based Costing
THE	Total Health Expenditure
TMS	Transaction Management System
UIS data	UNESCO Institute of Statistics data
VBM	Vande Bharat Mission
VHSNC	Village Health Sanitation and Nutrition Committee
VRDLs	Viral Research & Diagnostic Laboratories
VTMs	Viral Transport Media
WFH	Work From Home

## CHAPTER I

### RESURGENCE OF PANDEMIC COVID-19

1.1 The world witnessed the severe impact of Covid-19 pandemic that brought the global economy to a standstill. Economies around the world are still struggling to overcome the economic and social distress that the pandemic ravaged. India also faced a major first Covid wave and then a more distressing & devastating second wave that exposed the loopholes in the Indian Healthcare system. The Department-related Parliamentary Standing Committee on Health and Family Welfare examined the Outbreak of Pandemic Covid-19 and its Management and presented its 123<sup>rd</sup> Report to the Chairman Rajya Sabha on 21<sup>st</sup> November, 2020 and presented to the Parliament on 2<sup>nd</sup> February, 2021. The Committee, in its said Report, had assessed the response of the Government to contain and mitigate the pandemic and made several recommendations regarding its management, the poor state of health infrastructure, and possible second wave of Corona etc. The Committee in the said Report had also emphasized on the pivotal role played by ICMR in the fight against the pandemic and highlighted on the need to devise a suitable strategy to combat such outbreaks. Taking note of the eventuality of second Covid wave in other countries, the Committee in that Report had warned the Government regarding the possibility of the increase in Covid cases and the need for upgrading the health infrastructure to tackle any possible subsequent Covid wave. However, the alarming rate of Covid cases and deaths during the second wave uncovered weak planning and poor implementation of strategies laid down by the Government.

1.2 The Committee further presented its 130<sup>th</sup> Report on the Action taken by the Government on the Recommendations/Observations contained in the 123<sup>rd</sup> Report in the Parliament on 3<sup>rd</sup> December, 2021. The Committee, in that Report, recommended the Government to focus on strengthening of health infrastructure, ensuring adequate availability of beds, adequate supply of oxygen cylinders and essential medicines, etc. The Committee also recommended the Government to undertake massive R&D projects for effective vaccine development and aggressively push the vaccination programme in terms of granting approval to more vaccines, ramping up vaccines' production, enhancing delivery capacity and increasing the vaccination rate.

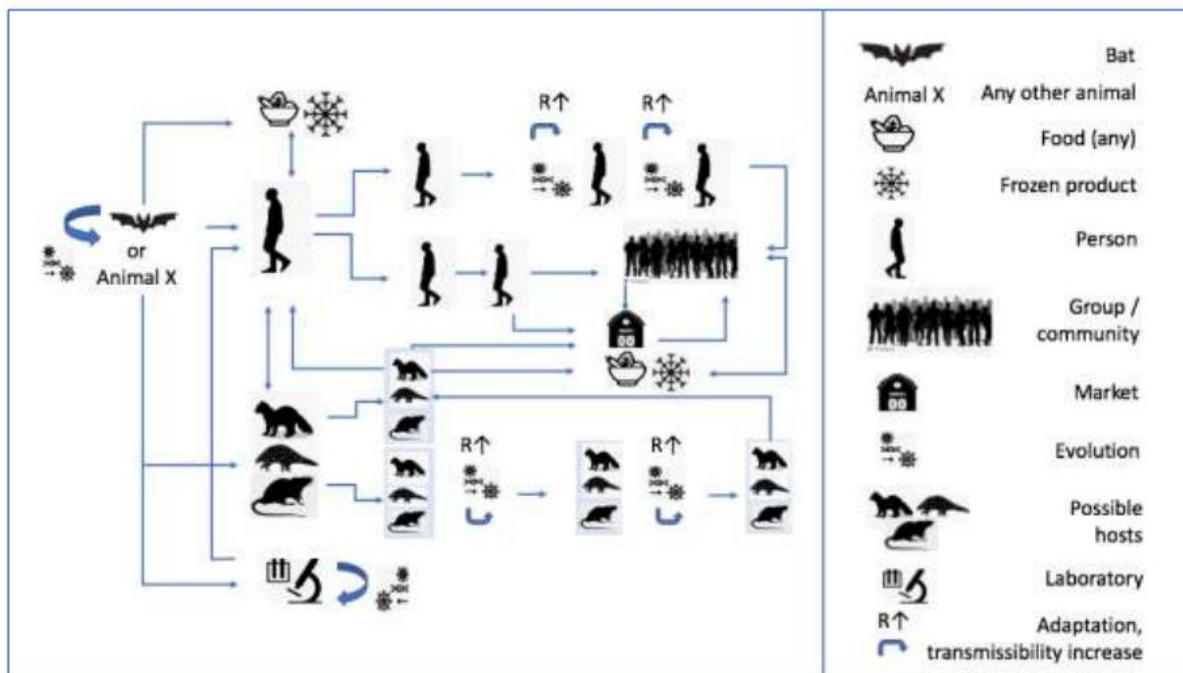
1.3 Pandemic Covid-19 altered the socio-politico economic world order thereby necessitating the Committee to continue to have critical assessment of the Pandemic Covid-19 beyond the ambit and scope of the Committee's 123<sup>rd</sup> Report on , "The Outbreak of Pandemic COVID-19 and its Management" followed by the 130<sup>th</sup> Report on, "The Action Taken by Government on the Recommendations/ Observations contained in its 123<sup>rd</sup> Report" thereon, by undertaking detailed study on the subject, "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID-19".

### OUTBREAK AND ORIGIN OF COVID -19

1.4 According to WHO, the outbreak of febrile respiratory illness of unknown etiology in December, 2019 originated from Wuhan, Hubei province of China. The outbreak has been epidemiologically linked to the Huanan Seafood Wholesale Market involving sale of sea food and live animals in mid-December, 2019. During the examination of the subject, "The Outbreak of Pandemic COVID-19 and its Management", the Ministry of Health and Family Welfare had submitted that all available evidence for COVID-19 suggests that the causative virus (SARS-CoV-2) has a zoonotic source. Many crucial epidemiological parameters like extent and role

played by sub-clinical/asymptomatic infections, period of communicability etc. still remain under investigation. The infection is spread through droplets or prolonged contact with infected patients.

1.5 The Committee is given to understand that, the World Health Assembly in May 2020 had requested the Director-General of the World Health Organization (WHO) to continue its work to identify the zoonotic source of the corona virus and the route of introduction to the human population, including the possible role of intermediate hosts. WHO worked closely with a multidisciplinary team of Chinese experts and examined four scenarios for introduction of the virus, namely, (i) direct zoonotic transmission to humans (spillover); (ii) introduction through an intermediate host followed by spillover; (iii) introduction through the (cold) food chain; and (iv) introduction through a laboratory incident.



**Fig. 1. Overall schema for possible pathways of emergence, providing a conceptual framework for possible routes for SARS-CoV-2 emergence. The icons are meant to be interpreted in a generic manner and the location and timing is not stated. The animals depicted reflect animal species that have been discussed in relation to potential infection but can be replaced by other species as well. Arrows indicate directions of possible transmission. The symbols indicating “evolution” are meant to reflect any mutations, recombination, variant selection leading to enhanced ability to infect other species and/or transmit.**

1.6 WHO in its Report released in March 2021 submitted that the joint team conducted a qualitative risk assessment considering the available scientific evidence and findings for each of these possible pathways of emergence. The WHO joint team had considered the following ranking of potential introduction pathways, from very likely to extremely unlikely: (the ranking of potential introduction pathways is from very likely to extremely unlikely) (1) through an intermediate host; (2) direct zoonotic introduction; (3) introduction through cold/ food chain; and (4) introduction resulting from a laboratory incident. In the Report, building from the evidence for the studies conducted so far, follow-up research studies were proposed for the first three options. The panel had further recommended for establishing a global expert group to support joint traceability research on the suspected origin of the epidemic.

1.7 Attention of the Committee is also brought to the WHO's Scientific Advisory Group for the Origins on Novel Pathogens (SAGO) that advises the Secretariat on technical and scientific considerations regarding emerging and re-emerging pathogens. Scientific Advisory Group for the Origins on Novel Pathogens (SAGO) was formed in 13<sup>th</sup> October, 2021 to study the emergence of future pathogens with pandemic potential and has been tasked with advising studies that are necessary to gather evidence to better understand the origins of SARS-CoV-2.

1.8 SAGO submitted its first preliminary Report in June 2022 that has pointed towards zoonotic origin as the most likely explanation for the origin of the novel coronavirus. However, the Report submitted that the original animal source, the intermediate host as well as the moment the virus crossed over into humans could not be identified. The panel has also recommended that additional investigations should be carried out with the staff in the laboratories tasked with managing and implementing biosafety and biosecurity at laboratories: (1) those in the proximity of the original COVID-19 outbreak working with SARS-like viruses in Wuhan, China and potentially with (2) those located worldwide where early COVID-19 cases have been retrospectively detected before 2020.

**1.9 The Committee observes that the origin of the virus still remains obscure and more studies need to be conducted to shed light on the origins of the SARS-CoV-2 virus. The Committee strongly believes that identification of the true source of the virus is crucial for establishment of new zoonotic reservoirs so that future reinfections and diseases in animals as well as humans are prevented. Moreover, the information is crucial to reduce any future risks due to the emergence and transmission of the zoonotic diseases like the recent outbreak of Monkeypox. The Committee is of the opinion that the large scale fatalities and the devastating impact of Covid-19 pandemic necessitate the need of being better prepared for possible future outbreaks viz the menace and management of Monkeypox. The Committee strongly believes that it is incumbent upon global scientists to accelerate its efforts in identifying novel pathogens and establish a robust surveillance mechanism for faster detection of the pathogens. In this regard, it becomes all the more important to identify the origin of the SARS-CoV-2 virus and investigate its origin along all the possible pathway of emergence.**

**1.10 The Committee takes into account that there is still lack of concrete evidence on whether the corona virus reached humans via a laboratory incident. Nevertheless, the Committee understands that if the origin of corona virus is allowed to remain a mystery, it will have colossal consequences over Bio-safety and Bio-security of the world. The Committee, therefore, strongly recommends the Government to reckon its diplomacy to appeal to the comity of nations to conduct more studies to identify the origin of Covid-19 and penalize the culprits at the International platform. The Committee further feels that the increasing number of emerging virus highlights the necessity of establishing a robust mechanism for systematic investigation of the origin and the route of transmission of the pathogens. The Committee accordingly recommends the Ministry to develop a healthcare framework in the country for investigating and managing future outbreaks more effectively. In this regard, the Committee strongly believes that the recently constituted Task Force Team led by Dr. VK Paul will track the Monkeypox situation and provide guidance to the Government on the expansion of diagnostic facilities in the country and combat the menace of Monkeypox.**

## CONSULTATION PROCESS

1.11 During the examination of the subject, the Committee heard the views of the Secretaries, Department of Health and Family Welfare and Department of Health Research in its meetings held on 12<sup>th</sup> January 2021 and 10<sup>th</sup> August, 2021, respectively. The Committee also heard the views of Principal Scientific Advisor to the Government of India and the Director, AIIMS in its meeting held on 22<sup>nd</sup> January, 2021. With Omicron becoming the dominant Covid variant globally, the Committee in its meeting held on 9<sup>th</sup> December, 2021 heard the views of Secretaries, Department of Health and Family Welfare and Department of Health Research on the "Challenges posed by Omicron variant of Covid-19, the strategy adopted and measures taken to combat the same". Continuing with the examination of the subject, the Committee in its meeting held on 4<sup>th</sup> April, 2022 heard the views of the Ministry of Women and Child Development, the Department of Biotechnology, SAMA- Resource Group for Women & Health and the National Institute of Public Finance and Policy (NIPFP). The Committee in its meeting held on 5<sup>th</sup> April, 2022 heard the views of Dr. Gagandeep Kang, Virologist and Microbiologist, Jan Swasthya Abhiyan and the representatives of the State Government of Maharashtra, Karnataka and Kerala on the subject "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID 19".

1.12 The Committee undertook study visits to (i) Srinagar and Chandigarh from 6<sup>th</sup> to 9<sup>th</sup> September, 2021 and (ii) Guwahati, Bengaluru and Mumbai from 25<sup>th</sup> to 29<sup>th</sup> April, 2022, held deliberations with the representatives of the State Governments regarding the status of the vaccination drive in the respective States and the steps taken/being taken to mitigate the effects of the Covid-19 pandemic.

## INSTITUTIONAL ARRANGEMENT

1.13 During the examination of the subject, the Ministry of Health and Family Welfare informed the Committee that the following two committees were constituted by the Prime Minister to tackle the unprecedented Covid-19 situation in the country:-

(a) **Task Force on Encouraging Research and Development in Drugs, Pharmaceuticals and Vaccines** headed by Principal Scientific Advisor to the Government of India, Shri K Vijay Raghavan constituted in May, 2020 with the aim to encourage Research & Development and manufacturing of vaccines in India; and

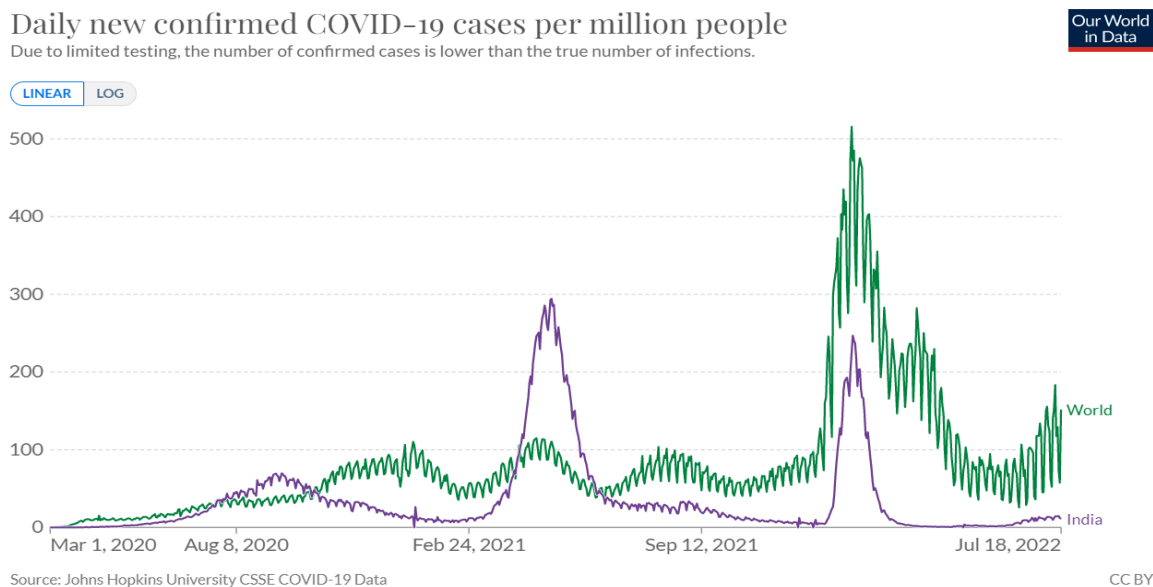
(b) **NEGVAC (National Expert Group on Vaccine Administration)** headed jointly by Member (Health), NITI Aayog Dr. V. K. Paul and Secretary, Ministry of Health and Family Welfare constituted in August 2020 with the aim to form prioritization groups for vaccination and to work out other modalities in vaccine management and distribution.

1.14 The Ministry further submitted that for appropriate management of suspect/confirmed COVID-19 cases, a three-tier arrangement of health facilities, viz, (i) Dedicated COVID Care Center (DCCC) with isolation beds for mild or pre-symptomatic cases; (ii) Dedicated COVID Health Center (DCHC) oxygen supported isolation beds for moderate cases and (iii) Dedicated COVID Hospital (DCH) with ICU beds for severe cases, had been implemented in consultation with the State Governments. Tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry etc. were also leveraged for case management.

## RESURGENCE OF PANDEMIC COVID-19

1.15 The Ministry of Health and Family Welfare submitted that India witnessed resurgence in COVID-19 cases in the first half of February 2021. The trajectory witnessed a steep rise in the months of April and May 2021. Evolution and spread of highly transmissible Delta variant of SARS-CoV-2, coupled with number of social factors including easing of lockdown, a lack of community adherence to COVID Appropriate Behaviour (CAB) combined with pandemic fatigue can be attributed for the surge in Corona-virus cases during the said period. After reaching a peak on 7<sup>th</sup> May 2021, the trajectory of COVID-19 cases declined considerably.

1.16 Attention of the Committee has been drawn to the statistics put forward by the *Our World in Data* where in daily new confirmed cases per million people have been plotted as follows:



1.17 In response to the Committee's query, the Ministry submitted that while it might be difficult to comment if the surge could have been prevented, as many of the contributing factors to resurgence of pandemic Covid-19 cases were beyond public health interventions. It was maintained that Union Ministry of Health & Family Welfare continued to monitor situation closely, provided required technical support and also supported the states through logistic and financial support to further strengthen the existing health infrastructure to tackle COVID-19 pandemic.

**1.18 The Committee observes that India is one of the countries with the heaviest burden of Covid-19 cases in the world. The enormity of the population of the country posed a major challenge in the face of this unprecedented pandemic. With the fragile health infrastructure and the huge shortage of the healthcare workers, the country witnessed itself reel under tremendous pressure. The Committee notes that the Government could not accurately anticipate the gravity of the possible resurgence of pandemic and its subsequent waves. The Committee believes that even when the trajectory of COVID-19 cases in the country registered a decline in the aftermath of first wave, the Government should have continued its efforts to monitor the resurgence of COVID-19 situation and its possible outrage in the country. The Committee notes that the Ministry has been cautioning States to maintain the vigil and chalk out situation and strategy & plan for any exigencies that may arise due to resurgence of COVID-19 in their respective States,**

**however, the Committee is unhappy to note that many States were unable to cope up with the arising uncertainties and medical emergencies in the wake of the pandemic resurgence of Covid-19 during the second wave that caused more than 5 lakh registered deaths.**

## **WAVES OF PANDEMIC OF COVID-19**

1.19 The Committee is given to understand that viruses constantly change through mutation, and new variants of a virus are expected to occur over time. Till date, multiple COVID-19 variants have been detected and are circulating globally. In December 2020, a new variant with an unusually large number of mutations named as the B.1.17 (Alpha) was reported in the UK, however, the exact origin of mutations is difficult to ascertain.

1.20 Taking note of the changing scenario, the Committee in its meeting held on 22<sup>nd</sup> January, 2021, raised concerns regarding the detection of new kind of Covid variants. In the same meeting, the Principal Scientific Adviser to the Government of India had submitted before the Committee that firstly a new variant could lead to an increase in the spread of the virus; secondly its impact could increase the incidence of the disease and thirdly it might lead to immune escape. He elaborated that immune escape variants could cause Covid-19 even among those people who have already been infected in the past or have been vaccinated. Though that is a low probability event, however if that occurs then the phenomenon could lead to an increase in transmission. Similar concerns were raised with the UK variant and South African variant. It was underlined that in such a scenario, as the transmission increases, the vaccine deployment must also be expedited. He further stated that as the virus changes, the vaccine could also be developed in a way so that it decreases the virulence of the virus. Under the stated situation, identification of the number of patients, sequencing of virus in a selected group, laboratory testing of the virus, impact on transmission etc were carried out. He also informed the Committee that CSIR, Department of Biotechnology and ICMR were working on this front.

1.21 The Committee notes that WHO in collaboration with other institutes has been monitoring the evolution of SARS-CoV-2 since January 2020. WHO has been classifying the different variants of Covid as specific Variants of Interest (VOIs) and Variants of Concern (VOCs). WHO defined Variants of concern (VOC) as follows:

A SARS-CoV-2 variant that meets the definition of a Variants of Interest (VOI) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- a. Increase in transmissibility or detrimental change in COVID-19 epidemiology; OR
- b. Increase in virulence or change in clinical disease presentation; OR
- c. Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.

### **Previously circulating VOCs:**

<b>WHO label</b>	<b>Pango Lineage</b>	<b>Earliest documented Samples</b>
<b>Alpha</b>	<b>B.1.1.7</b>	<b>United Kingdom, Sep-2020</b>
<b>Beta</b>	<b>B.1.351</b>	<b>South Africa, May-2020</b>
<b>Gamma</b>	<b>P.1</b>	<b>Brazil, Nov-2020</b>
<b>Delta</b>	<b>B.1.617.2</b>	<b>India, Oct-2020</b>



### Currently circulating variants of concern (VOCs):

<b>WHO label</b>	<b>Pango lineage*</b>	<b>Earliest documented samples</b>
<b>Omicron</b>	<b>B.1.1.529</b>	<b>Multiple countries, Nov-2021</b>

1.22 WHO defines Variants of interest (VOI) as a SARS-CoV-2 variant (i) with genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; and (ii) identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.

### Previously circulating VOIs:

<b>WHO label</b>	<b>Pango lineage*</b>	<b>Earliest documented samples</b>
<b>Epsilon</b>	<b>B.1.427 B.1.429</b>	<b>United States of America, Mar-2020</b>
<b>Zeta</b>	<b>P.2</b>	<b>Brazil, Apr-2020</b>
<b>Eta</b>	<b>B.1.525</b>	<b>Multiple countries, Dec-2020</b>
<b>Theta</b>	<b>P.3</b>	<b>Philippines, Jan-2021</b>
<b>Iota</b>	<b>B.1.526</b>	<b>United States of America, Nov-2020</b>
<b>Kappa</b>	<b>B.1.617.1</b>	<b>India, Oct-2020</b>
<b>Lambda</b>	<b>C.37</b>	<b>Peru, Dec-2020</b>
<b>Mu</b>	<b>B.1.621</b>	<b>Colombia, Jan-2021</b>

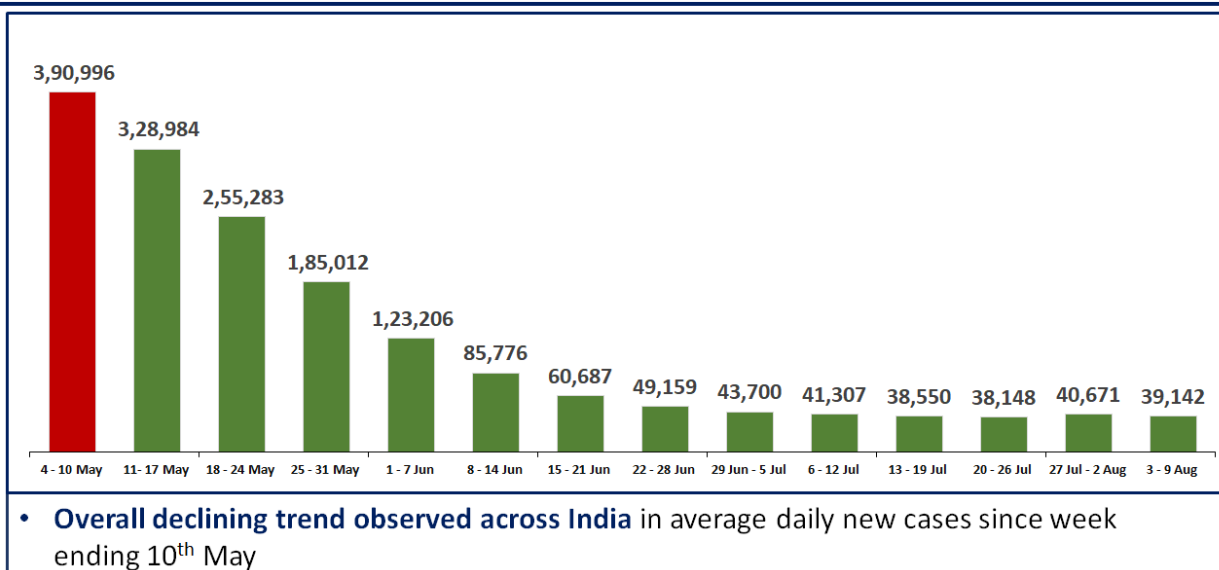
**There is no currently circulating variant of interest (VOI).**

### Second wave of Covid-19

1.23 The Committee notes that the newer variants of Covid-19, especially Delta variant was primarily responsible for the second wave in the country. The second wave of COVID-19 in India proved out to be more dangerous than the first wave and there was a considerable increase in the number of Covid positive cases as well as deaths. In the Committee's meeting held on 10<sup>th</sup> August, 2021, the Secretary, Department of Health and Family Welfare submitted that as on 9<sup>th</sup> August, 2021, the number of covid cases in India were 3.2 crore and active cases were 4.06 lakhs. 4.28 lakhs deaths and 23,455 case per million had been reported till 9<sup>th</sup> August, 2021 and 47.8 crore tests was conducted. As per information submitted by the Ministry, Average daily New Cases during the second wave were as follows:

## India – Average Daily New Cases

(As on 9<sup>th</sup> Aug 2021)



1.24 The Committee is of the view that the unprecedented rise in the number of Covid cases and deaths on such a large scale reveals absence of a coherent approach towards tackling the pandemic. The Committee in its 123<sup>rd</sup> Report had raised concerns about the subsequent Covid waves and recommended for better coordination between the Centre and the States. However, the second Covid wave saw exponential rise in Covid cases and crippling of the health infrastructure thereby unmasking the gaps in Government's Health policy.

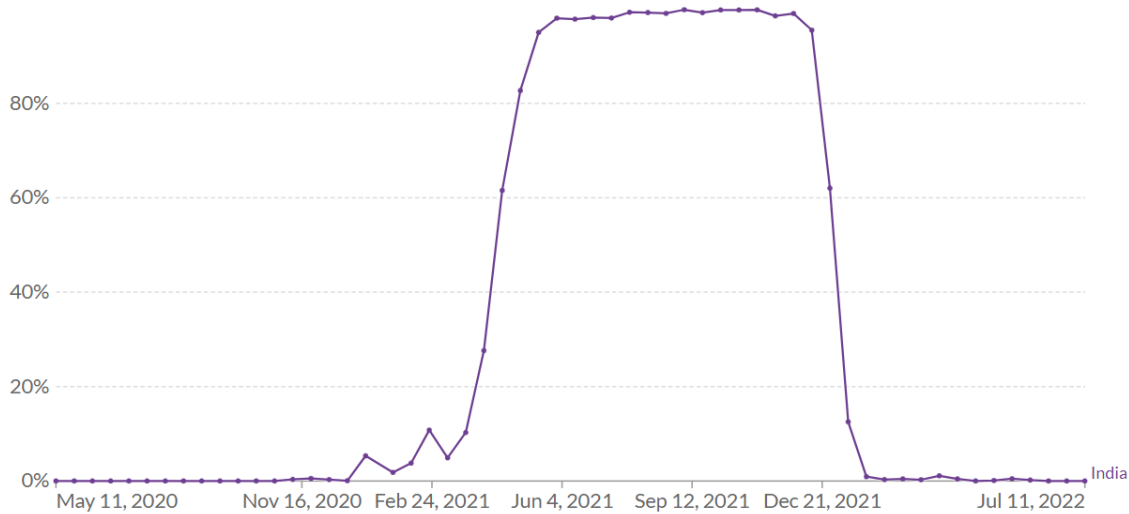
1.25 The Committee would like to recapitulate that during the first Covid wave, the country underwent a massive nationwide lockdown that was one of the driving factors behind the control in infection rate of the virus. A fatal upsurge in cases during the second wave highlights that the time gained during slowing down of the infection in the first phase could not be optimally utilized for better preparedness. Throughout the second Covid wave, lack of communication and coordination was evident amongst the health agencies and the whole medical governance system was disconnected and disjointed thus leaving the citizens hapless victims of the pandemic. The acute shortage of Oxygen in the hospitals and lack of Oxygenated & ICU Beds added to the chaos leading to the loss of many lives.

1.26 The Committee further notes that the share of Delta variant in all analyzed sequences was as low as 0.07% on 21<sup>st</sup> December, 2020 which further increased to 5.33% by 4<sup>th</sup> January, 2021. By 22<sup>nd</sup> February, 2021, 10.77% of the total sequences were reported to be of delta variant which increased to 27.63% by 5<sup>th</sup> April, 2021. With the surge in cases and onset of the second wave of Covid-19, the share of Delta variant in all analyzed sequences further increased to 82.69% by 3<sup>rd</sup> May, 2021 and by 31<sup>st</sup> May, 2021, the share had increased to 98.05%. On 13<sup>th</sup> December, 2021, 95.49% of the analyzed sequences were of the delta variant which eventually lowered to 0.93% by 24<sup>th</sup> January, 2022. The Share of delta variant in all analyzed sequences has been graphed as under (source: Our World in Data):

## Share of SARS-CoV-2 sequences that are the delta variant

Share of delta variant in all analyzed sequences in the last two weeks.

Our World  
in Data



Source: GISAID, via CoVariants.org

Note: This share may not reflect the complete breakdown of cases, since only a fraction of all cases are sequenced. Recently-discovered or actively-monitored variants may be overrepresented, as suspected cases of these variants are likely to be sequenced preferentially or faster than other cases.

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1.27 The Committee notes that India has sequenced a total number of 256,599 samples till date. As on 28th June 2021, INSACOG had processed over 45,000 samples and sequenced 36,883 samples. The number of sequenced samples was very low compared to the total number of cases during the second wave of the pandemic. Therefore, it is very difficult to get concrete data on the actual share of delta variants during the beginning of the second wave of Covid.

1.28 The Department of Biotechnology, in its Background Note, submitted that Indian SARS-CoV-2 Genomics Consortium (INSACOG) assess SARS-CoV-2 variants in India and is jointly managed by Ministry of H&FW, DBT, CSIR and ICMR. INSACOG also aims to correlate Whole Genome Sequencing (WGS) data with clinical/epidemiological data for advance preparedness for public health interventions. INSACOG monitors the genomic variations on a regular basis through the multi-laboratory network. INSACOG was initially established with 10 National laboratories and has expanded to 53 laboratories across the country in Hub and spoke model, where the 10 National laboratories act as mentor organizations for the other laboratories which has been added to the network, as part of infrastructure and genome sequencing capacity building efforts of the consortium. At present the consortium is a network of more than 300+ sentinel sites and 53 Central Govt/ State Govt./NGOs. 2 Private Genome Sequencing Laboratories have also connected with INSACOG Genome Sequencing Laboratories (IGSLs) and started working in the consortium.

1.29 INSACOG closely monitors mutations and regularly reports to Government for appropriate public health measures. Genomics data generated in INSACOG also has direct application such as public health intervention measures; develop diagnostics for specific SARS-CoV-2 variant, support the development of therapies and vaccines for specific variant; evaluate and improve understanding of re-infection cases and differentiate between prolonged infection and re-infection.

1.30 The sequenced viral genomes analyzed by the respective sequencing laboratories are regularly shared with the Central Surveillance Unit (CSU) that works under Integrated Disease Surveillance Programme (IDSP) at the National Centre for Disease Control (NCDC). The NCDC further correlates this data with the field data trends and establishes the associations (if

any) between the emerging SARS-COV-2 variants and epidemiological drifts based on COVID data generated by State and District Surveillance Units of IDSP.

**1.31 The Committee takes into consideration the anticipation and conclusion of virologists and microbiologists that virus will continue to evolve and possibly mutate into a more virulent and transmissible variant and so has been evident by the subsequent Covid waves across the world. The Committee, therefore, strongly advises the Government that there is an urgent need to expand the genome sequencing machinery in the country to keep a track of mutating variants.**

**1.32 The Committee notes that Indian SARS-CoV-2 Consortium on Genomics (INSACOG) is a consortium of 38 laboratories which monitors the genomic variations in the SARS-CoV-2. INSACOG, in its Bulletin dated June 20, 2022 has submitted that the total number of samples sequenced is 256,599. The Committee feels that considering the high number of total covid cases in the country, the number of samples sequenced is very low. The Committee, therefore, is of the firm view that genome sequencing is part of an effective virus containment strategy and facilitates better surveillance thereby entailing necessity for better policy formulation on Covid-19 management. Keeping into account the fact that India lags behind in genome sequencing and has sequenced very less number of samples when compared to other countries. The Committee strongly believes that there is a need to augment the genome sequencing facilities in the country. The Committee, accordingly, recommends the Ministry to intensify its efforts with regard to genome sequencing of the SARS-CoV-2 genome and ensure that the mutating variants are monitored efficiently and regularly. This is essential to understand the characteristics and complexity of the virus along with its ramifications and the conclusion so arrived must be scientifically utilized for vaccines development based on empirical facts and data with due clinical trials.**

**1.33 The Committee, in its 123<sup>rd</sup> Report, had analyzed the role of NCDC-IDSP and emphasized on the need to revitalize the enshrined role and responsibility of NCDC for effective control of the disease along with strengthening of the Central Surveillance Unit (CSU), State Surveillance Units (SSU) and District Surveillance Units (DSU). The Committee notes that NCDC-IDSP undertakes crucial tasks related to surveillance and conducts epidemiological investigation. The Committee strongly recommends that the sequenced data must be shared with the NCDC at the earliest. The Ministry must make efforts to strengthen the Integrated Disease Surveillance Programme (IDSP) at the National Centre for Disease Control (NCDC) so that the data provided by the sequencing laboratories are timely investigated and correlated with the field data trends**

1.34 On the infrastructural changes brought during the second wave of the pandemic with respect to testing facilities, laboratories, Oxygen cylinders, ICU beds etc., the Ministry submitted that the Union Government provided the required technical support and also supported the States through logistic and financial support to further strengthen the existing health infrastructure to tackle COVID-19 pandemic.

1.35 The Ministry also stated that with the intent to reduce the risk of cross infection to non-COVID patients as well as to maintain continuity of non-COVID essential health services in the country, a three-tier arrangement of dedicated COVID-19 health facilities was implemented in the country. The Ministry further submitted that the isolation bed capacity and ICU bed capacity which was only 10,180 and 2,168 before the first lockdown (as on 23<sup>rd</sup> March 2020) was being

enhanced continuously and as on 13th August 2021, there were 18,03,266 isolation beds and 1,24,598 ICU beds in the country.

1.36 The Committee was further informed that the availability of testing infrastructure and diagnostics was continuously being enhanced in the country. Starting with just one laboratory for testing of samples for COVID-19, the network of existing laboratories expanded vastly to test samples for COVID-19. The Ministry further submitted that as of 12th August 2021, a total of 2863 laboratories had been approved for COVID-19 Testing. Besides the Gold Standard RT-PCR (in 1755 labs), TrueNat (in 958 labs), CBNAAT (in 131 labs) techniques and other testing platform (in 19 labs) were also being used for testing. The Ministry of Health & Family Welfare on 16th April 2021 issued a detailed SOP on COVID-19 Containment & Management in Peri-urban, Rural & Tribal areas. The SOP (among other recommendations) calls for training of CHOs and ANMs in performing Rapid Antigen Testing and provisioning of Rapid Antigen Test (RAT) kits in all public health facilities including sub-centres (SCs) / Health and Wellness Centres (HWCs) and Primary Health Centres (PHCs).

**1.37 The Committee appreciates Government's efforts that the Covid-19 testing infrastructure in the country has come a long way since the detection of the first Covid case in January, 2020. Initially the Covid testing facility was available only at NIV Pune and gradually the testing facilities were expanded to other laboratories across the country. The Committee considers that the usage of highly specific molecular diagnostic tests is crucial for identifying the active cases and managing the risk of contamination. The Committee, in this regard, commends ICMR's push for a variety of other tests such as TrueNAT and CBNAAT systems which were used for comprehensive screening and confirmation of COVID- 19 cases.**

**1.38 The Committee takes into account that earlier diagnosis of the virus followed by timely isolation of the infected persons is extremely important in the pandemic management. The Committee, however, strongly believes that providing large scale testing facilities with faster results that correspond to the increased transmission rate of the virus should have been a crucial part of Covid management policy. The Committee observes that owing to the initial delayed action in the aftermath of outbreak of Pandemic by the Healthcare system to adapt to the rapidly increasing cases, there were considerable procrastination in getting the results of Covid Test and thereafter unbound spree of transmission went unchecked and uncontrolled. Incidents of results getting delayed by more than a week were also reported thereby leaving infected persons in lurch. The Committee observes that the people had to reluctantly approach private facilities for RT-PCR Tests which charged heavily. The Committee is concerned to note that there existed a visible divide in the testing infrastructure in the rural and the urban areas, thereby forcing covid infected persons to run from pillar to posts.**

**1.39 The Committee regrets the non-responsive attitude of the Government towards enhancing the health infrastructure in the aftermath of the receding first Covid-19 wave. With trends of Pandemic Covid-19 witnessing a steady decrease, the Government laid its guard down and failed to maintain the momentum of Covid case management attained during the first wave. The Committee expresses its disappointment over the lackadaisical approach of the Government machinery to testing of Covid cases with the fall in its trends and further ease in restrictions across the country. Both of these could be attributed to the tsunami of covid cases which was followed by enormous fatalities during the second wave and the Government agencies remained perplexed and witness to the deteriorating situation that went out of control.**

## **MISMANAGEMENT OF OXYGEN SUPPLY DURING THE SECOND WAVE**

1.40 The Second Covid wave was haunted by an acute shortage of Oxygen when the Indian health infrastructure crumbled under the high demand of Oxygen and hospital beds. Media reported traumatic experiences of patients and their families where desperate pleas were made across TV channels for Oxygen cylinders. Many Hospitals across Delhi sent out desperate SOS calls to Government authorities through social media and TV channels. Media reported that Madhukar Rainbow Children's Hospital in Malviya Nagar, Delhi sounded an alarm about their depleting Oxygen stocks. The hospital further reported that it will not take any admission which requires oxygen or ventilation support "due to inconsistent liquid oxygen supply". Aakash Healthcare in Dwarka appealed to government authorities to shift patients to other facilities "so that they can be saved". Most of the Hospitals made desperate plea to the Government for replenishing their dwindling stocks. As per Media Reports, many private hospitals also started installing their own oxygen plants to reduce dependence on suppliers amid the ongoing crisis.

1.41 A petition was filed in the Supreme Court seeking a high-level inquiry by a commission into the alleged non-supply and non-availability of medical oxygen for COVID-19 patients during the second Covid wave. Media reported that shortage of Medical Oxygen had resulted in several untimely deaths in the country during the second wave of the pandemic.

1.42 On a specific query regarding the shortage of Medical Oxygen in the country, the Ministry submitted that the daily liquid medical oxygen (LMO) supply was about 1292 MTs per day in February 2021 which was increased to 8593 MTs in April 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the States. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Restrictions were also imposed on industrial use of oxygen.

1.43 The Ministry further submitted that a dynamic and transparent framework for allocation of medical oxygen in consultation with States/UTs and all the stakeholders such as relevant Ministries, manufacturers/suppliers of liquid oxygen etc. was prepared. Online digital solutions viz. Oxygen Demand Aggregation system (ODAS) and Oxygen Digital Tracking System (ODTS) were developed to ascertain the demand for medical oxygen from all medical facilities and to track their transportation.

1.44 To avoid wastage of medical oxygen, guidelines on rational use of oxygen were issued on 25<sup>th</sup> September 2020, and further revised and disseminated to States on 25<sup>th</sup> April 2021. The Ministry further submitted that 1,02,400 oxygen cylinders were procured in April and May of 2020 and distributed to States. Further orders for additional 1,27,000 cylinders were placed on 21.04.2021 (54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type). Deliveries of the same had started and 73,352 (56,108 B-type and 14,244 D-type) cylinders had been delivered as on 3<sup>rd</sup> August 2021.

1.45 The Minister of State in the Ministry of Health and Family Welfare in reply to a question on 15<sup>th</sup> March, 2022 in the 256<sup>th</sup> Session of the Rajya Sabha stated that the Government of India sanctioned 1561 Pressure Swing Absorption (PSA) oxygen generation plants. These include 1225 PSA plants which have been installed and commissioned under PMCARES Fund in every district of the country. Additionally 336 PSA Plants were set up by PSUs of Ministry of Petroleum & Natural Gas, Ministry of Power, Ministry of Coal, Ministry of Railways etc. A total of 1541 out of 1561 PSA plants were commissioned by that time.

1.46 The Ministry also submitted that to generate oxygen at the health facility level, PSA plants were being established in each district hospitals, especially in far flung areas enabling the

hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country.

**1.47** The Committee finds that with the increase in the number of covid positive cases in the country, there was a severe pressure on the health infrastructure from the smallest to the large private hospitals. There were several instances of families of patients pleading for oxygen and waiting in queues for oxygen cylinders. Media relayed stories of hospitals running out of oxygen and making desperate appeals when hospitals were reportedly left with only few hours of oxygen supply. In April, 2021, the Delhi High court slammed the Delhi Government for alleged mismanagement in distribution of medical oxygen. The High Court in May, 2021 also asked the Central Government to divert the unutilized tankers of oxygen to Delhi from States where the Covid-19 situation was improving.

**1.48** The Committee reiterates its observations/recommendations made while examining the Covid situation in 2020. The Committee in its 123<sup>rd</sup> Report had warned the Government of the possible shortage of the Oxygen Cylinders and supply of Oxygen in the hospitals. The Committee is disappointed to note that the Ministry in its submission in 2020 had assured that the country is self sufficient in Oxygen and Oxygen Cylinders; however, their hollow claim was brutally exposed during the second wave. The Committee recalls its recommendation made in the 123<sup>rd</sup> Report where the Committee had strongly recommended the Government for encouraging adequate production of oxygen and ensuring its supply in the hospitals. Notwithstanding, the Government failed to manage the even distribution of oxygen in the States and amidst the skyrocketing demand, the Government could not maintain a steady flow of oxygen leading to an unprecedented medical crisis. The Committee notes that poor logistic management and failure of the Government in ensuring a quick response from the healthcare system speaks volume of the utter chaos in the Government machinery especially during the second wave. A poor monitoring of the oxygen generation capacity and availability of Medical Oxygen, Oxygenated and Ventilator beds in the hospitals further aggravated the situation.

**1.49** The Committee observes that in the Statement laid in the house in the 256<sup>th</sup> Session of the Rajya Sabha, the Minister of Health and Family Welfare submitted that as on 4<sup>th</sup> April, 2022, States/UTs reported a total of 5,21,358 deaths due to COVID-19 in the country. The Ministry submitted that the Government of India maintains data of total cases and deaths due to COVID-19 reported and updated by States/UTs on a regular basis. The Committee wonders that in response to the Union Government's request to States/UTs to furnish the details of Covid deaths owing to the lack of oxygen, 20 States/UTs responded and none of these State/UTs have reported confirmed death due to oxygen shortage.

**1.50** The Committee is disturbed at the unfortunate denial of the Ministry of Health and Family Welfare regarding Covid Deaths due to Oxygen shortage in the country. The Committee takes into account the media reports that there were many deaths due to Oxygen shortage in the hospitals; however, the sheer negligence of the fact shows the absence of empathy in the Government parlance. The Committee notes that there were no definite guidelines for identifying the deaths due to inadequate supply of oxygen. Oxygen shortage is not noted as a cause of death in the medical records and most of the deaths were attributed to co-morbidities. The Committee is disappointed at this utter ignorance by the Government and strongly recommends the Ministry of Health and Family Welfare to examine the number of deaths due to oxygen shortage especially during the second wave of Covid. The Ministry, in coordination with the States, must audit the deaths due to oxygen shortage and enable robust documentation of the covid deaths that will infact

**generate the responsive and responsible sense of government and cautious formulation of policy and combat situational health care emergency. The Committee further expects more transparency and more accountability from the Government agencies. The Ministry must meticulously examine the oxygen stricken Covid deaths and ensure that proper compensation is accorded to the families of the victims.**

**1.51 During its deliberations with the Ministry, the Committee noted that the PSA plants were being established in each district hospitals. The Committee observes that setting up Pressure Swing Adsorption (PSA) and ensuring its proper operation and maintenance incurs high costs. The Committee is concerned that the plants may be left unused when the Oxygen demand is low. The Committee, therefore, recommends the Government to ensure that the PSA set up is utilized optimally and any wastage of the resources is avoided. The Government must accordingly devise a system to make Oxygen readily available to the hospitals and strengthen the infrastructure for transporting oxygen to the Government and private Hospitals within the desirable span of time.**

**1.52 The Committee is of the view that technical expertise is required for operation of PSA plants. The Committee, therefore, recommends the Ministry to ensure that the required technical staff is available at the district hospitals and no unwarranted incident take place once the PSAs are installed in the hospitals. The Committee further recommends the Ministry to ensure that efficient Oxygen Management Protocols (OMP) are followed in all the hospitals and oxygen is scientifically administered and managed for optimum medical utilization in public and private hospitals.**

## **CHALLENGES AND LEARNINGS FROM THE SECOND WAVE OF THE PANDEMIC**

1.53 With regard to the challenges and learnings from the second wave of the pandemic and the preparation done by the Government to combat the possible third wave of the pandemic, the Ministry submitted the following information:

- i. Governance and building up a coordinated, collaborative response: Inter-sectoral coordination has been facilitated by establishment of suitable platforms including Group of Ministers, Empowered Groups to fast-track decision making.
- ii. Reliance on imported logistic: A public health response of this scale and magnitude could not have been possible without developing indigenous capacities in terms of essential logistic including personal protective equipment, diagnostics, ventilators and more recently in terms of vaccine manufacturing capacities.
- iii. Supporting States with adequate logistic: States are being supported in terms of supply of logistics
- iv. Black marketing of essential drugs like Remdesivir: Due to reports of shortage of Remdesivir, export of the drug has been banned since 11<sup>th</sup> April 2021 to improve local availability. All States/UTs and their Drug Controllers have been requested to verify stock of the drug and check malpractices and take other effective steps to curb hoarding and black marketing of Remdesivir.
- v. Sudden spurt in demand for medical oxygen: To generate Oxygen at the health facility level, PSA plants are being established in each district hospitals, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country.



- vi. Need for large number of trained manpower: To build the capacities of human resources including the medical manpower who help managing patients in hospitals; as well as non-medical personnel, front line workers, who may be involved in non-medical duties such as logistics, surveillance etc., for COVID-19 management, training resources for medical and non-medical personnel have been made available on the website of Ministry of Health & Family Welfare. Online training and webinars for Physicians and Nursing personnel is being conducted by AIIMS. Modules have also been made available on iGOT (online platform) by DOPT (<https://igot.gov.in/igot/>). The training modules have been translated to regional languages.
- vii. In view of resurgence of COVID-19 cases in the country and with a view to increase the availability of trained human resources to tackle the Covid-19 pandemic situation, the States were advised to explore avenues for utilization of services of Medical Interns, Final Year MBBS students, Final Year PG Students (broad as well as super-specialities) as residents, B.Sc./GNM Qualified Nurses, Final Year GNM or B.Sc. (Nursing) students under appropriate guidance and services of Allied Health Care professionals based on their training and certification. In addition, provisions have been made for States/UTs to decide on remuneration as in the NHM norms and suitable honorarium for distinguished Covid Services. Financial incentives/ remuneration were provided to persons who work for at least 100 days for Covid care.

**1.54 The Committee understands that the second wave of Covid-19 put the Indian healthcare system and the diagnostic infrastructure under insurmountable pressure, thereby, emphasized on the need for strengthening mitigation strategies. The Committee appreciates that the Government has upgraded testing infrastructure in the country; however, the number of testing facilities still remains low in proportion to its population.**

**1.55 The Second wave was undoubtedly marred by high cases, increased deaths, shortage of oxygen and beds in hospitals, reduced supplies of medicines and other important drugs, disruption of essential health care services, hoarding and black marketing of cylinders and medicines etc. The Committee is of the considered view that had the Government been successful in identification of the more virulent strain of virus in the population at an early stage and suitably implemented its containment strategy, the repercussions would have been less grave and many lives could have been saved.**

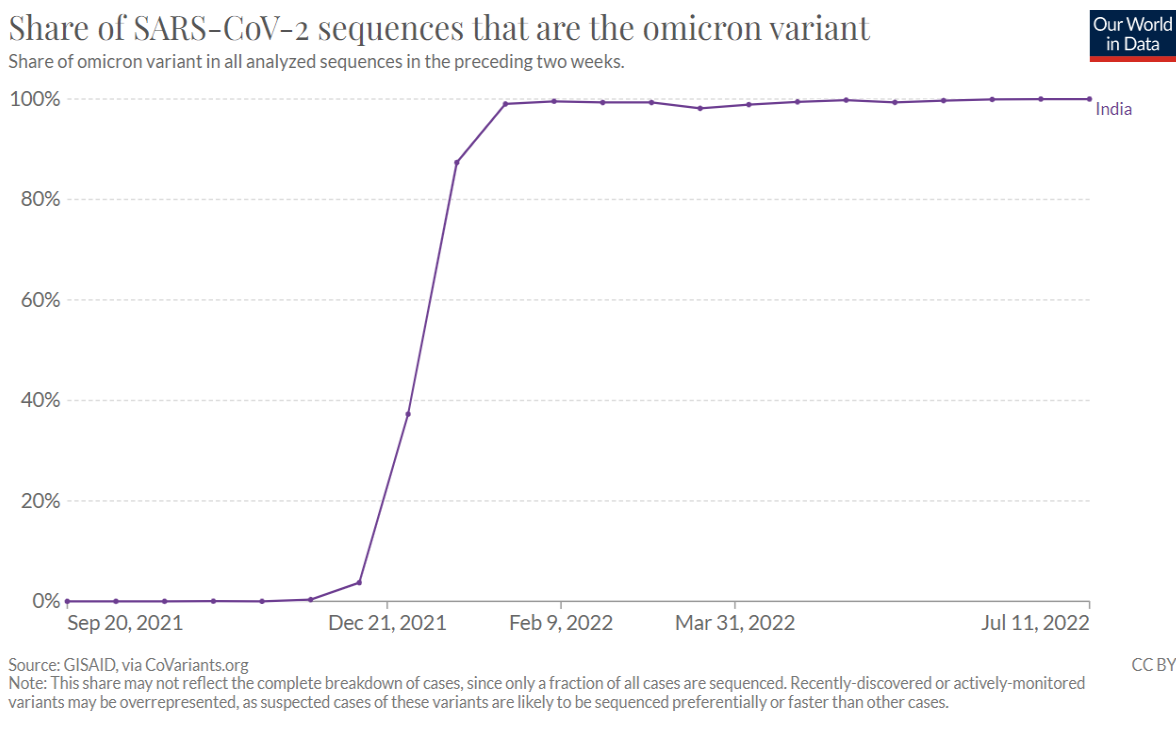
**1.56 The Committee also takes note of the constant rise in covid cases during the Kumbh Mela, Tablighi Jamaat in New Delhi and election campaigns in the West Bengal. The Committee notes that large gatherings with no social distancing are synonymous with hotspots of Covid. The Committee notes that managing a large crowd along with following covid protocols poses a challenge to the administration. Such massive gatherings on several social, political and religious occasions were also a major causing factor for the second covid wave. With covid fatigue hitting in among the citizens, the Government also raised celebratory flag and presumed that the whole situation was under control. However, a devastating second covid wave exposed all the false claims of the Government and resulted into large scale casualties.**

### **THIRD WAVE OF COVID-19**

1.57 The B.1.1.529 variant was first reported to WHO from South Africa on 24th November 2021. WHO on 26th November 2021 declared Omicron, first detected earlier in the Gauteng province, Southern Africa, to be a variant of concern, on the advice of its Technical Advisory Group on Virus Evolution (TAG-VE). As on 6th December 2021, a total of 45 countries had

reported a total of confirmed 956 cases and 55,992 probable cases of the Omicron variant. Of this, 21 cases were confirmed in India (12 from Rajasthan, 7 from Maharashtra and 1 each from Delhi and Gujarat).

1.58 The Committee notes that the share of Omicron variant in all analyzed sequences increased from 0.33% on 29<sup>th</sup> November, 2021 to 3.75% on 13<sup>th</sup> December, 2021. By 27<sup>th</sup> December, 2021, the share of Omicron variant increased to 37.27% which further increased to 87.35% by 10<sup>th</sup> January, 2022. The Committee further notes that India has sequenced only a fraction of total cases, however, as on 11<sup>th</sup> July, 2022; all the sequenced viruses are of the Omicron variant. Share of the Sars-Cov-2 sequences that are the omicron variant is graphed as under (source: Our world in Data) :



1.59 As part of the examination of the subject and the rising concerns posed by the Omicron variant of Covid-19, the Committee heard the views of Secretaries, Department of Health and Family Welfare and Department of Health Research in its meeting held on 9<sup>th</sup> December, 2021. The Secretary, DHR in the meeting submitted that the testing as well as the treatment protocol remained unchanged and ICMR NIV Pune was in the process of carrying out a study regarding the efficacy of the vaccines on the new variant.

1.60 The Ministry in its written submission stated that the 6 Empowered Groups earlier constituted by Ministry of Home Affairs, Government of India, under extant provisions of Disaster Management Act, 2005 have been reconstituted in 10 Empowered Groups to fast-track decision making and facilitate inter-sectoral coordination. These 10 Empowered Groups were tasked with (i) Emergency Management Plan and Strategy, (ii) Emergency Response Capabilities, (iii) Augmenting Human Resources and Capacity Building, (iv) Oxygen, (v) Vaccination, (vi) Testing, (vii) Partnership, (viii) Information, Communication and Public Engagement, (ix) Economic and Welfare Measures and (x) Pandemic Response and Coordination.

1.61 The Ministry of Health and Family Welfare in a statement laid in the Rajya Sabha in its 256<sup>th</sup> Session stated that besides regular review meetings at the level of Union Health Minister with all relevant stakeholders including subject experts, review meetings with States/UTs through video conferencing were conducted regularly to review preparedness and response measures to address COVID-19 pandemic. States/UTs were advised to undertake the following activities:

- i. Strict monitoring of International travelers in the community.
- ii. Contact tracing of positive individuals & follow up for 14 days.
- iii. Genome sequencing of positive samples through INSACOG Labs in a prompt manner.
- iv. Continued monitoring of areas where cluster of positive cases emerge.
- v. Further strengthening of COVID-19 testing infrastructure and ensuring early identification of cases through adequate testing across the States.
- vi. Ensuring preparedness of health infrastructure (availability of ICU, oxygen supported beds, ventilators, etc.) and upgrading health infrastructure under ECRP-II including in rural areas and for pediatric cases.
- vii. Commissioning all PSA plants, ensuring sufficient logistics, drugs etc.
- viii. Ensuring COVID-19 vaccination for the eligible population including coverage among young adolescents (15-18 years) and precaution dose for health care workers, frontline workers and elderly with co-morbidities.
- ix. Ensuring adherence to COVID Appropriate Behaviour.

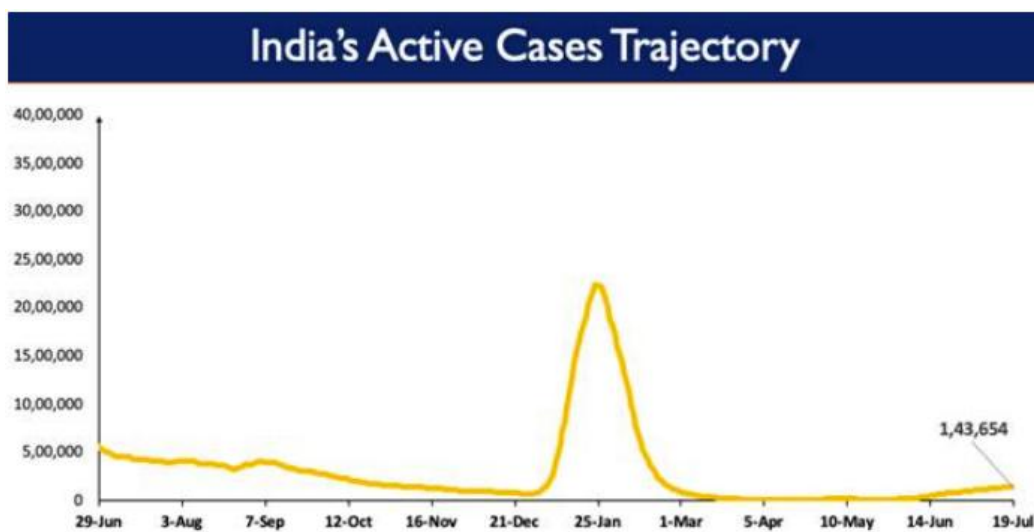
1.62 The Ministry further stated that it continues to provide support to States/UTs to enhance preparedness and response capacities against COVID-19 and other public health emergencies. Funding support is also provided to States/UTs through National Health Mission, State Disaster Response Funds (SDRF) and Emergency COVID-19 Response and Preparedness packages. Under ECRP Phase II, a package of Rs. 23,123 crore (with Rs. 15,000 Cr as Central Component) has been approved. Of this, as on 31st January 2022, funds to the tune of Rs. 7245.95 crore have been released to States/UTs as part of Central component to strengthen health infrastructure to manage any surge in cases. Omicron variant is the dominant variant in the country during the third wave. The current surge of COVID-19 cases in the country is showing a sustained declining trend since 21st January 2022.

**1.63 The Committee notes that the rate of spread of Omicron is higher than its previous delta variants. Omicron has led to a rise in the number of covid cases in India particularly among the young population. However, the rate of hospitalization and the severity of infection remained low compared to second wave that was fuelled by the Delta variant. The Committee is of the opinion that since many cases were mild and asymptomatic, there are more chances of cases remaining undetected and not making it to the official registry. The Committee understands that the death rates have been lower in the third wave; however, the Government must continue taking effective measures for enforcing Covid-Appropriate Behavior (CAB). The Committee further feels that a strict testing regime in the airports for international flights should have been followed and patients testing positive should have been immediately isolated. With the uncertainty brewing around newer and more virulent strains of the virus, it is imperative to generate public awareness to wear a mask and follow all the covid protocols.**

## NEW WAVE OF COVID-19 IN THE FUTURE

1.64 In response to a question raised in the 257<sup>th</sup> Session of the Rajya Sabha on whether the Government foresees any new wave or variant of COVID-19 in the coming future, the Minister of State in the Ministry of Health and Family Welfare submitted on 19<sup>th</sup> July, 2021 that given the emergence of variants of COVID-19 virus with variable transmissibility and other public health implications, Union Ministry of Health is closely following COVID-19 trajectory globally and in the country along with various Expert Committees. In addition, network of Indian SARS-CoV-2 Genomics Consortium (INSACOG) of laboratories is taking whole genome sequencing of samples for detection of mutant variants of the virus.

1.65 The Ministry of Health and Family Welfare on 19<sup>th</sup> July, 2022 submitted that India's Active Caseload currently stands at 1,43,654. Active cases now constitute 0.33% of the country's total Positive Cases. The India's active cases trajectory has been graphed as under:



1.66 The Committee notes that although the Covid-19 cases have been on a slow rise, fear of transmission of a more virulent strain of Sars-Cov-2, still persists. The Committee notes that the recent surge in cases reveals that Covid is here to stay and will become endemic. The Committee strongly recommends the Ministry to take note of any fresh surge in the Covid cases and conduct sequencing of adequate number of samples so that new Variants of Interest (VoI) and Variants of Concern (VoC) can be identified at the earliest. The Ministry must also ensure that adequate number of samples are tested so that Covid cases are well reported and documented. The Committee also recommends the Ministry to be prepared for any eventualities of more virulent strain of Sars-Cov-2 virus and carry out mock drills to identify any gap in the covid containment policy of the Government. The Ministry must also explore options to study sewage samples for early prediction of any possible outbreak of Covid waves in future and thereby formulate dynamic strategy to mitigate the resurgence.

1.67 The Union Government must coordinate with the States and assess the requirement of medicines, kits, oxygen etc so that shortage in supplies is averted in case of future outbreak. The Committee strongly recommends that the Ministry must closely monitor the trajectory of Covid in the country so that the system is better prepared to manage future resurgence of the virus, if any.

## CHAPTER II

### VACCINE RESEARCH AND DEVELOPMENT

2.1 In the midst of an emergency situation, the world scientific community accelerated to come up with a vaccine for the SARS-CoV-2 virus. There is no doubt that decades of previous scientific researches on different viruses helped the community in developing Covid-19 vaccine in such a shorter period of time. It is testament to the advancement in modern science that scientists were able to develop multiple vaccines for Covid which would have generally taken many years to develop. However, vaccine development is a complex process and involves different phases of clinical trials and stages. Only after a vaccine passes through each stage and achieves the required regulatory approval, the vaccine can be marketed.

2.2 Moderna, AstraZeneca, Pfizer etc were some of the first companies to begin human trials of the vaccines for Covid-19 and by July 2020, the work on experimental vaccines for Covid had started. Considering the urgent need of the vaccines, the Committee discussed various issues regarding vaccine research and its status in the country. During the discussion, the Ministry stated that the approval of any new COVID-19 vaccine by the national regulator i.e. CDSCO will be dependent on the safety, immunogenicity and efficacy profile of vaccine generated through non-clinical and clinical trial data and as per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940 and the available regulatory guidelines.

As per WHO the three approaches of designing vaccines are as follows:

#### 1. The whole-microbe approach

##### **Inactivated vaccine**

Under this approach, the disease-carrying virus or bacterium, or one very similar to it, is either inactivated or killed using chemicals, heat or radiation. This approach has been adopted in flu and polio vaccines. Under this approach, the vaccines can be manufactured on a reasonable scale.

##### **Live-attenuated vaccine**

A live-attenuated vaccine uses a living but weakened version of the virus or one that's very similar. The measles, mumps and rubella (MMR) vaccine and the chickenpox and shingles vaccine are examples of this type of vaccine.

##### **Viral vector vaccine**

This type of vaccine uses a safe virus to deliver specific sub-parts – called proteins – of the germ of interest so that it can trigger an immune response without causing disease. To do this, the instructions for making particular parts of the pathogen of interest are inserted into a safe virus. The safe virus then serves as a platform or vector to deliver the protein into the body. The protein triggers the immune response. The Ebola vaccine is a viral vector vaccine and this type can be developed rapidly.

## **2. The subunit approach**

A subunit vaccine is the one that uses the very specific parts (the subunits) of a virus or bacterium that the immune system needs to recognize. It doesn't contain the whole microbe or use a safe virus as a vector. The subunits may be proteins or sugars.

## **3. The genetic approach (nucleic acid vaccine)**

Unlike vaccine approaches that use either a weakened or dead whole microbe or parts of one, a nucleic acid vaccine just uses a section of genetic material that provides the instructions for specific proteins, not the whole microbe. A nucleic acid vaccine delivers a specific set of instructions to our cells, either as DNA or mRNA, for them to make the specific protein that we want our immune system to recognize and respond to.

The Committee notes that having a considerable number of vaccines in development increases the probability of a safe and efficacious vaccine. There are different approaches to designing a vaccine. As per WHO, the differences lie in whether the vaccines use a whole virus or bacterium; just the parts of the germ that triggers the immune system; or just the genetic material that provides the instructions for making specific proteins and not the whole virus. The Committee, therefore, strongly recommends for in-depth study of various approvals/platform for designing a vaccine and with due Research & Development activities followed by adequate clinical trials, the scientists discover/innovate universal vaccine to combats all form of influenza.

## **Vaccine Research in India**

2.3 In the meeting held on 22<sup>nd</sup> January, 2021, the Principal Scientific Advisor to the Government of India submitted that there were enormous challenges in early stage vaccine development which the country came across. He further submitted that there were three kinds of Committees, viz, (i) the Task Force on Focused Research on Corona Vaccine and other Science and Technology Issues, that is co-chaired by Dr. Vinod Paul and himself; (ii) National Expert Group on Vaccine Administration for Covid-19, NEGVAC, chaired by Dr. Vinod Paul and co-chaired by Shri Rajesh Bhushan, Health Secretary; and (iii) the National Technical Advisory Group on Immunization which evaluate vaccines and decided whether or not to roll them into the immunization programme which was chaired by the Health Secretary and co-chaired by the Director-General of ICMR and the Department of Biotechnology.

2.4 He further stated that discussions were also conducted with different companies such as Bharat Biotech, Serum Institute, Mynvax, Zydus Cadila, Biological E, Gennova on their plans regarding the early stages of vaccine development. The task force had the job to provide help to these companies on the scientific side through the Government Departments and settle their other problems. He further submitted that under the Vaccine and R&D Task Force, there were three major issues; the first being the vaccine development. He stated that the different kinds of platforms and different vaccine development agencies are first identified and then brought to the forefront. Secondly, before vaccine deployment, information was required on two fronts, namely on the extent of the pandemic and the people for trials. Testing and diagnostics were needed for this. Vaccines were given only to healthy people who did not have any problem and their safety was the utmost priority. He further submitted that ensuring the safety of vaccines was very important and the same was deliberated in the 14 meetings of the task force.

2.5 In the Committee meeting, the Principal Scientific Advisor to the Government of India also elaborated that as India did not conduct many Phase I, II and III trials, therefore, setting up

that whole sequence in the country was a challenge, in the midst of the pandemic, and that was done successful. Identifying clinical trial sites and putting in place networks were very important, to get harmonized clinical trial protocols and to partner with medical colleges to get them implemented. Therefore, the Department of Biotechnology and the Indian Council of Medical Research accorded the highest priority to this. Similarly, the regulatory response had to be rapid. Taking into account all the challenges of the pandemic, the Drug Controller put in place mechanisms which allow rapid evaluation in the context of pandemic. There were drug laboratories like those in Kasauli for testing and certification of vaccines before they were rolled out.

**2.6 The Committee emphasizes that the Government must incentivise multi-disciplinary research and efforts towards enhancing the research infrastructure in the country. The Committee recommends to promote collaborative studies among National and International Institutes and develop a roadmap for creating a vibrant research environment in the country.**

2.7 The Ministry submitted that the main objective of development of vaccine was to generate adequate data on quality, safety, immunogenicity and /or efficacy to support the application for manufacture or import of Vaccines in the country. The duration of the clinical trials of COVID-19 vaccines were different and were based on the various parameters such as phases of clinical trials, study objectives, endpoints, follow up period designed by the concerned sponsor or manufacturer or importer for assessment of Safety, Immunogenicity and Efficacy of vaccines.

#### **Emergency use authorization (EUA)**

2.8 The Ministry of Health and Family Welfare defines Emergency Use Authorization (EUA) as a regulatory mechanism to allow the use of vaccines and medicines to prevent and/or reduce the impact of life-threatening diseases or conditions as caused by COVID-19. Safety is particularly critical aspect of this scrutiny and a risk-versus- benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Indian regulators is aligned with global guidelines.

2.9 The National Regulator, Drugs Controller General of India (DCGI), gave initial nod to market authorization of two COVID-19 vaccines, Covaxin and Covishield subject to certain conditions. The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) had recommended for upgradation of status for the vaccines from restricted use in emergency situations to grant of new drug permission with conditions in the adult population on 19th January 2022.

#### **Emergency use authorization of Covishield and Covaxin**

2.10 The Secretary, Department of Health and Family Welfare had submitted that as on 12<sup>th</sup> January, 2021 two vaccines namely, Covishield and Covaxin were available in the country. He further submitted before the Committee that the research and development for Covishield had been done by Oxford University and it was being manufactured by Serum Institute of India and AstraZeneca. Covaxin was a completely indigenous vaccine whose manufacturing, R&D and trials were being conducted in India by Bharat Biotech, Hyderabad. The initial inactivated virus platform was provided by ICMR.

2.11 The Committee was informed that under normal situation for final approval of any vaccine, non-clinical data as well as complete data of Phase I, II, and III clinical trials

demonstrating safety, immunogenicity and efficacy of the vaccine were required. However, in case of pandemic situation like COVID-19, when there was a strong and urgent need for vaccine to protect population from the pandemic, the accelerated approved processes were followed to consider its approval for use in emergency situation based on acceptable data of safety, immunogenicity and efficacy without waiting for completion of all phases of clinical trials which take long period of time.

2.12 Regulatory provisions under Second Schedule of New Drugs & Clinical Trials Rules, 2019 allow the above, for drugs including vaccines intended to be used in life threatening or serious disease conditions or rare diseases and for drugs intended to be used in the diseases of special relevance to Indian scenario or unmet medical need in India, disaster or special defence use e.g., haemostatic and quick wound healing, enhancing oxygen carrying capacity, radiation safety, drugs for combating chemical, nuclear, biological infliction etc.

2.13 In case of COVISHIELD, the Subject Expert Committee (SEC) of CDSCO noted that the safety & immunogenicity data presented by the firm from the Indian phase II/III study was comparable with that of the overseas clinical trial data. Considering the serious nature of the COVID-19 pandemic and the emergency situation, there was an urgent need of vaccine in the country. Therefore, the Subject Expert Committee recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions. Accordingly, the permission was granted to Covishield for restricted use in emergency situation with conditions.

2.14 In case of COVAXIN, the SEC noted that Inactivated Whole Virion, Corona Virus Vaccine was having potential to target mutated corona virus strains. The data generated demonstrated a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The Ministry had submitted that the clinical trial is a large trial on 25800 Indian subjects in which already 22500 subjects have been enrolled including subjects with co-morbid conditions as well which has demonstrated safety till date. Moreover, the firm has presented the safety and efficacy data from Non-human primate challenge study where the vaccine has been found to be safe and effective. Therefore, the Subject Expert Committee recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains with the condition that the firm shall continue the on-going Phase III clinical trial and submit data emerging from the trial as and when available. Accordingly, the permission was granted to M/s Bharat Biotech vaccine for restricted use in emergency situation in clinical trial mode with conditions.

2.15 Once the applicant completes all the phases of clinical trials as per protocol and submits the requisite data, the vaccines approved for “restricted use in emergency situation” will be considered for final marketing permission for free use.

2.16 The Committee notes the Bharat Biotech Press Release on the final analysis for Covaxin which states that Covaxin has demonstrated an overall efficacy of 77.8% in phase 3 clinical trial. Covishield is backed by phase III data from studies in Brazil and the United Kingdom. The overall efficacy against symptomatic COVID-19 after more than 14 days after the 2<sup>nd</sup> dose is reported to be 66.7%.

**2.17 The Committee observes that the provisions for emergency use authorisation is absent in New Drugs and Clinical Trials Rules, 2019 and under Drugs and Cosmetics Act, 1940. It is regretful to note that the vaccines have been given EUA without any specific provision in the Indian drug rules and regulations. The laws in other countries are very**



clearly defined which made the granting of approvals of vaccine and drugs during the pandemic very transparent. However in India, the information regarding the protocol followed and the clinical trial data of the vaccines remained shadowed for a long time.

**2.18** The Committee is of the firm opinion that the procedure followed behind granting emergency or restricted approvals to drugs and vaccines must be clearly defined in the laws. Ambiguity on the vaccines trials as well as the procedure followed for EUA reflects greatly on the need of making amendments to the Indian Laws. The Committee accordingly recommends the Ministry to make specific provisions for EUA in the Indian drug laws. The Committee also notes the lack of clarity in the procedure followed for granting the approval for administering the booster doses. The Committee would like to be apprised on the protocol followed and the laws under which the approval was granted. The Committee feels that meticulous scientific findings must form the basis for any major changes in the course of the vaccination policy. The Committee further recommends the Ministry of Health and Family Welfare to carry out rigorous assessments of laboratory and clinical trial data before granting any future Emergency Use Authorization for vaccines. The Ministry must also share the data on quality, safety, production of protective antibodies and efficacy of the vaccines in the public domain.

#### **Support for development of vaccines under DBT**

2.19 The Department of Biotechnology submitted that DBT adopted a multi-pronged approach and supported development of COVID-19 vaccines for proof of concept and pre-clinical studies of nearly 14 vaccine candidates on diverse state-of-the-art scientific platforms. The list of vaccine candidates supported by DBT and BIRAC is as follows:

#### **List of COVID-19 Vaccine candidates supported by DBT and BIRAC as on 4<sup>th</sup> April, 2022**

<b>S. No.</b>	<b>COVID-19 Vaccine Developer / Manufacturer</b>	<b>Vaccine Platform</b>	<b>Stage of Development</b>
<b>Vaccine candidates in clinical stage of development</b>			
1.	Cadila Healthcare (ZyduScadila)	DNA Vaccine (ZyCoV-D)	Emergency Use Authorization (EUA)
2.	Biological E/ Collaboration	Subunit (RBD219-N1-C1) BECOV-2	EUA
3.	Gennova and HDT Biotech Corporation	mRNA (HGCO19)	Clinical (Phase III)
4.	Bharat Biotech & Washington University, USA	Replication deficient adenovirus (intranasal)	Clinical (Phase III)
5.	Serum Institute of India	Bacille Calmette-Guerin BCG vaccine	Phase III trial (as repurposed vaccine)
<b>Industry-based vaccine candidates in pre-clinical stage of development</b>			
6.	Genique Life Sciences	Virus Like Particle (VLP)	Advanced Pre-Clinical
7.	Aurobindo Pharma Limited with Auro Vaccines	Attenuated rVSV-vectored Vaccine	Early Pre-clinical
8.	Intas Pharmaceuticals Ltd.	Recombinant adeno-associated virus [rAAV]	Early Pre-clinical

		based genetic vaccine	
9.	Seagull Bio Solutions	Non-replicating measles virus vector in Active Virosome Platform	Early Pre-clinical
<b>Vaccine candidates under development by academia</b>			
10.	Institute of Chemical Technology, Mumbai	Protein subunit Intranasal vaccine	Early Stage
11.	National Institute of Biomedical Genomics (NIBMG)	Baculovirus expressed Virus-Like Particle (VLP) vaccine	Early Stage
12.	Translational Health Science And Technology Institute (THSTI)	Self-amplifying mRNA in a lipid nanoparticle	Early Stage
13.	Centre for Stem Cell Research, Christian Medical College, Vellore	Lipid encapsulated mRNA vaccine	Early Stage
14.	Indian Institute of Science, Bangalore	Bacille Calmette-Guerin BCG vaccine (repurposing)	Phase III validation study

2.20 DBT further submitted that ‘Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission’ was launched under the AtmaNirbhar Bharat 3.0 package, for the development of a safe, efficacious and affordable vaccine for COVID-19, which demonstrated major achievements.

2.21 Initial seed funding for candidate vaccine development of shortlisted projects of the ‘COVID-19 Research Consortium’ was provided under National Biopharma Mission and Ind-CEPI Mission. As the candidates advanced through clinical development, support for scale-up and manufacture was provided under Mission COVID Suraksha. The Department further submitted that 02 vaccines, namely, ZyCoV-D, World’s first COVID-19 DNA Vaccine, (developed by Zydus Cadila), CORBEVAX, India’s first protein subunit vaccine (developed by Biological E), received Emergency Use Authorization (EUA), for use in adolescents and adults (12 years and above). Additionally, the mRNA-based vaccine candidate developed by Gennova Biopharmaceuticals Ltd. and the Intranasal Vaccine candidates (based on Replication Deficient Adenoviral Vector expressing a stabilized spike protein) developed by Bharat Biotech International Ltd. (BBIL), are in Phase III Clinical trials.

2.22 The Department of Biotechnology further stated that the emergence of newer variants of SARS-CoV-2 over time, necessitated a focus on development of next generation vaccines based on novel platforms. The Translational Health Science and Technology Institute (THSTI), an Autonomous Institute of the Department of Biotechnology and Panacea Biotec, a research-based biopharmaceutical company and vaccine manufacturer, have come together to work on the development of broadly protective coronavirus vaccine, with support from the global initiative of Coalition of Epidemic Preparedness for Innovation (CEPI).

**2.23 The Committee appreciates the efforts of the Department of Health Research and the Department of Biotechnology that have been at the forefront of the vaccine research and development in the country. The Committee time and again has emphasized on the need for strengthening the research ecosystem in the country. The Committee further believes that both the Departments must also work towards strengthening the clinical trials ecosystem in the country along with data transparency. The Committee understands**

that vaccine development faces a slew of challenges ranging from procuring the raw material to conducting human trials. However, the present situation necessitate development of effective interventions so that the future outbreaks as the like of Covid-19 are mitigated. The Committee strongly recommends the Ministry to strengthen the end-to-end vaccine development programme and extend support to vaccine candidates which are at different stages of development.

2.24 The Committee also appreciates, "Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission" which was announced as part of the third stimulus package. The Committee recommends Ministry of Health and Family Welfare and the Department of Biotechnology to continue work towards development of vaccines and ensure that the vaccines are introduced in the market for free use.

2.25 The Committee strongly feels that there is an urgent need to develop vaccines that are effective against all the variants of concerns that have been discovered so far and also the future newer variants. The Committee recommends the Ministry to take initiatives to develop a universal covid vaccine that is effective against all the variants. The Ministry should encourage research collaboration between ICMR and other research Institutes in the country.

#### **Vaccines being administered in the country**

2.26 In reply to a specific query, regarding the Covid vaccines administered in the country, the Department of Health Research submitted that as on June 2022, Five Covid-19 vaccines have been administered in India so far which are Covishield, Covaxin, Sputnik, ZyCoV-D and Corbevax.

2.27 The Committee is given to understand that the Platform Technology of the five covid vaccines being administered in the country is as follows:

<b>S.No.</b>	<b>Vaccine Candidate</b>	<b>Platform Technology</b>
1	ChAdoX1 Oxford vaccine	Chimpanzee adenovirus vectored recombinant vaccine expressing spike protein
2	COVAXIN- Bharat Biotech	Inactivated whole virion vaccine
3	Gamaleya Research Institute (Sputnik V)	Human adenovirus vectored recombinant vaccine expressing spike protein
4	ZyCoV-D (Cadila)	DNA vaccine
5	Corbevax	Protein subunit vaccine

2.28 As per a Public notice from CDSCO the following COVID 19 vaccines have been approved in India as of February 2022:

### COVID-19 vaccines approved for Manufacture for Sale or for Distribution in the country

No	Vaccine	Applicant	Date of approval	Age group & Dosing schedule
1	ChAdOx1 nCoV-19 Corona Virus vaccine Recombinant) (COVISHIELD)	M/s Serum Institute of India Pvt. Ltd.	27.01.2022	For ≥ 18 years age Two doses, 4 to 6 weeks apart (Overseas Data available for 12weeks)
2	Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN)	M/s Bharat Biotech	27.01.2022	For ≥ 18 years age Two doses, Day 0 & 28

### COVID-19 vaccines approved for Restricted Use in Emergency Situation in the country

No	Vaccine	Applicant	Date of approval	Age group & Dosing schedule
1	Gam COVID Vac (component I & II) (SPUTNIK-V)	M/s Dr. Reddy's Lab. Ltd. (Importer)	12.04.2021	For ≥ 18 years age Two doses, Day 0 (comp I) & Day 21 (comp II)
2	mRNA-1273 COVID-19 vaccine (Moderna vaccine)	M/s Cipla Ltd. (Importer)	29.06.2021	For ≥ 18 years age Two doses, Day 0 & 28
3	Gam COVID Vac (component I & II) (SPUTNIK-V)	M/s Panacea Biotech Ltd	02.07.2021	For ≥ 18 years age Two doses, Day 0 (comp I) & Day 21 (comp II)
4	COVID-19 vaccine (Ad26.COVS-2) [recombinant] (Janssen Vaccine)	M/s Johnson & Johnson Pvt. Ltd. (Importer)	07.08.2021	For ≥ 18 years age Single dose
5	COVID-19 vaccine (Ad26.COVS-2) [recombinant] (Janssen Vaccine)	M/s Biological E Limited	18.08.2021	For ≥ 18 years age Single dose
6	Novel Corona Virus-2019-nCov vaccine (recombinant DNA) (ZyCoV-D)	M/s Cadila Healthcare Limited	20.08.2021	For ≥ 12 years age Three doses (Day 0, 28 and 56)
7	Gam COVID Vac (component I & II) (SPUTNIK-V)	M/s Hetero Biopharma Ltd	07.10.2021	For ≥ 18 years age Two doses, Day 0 (comp I) & Day 21 (comp II)
8	Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN)	M/s Bharat Biotech	24.12.2021	For ≥ 12 to 18 years age Two doses, Day 0 & 28
9	SARS-CoV-2 vaccine containing Receptor Binding Domain (RBD) of SARS-CoV-2 gene (CORBEVAX)	M/s Biological E Limited	28.12.2021	For ≥ 18 years age Two doses, Day 0 & 28
10	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine (COVOVAX)	M/s Serum Institute of India Pvt. Ltd.	28.12.2021	For ≥ 18 years age Two doses, Day 0 & 21
11	Recombinant adenoviral vector vaccine containing particles of serotype 26 containing the protein S gene of the SARS-CoV-2 virus (SPUTNIK Light)	M/s Dr. Reddy's Lab. Ltd. (Importer)	05.02.2022	For ≥ 18 years age Single dose

**2.29 The Committee observes that the country's first indigenous vaccine- Covaxin works on inactivated virus platform. With the constant mutation in the virus, there is an urgent need to evolve strategies for development of second-generation vaccines. The Committee,**

accordingly recommends the Ministry to encourage vaccine development on other newer and more efficient platforms and also evaluate the efficacy of the existing Covid-19 vaccines. The Ministry must make continuous efforts in developing vaccines that are variant neutral and whose efficacy remains unchanged against other strains of virus. The Committee reiterates its recommendation that all the Ministries concerned must collaborate with other National and International Institutes on vaccine research and development front and benefit the nation with latest innovation.

**2.30** The Committee appreciates that the scientific community around the world sprung into action and developed Covid-19 vaccines in record time. It is a well established fact that the Indian pharmaceutical companies have a worldwide presence and have the ability to produce vaccines on a large scale. Taking into account that the company that produces the largest number of vaccines in the world is an Indian company, the Committee observes that India has huge potential in supplying the global demand of vaccines, however, the Committee discovers that there is a gigantic scope for more innovation and research in the sector. The Committee, therefore, strongly recommends that the Government should look forward for strengthening the research ecosystem so that vaccines on newer and more scientific platforms are developed. The Committee, accordingly, recommends the Government to increase the budget of Health Research and ICMR so that newer innovations see the light of the day. India should not just focus on being a mass producer of vaccines but also aim at creating a niche space for the Indian Research fraternity in the vaccine and drugs development sector.

### **Fund Allocation for Vaccines**

2.31 During the examination of the Demand for Grants of the Ministry of Health and Family Welfare, the Committee had examined the Budget allocated for Covid vaccination. During the detailed examination, the Ministry had submitted that in BE 2021-22, Rs. 35,000 crore was budgeted for procurement of COVID-19 Vaccines under Covid-19 vaccination programme. As on 3rd February 2022, an expenditure of Rs. 27945.15 crore has been incurred against these allocations which have been utilized for procurement of COVID-19 vaccines for free of cost supply to States/UTs. All the payments have been made to M/S HLL (procurement agency) for procurement of COVID-19 Vaccines.

### **India Covid-19 Emergency Response and Health System Preparedness Package**

2.32 In response to a Question regarding the Package in the 256<sup>th</sup> Session of Rajya Sabha, the Minister of State in the Ministry of Health and Family Welfare submitted that the Government of India provides the requisite technical and financial assistance to States/UTs to manage the COVID-19 pandemic. During 2019-20, Rs. 1113.21 Crore were provided as an additional support to States/UTs under National Health Mission for management of COVID-19.

2.33 During the year 2020-21, under the “India COVID-19 Emergency Response and Health System Preparedness Package (ECRP- Phase I)”, funds to the tune of Rs. 8473.73 Crore were released for States/UTs for health system strengthening. "India COVID-19 Emergency Response & Health System Preparedness Package: Phase-II" was approved by the Cabinet with Rs 23,123 crores (with Rs. 15,000 Cr as Central Component & Rs. 8,123 Cr as State component) and implemented from 1st July 2021. The scheme aimed to upgrade available health infrastructure through increase in isolation beds, ICU beds for adults as well as paediatric cases, drugs and diagnostic support, promotion of telemedicine with particular focus on peri-

urban and rural areas. As on 8th March 2022, an amount of Rs. 9616.05 crore has been released (central share) to States/UTs.

**2.34 The Committee is of the view that the funds allocated for Covid-19 management should have been judiciously distributed among the States so that the financial burden of the poorer States is aptly managed. The Committee recommends the Government to ensure that adequate funds are reserved for purchasing and administering of vaccine doses. The Ministry may submit the expenditure profile of the Rs. 35,000 crore funds allocated for vaccination other emergency response and Health System preparedness packages and allocation from PM Covid Care Funds. The Committee again emphasizes that the Ministry must ensure equitable distribution of funds among the States.**

**2.35 As per the information submitted by the Ministry, a large percentage of the fund has already been transferred to the States, however, the Committee is apprehensive about the utilization of the funds under the Emergency Covid Response Package (Phase I & II). The Committee accordingly recommends the Ministry to monitor the utilization of the funds by the States and ensure that adequate infrastructure is available in the States. The Centre along with the States must ensure that the allocated Covid fund is utilized for implementation of IT, training and capacity building of human resources besides vaccine administration. The Committee, therefore, strongly recommends the Ministry to follow up with the States to ensure that the funds are optimally utilized by the States and seek utilization certificate from the States/UTs.**

2.36 The Committee during its study visit to Chandigarh was given to understand that the Ministry of Health and Family Welfare had released only a sum of Rs 13,75,840/- for COVID Vaccination during January 2021 to the UT of Chandigarh. The UT further submitted that some more funds were released on the last day of financial year 2021-22 that could not be drawn due to time restrictions.

**2.37 The Committee expresses its deep concern over the practice of releasing grants on the last day of the financial year. The Committee has time and again recommended the Government to adopt financial prudence and avoid last minute disbursement of funds. However, such poor financial management speaks volume of the lack of communication between the Union Government and the UT. The Committee recommends the Ministry to frame guidelines of financial prudence in consultations with the States and ensure that the guidelines are judiciously followed. The Ministry of Health and Family Welfare must act as a facilitator and guide the States to ensure optimum utilization of the funds. The Committee, therefore, recommends the Ministry to adopt prudent fiscal analysis and devise a feasible roadmap so that such instances of poor financial mismanagement are not repeated.**

## **CHAPTER III**

### **VACCINE PROCUREMENT AND DISTRIBUTION**

3.1 The vaccination drive in the country began with the vaccination to all Health Care Workers. Over the time different Phases of the vaccination program was expanded to include vaccination of Front Line Workers, citizens more than 60 years of age, citizens more than 45 years old age, citizens more than 18 years of age and eventually children in the age group 15-17 and then 12-14.

#### **Changes in the Vaccine Procurement Policy**

3.2 The Committee is given to understand that under the National COVID Vaccination Program, from 16th January to 30th April 2021, 100% of vaccine doses were procured by Government of India and provided free of cost to State Governments. State Governments in turn had to administer vaccination free of cost to defined priority groups. To increase the pace of vaccination, participation of private hospitals was also enlisted where individuals could also choose to get vaccinated at a prescribed rate.

3.3 The Government of India revised the Guidelines as 'Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy'. Under the revised guidelines effective from 1st May, 2021, Government of India was procuring 50% of the vaccine produced and was continuing to provide them to States free of cost for administering to priority groups. The State Government and private hospitals were also empowered to directly procure from the remaining 50% vaccine pool.

3.4 The 'Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy' was in effect from 1<sup>st</sup> May 2021 to 20<sup>th</sup> June 2021. The aforesaid strategy was implemented in response to the suggestions of many State Governments to be permitted the flexibility to procure vaccine directly and administer them as per their own prioritization based on local requirements.

3.5 However, many States communicated that they were facing difficulties in managing the funding, procurement and logistics of vaccines, impacting the pace of the National COVID Vaccination Program. It was also noted that smaller and remoter private hospitals were also facing constraints. Keeping in view the aforesaid aspects, the experiences gained from 1st May 2021 and the repeated requests received from States, the Guidelines for National COVID Vaccination Program were revised as 'Revised Guidelines for implementation of National COVID Vaccination Program' that came into effect from 21<sup>st</sup> June 2021.

#### **Revised Guidelines for implementation of National COVID Vaccination Program**

3.6 Under the Revised Guidelines for implementation of National COVID Vaccination Program, the Government of India procures 75% of the vaccines being produced by the manufacturers in the country for free supply to States/UTs. The price of vaccine for procurement by Government of India is negotiated by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and its subgroups involving detailed deliberations with the vaccine manufacturers.

3.7 Vaccine doses provided free of cost by Government of India is allocated to States/UTs based on criteria such as population, disease burden and the progress of vaccination. Wastage of vaccine affect the allocation negatively. Further the Ministry submitted that the Revised Guidelines for implementation of National COVID Vaccination Program ensures free supply of

COVID-19 vaccines to all States/UTs and all citizens irrespective of their income status at Government CVCs.

3.8 In a specific query regarding the split between public and private procurement of vaccines, the Ministry submitted that the quantity of vaccine available for procurement by Private hospitals was upto 25%. If the private hospitals were not able to procure the available quantity, then the same were being procured by Govt. of India for free of cost supply to States/UTs.

3.9 On a specific query regarding whether the States could approach foreign companies for supply of foreign vaccines, the Ministry submitted that under the 'Revised Guidelines for Implementation of National COVID Vaccination Program', effective from 21<sup>st</sup> June 2021, Government of India was procuring 75% of the vaccines being produced by the manufacturers in the country and was providing it free of cost to States/UTs. Hence, there was no need for any State/UT to approach any foreign company for supply of vaccines.

**3.10 The Committee notes that procurement and delivery of vaccines for catering to the targeted group of people requires huge amount of financial resources. The Committee observes that a robust assessment of the logistic requirements and streamlining of the procurement process is crucial in ensuring the supply chain of the vaccines in the country. As the beginning of the National Covid Vaccination Program, much confusion prevailed on the Government's vaccine procurement policy. The Committee takes into account that some States raised objection to the provision of Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy due to the financial constraints in the procurement of the vaccine that disturbed the vaccine demand supply continuum. States complained about acute shortage of vaccines in the third phase of vaccination, i.e. 18-44 age Group while vaccination was the only real weapon or the last hope to combat Covid-19. The Committee is of the opinion that the Centre's erstwhile policy of not providing free vaccines to age group of 18-44 years was devoid of any justification and generated hue and cry amongst vaccine willing citizens.**

**3.11 The Committee takes note that the Indian Government did not make any upfront payments or signed any prepurchase agreement with the vaccine manufacturers during the developmental phase of vaccines. The need of such agreement was felt when the vaccine supply could not match the vaccine demand from the States. The Committee notes that as most of the vaccine centres used to get full to its capacity at quick pace, booking a slot on Cowin became herculean task at the early stage . The Committee is of the view that the Government should have taken steps to enhance vaccine capacity in the country and procure additional vaccine doses. The Committee believes that a better assessment of the vaccine requirement in the country could have accelerated the vaccination drive. However, absence of a micro-level planning greatly impacted the supply chain of vaccines.**

**3.12 The Committee further notes that the Procurement Policy was modified from time to time to overcome the limitation of each Procurement Process. However, the Committee is of the view that there exists a huge disparity between the States and many economically weaker States were incapable of managing such intricate vaccine logistic requirements on their own. With the change in the guidelines of the procurement policy, the Central Government could negotiate with the vaccine manufacturers and settle on a fair and better price. The Committee recommends the Ministry to make elaborate arrangements for ensuring procurement in emergency situations.**



**3.13 The Committee further recommends the Ministry to seek technical as well as financial assistance so that procurement planning strategy can be further strengthened for future such emergencies.**

#### **Distribution Plan and its specific course of action for vaccination for COVID-19**

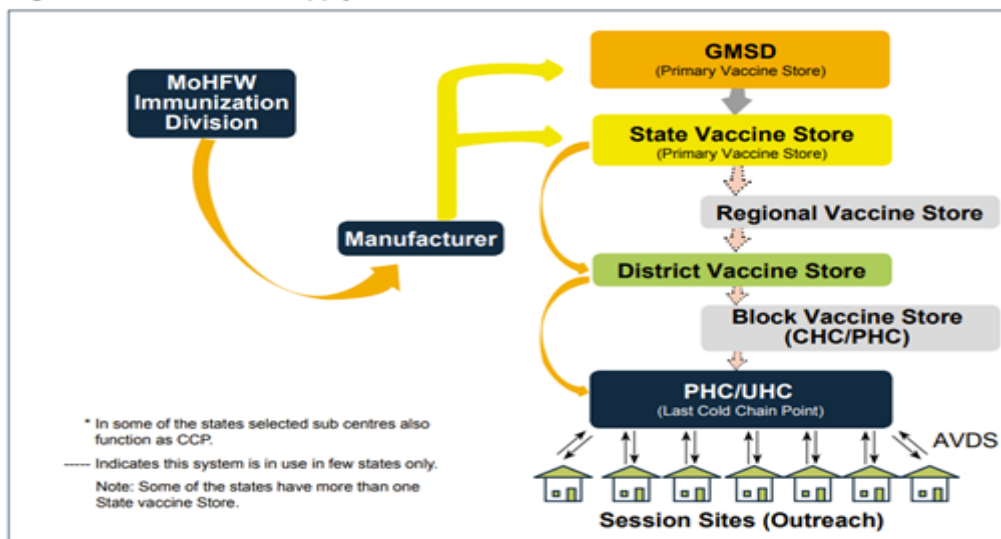
3.14 The Committee is given to understand that the existing immunization supply chain network and infrastructure under Universal Immunization Programme (UIP) was utilized for distribution of COVID-19 vaccine. The Ministry submitted that annually nearly 60 crore doses of vaccines were utilized under UIP which reach to the beneficiary in a temperature controlled environment which was managed through a network of around 29 thousand Cold Chain Points comprising of Government Medical Supplies Depot (GMSD), State Vaccine Stores, Regional Vaccine Stores, District Vaccine Stores and Cold Chain Points at sub-district level. The storage of vaccines in above mentioned stores was done in Walk in Coolers, Walk in Freezers, Ice-lined Refrigerators and Deep Freezers. Transport of vaccines between these stores was done using insulated vaccine vans and passive cold chain equipment like Cold Boxes and Vaccine Carriers.

3.15 The Handbook for Vaccine & Cold Chain Handlers defines the following five levels of vaccine stores:

1. GMSD and State Vaccine Store (Primary Vaccine Stores): Any facility that receives vaccine from the manufacturer is a Primary Store. Government Medical Store Depot (GMSD) and State Vaccine Stores (SVS) are Primary Stores and receive vaccine directly from manufacturers. The vaccine store in a state which receives vaccine either from a manufacturer or from a GMSD is a state vaccine store (SVS). A state may have multiple state vaccine stores which may be located beyond the state head quarter. The State Vaccine Store supplies vaccine to the Regional Vaccine Store and if there is no RVS the vaccine is supplied directly to DVS.
2. Regional Vaccine Stores: Any facility that receives vaccine from a State Vaccine Stores (SVS) and distributes to districts is a Regional Vaccine Store (RVS). The existing Divisional Vaccine Stores of the states (wherever applicable) which receive vaccine from the SVS and distribute to the districts (DVS) will fall under this category and should be considered as Regional Vaccine Stores.
3. District Vaccine Stores: These are the stores at district level which receive vaccine from state/regional vaccine stores and distribute vaccines to CHC/ PHC/UHC/ last cold chain point etc.
4. Block Vaccine Stores (CHC/PHC): These are facilities which receive vaccine from District Vaccine Stores and distribute to the last cold chain points. Any intermediary store between the district vaccine store and the last cold chain point fall in this category.
5. Last Cold Chain Point: These are facilities which receive vaccines from District/Block level CHC/PHC Vaccine stores and distribute vaccines to the session sites on session days. In the immunization supply chain network this is the last point having vaccine storage facility and doesn't issue vaccine to any other vaccine store but only for the immunization sessions.

3.16 In some states certain sub-centers also function as last cold chain point in order to meet the “time to care” approach after fulfilling the requisite criteria of serving as a cold chain point.

Figure 3: Immunization supply Chain levels in India



Handbook for Vaccine & Cold Chain Handlers, India 2016 · 3

3.17 In an earlier query regarding the supply of vaccines, the Ministry submitted that all the identified beneficiaries for COVID-19 vaccination was registered on Co-WIN software and on the basis of registered beneficiaries; the supplies of vaccine to the Cold Chain Points were made. Adequate buffer quantities were maintained at (Government Medical Supplies Depot) GMSDs for meeting any exigencies with respect to requirement of vaccines.

**3.18 The Committee notes that a robust cold chain infrastructure forms the crux of the National Vaccination Programme. Under the Universal Immunisation Programme, the Government has been providing vaccination for other diseases to the citizens. However, considering the large scale of Covid vaccination program, there was an urgent need to provide adequate cold chain equipments to the States so that the vaccines were smoothly distributed and rolled out upto the last corner of the country. The Committee is of the view that the vaccines need to be stored in refrigerated conditions and the temperature has to be monitored on a real time basis. Insulated vaccines vans are required for transportation of the vaccines across the country within stipulated timeframe. The Ministry, therefore, must assess the ground requirements of the cold chain supply and ensure that adequate number of insulated vans and cold chain equipments are available. The Committee points out that since adequate cold chain infrastructure is absent in many rural parts of the country, therefore, the Ministry must make concerted efforts to address future challenges arising from newer variants and newer diseases, keeping a vigil on assured adequate vaccine cold-chain supply. The Committee emphasizes that the Ministry must accordingly work towards establishing an efficient network of cold chain logistics for ensuring efficient last mile-delivery of the vaccines in required environment.**

**3.19 The Committee also notes the five levels of vaccine stores and recommends the Ministry to ensure that vaccine store at each level fulfil the requisite criteria for adequate storage of vaccines. The Ministry along with the States must ensure that the personnel are well trained to manage the vaccines at these cold chain points. Any damage to the vaccines**

**at any level must be taken very seriously and all efforts must be made to ensure that the vaccines are transported at desired temperature.**

3.20 The Secretary further submitted that steps had been taken to ensure sufficient number of cold chain points and also uninterrupted supply of syringes and other logistics in the country. The States were informed that once the Vaccines reach the State's vaccine store, and it was their responsibility to take the vaccine from the vaccine store to the vaccination point. The States could make use of the refrigerated trucks. Where the distance is less, States could make use of ice boxes where dry ice is kept and the vaccine can be transported in these ice boxes. The Ministry also submitted the list of State/UT wise Cold Chain Points (CCPs) and their capacity to store vaccines which is attached as *Annexure 1*. The capacity of the cold chain facilities at each level of storing vaccines i.e. State (SVS/RVS), District (DVS) or at the lowest facility (last CCP) were sufficient to handle the supply of COVID-19 vaccine under the National COVID-19 vaccination programme.

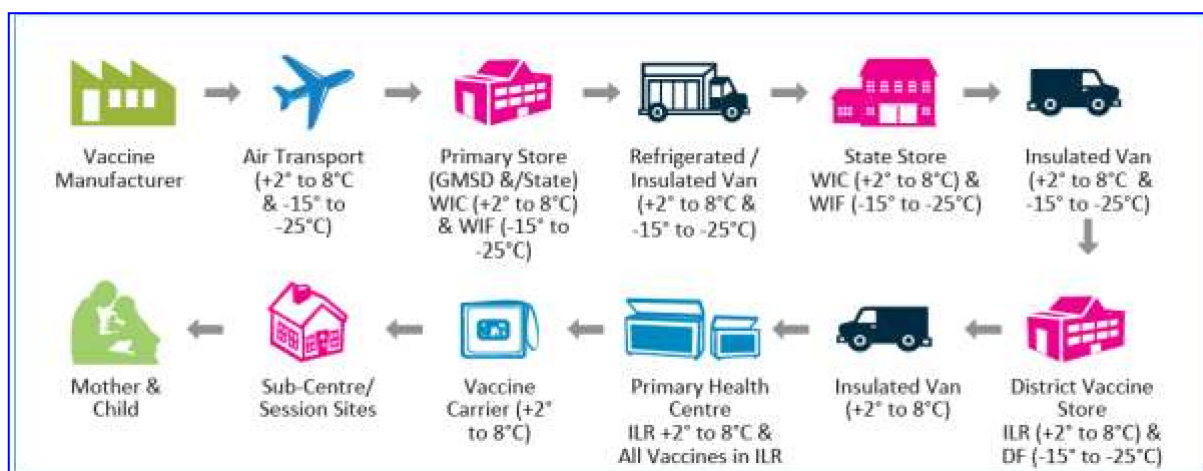
### **Electronic Vaccine Intelligence Network- eVIN**

3.21 The Committee is given to understand that Electronic Vaccine Intelligence Network (eVIN) is an innovative technological solution which is aimed at strengthening the vaccine supply chain systems across the country. The Ministry of Health and Family Welfare introduced eVIN in 2015 to strengthen the Universal Immunization Programme (UIP) under National Health Mission (NHM). eVIN is an indigenously developed technology system that aims to provide real-time information on vaccine stocks, flows and storage temperatures of the vaccines across all cold chain points in the country.

### **Vaccine distribution Management in States**

3.22 The Committee while examining the subject also noted the existing disparity in the cold chain infrastructure in the country. States like Maharashtra have a robust vaccine distribution Management system. The State Government of Maharashtra submitted that 24 WICs (walk-in-coolers) and 4 WIFs (walk-in-freezers) were placed at State and Regional vaccine stores. Vaccines were stored in walk-in-coolers and frozen ice packs prepared in walk-in-freezers. There were more than 5000 ILRs (Ice-lined Refrigerators) and more than 4500 DFs (Deep Freezers) at district and peripheral cold chain points. The State Government submitted that for transportation of vaccines from State to Regional vaccine stores, they had 3 refrigerated vaccine vans. For transportation of vaccines from Regional to District and from District to peripheral cold chain points, they had a 39 insulated vaccine vans.

### ***Cold chain infrastructure:***



3.23 The State of Maharashtra further submitted that vaccines were transported in cold boxes with conditioned icepacks through insulated vaccine van from Regional to District and District to peripheral cold chain points. Vaccines were transported in vaccine carriers with conditioned ice packs from peripheral cold chain points to vaccination session sites

3.24 The Committee also takes note of the submission of the State of Uttarakhand with regard to their cold chain infrastructure. The State of Uttarakhand submitted that a total of 22 well maintained and GPS system installed vaccine vans were running in the State to make the vaccine available from SVS to RVS, RVS to DVS, DVS to BVS (Block Vaccine Store) and from there to the most remote Cold Chain Point (CCP). A total of 319 (including 1 SVS, 3 RVS, 13 DVS, 26 BVs and 276 Peripheral CCP) well maintained and temperature logger equipped CCP were present in the State. State of the art equipment was utilized and routinely monitored by well trained staff to maintain and distribute Covid-19 vaccine by the State which includes 7 walk in coolers (WIC), 4 walk in Freezers (WIF), 727 Ice Lined Refrigerators (ILR) and 618 Deep Freezer(DF).

3.25 The Committee notes that the use of modern cold chain equipments for storing and transportation of vaccines at the recommended temperature is the keystone for maintaining the quality and efficacy of the vaccines, however, the Committee finds that there is huge scope for improvement in the cold chain equipments in the country. The Committee points out that there is a need to upgrade the cold chain equipments in many States and adopt modern refrigerant technology so that the vaccines can be better monitored. The Committee also notes that use of eVIN has facilitated real time monitoring of the vaccines in the States. The Committee strongly recommends the Ministry to make eVIN functional in all the States and UTs and build technical capacities so that the cold chain handlers as well as the Programme Managers have a complete overview of the vaccine supply and consumption pattern.

3.26 The Committee takes into account the fact that the lack of ultra cold chain vaccine infrastructure in the country has limited the choice of vaccines. The m-RNA vaccines from Moderna, Pfizer etc that need a temperature of -70 to -80 C for storage could not be explored as vaccine options in India when these were some of the first vaccines that were given EUA in the western countries. The Committee believes that a poor cold chain

**infrastructure not only limits the choice of the vaccines but also increases the risk of vaccines wastage.**

**3.27 The Committee also notes that in regions with difficult geographical terrain and poor connectivity, digitization of vaccine stock inventory and its storage temperature may not be possible. The Committee is concerned especially for States like Uttarakhand, Himachal Pradesh and the North Eastern States where road as well as network connectivity is very poor. Ensuring a robust vaccine distribution mechanism and monitoring the temperature while ensuring last mile delivery of the vaccines may be a challenge in such areas. The Committee, accordingly, recommends the Ministry to coordinate with the States and encourage use of modern technologies, Drones, Helicopters for the robust distribution of the vaccines.**

### **Vaccine Pricing**

3.28 The Secretary, Department of Health and Family Welfare submitted that Indian vaccines were more economical and affordable compared to foreign vaccines. The price of Pfizer vaccine in USA was \$19.50 or Rs. 1,431 and this vaccine had to be stored at - 70 degree temperature. According to him, Pfizer vaccine had two issues, firstly its price per dose was high and it needed to be stored at a very low temperature. He also stated that the Moderna Vaccine price range in rupees was Rs. 2,348 to Rs. 2,715 per dose. This could be stored between 2 to 8 degree temperature. The cost of Sino Farm, a Chinese Vaccine was Rs. 5650 per dose and this could be stored at 2-8 degree temperature. The cost of another Chinese vaccine, Sino Wake was Rs. 1027 per dose which could also be stored at 2-8 degree. The price of Novavax vaccine was US \$ 16 per dose or Rs. 1141 per dose. The price of other vaccines, Sputnik V and Johnson & Johnson vaccine was Rs. 734 per dose.

3.29 The Secretary further submitted that the price of vaccine manufactured by Serum Institute of India in collaboration with Astrazeneca was quoted at Rs. 250 per dose. However after protracted negotiations, the price was fixed at Rs. 200 per dose. The price of Covaxin was initially quoted at Rs. 350 per dose. However the final price was Rs. 295 per dose. It was also submitted that Bharat Biotech was giving 30 percent doses free of cost; therefore, the final price of Covaxin came out to be Rs. 206 per dose.

3.30 The Secretary also submitted that the foreign vaccines were exorbitantly high priced whereas, Indian manufacturing and Indian R&D established the fact that India would be bringing about a price disruption in the global vaccine market.

3.31 The Committee is given to understand that the price of vaccine for procurement by Government of India is negotiated by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and its subgroups involving detailed deliberations with the vaccine manufacturers. Under National COVID-19 Vaccination Programme, COVID-19 vaccine is available free of cost at Government COVID-19 Vaccination Centres (CVCs) to all eligible beneficiaries irrespective of their socio-economic status. The vaccine manufacturers were free to fix the price of vaccine for procurement by Private Hospitals in a transparent manner. However, Government of India fixed a maximum service charge of INR 150 per dose over and above the price of vaccine for vaccine administration at Private COVID-19 Vaccination Centres (CVCs). State Governments were advised to monitor the price charged at the private hospitals.

**3.32** The Committee observes that the price of Indian vaccines compared to the foreign vaccines is less, however, the Committee observes that mRNA vaccines because of their high potency have been greatly explored over the conventional vaccine platforms such as subunit, killed and live attenuated virus etc. The Committee is given to understand that mRNA vaccines provide greater flexibility in comparison to other vaccine platforms. With the virus constantly mutating and increasing risk of vaccine escape, mRNA vaccines provide a better alternative and more flexibility. The potential for low cost manufacture of the mRNA vaccines is also a major advantage. The Committee, accordingly, recommends the Ministry to explore such versatile vaccine platforms in the country and work towards producing cost effective indigenous mRNA vaccines.

**3.33** The Committee notes that the bargaining powers of the vaccine manufacturers are high due to the high demand of the vaccines, however, the Ministry through bulk negotiations have settled at a fair price for free administration of the vaccines in the Government facilities. The Committee further notes that the vaccine manufacturers fix the price of vaccine for procurement by Private Hospitals and these private hospitals subsequently charge high price for administering the vaccines. The Committee strongly recommends the Ministry and the States to strictly monitor the exorbitant rates being charged by the private hospitals.

**3.34** The Committee further notes that with the increase in the number of vaccine candidates in the market, the private hospitals as well as the Government will be at a better position to negotiate the price. The Ministry must accordingly ensure that the vaccines prices are negotiated on favourable terms and the demand supply gap is adequately abridged.

#### **Booster Doses**

**3.35** In the meeting held on 5<sup>th</sup> April, 2022 the representatives of the State Government of Kerala suggested that precaution dose ( 3<sup>rd</sup> dose) should be made available (i) to the age group 18 years and above travelling abroad ( students, researchers, travellers) and carving out exceptions of time duration specification; (ii) eligible people with comorbidity; and (iii) Precaution dose for those who have taken 2 doses abroad should also be worked out.

**3.36** The State Government of Kerala submitted that vaccination has shown that it reduces the severity of infection. The data suggests that the mortality among elderly is high in the age group 60 and above. The precautionary dose in the age group 60 to 70, 70 to 80 , 80 and above to be done based on study by calibration of Antibody titre and duration for giving additional dose.

**3.37** The Committee notes that Booster or Precautionary doses commenced for all adults at Private vaccination Centres from April, 2022. The Committee would like to be apprised of the evidence based research and the clinical trials conducted in the country that necessitated the administering of booster doses in the country. The Committee would like to be informed on the reasons for the change in the vaccination policy of the Government and inoculating the citizens with the precautionary dose of the same vaccine. The Committee also notes that some reports suggest that a booster dose of a vaccine of a different platform could be better than a vaccine of the same platform. The Committee feels that such proposition requires deep research and any implementation of such suggestion must be substantiated by in-depth research data, scientific interpretations and clinical trials.

**3.38** Attention of the Committee is also drawn to the study of CMC Vellore on the inter-mixing of doses of Covishield and Covaxin which claims to provide better immunity. Media Reports have suggested that the CMC Vellore study reveals that heterologous immunisation provides better results than homologous vaccination. However, no official information or updates have been provided by the Ministry of Health and Family Welfare in the public domain. The Committee would like to be apprised on the findings of the aforementioned research study. The Committee further recommends the Ministry to encourage such studies on the potency and efficacy of the vaccines and ensure that bureaucratic hurdle and inordinate delays do not stall the findings of the research.

**3.39** The Committee reiterates that research studies that provide data on the efficacy of vaccines must be encouraged. The results of such study can help the Government in developing a better containment strategy and effective vaccine administration policy. The Ministry must expedite the decisions on such studies and its vaccine policy must be guided by scientific evidence and amended accordingly. The Committee further recommends the Ministry to commission epidemiological and vaccine effectiveness studies so that strong evidence on the vaccines efficacy is generated and guaranteed so as to alley the apprehension and hesitancy against the booster dose.

**3.40** Attention of the Committee has also been brought to the concerns of few States that have sought the Union Government's permission to use the available vaccines for booster doses for the 18-59 age group. The Committee recommends the Ministry to address the concerns of the States and allow them to use the available doses for booster doses if full vaccine coverage in the adult population has been achieved. The Committee further recommends the Ministry to ensure that any excess stock of vaccines is not wasted so that country achieves 100% vaccination of its citizens.

## CHAPTER IV

### UNFOLDING OF THE NATIONAL COVID-19 VACCINATION PROGRAMME

4.1 The Vaccination Programme of India against Covid-19 is the largest vaccination programme in the world. For a country with the second largest population, the mass vaccination drive seemed an uphill task. National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) provided guidance on all aspects of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc. All the recommendations made by NEGVAC were implemented under National COVID-19 Vaccination Programme.

4.2 The Committee is given to understand that with the rapid increase in the number of Covid cases across the world, it was more than necessary to produce safe and effective vaccines against the SARS-COV-19 virus. The main goal of the National Vaccination Strategy was to alleviate the severity of the pandemic, minimize deaths and the incidence of covid cases in the country. An effective vaccination strategy could go a long way in reducing the mortality and severe hospitalization rate. The National Regulator, Drugs Controller General of India (DCGI) initially gave nod to market authorization of two COVID19 vaccines, Covaxin and Covishield subject to certain conditions. Sputnik V, Corbevax and Covovax were the other three vaccines that are being administered to the Indian population till date. With the virus continuously mutating and evolving into a more transmissible and virulent form, vaccination of the whole population forms the keystone in India's fight against the pandemic.

#### Sequential roll out of Covid-19 vaccination

4.3 In the Committee meeting held on 12<sup>th</sup> January, 2021, the Secretary, Department of Health and Family Welfare submitted that there was a close collaboration with States/UTs for vaccine roll-out preparedness. 26 virtual trainings and meetings were held with the State Governments to discuss operational and communication guidelines. More than 2300 master Trainers were trained to further train 61,000 individuals who were known as Program managers which included District Immunization Officer, Block Immunization Officer, Medical Officer etc. Two lakh vaccinators who would actually vaccinated people were to be trained and three lakh seventy thousand other vaccination team members were also trained.

4.4 The Secretary, Department of Health and Family Welfare submitted that the entire vaccination programme was based on the five principles which were as follows:

- (i) The first principle is, "*Ensure People's Participation*". The duty of the Government is to provide vaccine, logistics, training, creating SOP etc; however, people should actively participate in the vaccination programme without any hesitation.
- (ii) The second principle is "*Utilize experience of elections and universal immunization programme*". There is a need to learn from the experience of conducting elections. Under the Universal immunization programme, around 2 crore 70 lakh children are annually vaccinated for 12 diseases. Under the same Programme, almost 3 crore mothers are also vaccinated. There is a need to learn from both the experiences.
- (iii) The third principle is '*No compromise of existing healthcare services, especially, national programmes and primary healthcare*'. There is a need to ensure that other primary healthcare services are not impacted due to the vaccination programme.



- (iv) The fourth principle is '*No compromise on scientific and regulatory norms*'.
- (v) The fifth principle is '*Orderly and smooth implementation driven by technology*'. The Secretary further submitted that the vaccine roll out will be smooth, transparent as well as in orderly manner.

**4.5 The Committee is of the view that a robust implementation of the five principles will ensure the success of the National Vaccination Program. The Committee recommends the Ministry to ensure participation of the key officers from State to the Block level along with active participation of the masses. The Committee also recommends the Ministry to ensure that diversion of healthcare forces to manage Covid-related uncertainties must not cause any disruption in the delivery of primary health care services. The Committee further recommends that that past experiences of universal immunization and elections must be utilized in smooth implementation of the National Vaccination Program. At the same time, every effort should be made so that there is no compromise on scientific and regulatory rules and norms.**

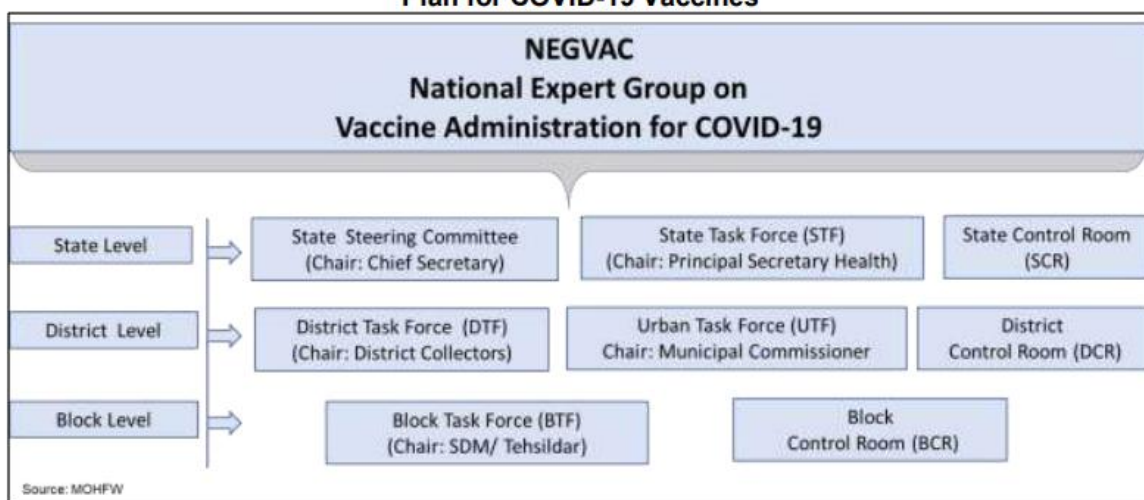
### **National Covid-19 Vaccination Programme**

4.6 In a specific query with regard to the major recommendations made by NEGVAC for successful implementation of the vaccination programme, the Ministry of Health and Family Welfare submitted that the National Expert Group on Vaccine Administration for Covid (NEGVAC) provided guidance on all aspects of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc. All the recommendations made by NEGVAC have been implemented under National COVID-19 Vaccination Programme. Major recommendations made by NEGVAC were as follows:

- Preparation of operational and communication guidelines for National Covid vaccination Program
- Use of COVID-19 vaccines like Covishield, Covaxin & Sputnik V who received EUA by DCGI in National Covid vaccination Program.
- Prioritization of beneficiaries for Covid vaccination programme in a phased manner
  - a. Health Care Workers – 16th January 2021
  - b. Front Line Workers – 2nd February 2021
  - c. Person aged  $\geq 60$  years and 45 – 59 years with identified 20 co-morbidities – 1st March 2021
  - d. All persons aged  $\geq 45$  years – 1st April 2021
  - e. Persons aged 18 years & above – 1st May 2021
- Revision in dose interval of Covishield Vaccine from 4-6 weeks to 12-16 weeks.
- Work Place Vaccination for employees >45 years
- Liberalized Pricing and Accelerated National COVID-19 vaccination Strategy
- COVID-19 Vaccination recommended for all Lactating Women and pregnant women
- COVID-19 vaccination of staff of Indian Mission posted abroad
- Near to Home Vaccination (NHCVC) for Elderly and Differently Abled Citizens
- For individual going abroad, relaxation allowed in administration of 2nd dose of Covishield vaccine prior to 12 weeks (may be 4 to 6 weeks)
- Vaccination of foreign nationals, vaccination of persecuted Hindu & Sikhs refugees from Pakistan, Bangladesh and Afghanistan.

4.7 The Ministry of Health and Family Welfare also outlined a well-defined governance framework from national to block level for successful planning, implementation, and monitoring of the COVID-19 vaccination program. The Secretary further submitted that two Committees would be formed at the State level to supervise the entire programme. The State's Steering Committee, headed by the Chief Secretary of the State would look at coordination issues with other Departments within the States and logistical issues which require multi-stakeholder planning. The State Task Force, chaired by the Principal Secretary Health will look at actual administration related issues of the vaccination programme. He further submitted that there would be a District Task Force headed by the District Collector that monitors the functioning of vaccination booths and availability of vaccines. The Block Task Force has also been formed that would be headed by Block Development Officer that would monitor the vaccination programme at the block level.

**Figure 1: India—Governance Framework for the National Deployment and Vaccination Plan for COVID-19 Vaccines**



COVID-19 = coronavirus disease, MOHFW = Ministry of Health and Family Welfare. NEGVAC = National Expert Group on Vaccine Administration for COVID-19, SDM = subdivisional magistrate.  
Source: Ministry of Health and Family Welfare.

### **Prioritized group of population and criterion of selection of priority group for vaccination**

4.8 In the Committee meeting held on 12<sup>th</sup> January, 2021, the Secretary, Ministry of Health and Family Welfare submitted that in the first phase, almost one crore healthcare workers in the Public as well as Private Health facilities was to be vaccinated. In the second phase, almost two crore front line workers that include the State and Central Police Personnel, armed forces personnel, home guards, civil defense and disaster management volunteers, municipal workers, prison staff as well as revenue workers involved in containment and surveillance was to be vaccinated. In the third phase, approx 27 crores in the prioritized age-groups were to be vaccinated. In this category, there are sub-groups as well, initially people above 60 years of age would be vaccinated, then people falling in the age bracket of 50-60 years would be vaccinated and then people below 50 years with co-morbidities would be vaccinated. The Secretary also stated that the cost of vaccination of healthcare workers and Front Line workers would be borne by the Central Government.

4.9 The priority groups for COVID-19 vaccination along with the rationale for their inclusion are as tabulated below:

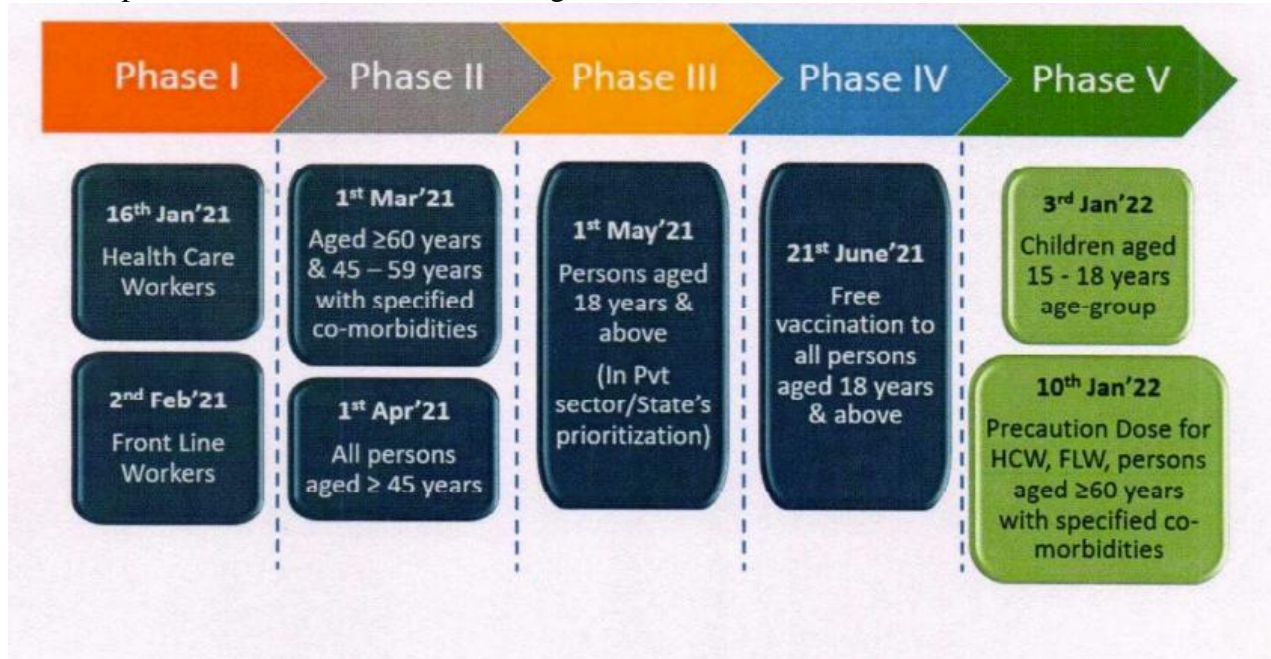
Sr. No.	Prioritized group	Rationale	Includes
1	<b>Health Care Workers (HCWs)</b> (approx. 1 crore)	<ul style="list-style-type: none"> <li>High risk of exposure to COVID-19 Involved in management of health services</li> <li>Regular contact with vulnerable population</li> </ul>	All workers in healthcare settings - both Government & Private
2	<b>Front Line Workers (FLWs)</b> (approx. 2 crore)	High risk of exposure to COVID-19 Involved in management of essential services	State and Central Police personnel Armed Forces personnel Home Guards, Civil Defense & Disaster Management Volunteers Municipal Workers Prison staff Revenue workers involved in containment and surveillance
3	<b>Prioritized age-groups</b> (approx. 27 crore)	High risk of mortality due to COVID-19	Person above age of 50 years Persons <50 years with associated comorbidities

4.10 The Secretary further submitted that the Ministry ensured sufficient number of cold chain points and also uninterrupted supply of syringes and other logistics in the country. A 24X7 helpline in two languages English and Hindi was also opened by the Central Government, similar help lines were to be opened by various State Governments in their respective local languages.

**4.11 The Committee takes note that undertaking covid vaccination drive at such a large scale requires huge capacity and financial resources which many States may lack. The Committee, therefore, is of the firm view that the Government should generously equip the State Government with technical import and financial assistance. In all circumstances, The Centre had to take a lead role in devising policies to substantially mitigate the impact of the pandemic. The Committee understands that mass vaccination for a country as vast and as diverse as India poses a big challenge. The Central Government adopted a targeted vaccination strategy by according the highest priority to the group at the highest risk. The Committee, in its 123<sup>rd</sup> Report, had pointed out that smart vaccination might be used as an immediate strategy so that the whole population should be vaccinated. The Committee agrees that for a country as heterogeneous as India a smart vaccination strategy was the need of the hour. However, the Committee observes that the response of the Union Ministry of Health and Family Welfare on the vaccine front was delayed at the initial stage. In India, mass vaccination started in June, 2021 when vaccination was made free for persons aged 18 and above. The Committee notes that repercussions of the delay in the vaccination program were evident in the high fatality during the second wave.**

## Different Phases under the National Vaccination Program

4.12 The National Vaccination Program began on 16<sup>th</sup> January, 2021 in the country. The different phases under the Vaccination Program are indicated as under:



### Phase I

Under Phase I, the free vaccination of health care workers was started from 16th January, 2021. The free vaccination for Front Line Workers began from 2nd Feb 2021.

### Phase II

Under Phase II from 1st March, 2021, free vaccination for persons above the age of 60 years and 45-59 years with co morbidities was started; the National vaccination Program was further expanded to persons above the age of 45 from 1st April, 2021.

### Phase III

From 1<sup>st</sup> May, 2021, the vaccination drive was expanded to persons aged 18 years and above. Upto 50% of the vaccines were procured by the States and the private sector.

### Phase IV

From 21<sup>st</sup> June, 2021, vaccination was made free at all Government Centers for all persons aged 18 years and above.

### Phase V

The next phase of the vaccination programme commenced in January 2022. From 3<sup>rd</sup> January, 2022, 15-18 year olds were included in the vaccination drive. From 10<sup>th</sup> January, 2022, precautionary dose for Health care workers, Front line workers and persons aged 60 and above with specified co morbidities was also made available.

4.13 Under the next phases of the vaccination drive, the Government started COVID-19 vaccination for the 12-14 age groups from March 16, 2022. The vaccine to be administered would be Corbevax which is manufactured by Biological E. Limited, Hyderabad.

Vaccines that can be used in different age groups

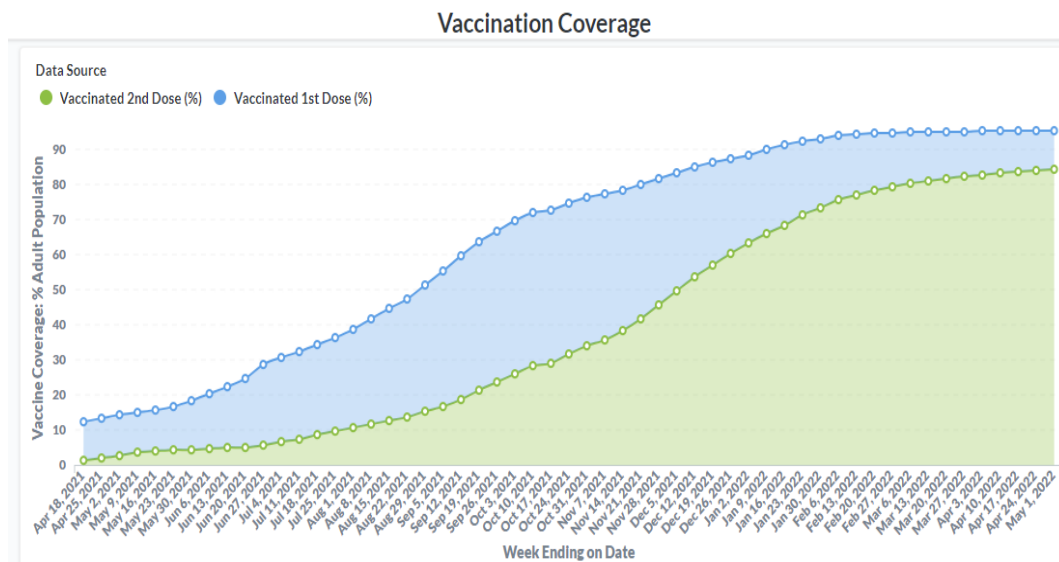
Age Group	Vaccine to be used
12-14 years (All beneficiaries born in year 2008, 2009, 2010)	Corbevax (at Govt. CVCs), 2 doses at interval of 28 days
14-18 years	Covaxin (at Govt. CVCs and Pvt. CVCs)

4.14 The Committee is given to understand that the administration of the Booster or precautionary dose to adults above 18 years of age in the Private vaccination Centres began on 10th April, 2022. The adults who had completed 9 months after the administration of the second dose are eligible for the Booster dose. The booster dose was further opened for all in the Government centres.

4.15 The Central Government announced that free Covid-19 precautionary doses will be administered to the 18-59 age group at Government Vaccination Centres under a 75-day special drive starting from 15<sup>th</sup> July.

### Vaccination Trends in the country

4.16 As per Government data, as on 1<sup>st</sup> May, 2022, the total vaccine coverage in the adult population is 95.83%, out of which 10.83 % have been vaccinated 1<sup>st</sup> dose and 84.5 % have been vaccinated 2<sup>nd</sup> dose. The same can be referenced under:



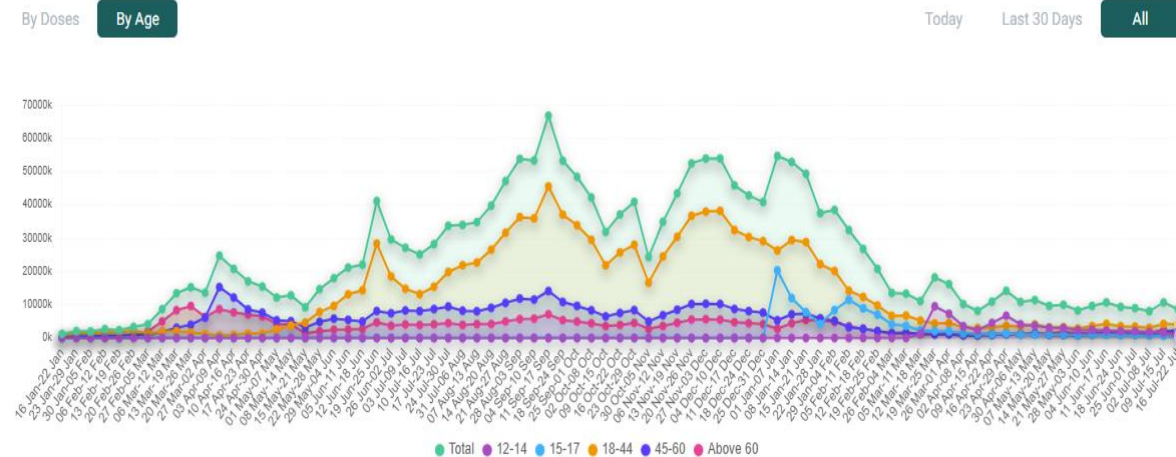
4.17 As per the estimates of the Government, as on 26<sup>th</sup> July, 2022, 2,02,73,81,972 doses have been administered across the country of which 99,16,07,756 doses have been administered to Males and 95,38,05,312 doses have been administered to Females.



as on 26<sup>th</sup> July, 2022

<b>Total vaccination doses administered</b>	<b>2,02,73,81,972</b>
Dose 1	1,02,05,60,908
Dose 2	93,05,93,651
Precaution Dose	7,62,27,413

Vaccination Trends ⓘ



**4.18** The Committee notes that in countries like the USA, mass vaccination started in December, 2020 whereas in India, the first phase of the vaccination drive started in January, 2021 with the healthcare workers getting the shots. The beginning of the vaccination drive had been slow owing to the exclusion of the other groups. Vaccination was made free at all Government Centers for people above 18<sup>st</sup> June, 2021.

**4.19** As per the vaccination trend, the Committee observes that the vaccination rate has not been steady and the vaccination reached its peak in September 2021. The Committee understands that although the one size fits all approach does not bear fruit and the situation in India cannot be compared to other countries considering the large scale of the vaccination drive, however, the Committee strongly believes that India has immense potential and is home to the best of the brains in the world. The country must emulate the best of the practices from the western world and be the harbinger of innovation not only in its public policies but also in its approach to ameliorate the health sector. The Committee emphasizes that, had the vaccination drive been carried out in full swing as was done in the western countries; the country would have been at a better position to face the subsequent Covid waves. However, the exclusion of a large population from the program during the initial period aggravated the health inequities. The Committee strongly believes that the vaccination has to be made free and universal. The Committee accordingly recommends the Ministry to ensure adequate supply of vaccines so that the target of universal free covid vaccination is achieved.

## CoWIN App

4.20 The Secretary submitted that the Government developed a digital platform called CoWIN where all the data of vaccine, like vaccine movement information, storage information, dose information etc. could be recorded, monitored, updated. The platform tracked the recipient of the vaccination dose and inform them about the timings and place to get the second dose of vaccine which needed to be taken after 28 days of taking the first dose. After the successful vaccination, the platform generated an electronic certificate and sent it on the registered mobile number.

4.21 The State of Kerala in its submission stated that the CoWIN software was used for the registration and for entering the Covid vaccination details. The eVIN software was being used for the vaccine stock entry and to assess the vaccine stock details. CoWIN, the digital platform for COVID vaccination program, turned out to be an important software in the field of immunisation. It gave visibility about the program to the public as well as program managers at all levels. While beneficiaries were able to get a digital record of their vaccination, program managers were able to keep a track of the vaccination program in their region/ district/ State level.

4.22 With regard to the vaccination drive in the areas with poor connectivity, the State Government of Maharashtra submitted that in the areas with limited internet connection, particularly in tribal Districts, State Government followed the physical format to collect the individual data for the vaccination Programme and after coming within the network area after their field activity, field workers entered records into the online app. By following this strategy, records were reported same day or the next day. So there was no delay in process. However, such facility was also made available by Government of India in Cowin app to upload that data by next day till 5.00 PM and that feature was utilized by Health Care Workers as and when required during vaccination drive for smooth reporting and monitoring.

4.23 Attention of the Committee has also been brought to the initiatives taken by the State of Karnataka to enable Cowin operational guidelines which are indicated as under:

- To enable timely tracking of vaccine transporting vehicles and to avoid delay in vaccine supply to periphery "Vaccine vehicle live tracking app" has been developed by the State.
- COWIN-KAR, a pilot project and a new initiative developed by Government of Karnataka, by using Application Programming Interface adopted by CoWIN Portal, to ease the process of COVID vaccination online registration to the public.
- Government of Karnataka initiated receipt of Indents from Private Hospital through KPME portal before the feature was enabled in CoWIN

**4.24 The Committee appreciates the Ministry's initiatives in developing a digital system, "CoWin" to monitor vaccine administration in the country. The Committee notes that a platform was crucial for rolling out of the country wide vaccination program and the CoWIN app formed the backbone of the country's vaccination drive. However, some technical glitches were reported in the app and some issues were raised during beneficiary registration on the COWIN App. The Committee is of the view that enabling a strong IT framework through Cowin Platform and imparting necessary training to all the stakeholders was crucial for success of the vaccination Program.**

**4.25 The Committee observes that tracking of the vaccine transporting vehicles is crucial for ensuring the timely supply of the vaccines. The Committee appreciates the efforts of the Karnataka Government and recommends that all the States must also use such vaccine vehicle live tracking app for better vaccine management on a real time basis.**

**4.26** The Committee understands that there exists a huge digital divide between the rural and the urban population. With poor accessibility and connectivity, many areas of the country still remain disconnected from the digital ecosystem. The Committee notes that rural areas tend to be neglected as the level of awareness is very poor. The Committee recommends the Ministry to take effective measures to ensure that the rural areas especially the tribal areas are also included in the vaccination drive. The Committee notes that in the absence of internet connectivity, entering data in the app is a challenge. The Committee accordingly, recommends the Ministry to ensure that the data collected in the physical form is uploaded in the Cowin app at the earliest. The Committee is of the view that the Ministry must aim towards an inclusive vaccination policy and the vaccination drive must include the marginalized and the vulnerable population of the country too.

**4.27** The Committee also notes that through CoWin the Ministry has been successful in administering 2 billion Covid doses and CoWin holds a huge repository of the vaccination data. However, various stakeholders during the discussion highlighted the absence of any data on the efficacy of the vaccine. The Committee accordingly notes that even with an outstanding CoWin data system, the country has no extensive records of after immunisation effects in its population. The Committee strongly recommends the Ministry to facilitate linkages between CoWin and other data systems and share the data in the public domain. The Committee is of the opinion that building inter-operable data systems that ensure real time data exchange can provide a better assessment of the efficacy of the vaccines. The Committee further feels that this digital ecosystem can be aptly utilised for not only monitoring the vaccine supply chain but also promoting concrete research and formulating better policy decisions.



## CHAPTER V

### IEWS OF STATE GOVERNMENTS/ THE DEPARTMENTS/MINISTRIES AND OTHER STAKEHOLDERS

5.1 The Committee, during the examination of the subject, "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID 19" heard the views of various Stakeholders and other Departments/Ministries. The Committee also sought views of the other Ministries and State Governments on the subject. Continuing with the examination of the subject, the Committee also undertook two study visits (i) to Srinagar and Chandigarh from 6<sup>th</sup> to 9<sup>th</sup> September, 2021 and (ii) to Guwahati, Bengaluru and Mumbai from 25<sup>th</sup> to 29<sup>th</sup> April, 2022. Some of the submissions from various stakeholders in brief are enumerated as under:

#### ROLE OF OTHER MINISTRIES IN COVID-19 MITIGATION AND MANAGEMENT

##### Department of Biotechnology, Ministry of Science & Technology

5.2 The Department of Biotechnology (DBT) informed that it had been identified as the nodal department for vaccine development and manufacturing and was involved in strengthening regional scientific cooperation with partnering nations and facilitating clinical trials of Indian COVID-19 vaccines in neighbouring countries.

5.3 Based on the recommendations of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), a summary of the actions taken by DBT was submitted as under :-

##### (A) Partnerships for Accelerating Clinical Trials (PACT) initiative:

The PACT (Partnerships for Accelerating Clinical Trials) programme was launched as a 'Science Diplomacy' initiative for supporting COVID-19 vaccine development activities in partnering countries. The activities being undertaken under PACT include:

- i. Facilitation for Phase III clinical trials of Indian COVID vaccines in neighboring and friendly countries

Discussions with representatives of partnering nations were being held for advancing development of Indian COVID Vaccines. Consultations were held with eight nations for Phase III clinical trials of COVAXIN.

- ii. Trainings for strengthening clinical trial research capacity in neighboring countries

A series of online training courses were being organized by Biotechnology Industry Research Assistance Council (BIRAC) and Clinical Development Services Agency (CDSA) under the aegis of the National Biopharma Mission and Ind-CEPI Mission of DBT.

The first series was organized September, 2020 through December, 2020. Four modules encompassing sessions on Good Clinical Practice (GCP), Ethical Considerations in Clinical Research, Good Clinical Laboratory Practice (GCLP) and Large Vaccine Field Trials, have been conducted.

More than 100 participants from seven neighbouring /friendly countries – Afghanistan, Bangladesh, Bhutan, Maldives, Mauritius, Nepal and Sri Lanka – have participated in the training series.

**(B) Implementation of Mission COVID Suraksha**

‘Mission COVID Suraksha - The Indian COVID-19 Vaccine Development Mission’, launched by the Government of India (GOI) to accelerate indigenous COVID-19 vaccine development efforts

The Mission was announced under AtmaNirbhar 3.0 Package, with a provision of Rs. 900 Cr. to the Department of Biotechnology (DBT) for supporting the development of a comprehensive ecosystem for enabling the development of a safe, efficacious and affordable vaccine for COVID-19. The Mission was being led by DBT and was being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking of DBT.

Three Requests for Expression of Interests (REOIs) for COVID-19 vaccine development and supporting ecosystem were issued by DBT-BIRAC focusing on (1) Development of COVID-19 Vaccine Candidates, (2) Enhancement of Capacity to support COVID-19 Vaccine development and (3) Enhancing capacity for conduct of Human clinical trial for COVID-19 Vaccine Candidates.

**(C) Upgradation of DBT laboratories at Pune and Hyderabad as Central Drug Laboratories (CDLs)**

Based on the recommendations of the NEGVAC and the Task Force for Focused Research on Corona Vaccines, and other S&T issues (Vaccine Task Force, or VTF), detailed proposals were submitted by two Autonomous Institutes of DBT, viz., National Institute of Animal Biotechnology (NIAB), Hyderabad and National Centre for Cell Science (NCCS), Pune, for the development of CDLs. In principle approval for the same accorded by the PMO.

**(D) Coordination with the COVID-19 Working Group:**

The Working Group (WG) on COVID-19 vaccines were established by the Standing Technical Sub-committee (STSC) of the National Technical Advisory Group on Immunization (NTAGI), co chaired by Secretary, DBT and Secretary, Department of Health Research (DHR) & Director General, Indian Council of Medical Research (DG, ICMR), to provide evidence-based recommendation on use of COVID-19 vaccines. The Department of Biotechnology worked closely with the COVID-19 WG on aspects related to introduction of validated assays for robust clinical development of COVID-19, it was also involved in deliberations on vaccine prioritization, delivery and other logistics

**(E) Other activities:**

Coordination was provided for the Development of the concept proposal on ‘Vaccine Maitree’, a mechanism for making available safe and efficacious COVID-19 vaccines at affordable prices from India to partnering nations

**5.4 The Committee takes into account that DBT strengthened the Regional Scientific Co-operation and looked forward in taking a lead role in ensuring that the indigenous vaccines undergo rigorous clinical trials in the neighbouring countries. The Committee, in**

**this regard, recommends the Ministry to collaborate with research bodies and apex institutes of the neighbouring countries so that regional cooperation is further strengthened and scientific fervour is promoted in India and the neighbouring countries. The Committee also recommends the Ministry of Health and Family and the Department of Biotechnology to work towards upgrading the clinical trials infrastructure in the country.**

**5.5 The Committee appreciates the PACT (Partnerships for Accelerating Clinical Trials) programme and recommends the Department of Biotechnology and the Department of Health Research to launch various programs for studying other diseases alongwith their drug and vaccine development. The Committee also recommends the Ministry of Health and Family Welfare and the Department of Health Research to collaborate on development of Indian Covid-19 vaccines.**

**5.6 The Committee appreciates, "Mission Covid Suraksha-The Indian Covid-19 Vaccine Development Mission" which is aimed at accelerating indigenous Covid 19 vaccine development efforts. The Committee hopes that the Mission is successful in developing more indigenous vaccines that are affordable and easily accessible. The success of the Mission can break the barrier of shortage in vaccine supply, thus ensuring vaccines for all and promoting vaccine equity across the world.**

**5.7 The Committee is of the firm opinion that India should ensure adequate availability of vaccines in the country alongwith expanding its collaboration with other countries under "Vaccine Maitree". The Committee believes that India's vaccine diplomacy would promote vaccine equity i.e. global equitable vaccine distribution among the less developed Asian, African and Latin American countries.**

#### **Ministry of AYUSH**

(i) Ministry of AYUSH requested all States/UTs to provide pro-active support to the respective Health Department at the State and District for the following activities for mitigating the impact of this pandemic-

- (a) Identification of HQWC (Health Care Workers) with AYUSH.
- (b) Provide vaccinators, legally authorized to give injections and other team members.
- (c) Use their platforms for dissemination of IEC.

(ii) It was suggested by the Ministry that trained AYUSH Health Workers should also be considered as vaccinators so that vaccination may be expeditiously implemented throughout the country.

**5.8 The Committee understands the piloted role of Ministry of Ayush in National Covid-19 vaccination programme as the Ministry provided pool of Healthcare workers as vaccinator. The Committee recommends that the Ayush institutional structure must be massively utilised as platform for dissemination of IEC activities, thus enhancing public awareness for mitigation of Covid-19.**

## **DEPARTMENT OF PHARMACEUTICALS, MINISTRY OF CHEMICALS & FERTILIZERS**

5.9 The Secretary, Department of Pharmaceuticals as a member of larger group of NEGVAC chairs the Sub Group-II with members from Ministry of Health & Family Welfare, which is mandated to look into the effective co-ordination of logistic aspects of COVID Vaccination. The sub-group provides support to the Ministry of Health & Family Welfare (MoHFW) to plan the logistics and distribution of the vaccine. The procurement of the vaccine, syringes and consumable, augmentation of cold chain and implementation of the vaccination programme including distribution of vaccines was being done by the Ministry of Health & Family Welfare.

**5.10 The Committee recommends the Government to lay special emphasis on the strengthening of the end-to-end vaccine supply chain and logistics systems. The Ministry of Health and Family Welfare in coordination with the States must ensure strengthening of the cold-chain infrastructure and fair distribution of the vaccines to all the States/UTs.**

## **MINISTRY OF PANCHAYATI RAJ**

5.11 The Ministry of Panchayati Raj has been undertaking various IEC activities by writing regular letters to States/UTs issuing several advisories and creating awareness to curb the spread of Corona virus. Ministry issued letter along with a shareable Google Drive link containing IEC materials provided by Ministry of Health & Family Welfare for COVID-19 Vaccination Programme.

5.12 Further, the Ministry undertook various other activities related to Covid-19 mitigation including:-

- (i) circulation of the Google Drive link through WhatsApp Groups,
- (ii) sending Bulk SMSs to about 2.34 lakh Gram Panchayats registered on the GPDP portal of the Ministry,
- (iii) allotting a dedicated section on the Website for all the Covid-19 related activities,
- (iv) creating awareness through Social Media.

**5.13 Taking into account the Urban-Rural vaccination gap, the Committee is of the view that the existing infrastructure of Panchayati Raj can be optimally reckoned for dissemination of IEC for creating public awareness regarding the benefits of vaccine.**

**5.14 The Committee, in this regard recommends that the Panchayati Raj Institutional arrangement and grass root local bodies must be massively utilized for mass rural vaccination. The Ministry must also utilize the State machinery to increase the uptake of the precautionary dose in the rural areas.**

## **STUDY VISIT TO JAMMU AND KASHMIR AND CHANDIGARH**

### **Views received from UT of J&K**

5.15 The UT of J&K submitted that under National Health Mission, Ministry of Health & Family Welfare, Government of India released Rs.230.11 crores for management of COVID-19 during the financial year 2019-20 & 2020-21, which included Rs.5.84 crore for operation cost of COVID vaccination:

- (i) During the financial year 2019-20, COVID funds were released on the funding pattern of 90:10 ratio.
- (ii) During the financial year 2020-21, Emergency COVID Response Plan (ECRP) part-1 was fully funded by MOHFW, Government of India (World Bank)

5.16 The Government of UT of J&K was providing free vaccination to all people in age group of 18 and above. For this the Government had adopted the IEC mechanism through print and electronic media and use of influencers of the civil society. Moreover, session sites were also being increased keeping in view the response of the people. Also, the Directorate of Family Welfare, J&K vigorously conducted the special camps for vaccination of people who lacked ID cards, homeless people and those living in shelters, children in institutional care, prison/open jail/people under BPL and people with disabilities. (Directorate of FW&I)

5.17 No incidence of side-effects or acute illness among the vaccine receivers was reported after the vaccination shot in the Union Territory. A proper monitoring mechanism was functioning in the UT and as per the guidelines of the Ministry of Health & Family Welfare, Government of India from time to time the J&K Government had constituted the Adverse Events Following Immunization (AEFI) Committees at the UT Level, District Level and Block Level for proper monitoring and management. (Directorate of FW&I)

5.18 1600 vaccination centers were established in the UT. All these centers were equipped with the required technical staff and health care workers. The UT conducted special training program for the healthcare workers for conducting the vaccination drive. No shortfall of healthcare workforce was faced. Outreach sessions were conducted by the UT for ensuring that the vaccination drive reached the remotest parts of the UT. The efforts were ongoing in all the districts and helped achieve better coverage.

**5.19 The Committee hopes that the UT of J&K would achieve the set target under its vaccination drive through coveted IEC mechanism. The Ministry of Health and Family Welfare must monitor and guide the UT for effective management of covid cases in the UT of J&K.**

### **VIEWS OF THE STATE GOVERNMENT OF HARYANA ON THE SUBJECT**

5.20 The State Government of Haryana submitted that as on 8<sup>th</sup> September, 2021, the coverage of Vaccination was 182979 and the cumulative coverage of Vaccination was 17591336. The Vaccination Status as on 8th September, 2021 was as under:

(source-Co-WIN Portal)

Category	Dose 1 <sup>st</sup>	Dose 2 <sup>nd</sup>	Total (1 <sup>st</sup> & 2 <sup>nd</sup> Dose)
HCW	251,288	232,260	483,548
FLW	251,036	225,258	476,294
60 years & above	2,232,018	1,306,669	3,538,687
45≤ 60 years	2,913,115	1,418,237	4,331,352
18-44 years	7,396,707	1,364,748	8,761,455
Total Vaccination	13,044,164	4,547,172	17,591,336
<b>Total</b>	<b>17,591,336</b>		

5.21 The State Government of Haryana further submitted that as on 8th September 2021, there were 68 Dedicated Covid Hospital (DCH), 579 Dedicated Covid Health Centre (DCHC), 505 Dedicated Covid Care Centre (DCCC) leading to a total of 1152 Covid Facilities in the State. The total Covid Hospital and Beds at a Glance (upto 8th September, 2021 ) Haryana was as under:

*COVID-19 Facility (data source-S3 portal)*

Availability of Beds (Data Source-NHM Portal)	Total	Occupied	Available
Type of Beds			
Non-Oxygen Beds	13668	17(0.12%)	13651(99.88%)
Oxygen Beds (other than ICU)	13787	130(0.94%)	13657(99.06%)
Oxygen Beds (ICU)	3571	261(7.31%)	3310(92.69%)
Ventilators	1590	40(2.52%)	1550(97.48%)

5.22 The State Government submitted that the Government of India had sanctioned an amount of Rs.304 cr. for COVID-19 vaccination for Health care workers and Front Line Workers. This budget had been utilized by Districts and the State for COVID vaccination activities. From 1<sup>st</sup> May, 2021, under the Liberalized policy, the State Government had procured COVID vaccine for Rs.47.9 crore. Later, GOI decided to provide vaccine free of cost to the State.

5.23 Haryana had adopted all SOPs and guidelines given by Ministry of Health & Family Welfare, Government of India from time to time to implement successful vaccination drive in the State. Accountability and review mechanisms were established at all levels chaired by CS, ACS Health, MD NHM and DCs at district level. Cascade training from program managers to vaccinators were conducted and regular orientations done from time to time. Dry runs were carried out across the state for smooth roll out of campaign. The State also submitted that initially vaccine hesitancy was encountered but was addressed through advocacy, IPC, IEC and involvement of different stakeholders.

5.24 The State Government further submitted that a total of 1058 Adverse Events Following Immunization (AEFIs) have been reported out of which 1021 are minor events and only 15 were severe and 22 serious. The State revamped AEFI committees for investigations and classification of AEFIs related to COVID vaccination as per directions from Government of India. The State Government also submitted that every CVC is equipped with AEFI Kit to manage AEFI cases and were linked with AEFI management centers for further management. All AEFIs were uploaded on SafeVac/CoWIN Portal. Total No of CVCs in Haryana (CoWIN) was 9833. The Centres where vaccination was being done were equipped with technical staff and Health care workers, as per Government of India guidelines. Special training for COVID-19 vaccination had been given to all Health care workers in cascade manner as per training aids provided by Government of India. Line departments e.g. WCD/Education department/ PRI/SHG etc. were looped in besides ASHAs and AWWs for support in vaccination drive.

5.25 It was ensured that sessions were held aiming to cover all population groups and geographical areas. Also special Near-to-Home sessions were being conducted in remote parts to reach all beneficiaries. Special sessions were also planned to cover homeless population, prison inmates, specially-abled, etc. State was doing vaccination of vulnerable groups through conducting Near to Home CVCs.

5.26 The State Government of Haryana further submitted that the funds received from Government of India were utilised for diagnostics, drugs & supplies, temporary HR, mobility support, etc. State would like to continue the assistance from Central Government.

**5.27 The Committee is of the view that the Ministry of Health and Family Welfare must ensure that appropriate accountability and review mechanisms are established in each State and adequate training is provided for ensuring smooth roll out of the vaccination drive. The Committee further recommends the use of Information Education and Communication (IEC), Interpersonal communication (IPC) strategies to generate awareness among the community to counter vaccine hesitancy in the States.**

**5.28 The Committee, in this regard, commends the role of Government of Haryana for conducting special sessions to cover homeless population, prison inmates, specially-abled, etc. The Committee recommends the Ministry to ensure that the vulnerable and marginalized groups are not excluded from the vaccination drive.**

**View of the UT of Chandigarh:**

5.29 The UT of Chandigarh submitted that the Covid vaccination Centers in the UT of Chandigarh are as follows:

S.No.	Facility Type	Number of vaccination Center
1.	Government	46
2.	Private	10
3.	Mobile Van	*15
	Total	71

\* 15 CVCs functional through mobile ambulances at different locations in the city.

5.30 4 Mobile CVCs established in A.C. CTU buses visiting all areas/sectors of UT Chandigarh along with provision of ambulances for safety, NGOs were also involved for funding the volunteers for Door to Door Vaccination cum Survey.

5.31 All residential welfare association, Market Committees, NGOs, Management committees of various Temples, Gurudwaras & Mosques were involved and the vaccination camps were conducted at their respective premises.

5.32 The UT further submitted that all HWCs/Hospitals/other Govt. facilities were developed as COVID Vaccination centers. All members of Vaccination Teams trained and regular sensitization and updating of vaccination team members was done by WHO & UNDP as per GOI Guidelines and SOPs. Additional vaccinators/verifiers were also engaged on daily basis.

5.33 Meetings were regularly held with Anganwadi Supervisors and workers to mobilize residents for Vaccination. COVID Vaccination for lactating and pregnant women was being carried out.

5.34 To make Vaccination Drive successful in the State, all CVCs were kept open even during Sundays and Gazetted Holidays. For door to door campaign, microplans were made by medical officer incharges and teams were constituted for providing vaccination services on Pulse Polio Pattern with provision of A/C Vaccination buses at their doorstep. Schools, Colleges, tourist places were also covered in coordination with their management by Mobile Vaccination Teams along with provision of ambulances for safety. Resident welfare associations, Market Committees, NGOs, Management committees of various Temples, Gurudwaras & Mosques involved and the vaccination camps were conducted at their respective premises. Special vaccination camps were arranged for disabled, elderly, bed ridden beneficiaries and people without I.D. proof. Arranged special COVID vaccination camp in Model Jail. Special Vaccination camps at SAMARTH, ASHRIYA, SOREM, Chandigarh Spinal Rehabilitation Center and Missionary of Charity were also organised.

#### COVID Vaccination status as on 7<sup>th</sup> September, 2021

Sr. No.	Category	Target	1 <sup>st</sup> Dose (Actuals)	2 <sup>nd</sup> Dose (Actuals)
1	Above 18 years	7,29,822	8,35,465 (114.48%)	3,37,152 (46.20%)
2	45 to 59 years	1,73,178	1,82,204 (105.21%)	1,07,936 (62.33%)
3	Above 60 years	98,959	1,00,463 (101.52%)	74,896 (75.68%)
4	HCWs	26,237	27,032(103.03%)	22,951 (87.48%)
5	FLWs	22,428	48,350 (215.58%)	64,903 (289.38%)

Covishield Vaccine Wastage: (-2.22%)

AEFI Cases Reported- COVID Vaccination as per CoWIN

Total Vaccination Administered	AEFI cases reported	% AEFI cases reported
11,72,616	217	0.018%

#### COVISHIELD Vaccine Stock Details as on 7<sup>th</sup> September, 2021

Sr. No.	Covishield Vaccine received till date	Doses	Available stock Govt. Facilities	Available stock Private Facilities
1	12,27,200		1,01,050	26,720



### Schedule of vaccine supplies for September, 2021

Date	Covishield Doses
16.09.2021	98600
26.09.2021	98610
<b>Total</b>	<b>197210</b>

### Allocation for September, 2021

Facility Type	Government	Private	Total
Allocated	295810	39440	335250
Received	98600	0	98600
Remaining	197210	39440	236650

**5.35 The Committee appreciates the involvement of residential welfare association, Market Committees, NGOs, Management committees of various Temples, Gurudwaras & Mosques in the National Covid-19 vaccination programme to ensure the success of the vaccination drive in the UT of Chandigarh. The Committee recommends the other State Governments to follow suite and also conduct special vaccination campaign for elderly, differently-abled persons, bed-ridden beneficiaries and people without any identification Card.**

### STUDY VISIT TO GUWAHATI, BENGALURU AND MUMBAI

#### Views of the State Government of Assam

5.36 With regard to Covid-19 Vaccination, the State Government of Assam submitted that a total of 4,45,34,576 doses of Covid vaccinations were administered in the State till 24<sup>th</sup> April, 2022 with 2,38,67,271 1<sup>st</sup> dose; 2,03,16,251 2<sup>nd</sup> dose and 3,51,054 precaution dose with Government of India supply of vaccines. State Government also procured vaccines for Rs. 45.17 Cr in the initial phase. A massive "Har Ghar Dastak" programme to achieve 100% vaccination was undertaken in the month of November/December, 2021, across the state.

5.37 With regards to Covid-19 Management, the State Government submitted that under the continuous guidance of Government of India, Covid-19 was managed with 3Ts (Testing, Tracking and Treatment) and strict Covid appropriate behavior. A total of 2.83 Crore Covid tests had been done and 7,24,204 Covid positive cases had been recorded in the State till 24<sup>th</sup> April, 2022. 7,16,212 patients had already recovered/discharged showing recovery rate of 98.90%.

5.38 The State Government further submitted that infrastructure facilities including Oxygen supported beds increased tremendously with the help of 1000 PM Care Ventilators, 5145 numbers of Oxygen Concentrators and 7244 Oxygen Cylinders received from Government of India. Total 40 Oxygen Generation Plants sanctioned under PMCARES Fund have been commissioned with a total output of 63.40 MT/day. In addition, 47 CSR and government funded PSA plants were established in all Districts and Medical Colleges.

5.39 The State Government further submitted that the production of Medical Oxygen was increased to 188.61 MT/day and storage capacity of liquid medical oxygen to 755.37 MT to meet the demand in case of future waves. Covid Drug Kit containing basic drugs like

Paracetamol, Cough Syrup, Gurgle, Vit D3, Vit C, Zinc for home isolation patients were provided free of cost. Remdesivir and Tocilizumab were made available even in private hospitals at subsidized price. A total of 2726 numbers of families benefitted under CM's Prarthana, SishuSeva and Covid-19 Widow support, scheme initiated by Government of Assam. A total of 5734 no. of beneficiaries received assistance from Ex-Gratia Assistance Scheme Under State Disaster Relief fund (Rs. 50,000).

5.40 The State Government further submitted that the Government of India provided financial assistance of Rs. 221 Cr. under ECRP-1 and Rs. 812 Cr. under ECRP-II for strengthening ICUs/Oxygen beds for Covid treatment, procurement of protective materials like PPE Kits, N95 Masks, Hand sanitizers and essential medicines for Covid management.

**5.41 The Committee emphasizes on the need of expanding "Har Ghar Dastak" Programme across the country. The Committee further desires that other State Governments must follow the Covid-19 mitigation strategy of the Government of Assam where funds raised under Corporate Social Responsibility have been utilized to strengthen the public health infrastructure in the State that is being optionally utilized in Vaccination drive in the State.**

#### **VIEWS OF THE STATE GOVERNMENT OF MANIPUR ON THE SUBJECT DURING THE STUDY VISIT OF COMMITTEE TO GUWAHATI**

5.42 The State Government of Manipur submitted that it was receiving Covid-19 vaccines such as Covishield, Covaxin and CorbeVax from Government of India through GMSD Kolkata. GMSD Kolkata issued Covid-19 vaccines to State Vaccine Store Imphal since the beginning of the Covid-19 vaccination drive in the State. There was one State Vaccine Store (SVS) at state level, 16 District Vaccine Stores (DVS) at district level and 114 Cold Chain Point (DDP) below district level where vaccines were used to store at the recommended temperature (+2 C to +8 C) ensuring the safety of vaccines. State Vaccine Store (SVS) issues Covid-19 vaccines to District level Stores (DVS) as per district requisition and indent they put up to SVS. Further, DVS is issuing vaccines to the Cold Chain Points as per indent the In-charge of the health Facility/Cold Chain Point puts up to DVS. In this way, Cold Chain Points distribute Covid-19 vaccines to all planned vaccination sites. In brief, vaccine distribution system from State Vaccine Store to the last beneficiary was done in such a manner that there would be adequate availability of vaccine stock, ensuring that there was no shortage of vaccine stock at all vaccine stores. Vaccines received from GMSD Kolkata were being stored at State Vaccine Store (SVS). In brief, Covid-19 vaccines distribution was done in the following manner:

- 1- Vaccines were rationally distributed from SVS to the districts as per indent put by the DIO of the respective districts.
- 2- It was further distributed from district level vaccine store (DVS) to the respective district Cold Chain Points below the district level.
- 3- From Vaccine Cold Chain Points, it was issued to the designated Covid-19 vaccination sites. It might be at health facilities, community hall and any other out-reach session sites which were designated for the same.
- 4- Maintaining vaccine cold chain system at all level till the last beneficiary was the backbone of vaccine distribution system. Vaccines were stored at the recommended temperature i.e. +2 C to +8 C at all vaccine stores ensuring the same till the last beneficiary in order to maintain the vaccine potency and its efficacy.

- 5- Vaccine distribution system/flow was from SVS to DVS, DVS to CCP, finally from CCP to the covid-19 vaccination sites.
- 6- Electronic Vaccine Intelligence Network (eVIN) rolled out in 2016 in the state, an initiative of MOHFW, Government of India on vaccine logistic management, has been a key role in vaccine distribution system, real time monitoring of vaccine flow, vaccine stock management, cold chain management and temperature of vaccine. eVIN aims to support the Government of India's Universal Immunization Programme by providing real-time information on vaccine stocks and flows, and storage temperatures across all cold chain points in Manipur.

**5.43 The Committee appreciates the utilization of eVIN in the State of Manipur, however, the Committee notes that collection of real time information may be difficult in many geographically tough terrain of the State thereby necessitating further improvement in Vaccine logistic management. The Committee, further recommends the State to ensure that vaccine centres and cold chain points are well integrated in the eVIN.**

#### **VIEWS OF THE STATE GOVERNMENT OF ARUNACHAL PRADESH ON THE SUBJECT DURING THE STUDY VISIT OF THE COMMITTEE TO GUWAHATI**

5.44 The State Government of Arunachal Pradesh submitted that the Covid-19 vaccine was transported from GMSD Kolkata to Lilabari Airport through air service. Vaccine van collected the vaccine from the airport and it was transported to State Vaccine Store naharlagun by road. The vaccine from SVS was transported similarly through vaccine van in all district vaccine store (DVS) as per target beneficiary and consumption pattern. Finally the vaccine was collected by each planning unit from DVs for administration at the COVID vaccination centres or CVC linked outreach session. Throughout these processes, the vaccine was maintained at proper cold chain system (2-8 degree Celsius). The stock of Covid-19 vaccines is maintained online through eVIN (Electronic Vaccine Intelligence Network) platform. Through this application, the vaccine stock and consumption could be checked on real time.

5.45 The State Government further submitted that for CVC linked outreach session, Alternate Vaccine Delivery (AVD) mechanism was followed for transporting vaccine from cold chain point to session site. Following completion of vaccination session, the vaccines were transported back to the cold chain point through AVD mechanism. The Covid vaccine was provided in 353 notified Covid vaccinations Centre (CVCs) in Arunachal Pradesh from Monday to Sunday.

5.46 As per availability of Covid-19 vaccine at SVS and based on the requirement (calculated as per consumption pattern) at the district, the vaccine was allocated to the district periodically. A distribution plan for all districts was prepared, so that the districts were able to collect the vaccine in shortest possible time and route. Concept of first expiry first out (FEFO) was followed, wherein the vaccines vial with early expiry were used first, to avoid any wastage of vaccine due to expiry. Also, since the Covid vaccine was a multi dose vial, in order to avoid vaccine wastage, the beneficiaries were mobilized for minimum usage of doses from each vial. In many instances inter-district and intra-district re-allocation of Covid-19 were done by which the vaccine from excess stock cold chain points were shifted to cold chain point having better consumption pattern.

5.47 The State also submitted that the Covid-19 vaccine for Defence was also allocated to each district in a similar process as per the target beneficiaries shared by the Ministry. The

Nodal Officer of AFMS in each district collected the vaccine from the DVS and the vaccine was administered to the beneficiaries at the respective Defence Health Unit premises.

5.48 In times of excess stock of vaccine with short expiry, the State intimated MoHFW, Government of India for shifting of vaccine to neighbouring state also for early consumption. For maximum consumption of Covid-19 vaccine various strategies such as circle saturation strategy, Tika Mahotsav, Azadi Ka Amrit Mahotsav, Har Ghar Dastak and Har School Dastak were opted and ongoing for augmenting the 1<sup>st</sup> dose and 2<sup>nd</sup> dose coverage. As on 24<sup>th</sup> April, 2022, the 1<sup>st</sup> dose and 2<sup>nd</sup> dose coverage of 18 years & above in Arunachal Pradesh was 83% and 71% respectively.

**5.49 The Committee takes note of the CVC linked outreach session, Alternate Vaccine Delivery mechanism being followed in the State of Arunachal Pradesh for transporting vaccine. The Committee strongly recommends the State Government to ensure the last mile delivery of vaccines especially in the remotest area of the State. The Committee appreciates the use of First Expiry First Out (FEFO) concept in the State where vaccine vials with early expiry are used first. However, the Committee recommends the State Government to ensure that the temperature of the vaccines are maintained accurately and avoid any wastage of vaccine. The Committee further recommends the Ministry to ensure that FEFO is followed in all the States so that vaccine vials are not wasted due to expiry of the vaccines.**

#### **VIEWS OF THE STATE GOVERNMENT OF KARNATAKA**

5.50 The State submitted that Government of India ensures availability of COVID-19 vaccines for the State. The State further bears the responsibility of distribution to be transparent & equitable. This process needs to be less time consuming i.e effective and efficient at the same time. There is also a need to ensure proper preparedness of the supply chain system to enable accurate estimations and calculations of storage space, ensuring functional status of all cold chain equipment's.

#### **Vaccine procurement policy**

- i. Since the Government of India launched COVID vaccination drive on Jan 16, 2021, all states including Karnataka were supplied vaccines (COVISHIELD and COVAXIN) free of cost for the vaccination of health care workers and followed by front line workers.
- ii. From 1st April 2021 started vaccination for all the beneficiaries above 45 years. Private facilities conducting vaccination were mandated to deposit Rs.150 per dose per person as vaccine cost to Government of India.
- iii. Till 1<sup>st</sup> May, 2021. Government of India was supplying vaccines to conduct vaccination for the beneficiaries above 45 years free of cost at Government CVCs and to private CVCs at Rs. 250/- (including services charges)
- iv. From 1<sup>st</sup> May, 2021, Government of India opened up vaccination for 18-44 years and changed the vaccination policy. As per this policy, the 25% of the manufactured vaccines were to be procured by State to vaccinate beneficiaries in the age group of 18-44 years and 25% to be procured by private institutions.
- v. However, Government of India continued to supply free vaccines to the States to vaccinate eligible beneficiaries above 45 years free of cost at Govt. CVCS.
- vi. Later, from 21<sup>st</sup> June, 2021 Government of India revised the vaccination policy, 75% of the produced vaccines would be supplied to State for the vaccination of all the eligible beneficiaries above 18 years free of cost at Government CVCS. However, Private CVCS would continue to procure 25% of the manufactured vaccines

- vii. Government of India made provision to raise the indent on CoWIN portal, to be activated in due course. Payment would be done through NHA portal. Vaccines would be allocated to districts and districts would distribute the vaccines to private hospitals based on the indent raised.

## **VIEWS OF THE STATE GOVERNMENT OF MAHARASHTRA**

5.51 The State Government submitted that it implemented the recommendations made by NEGVAC communicated by GOI for successful implementations of Vaccination Programme. For monitoring the implementation of vaccination programme as per Specific, Measureable, Achievable, Relevant and Time Bound (SMART) Principle objectively, various levels task force committees were formed at State, Region, District/City & Block level. Regular review by these committees was taken and also feedback and corrective measures were suggested for successful implementation and for improvement in the vaccination coverage. Microanalysis of vaccination data was done to identify areas of low coverage if any, reasons were identified and corrective steps taken

5.52 The State of Maharashtra has one State Vaccine Store; 8 Regional Vaccine Store; 34 District Vaccine Stores and 27 Corporation Vaccine Store & more than 3000 peripheral cold chain points. There were 24 Walk in coolers & more than 5000 Ice Lined Refrigerator in the States to store Covid vaccine & also there were 3 refrigerated vaccine vans, 44 insulated vans to transport vaccine from one store to another. Hence State had enough capacity to store vaccine at various levels. On the day of receipt of vaccine from GOI at State level, all regional level vaccine vans were called on the same day and time. Same protocol was used at district and regional level for faster transport of vaccines to all cold chain points. Additional fuel grants were distributed for transportation of Covid vaccines.

5.53 State Government further submitted that it had imparted training to programme managers, District immunization officers through virtual training platform. Update on new knowledge were given on time to time as and when received from GOI also detailed written guidelines were given. For immediate implementation of programme guidelines and to achieve faster vaccination coverage immediate time bound training and feedback mechanism through review Video Conferencing / virtual online meeting was necessary.

5.54 All Covid vaccination related trainings and updates were imparted to all programme managers in a time bound manner. Vaccine distribution was done through meticulous planning and prioritization of areas based on number of beneficiaries remaining for 1st & 2nd dose, number of active Covid cases, balance stock available, special situations (floods, festivals etc.). All minor and major AEFIs were meticulously tracked and managed on time to gain public confidence in vaccination. Community awareness and demand generation was done through effective IEC, various social media platform and media briefing. To counteract various myths misconceptions & rumours spreading on WhatsApp, social media platforms were utilized in a big way. Vaccination coverage was monitored through regular analysis of coverage data on coverage of 1<sup>st</sup> & 2<sup>nd</sup> dose, due beneficiaries etc. Accordingly based on analytical reports frequent review VCs were taken, feedback letters & telephonic follow up was done. Vaccine wastage based on COWIN Report was monitored similar to vaccination coverage.

**5.55 The Committee commends the role of the State Government of Maharashtra where the Pandemic Covid-19 has shown heinous expression resulting into large number of deaths, however, the SMART (Specific, Measureable, Achievable, Relevant and Time Bound) monitoring of the implementation of vaccination programme led to effective**

**management of the Pandemic. The Committee appreciates the vaccine distribution plan of Government of Maharashtra which was formulated through meticulous planning and prioritization of areas based on consideration of the number of active Covid cases and micro analysis of vaccination data. The committee further applauds the specific strategy for Covid-19 Management in 'Dharavi' -Asia's largest slum area in Mumbai. The Committee recommends the Ministry to undertake case study of 'Dharavi' Model of Covid Management to arrive at the managerial skill, planning & strategic course of action for combating any possible pandemic in the country.**

## **VIEWS OF THE OTHER STATES/UTS ON THE SUBJECT**

### **VIEWS OF THE UNION TERRITORY OF LADAKH**

5.56 Vaccination Distribution Management: In UT of Ladakh, Covid-19 vaccine distribution was done according to the SOP's conveyed by MOHFW. In UT of Ladakh, 216 covid vaccination centres were established. These centres were established at all the block head quarter and sub-centres, as per requirement of local population which was scattered across vast geographical area. The block wise list of beneficiaries was submitted to Districts and based on these lists, the vaccines were released to the blocks for further distribution to the vaccination canters. The cold chain requirement and maintenance was strictly followed as per guidelines in this regard. It is pertinent to mention here that the wastage factor for Covid-19 vaccine was below 1% in UT of Ladakh. Also, UT of Ladakh never faced any shortage of vaccine doses since the launch of Covid-19 vaccination.

5.57 In respect of strategy for Mitigation of Pandemic, following steps were taken by UT Administration:

- i). Screening of travellers at all entry points into Ladakh: UT Administration established Covid-19 check posts at all entry points, both for road and air travellers. The screening was done as per protocols published time to time by the State and District Disaster Management Authorities.
- ii). Contact tracing & isolation of Covid-19 positive patients: The guidelines of ICMR for contact tracing were followed throughout the period of pandemic. The isolation of Covid-19 patients was done as per the guidelines issued from time to time.
- iii). Establishment of PSA oxygen plants across different health institutions: UT Administration installed 13 new PSA Oxygen plants since the beginning of pandemic at 10 different health institutions across Ladakh to tackle the pandemic. The details of Health Centres where new PSA oxygen plants were installed:
  1. SNM Hospital, Leh = 2500LPM (03 PSA Plants).
  2. COVID Dedicated Kargil = 2000 LPM (02 new PSA Plants).
  3. PHC Tangsti= 350 LPM(new PSA Plant).
  4. CHC Disket Nubra = 350 LPM(new PSA Plant).
  5. PHC Nyoma = 120 LPM(new PSA Plant).
  6. CHC Padum Zaskar = 100LPM(new PSA Plant).

7. CHC Drass = 100 LPM(new PSA Plant).
  8. CHC Chicktan = 250 LPM(new PSA Plant).
  9. PHC Khaltsi = 250 LPM(new PSA Plant).
  10. Maha Bodhi Hospital Leh=80 LPM(new PSA Plant).
- iv). Oxygen Cylinders and Concentrators: In addition, 634 numbers of Oxygen Concentrator and 2643 No. of mega oxygen cylinders were procured and distributed to various health institutes of the UT-Ladakh.
  - v). Establishment of additional ICU and Oxygen Beds in both District Hospitals: UT Administration established 90 bedded additional facilities in both District Hospitals. This additional facility included 10 bedded ICU for paediatric and 10 bedded ICU for Adults in each District hospitals.

## **VIEWS OF THE STATE GOVERNMENT OF MEGHALAYA**

5.58 The Government of Meghalaya along with the rest of India launched the Covid vaccination drive on the 16th of January 2021 in all the 11 districts simultaneously.

5.59 Meghalaya was using Covishield vaccine which provided by Govt. of India free of cost. Vaccines reach the State Vaccine Store from the GMSD Kolkatta. From the SVS it is distributed to the various District Vaccine Stores following which it was distributed to the last Cold Chain Points. Distribution of the vaccines was based on the microplans and due list of the beneficiaries of each district. Electronic Vaccine Intelligence Network (eVIN) helped in monitoring and planning for distribution to the districts

5.60 The State took care for Maintenance of Covid Appropriate Behaviours (CAB). It was mandatory to produce Final Vaccination Certificate or negative RTPCR Test Report within 72 hrs for entry into the State. Vaccination of eligible beneficiaries commenced since 16<sup>th</sup> January 2021 and it was ongoing . Vaccination Status of the shopkeepers and their staff displayed in all the shops.

5.61 The State had 1084 total Covid beds out of that beds with oxygen were 942, ICU beds were 142 and there were 14 Oxygen Plants. Awareness activities on Covid-19, Covid appropriate behaviours (CAB) and vaccination were also going on through various Platform.

**5.62 The Committee appreciates the steps taken by the State Government of Meghalaya for ensuring the vaccination Status of the shopkeepers and their staff that are being displayed in all the shops. The Committee further recommends the State to ensure that the information regarding vaccine availability and other logistics are reflected on a real time basis for better vaccine distribution and management in the State.**

## **VIEWS OF THE STATE GOVERNMENT OF WEST BENGAL**

5.63 The State of West Bengal successfully implemented the Covid vaccination programme from the initiation of vaccination drive on 16<sup>th</sup> Jan, 2021. Since inception of the COVID vaccination programme, the State focussed on the timely receipt, distribution, security and optimal utilization of the vaccine. State also laid guidelines for successfully managing all the

Adverse Events Following Immunization (AEFIs). Detailed planning, strong cold chain system and robust security measures have led to the successful and unhindered supply of vaccines and eventual vaccination in the remotest parts of the State.

5.64 Regarding 'vaccine development, distribution management and mitigation of pandemic Covid-19', the State felt that Ministry of Health & Family Welfare should ensure timely supply of vaccine to have full vaccinations of all. While distributing the supply, a buffer stock should be maintained for each state so that pace of vaccinations could be maintained.

5.65 There were many instances where the State or districts had sufficient vaccine stocks but syringes were in short supply. So, the allocations of vaccines and syringes should be duly harmonised for running a successful vaccination programme. COVID 19 pandemic has shown the importance of creating Public Health Infrastructure especially at PHC/HWC level. Ministry of Health & Family Welfare should ensure enough financial support both for physical infrastructure as well as human resource deployment.

**5.66 The Committee notes the submission of the State Government of West Bengal where instances of shortage in supply of syringes have been reported. The Committee, accordingly, recommends the Ministry of H&FW to work in tandem with the State Government and ensure that such instances are avoided for making the vaccination drive a success in the State. The Committee strongly recommends the State Government to manage the logistics of the vaccine distribution system and in case of shortage in supply of any related equipment timely communication to the Union Government should be ensured.**

#### **VIEWS OF THE STATE GOVERNMENT OF TAMIL NADU**

5.67 As per the instruction and Guidelines of Government of India, the Covid-19 Vaccination drive was initiated in the state of Tamil Nadu from 16.01.2021 and continues till now. Until 24.11.2021, 7,52,91,000 doses vaccine were received from Government of India and 6,74,66,158 beneficiaries vaccinated with both Covishield and Covaxin.

5.68 In the State of Tamil Nadu, one State vaccine Store, 10 Regional vaccine Stores, 46 District vaccine Stores and 2685 Cold Chain Points were available for storing and distribution of vaccine including Covid vaccines. The Government of India has also supplied 3,17,39,900 Auto-Disable (AD) Syringes to the State of Tamil Nadu and 3,18,60,900 AD Syringes were procured through Tamil Nadu Medical Service Corporation Limited (TNMSC), Chennai. The Covid vaccines and AD Syringes were received in State Vaccine Stores. From the State Vaccine Store, the vaccines and Syringes were distributed to Regional Vaccine Stores. From Regional vaccine Stores, the vaccines and Syringes were distributed to District Vaccine Store. The District Vaccine Store distributed vaccines to the cold chain points through the Vaccine Carrier Vehicles on the next day morning for administering the same to the beneficiaries in the concerned districts immediately without any delay, so as to cover the eligible population as per Government of India guidelines.

#### **VIEWS OF UT OF ANDAMAN AND NICOBAR**

5.69 The UT submitted that vaccine helped in reducing the Covid cases and its fatality as also reduced the prognosis of diseases which lead to lower the number of bed occupancy in the hospital due to Covid. UT of A&N Islands saw 4994 number of positive cases and 62 deaths (data as on 16.11.2021). However, this UT did not report a single death due to Covid-19 who



were fully vaccinated against the virus. This shows the efficacy of the vaccine in mitigating the Covid-19 pandemic.

5.70 The supply chain of Covid-19 vaccine was also efficient by using Routine Immunization (RI) logistic management. Due to difficult topography of these Island, RI vaccine were sent to hard and remote areas to reach in advance and transportation support was taken from Civil Aviation Department, Department of Shipping and Defence, the same was adopted for Covid vaccine and logistic across these Islands. Accordingly to the UT, the present process of vaccine distribution and management was an infallible one and with introduction of IT based solutions like e-VIN and Co-WIN, information were received quickly by the decision makers for vaccine and vaccination management.

5.71 As the far flung and remote islands of this UT have poor network connectivity, live data entry was not possible and hence the UT requested that back log entry option or off-line mode of entry be permitted on the actual data of administration, so that the extent of vaccination coverage could be properly captured.

5.72 As on 21<sup>st</sup> November, 2021 of the 2.86 lakh eligible target beneficiaries in A&N Islands, 2.38 lakh beneficiaries accounting for 83.2% of target beneficiaries were administered with 2<sup>nd</sup> dose of Covid vaccine/fully immunized. This UT achieved 100% coverage of 1<sup>st</sup> dose of Covid-19 vaccination of eligible target beneficiaries on 19.09.2021.

**5.73 The Committee understands that far flung and remote islands of the UT of Andaman & Nicobar have poor network connectivity and live data entry may be a herculean task. The Committee recommends the UT to ensure that the entries are logged as soon as the network connectivity is restored so that national data on the vaccination is compiled without delay.**

#### **VIEWS OF THE STATE GOVERNMENT OF MADHYA PRADESH**

5.74 The State of Madhya Pradesh's vaccine storage and supply status up to last mile with HR involvement is given below:

- Infrastructure:- The state has 4 State vaccine store and 3 Regional Vaccine store from which vaccine and syringes transfer to 51 district and then at 1244 Cold Chain Points to session site with proper monitoring and during the transportation no single vial was broken.
- Monitoring Software:- The State has three software for monitoring for Cold chain and Covid-19 vaccination namely NCCMIS, Evinae and Cowin application.
- Storage and maintenance:- State has 15 Walk in Cooler & 09 Walk in freezer at 4 SVS and 3RVS. 2,680 Ice Lined Refrigerator, 2,328 deep freezer, 95,860 Vaccine carrier and 5,617 cold boxes with CCP for the maintenance of these cold chain equipment's there is 51 cold chain technicians and daily follow-up taken by state team.
- Transportation:- In state there are 91 Vaccine van for transportation of vaccine and syringes timely at session site.
- Distribution:- MP state has 4 State vaccine store namely Bhopal, Indore, Gwalior & Jabalpur where vaccine were received from Government of India through direct supply from supplier or from GMSD and Distribution to 3 Regional Vaccine store namely, Sagar, Ujjain & Rewa. With proper monitoring, during the transportation of 8.5 crore doses of vaccine not a single vial was broken.

5.75 The State submitted that it followed the structure of STD (i.e. Storage, Distribution and Transportation) for smooth functioning of the vaccination programme. Best Practices in MP for Cold Chain and Vaccine management were as under:-

- Proper allocation of vaccine and syringes provided to the districts as per respective targets and monitoring from the State.
- Stock register, Cold Chain Equipment's register, Vaccine Arrival Report etc. maintained properly and up to date.
- All protocol displayed very well in all session site to motivate people for Covid-19 vaccination.
- On daily basis feedback was taken by the State controlling authority from district through Regional Joint Director and District Immunization Officer and if reported it would be resolved as soon as possible.
- Cold chain equipment have dedicated thermometers and have dedicated temperature log books which were updated. Monitoring of temperature from state level done through Temperature logger on daily basis.
- Ice Lined Refrigerator and deep freezer were placed as per specified guidelines of minimum gap of 10 cm and were also kept on the stands.
- Contingency storage plan was displayed in all stores.
- Dedicated stabilizers for Cold Chain Equipment's were placed at all stores.
- A chart showing vaccine stock positions of all vaccines was displayed in all stores.
- Before Covid-19 some district Cold Chain Technician post were vacant, these posts were also filled for on time and good maintenance of Cold Chain Equipment's.
- Office in charge system was introduced at State level for smooth monitoring of vaccination programme of every district of state.

*(Date Source:- NCCMIS, EVINae & Cowin application as of 17<sup>th</sup> Nov, 21.)*

**5.76 The Committee takes notes of the best practices adopted while implementing national Vaccination Programme in Madhya Pradesh especially for Cold Chain and vaccine management. The Committee recommends the adoption of the best practices during execution of Vaccination drive by other States too.**

#### **VIEWS OF THE UT OF DADRA & NAGAR HAVELI AND DAMAN & DIU**

5.77 With reference to the subject, the UT Administration of Dadra and Nagar Haveli and Daman and Diu submitted that it adopted all the measures in line with the guidelines of the Ministry of Health & Family Welfare, due to which, a sustained decline in the number of Covid cases was witnessed. Moreover, the UT achieved 6.63 lakh out of a total population of 5.88 Lakh which was 112% of the beneficiaries eligible for 1<sup>st</sup> dose, through robust screening of households by the Health staff.

5.78 Vaccination was being done through development of volunteers in addition to the Health Staff for a comprehensive coverage at all the Covid Vaccination Centres. In addition, Covid vaccination was done through 'Har Ghar Dastak campaign' through House hold visits and Mobile Vaccination Vans in line with the guidelines laid down by the Ministry of Health & Family Welfare. The UT received vaccine stock through GMSD Mumbai, with adequate and fast supply and no shortage.

5.79 UT Administration informed that there was mismatch in the population data of the Ministry, electoral data and UT survey data that were eligible for 1<sup>st</sup> dose. The resolution of the

said issue would be very helpful for UT Administration in reflecting the actual achievement figures of Vaccination Coverage in the UT.

**5.80 The Committee applauds the role of UT Government of Dadra and Nagar Haveli for vaccinating all eligible beneficiaries for 1<sup>st</sup> dose. However, the Committee recommends the Central Government to address the concerns of the UT of Dadra and Nagar Haveli and Daman & Diu by rectifying the total population of UT.**

## **VIEWS OF THE STATE GOVERNMENT OF TELANGANA**

5.81 The State submitted that as a part of prevention and control of the Covid-19 containment frame work and five - fold strategy of Test -Track-Vaccinate and adherence to Covid Appropriate Behaviour was being followed across the state as stated below:

- Testing: Covid-19 tests through 30 Government RTPCR testing centres and 1,231 Government Rapid antigen testing centres. In addition to government infrastructure 76 private RTPCR testing centres were also conducting Covid testing.
- Treatment: a dedicated 55,442 beds were allotted for treatment of the Covid-19 cases in Govt. and Pvt. Health facilities. Based on the estimation that Pediatric age group would be more susceptible to anticipated third wave, steps were taken to create 6000 Pediatric Covid Beds out of which 1,875 are ICU Beds, along with all the infrastructure and equipment required to manage the cases and reduce the case fatality to the maximum extent possible by providing timely and tertiary care treatment. All the infrastructure like portable ECG machines, infusion pump, syringe pumps, bubble CPAP machines, HFNC machine, portable USG with 3 probes including ECHO probes, paediatric High Frequency Oscillatory ventilators, paediatric ventilators with NIV mode with compressor, Oxygen Hoods, Open Radiant Warmers, Phototherapy Units, Air mattresses, Infrared Vein Finders, BIPAP Machines, 3 Para Multichannel monitors, 5 Para Multichannel monitors, Infrared Thermometers were made available in all the Hospitals. Essential drugs were kept with the hospitals and central medical stores of that particular districts like Steroids in injection and Tablet form, Inj. Remedesivir, Inj. Kiposomal Amphotericin, Tab. Posaconazole, Inj. Tocilizumab, Inj. Casirivimab and Imdevimab (Cocktail) treatment, Tab. Paracetamol, Tab. Vitamin C, Tab. Zinc, Tab. Vitamin D3, Tab Multivitamine.t.c.
- Screening: a special state initiative screening of the OPD at public health facilities for fever initiated on 6<sup>th</sup> May 2021 and distributed fever treatment kits with advise for home isolation. And also daily screening at schools and colleges was being conducted.
- Establishment of oxygen cylinders: 82 PSA plants were being established in the state of Telangana. 50 PSA plants were sanctioned under PM CARES and 32 under CSR donations.
- Training: Medical and Para-Medical staff of the designated hospitals were trained regarding management protocols of Covid cases. Online training was conducted to all the Covid hospital staff both (Doctors and paramedical) on the management of Pediatric Covid cases as a measure to minimize the morbidity and mortality if there was a surge in pediatric cases.

5.82 They further submitted that as a part of intervention based preventive measure, Covid-19 Vaccines - Covishield and Covaxin, approved by the CDSCO (Central Drugs Standard Control Organisation) was initiated across the State.

5.83 During the 2<sup>nd</sup> wave of Covid-19, considering the rise of the positive cases, population mobility and the availability of the vaccine, the state identified 44 vulnerable groups of people who were super spreaders and more susceptible to infection and vaccinated them in phased manner, resulted in coping up with the spread of virus in the areas of Greater Hyderabad Municipality Corporation, Urban local bodies and in Rural areas across the state.

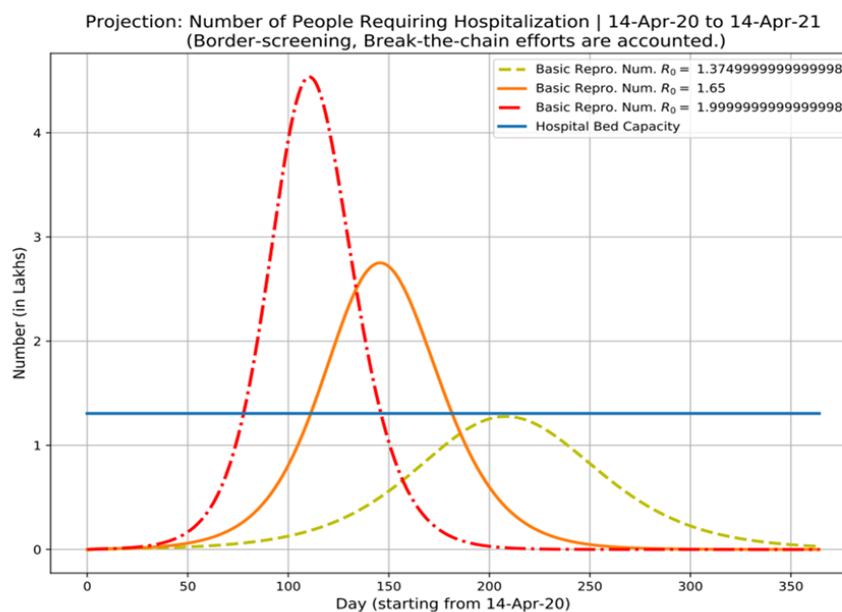
5.84 Covid -19 vaccination was ramped up in the state to maximize vaccination in all the villages and wards by establishing sub centre level vaccination teams. Over all 7920 teams were formed in the state to cover all the eligible beneficiaries at every village/ward area to boost 100% vaccination coverage. Vaccination was made available at every door step for the feasibility of the beneficiary. Teams visit every house to ensure all the eligible beneficiaries were vaccinated and there were no one left unvaccinated in the household.

5.85 Under the leadership of the District Collectors, coordination teams were formed with the line departments to monitor and mobilize the beneficiaries for getting vaccinated. Mobilization teams formed specially to mobilize the beneficiaries and to guide them to CVC for Vaccination. The CVC staff were trained to curb and manage and AEFIs at the session sites.

### CASE STUDY OF THE STATE OF KERALA

5.86 The Committee, in its meeting held on 5th April, 2022, heard the views of the representatives of Kerala Government. The Committee was given to understand that the experience of Nipah outbreak in 2018 and 2019 helped the Kerala Government in taking all the prevention activities against the Covid-19 pandemic. It was further brought to the notice of the Committee that at no point the health infrastructure was overwhelmed in Kerala. Managerial, Public Health and Clinical interventions were planned at the outset of the pandemic itself. PPE procurement was ordered in Sept 2019 and the guidelines were published and all activities were started in the 3rd week of Jan 2020. Subject specific Management units with specific roles and responsibilities were established. The State further submitted that the Principle adapted by the State Government was to flatten the curve and delay the peak.

#### Principle adapted – Flatten the curve and delay the peak



5.87 The representatives of the State Government further stated that irrespective of adverse situation, namely (i) Epidemiological vulnerability (high proportion morbidity due to NCD); (ii) Demographic vulnerability (proportion of elderly is double of national average) and (iii) High population density and urbanization (Population density is very high and is distributed all over the State), the State has been able to manage the pandemic. It was further submitted that there had been low transmission, high case detection, high testing rate (tests per million) and the mortality had been low (Case fatality rate 1.04%) in Kerala. Regarding the novel strategies adopted by the Government of Kerala to contain the impact of the pandemic, the State Government submitted that it followed the Hub and Spoke Model of Oxygen Management.

#### **Hub and Spoke Model of Oxygen Management**

- i. Oxygen audit was also done daily to monitor the Oxygen generation capacity and Oxygen consumption in the COVID hospitals.
- ii. All the hospitals under the Government and Private hospitals are mapped under a software.
- iii. Mapping includes the available storage capacity, inventory of oxygen available on a daily basis and daily consumption.
- iv. All the Liquid Medical Oxygen vendors and their daily production capacity and delivery is mapped in the same software.
- v. All dealers and sub dealers of oxygen cylinders were mapped with the hospital under the same portal.
- vi. The software also has provision to calculate the estimated requirement of oxygen based on the patients on oxygen support and ventilators.
- vii. Oxygen Monitoring team and war room constituted in the districts and also in the state level.
- viii. The oxygen cylinder and LMO demand of all the hospitals to be raised through the software were analysed with estimated projection arrived by the software by the district team and sanction were issued to the concerned oxygen distributors and dealers mapped against the hospital.
- ix. The LMO requirement of distributors were raised in the same software which would be sanctioned by the state level team to the manufacturer.

5.88 The representative further submitted that the State never had any shortage of hospital beds, oxygen, or essential medicines. In fact, the State shared some of the surplus oxygen with other states in need. This was due to meticulous planning in expanding the infrastructure facilities over the past year.

**5.89 The Committee applauds the proactive response of the State Government of Kerala in covid case management. The State was very efficient in minimizing the impact of the first wave of the pandemic and the State Health machinery was never stretched to its limits. Various State interventions were planned at the outset of the pandemic itself which helped the State to manage the pandemic efficiently. The robust Institutional arrangement and timely & effective measures further helped in delaying the peak.**

**5.90 The Committee appreciates the novel approaches adopted by the State Government of Kerala to manage the pandemic. The State Healthcare system did a commendable job to ensure that the covid cases are timely tracked and contained. The Committee takes notes that the State of Kerala had a robust monitoring system and a well planned infrastructure in the form of Domiciliary Care Centre, Covid first line treatment Centre, Covid second line treatment centre and Covid hospital. The Committee strongly feels that a strong**

**primary health care network along with trained grass root healthcare workers was crucial for containing the pandemic. The containment strategies and efficient planning adopted by the State helped the State in averting the medical emergency due to shortage of medical oxygen and beds in the hospitals. The Committee further acknowledges the hub and spoke model adopted by the State for efficient management of Oxygen in the State. The Committee notes that timely mapping of hospitals through software as done by the State of Kerala should have been adopted by the other States for better management of Oxygen across hospitals.**

**5.91 The Committee feels that the pandemic has given us the opportunity to plug the loopholes of the Indian Healthcare System and shifted the focus on the need of ushering change in the healthcare sector. The Committee observes that the State Government of Kerala adopted many novel approaches in its fight against the pandemic. The Committee strongly recommends the Ministry of Health and Family Welfare to study the Kerala Model and other novel approaches adopted by other States. The Committee recommends that the Ministry must co-ordinate and play pivotal role in exchanging of new ideas and new learning during the pandemic and related strategic management and ensure implementation of the successful models viz. the Kerala Model in other States and strengthen healthcare delivery system to meet any future medical emergency.**

## **VIEWS OF VARIOUS STAKEHOLDERS ON THE SUBJECT**

### **Ms. Gangadeep Kang**

5.92 About vaccine development, she stated that India's vaccine manufacturing companies started early to build collaborations and initiate planning for manufacturing vaccine. Notification in April/May 2020 stated that companies could manufacture vaccine as a critical first step in assuring companies that there was governmental urgency. The Government of India supported vaccine companies directly or indirectly (e.g. strain sharing by ICMR, facilitation of clinical trials by DBT/BIRAC and ICMR). Scale-up of manufacturing was more challenging than was anticipated, leading to shortages because of rapid expansion of eligibility for vaccine in the first half of 2021.

5.93 With regard to distribution management, she stated that the roll out of India's first wide age range vaccination campaign was generally done well, given the challenges. Initial mis-steps included rapid expansion of age ranges (should have covered a substantial proportion of the first target groups before expansion to younger age groups—specifically moving below 60 years should have been after at least half of more than 60 years had been covered). From over-reporting adverse events following immunization, moved rapidly to under-reporting and poor quality data collection, which persists. Pregnant women were not included in risk groups at an early stage, partially leading to establishment of vaccine hesitancy. Impact of COVID19 vaccine roll-out on other healthcare is needed for future planning

5.94 Regarding Mitigation of COVID-19, Ms. Kang stated that shortages of personal protective equipment, diagnostic testing, drugs, vaccines and oxygen and documented-solutions were ultimately found, but some delays/shortages were avoidable. Lack of any data on effectiveness of any intervention (e.g. lock down, drugs such as hydroxychloroquine, level of permissible crowding indoors and outdoors could have been generated) so several interventions were either inappropriate or prolonged beyond utility. Cowin was not linked to testing database despite advice from beginning of roll out, which led to lack of data on need for boosters

5.95 She stated that India was in a good position at present, but future variants are inevitable and unpredictable. Preparedness of vaccination strategies requires much more clinical research than is currently being done, as well as a focus on new vaccine candidate development and evaluation. Distribution management (if not impacting other existing activities) has the potential to deliver other future health related programmes at scale (e.g. screening, other vaccines). COVID-19 mitigation is not over, revision of surveillance, and rapid response care strategies is needed as well as building inter-operable data systems.

### **Jan Swasthya Abhiyan (JSA)**

- JSA submitted that as of January 30, 2022, India reported at least 70,102 cases of Adverse Events Following Immunization (AEFI), and **1,013 fatalities following COVID-19 vaccination**, as per information given by Ministry of Health & Family Welfare to the Parliament. However details of these deaths and adverse events were not being released to scientific and medical community.
- Sir Ganga Ram Hospital, Delhi reported seven cases of Vaccine Induced Thrombotic Thrombocytopenia (VITT) from different hospitals in the country since June 2021. This well known often fatal adverse event of Astra Zeneca COVID vaccine (same as Covishield) has been reported from European countries.
- **According to Jan Swasthya Abhiyan, India needed to operationalise an effective, functional, transparent and accountable system for reporting severe adverse events following COVID vaccine**
- Like 19 other developed countries, **“no fault compensation” should be provided to persons who developed specified severe events related to COVID vaccination**, including deaths which were observed during Phase IV.

### **Jan Swasthya Abhiyan suggested some urgently required health system reforms:**

- **Ensure affordable medicines:** During COVID period, unilateral decisions have been taken by NPPA by removing many drugs from price control. Government should avoid further hike in medicine prices, instead **introduce comprehensive drug price control mechanisms to cover all essential medicines, including all equivalents.**
- **Revive and ensure non-COVID health services** – during the COVID epidemic, routine public health services including deliveries, TB and HIV care, dialysis, mental health etc. have been severely affected, need to be brought back on track and streamlined
- **Strengthen public health services and health manpower** - regular recruitment of staff instead of contracts, filling all vacant posts, upgrading honorarium and working conditions of ASHAs and frontline health workers. **Expanding capacity of public health services in rural and urban areas through adequate, massive increase in central government expenditure on health (achieve at least NHP target of 2.5% of GDP now)**
- **Regulate private hospitals** through full operationalisation of CEA 2010 in 11 states, promote similar healthcare regulatory legislations in other states. MOHFW should revive rate standardisation, notify standards, State governments must cap fees for services by private hospitals. Governments must urgently curb irrational prescriptions.

- **Reject healthcare privatisation** - Central government and State governments must reject all policy proposals for further privatisation of Healthcare, including recent recommendations provided by NITI Aayog
- **Privatisation oriented commercial health insurance schemes and Digital health cards should not substitute for robust, comprehensive, responsive public health care services.**
- **Promote public system – people partnerships** in rural and urban areas, learning from positive examples during COVID. Need to involve Panchayats, civil society organisations and community groups, by including them in multi-stakeholder committees and forums from community to state levels.
- **Democratise public health governance:** Need for transparency, openness and participation at all levels while implementing India’s COVID recovery plan. Move away from ‘Militarised’ health responses and securitization of health systems.
- **Expand democracy to promote people’s health** - including equitable centre-state relations, transparency in decision making and data management, participatory oversight and planning at all levels, special measures to address gender and social inequities, involving diverse civil society organisations instead of constriction of funds and activities.

**5.96 The Committee finds that Jan Swasthay Abhiyan (JSA) has suggested useful course of action for strategic management of Pandemic Covid-19 that *inter-alia* include report of Serious Adverse Events (SAE) following Covid vaccine, assurance of affordable Medicine, Strengthening of public health sector & health manpower and promotion of PPP Model in health reforms. The Ministry of Health and Family Welfare may examine the suggestions at length for better health management in the country.**



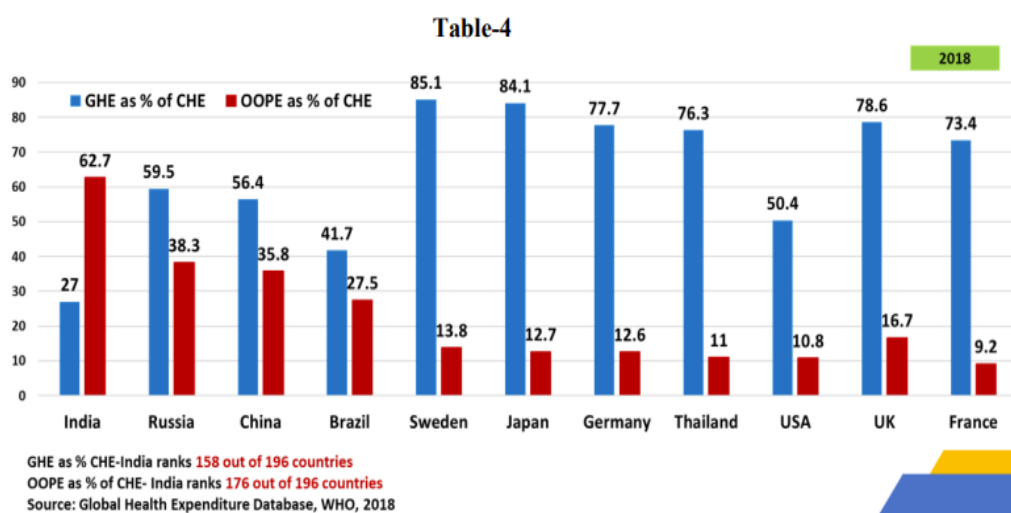
## CHAPTER VI

### CHALLENGES IN COVID-19 MITIGATION AND MANAGEMENT

6.1 The Committee has been given to understand that the pandemic caused an unprecedented crisis and the Indian health infrastructure struggled to handle the emergency of such high proportions. The Committee in its deliberations with the various Departments/Ministries and other stakeholders has identified many problems/challenges faced during the smooth implementation of the National Vaccination Policy. Some of the challenges and other related issues are enumerated as under:

#### Poor government expenditure on Health

6.2 During the examination of the Demand for Grants of the Department of Health and Family Welfare, the Ministry had submitted that as per the WHO's Global Health Expenditure Database 2018, the Government Health Expenditure (GHE) as percentage of Current Health Expenditure (CHE) is only 27% and the Out of Pocket Expenditure (OPE) as percentage of the Current Health Expenditure is 62.7%. India ranks 158 out of 196 countries in GHE as percentage of CHE and 176 out of 196 countries in OPE as % of CHE. The GHE and OPE as % of CHE of different countries are indicated as under:



6.3 Attention of the Committee is also drawn to the latest National Health Accounts Estimates for India 2017-18 which was released in 2021. The trend of Total Government Health Expenditure comprising of both current and capital expenditure is as under:

#### Trend in Government Health Expenditure capture from 2013-14 to 2017-18 NHA

Indicator	NHA 2017-18	NHA 2016-17	NHA 2015-16	NHA 2014-15	NHA 2013-14
<b>Government Health Expenditure as percent of Total Health Expenditure</b>	40.8	32.4	30.6	29	28.6
<b>Government Health Expenditure as % of GDP</b>	1.35	1.2	1.18	1.13	1.15
<b>Government Health Expenditure as % of General Government Expenditure</b>	5.1	4.4	4.07	3.9	3.8

Source: National Health Accounts

**6.4** The Committee is disappointed to note that the Government Health Expenditure as a percentage of Current Health Expenditure is only 27% and the Out of Pocket Expenditure as percentage of the Current Health Expenditure is 62.7%. The Committee while examining the Demands for Grants of the Ministry has repeatedly recommended for increase in Public investments in the health sector.

**6.5** The Committee in its 134<sup>th</sup> Report on the Demand for Grants of the Department of Health and Family Welfare had noted that BE of 2022-23 was just a 0.2% increase over RE 2021-22. The Committee had noted that despite the pandemic necessitating high investments in health sector, the Government had failed to increase the Health Budget. As per National Health Accounts Data 2017-18, the Government Health Expenditure as percentage of GDP is 1.35%. The Committee further recalls that under National Health Policy, the GHE was targeted to increase to 2.5% of GDP by 2025.

**6.6** The Committee reiterates its recommendation that the Government must increase its investment in public health systems and public health research. Indian States like Kerala that have a robust healthcare infrastructure were at a far better position to anticipate the uncertainties of the pandemic. The quick response strategy of the State reflected the advantages of a strong public healthcare infrastructure. The Committee in its 126<sup>th</sup> Report on Demands for Grants 2021-22 had explicitly recommended the Government for increasing its health expenditure to 2.5 % of GDP in the next two years and to 5% by 2025. The Committee accordingly reiterates its recommendation that the Ministry must set higher targets and ensure that the Government Health Expenditure is increased to 5% of GDP. The Committee further recommends the Ministry to nudge the States with Health Budget less than 8% of the State's GDP to increase the State Government's investment in the health sector.

### **Gender Gap in Vaccination**

**6.7** Sama Resource Group for Women submitted that gender inequity that is ingrained in the health system exposed the harsh realities of gender inequities during the pandemic in the context of access to health care technologies and vaccination rollout, which has only worsened with Covid-19.

**6.8** Although vaccination rollout prioritized frontline health workers, who were largely women, when the vaccination drive opened for the larger public, data revealed that women seemed to be lagging far behind in comparison to men. In July 2021, Co-WIN data revealed that *only 867 women were vaccinated as compared to 1000 men*. Out of the 309 million Covid-19 vaccines delivered since January 2021, *only 143 million were given to women as compared to 167 million given to men*. This gender gap was worrying as it was far greater than 6%.

**6.9** This gender gap in vaccinations is not only attributed to the skewed sex ratio in the country but also to several underlying gender inequality-related issues such as, limited mobility to reach health facilities or vaccination sites, restricted decision-making power in health seeking, limited access to and control over resources needed for advancing their health, including access to smartphones, internet for information about vaccines and vaccine safety ,rumours and misconceptions about vaccine safety and lack of clinical trial data on pregnant and lactating women.

**6.10** Further, the digital divide and the requirement of registering on the CoWIN platform also makes it difficult for women to access vaccinations. Vaccine hesitancy is higher among women than men. Rumours like women should not take Covid-19 vaccines during menstruation

or that vaccines will affect fertility might have also deterred women from coming forward to take vaccines.

**6.11 The Committee regrets that women remain the most affected group in any calamity. Women have long been denied basic rights and gender inequities are very high, especially in economically weaker and poorly accessible regions. The Committee notes that as per the Government official data a total of 1.99 billion doses have been administered in the country till mid July, 2022. Out of the total doses, 988 million doses have been given to Males and 950 million doses to women leading to a difference of over 38 million doses.**

**6.12 The Committee notes the success of vaccination drive is correlated to registration on Cowin and easy access to the health care centre for vaccination. However, with women having no access to internet or any digital tool and her high dependence on the male member of the family for any information further widens the gender gap in vaccination. The Committee further notes that rumours, such as the impact of vaccination on menstruation etc further leads to lower willingness to be vaccinated. The Committee strongly recommends the Ministry to conduct more awareness campaigns especially in region with poor rate of vaccination among women. The Ministry must make all out efforts to bridge this gender gap in vaccination.**

#### **RURAL-URBAN VACCINE DISPARITY**

**6.13 The Committee observes that the vaccination rate was very poor in the rural areas in the beginning of the vaccination drive. Internet connection and a mobile phone was the foremost requirement for registering oneself in the Cowin App and walk-in Covid vaccination had not yet started. Rural areas with poor digital literacy did not see an uptake in the vaccination drive. The Committee further notes that many villages across India do not have access to pucca roads, electricity and drinking water. These regions are rendered inaccessible either due to their rough geographical terrain or precarious security situation. With regions devoid of electricity, maintaining the temperature of the vaccines especially in inhospitable terrain is a difficult challenge.**

**6.14 The Committee accordingly recommends the Ministry to open more vaccination centres in the rural areas. The Ministry must also explore use of newer refrigeration technology, such as "solar direct drive" that resolves the battery powered vaccine refrigerator problems and ensure that vaccines are made available in such remote areas. The Committee reiterates its recommendation that the Ministry must use modern technology and equipments to expedite the delivery of vaccines. The use of drone by the State Government of Maharashtra for delivering vaccines is a good example of making vaccines easily available in difficult terrains. The Committee recommends the Ministry to deploy helicopters, boats, motor bikes and every possible means of transport to achieve last mile delivery of vaccines.**

#### **VACCINE HESITANCY**

**6.15 Sama Resource Group for Women in its written submission stated that vaccine hesitancy became evident when vaccination opened for the adult population, i.e., those aged above 18 years were eligible for immunization yet people were reluctant to get inoculated. An underlying reason being people were not aware about the working of the vaccines, its benefits and side-effects. Vaccine hesitancy should not have come as a surprise as over the years, there have been seldom vaccines launched for adult population with the exception of mothers for**

Tetanus (TT vaccine). A vaccine needed to be taken for preventing a disease was deemed an unusual notion across several rural parts of the country. Lack of efforts to provide people with clear information about its adverse effects and establishing a chain of referral in case of adverse event, has led to a sense of fear, mistrust in people.

**6.16 The Committee agrees that a lot of misconceptions about the vaccines have given rise to vaccine hesitancy in the Indian population. With Covid vaccines getting the Emergency use authorization amidst the lack of information in the public domain, a certain sense of doubt prevailed in the people's mind. The Committee also notes that several instances of vials of vaccines getting wasted due to people not turning up to the vaccination centres have been reported. The vaccines have to be maintained at the recommended temperature and the vials of vaccines have to be used and discarded within hours of being opened.**

**6.17 Vaccine hesitancy has also been recognised as one of the reason behind low vaccine coverage in certain areas leading to regional disparities in Vaccine Distribution Plan. The Committee therefore believes that there is an urgent need to provide correct information on vaccines and address the issue of vaccine hesitancy. The Committee accordingly recommends the Ministry to feature strong community engagement strategies in the vaccination Programme along with social media engagement. The Ministry must also explore involving celebrities and influential community voices for increasing the outreach of the vaccination programme.**

**6.18 The Committee strongly urges the Ministry to disseminate information and spread public awareness regarding the safety and efficacy of the vaccines. The Committee further recommends the Ministry to continue conducting various Communication strategy activities especially in rural areas and areas with poor accessibility. The Committee also recommends the Ministry to conduct at-home inoculations especially for the aged and people with special need.**

## **VACCINE EQUITY**

6.19 A robust supply of vaccines is necessary for ensuring vaccine equity across the globe and within the country. The Committee notes that the developed nations are better adapted to face the economic as well as the scientific challenges in the wake of a pandemic. However a shortage in supply of vaccines across any region of the world jeopardises the mitigation efforts against the pandemic and is a threat to global safety.

### **Shortage in vaccines in India and other Developing Nations of the world**

**6.20 The Committee was given to understand that the Indian Government had targeted vaccination for the entire adult population by December, 2021, however, the Government failed to achieve its targets set for the total vaccination drive. Attention of the Committee has also been brought to instances of vaccine shortage in few States, thereafter, the States were forced to divert stock meant for the 18-44 age group to the 45 plus group for their second dose. The Committee, therefore, strongly recommends the Government to refresh its target of 100% vaccination of the Indian population along with booster doses and make concerted efforts to achieve the targets.**

**6.21 The Committee further notes that there exists a huge economic divide in the world and the pandemic has further widened the divide between the rich and the poor countries. With the development of vaccines, the western countries started stockpiling of the vaccines and were the first to provide booster doses to its citizens while the low and middle income**

**countries struggled to administer even the first dose of the vaccine. The Committee, therefore, recommends the Government to revisit its vaccine diplomacy and take a lead role at international fora to ensure that the third world countries get adequate doses of vaccines. The Committee believes that global vaccination is very crucial for minimizing the possibility of any future outbreaks of pandemic due to resurgence of mutated virus in any other country. The Committee, in this regard strongly advocates equitable global distribution of vaccines.**

6.22 Jan Swasthya Abhiyan (JSA) in its written submission has stated that to overcome supply side constraint, the government should have employed compulsory licensing provision to allow manufacture of Covid vaccines in the already existing vaccine manufacturing units in the public sector. These plants have been the main source of high quality vaccines at very low prices for 40 years after independence for the national vaccination programme.

6.23 JSA further submitted that the scientists of the ICMR were able to produce a good Covid-19 vaccine within a year is a matter of great pride. It would have been quite logical for the government to allocate to the existing public sector vaccine manufacturing units to produce this vaccine. But due to the continued policy of privatization even during this national health emergency, the manufacturing of Covid-19 vaccine has remained entirely in the private sector.

6.24 As informed by the Ministry of Health and Family Welfare, the price of vaccine manufactured by Serum Institute of India in collaboration with Astrazeneca was initially quoted at Rs. 250 per dose. However after protracted negotiations, the price was fixed at Rs. 200 per dose. The price of Covaxin was initially quoted at Rs. 350 per dose and later the final price was fixed at Rs. 295 per dose.

**6.25 The Committee agrees that the Government should have employed a better pricing mechanism for controlling the price of the vaccines. The prices of the vaccines in the Private Hospitals and vaccination centres were very high allowing high profiteering by the vaccine manufacturing firms and the Private hospitals.**

6.26 The Committee further notes that the vaccine manufacturing firms slashed the prices of vaccines for private hospitals to Rs 225 per dose in April, 2022. During the peak of the pandemic, the Covid vaccines were being administered at Rs. 900-1400 in the Private hospitals. The Committee understands the demand-supply economics and believes that private firms have to be allowed to make some profit so that investment can be made in research & development and increasing the production capacity. However, the Committee fails to understand such high fluctuations in the prices of the vaccine that leave enormous space for vaccine manufacturing firms to earn exorbitant profits on the production of vaccines.

#### **Waiver of Intellectual Property Protection for Covid Vaccines and other Covid-19 Diagnostics and Therapeutics**

6.27 Attention of the Committee has also been drawn to the proposal of temporary waiver of Intellectual property protection for covid vaccines and other COVID-19 diagnostics and therapeutics at WTO. The Committee believes that exclusive control over vaccines via patents can pose a hurdle in ensuring vaccine access to countries that lack the vaccine manufacturing capacity. The looming fear of future resurgence and more virulent viruses persists and global eradication of the Covid is crucial for halting this pandemic. The Committee, therefore, believes that transfer of technology and waiver will significantly bridge the large demand supply gap as the vaccines will be produced without authorization from the patent holder. The Committee strongly believes that for ensuring

vaccine equity, there is a need to expand the vaccine manufacturing capacity across the globe and waive the Intellectual Property Protection (IPP) for Covid-19 vaccines. This can help countries in scaling up the production of vaccines and make vaccines more affordable and accessible to everyone. The Committee, however, also believes that special emphasis will have to be laid on ensuring safety and quality standard for mass vaccine manufacturing. The Committee further notes that the move to waive Intellectual Property Protections (IPP) must not disincentivize the Pharmaceutical companies to invest on vaccine research rather the Industry and the countries across the world must unite and work together to expand the global vaccine manufacturing capacity.

**6.28** The Committee accordingly urges the Government to continue making efforts for waiver of IP Protection for Covid vaccines and other COVID-19 diagnostics and therapeutics so that the vaccines are produced on a large scale and 100% vaccination of the world population is achieved.

### **REVAMPING OF PUBLIC SECTOR VACCINE MANUFACTURING UNITS**

6.29 The Committee notes that Serum Institute of India (SII) and Bharat Biotech were the two main private vaccine manufacturing units that were responsible for ensuring the adequate supply of vaccines in the country. The Committee is given to understand that presently there are seven public sector vaccine manufacturing units, namely, Central Research Institute (CRI) in Himachal Pradesh; BCG Vaccine Laboratory (BCGVL), Pasteur Institute of India (PII) and HLL Biotech in Tamil Nadu; Bharat Immunologicals and Biologicals Corporation Limited, Uttar Pradesh; Haffkine Bio-Pharmaceutical Corporation Limited, Maharashtra; and Human Biologicals Institute, Telangana.

**6.30** The Committee understands that ensuring a consistent supply of vaccine during the pandemic Covid-19 posed a major challenge, thereby, arising an urgent need to accelerate the Covid-19 vaccination drive. However, the Committee laments that the public sector vaccine units were not reckoned to service in times of crisis and their contribution to the Covid-19 vaccine production remained negligible in the fight against the pandemic Covid-19.

**6.31** The Committee has been given to understand that in 2008, the vaccine production in CRI, PII and the BCG Vaccine Laboratory (BCGVL), Chennai were halted for non-compliance with Good Manufacturing Practices (GMP). The Committee observes that although the licenses were restored in 2010; however these vaccine units continued to remain underutilised. The Committee strongly believes that revival of these units is imperative to bridge the gap between vaccine demand and supply and to make vaccines more affordable and accessible. The Committee further notes that the Madras High Court in May 2021 had asked the Central Government as to what steps were being taken to revive the existing Vaccine Institutes owned by the Government. The Supreme Court in December, 2021 had also sought the response of the Central Government on its policy to revamp public sector vaccine manufacturing units. The Committee, accordingly, strongly recommends the Ministry of Health and Family Welfare to revive the existing vaccine manufacturing units and issue production licences to the GMP compliant vaccine manufacturing units.

**6.32** The Committee, in this regard, would like to be apprised of the total number of Public Sector Vaccines Units that are owned by the Central Government and the State Governments. The Committee must also be informed about the financial status and the annual Budget that has been allocated to these Public Sector Manufacturing Units over the

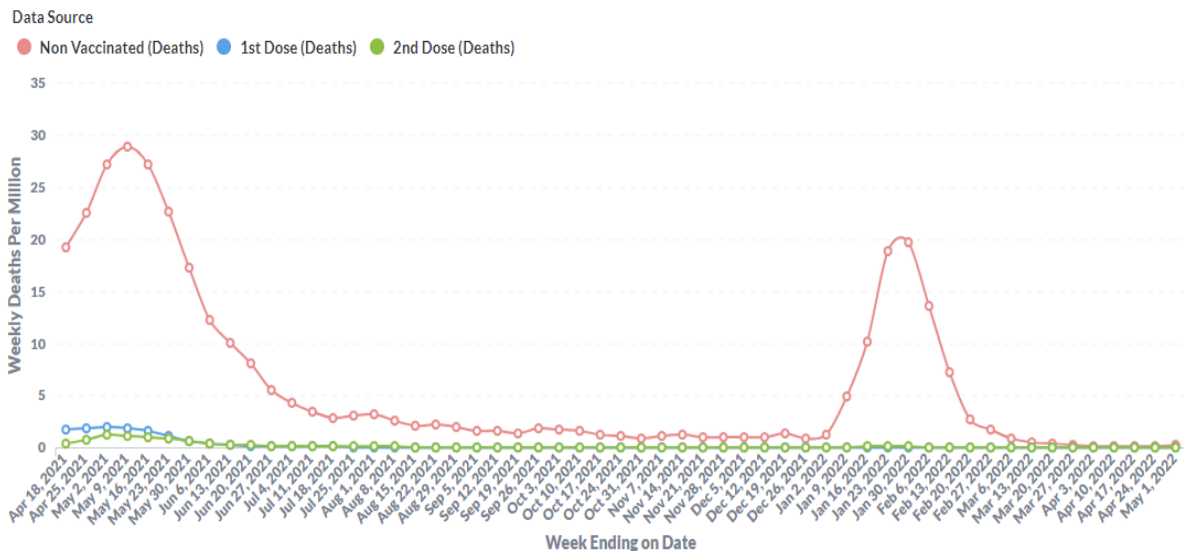
**past four years. The Committee recommends the Ministry to monitor the revival of these units and henceforth, furnish quarterly Reports to the Committee. The Committee desires that the Ministry of Health and Family Welfare must forward the revival plan alongwith financial requirement to the Ministry of Finance for approval at the earliest.**

**6.33 The Committee further notes that India has been advocating the waiver of Intellectual Property rights of Covid vaccines at the global level, however, the Committee is perplexed to note that the Government has taken no major initiative to waive the Intellectual Property Rights for the indigenous vaccine Covaxin which was developed in collaboration with ICMR. The Committee strongly recommends to examine the possibility of technology transfer of Covaxin to the Public Sector Units and start its production in these Units.**

6.34 The Committee is given to understand that two key policy initiatives namely (i) National Disaster Management Guidelines—Management of Biological Disasters issued in July 2008 and (ii) The National Vaccine Policy, 2011 are very much relevant to the current COVID pandemic. The National Disaster Management Guidelines Management of Biological Disasters, which was issued in 2008 aimed to develop a holistic, coordinated, proactive and technology driven strategy for management of biological disasters, through a culture of prevention, mitigation and preparedness to generate a prompt and effective response in the event of an emergency. The National Vaccine Policy document addresses broad issues of strengthening the institutional framework, processes, evidence base and framework required for decision making for strengthening Universal Immunization Programme (UIP) in India and to streamline the decision making process on new and underutilized vaccine introduction.

**6.35 The Committee notes that the National Disaster Management Guidelines, Management of Biological Disasters contained comprehensive guidelines for undertaking biosafety and biosecurity measures. It aimed to strengthen the existing regulatory framework so that the country adopts a resilient response strategy in the wake of any imminent biological disaster. The Committee believes that had the Ministry implemented the guidelines and addressed the gap that was highlighted in the Report, the country would have been better prepared to tackle the pandemic. The Committee further notes that if the Government had implemented the National Vaccine Policy, 2011 in letter and spirit, the issues of vaccine-security, management, regulatory guidelines, vaccine research & development and product development could have been dealt in a better manner. The Committee recommends the Ministry to assess the functional status of National Disaster Management Guidelines, 2008 and National Vaccine Policy, 2011 and apprise the Committee of the initiatives being taken for implementation of these policies at the ground level to achieve the set objectives in these guidelines/policy.**

6.36 Attention of the Committee is also brought to the estimates of the Government where the Vaccine Effectiveness in Preventing Mortality by 1<sup>st</sup> Dose is 99.0% and Vaccine Effectiveness in Preventing Mortality by 2<sup>nd</sup> Doses is 99.4%. The Vaccine Effectiveness on Mortality (Person-Time Analysis) has been graphed as under:



**6.37** The Committee observes that vaccination has caused a phenomenal mitigating impact on the continuum of the pandemic Covid-19. The Committee notes that the vaccine effectiveness in Preventing Mortality is very high and the death among the non- vaccinated has been the highest during the second and the third wave. The Committee, therefore, strongly recommends the Government to continue with National Covid-19 control Plan through massive vaccination drive so as to mitigate the causation factor of mutating variants of Covid-19.

**6.38** The Committee further points out the unrealistic target set by the Government for completion of the vaccination drive in the country by December 2021. Various studies have been conducted across the world on the additional deaths that would have been averted had the vaccination coverage targets been achieved by the country. With the waning of vaccine efficacy in the population and the risk of emerging mutated variants across the world, the success of the vaccination Program is a keystone of the Covid mitigation policy. The Committee, therefore, accordingly recommends the Ministry to focus not only on the vaccine supply side barrier but also on the demand side barriers so that vaccination targets are achieved. The Committee also recommends the Ministry to take necessary measures to increase the uptake of precautionary doses so that the mortality rate is lowered given the rise in fresh infections. The Committee cautions the Government against mutating variants of Covid-19 and strongly recommends to have the vigil for total elimination of virus through resilient mitigation policy and effective mass vaccination Program.

**6.39** The Committee further notes that geographically tough terrain with poor connectivity may not permit live data entry of vaccination, hence back log entry option or off line mode of entry must be permitted so that the extent of actual vaccination coverage can be observed and any possible gap for vaccination is abridged.

## NEED OF STRONG PUBLIC-PRIVATE PARTNERSHIP IN THE HEALTH SECTOR

**6.40** The Committee understands that the Government with its limited resources, faces a far big challenge to bring in structural changes in the Public Health System. It is a well established fact that there is an urgent need to augment and develop the health ecosystem in the country to keep the health index of the whole population to global standard. The



Committee believes that Public Private Partnership in the Health Sector can facilitate bridging of the gaps in the healthcare infrastructure and ensure an efficient delivery of healthcare services upto lower rungs of the society. The Committee, taking a clue from the success of the PPP model in various sectors such as infrastructure, tourism, education recommends the Government to adopt a similar model in the health sector. The Committee finds that the Public Private Partnership in Health Sector is still an unexplored area and therefore, can prove momentous in increasing the reach of healthcare facilities. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to collaborate with the Private Sector on novel Projects related to the Health. The Business Houses and Companies must be encouraged to devote a substantial part of their CSR funding in the Health Sector to build necessary health infrastructure.

6.41 The Committee also recommends the Government to launch new Schemes and initiatives that incentivises the Private Sector to bring in the funding and the expertise in the health sector. The Government must leverage the key resources of the Private sector and take full advantage of the expertise, finances, technology and human resource that the PPP model offers in combating National emergency situation in health sector like the pandemic Covid-19.

#### **NEED OF CHANGE IN VACCINATION POLICY**

6.42 The Committee is of the opinion that the effectiveness studies of the vaccines on the newer variants of the virus should have been conducted by the research bodies in India along with the beginning of the vaccination drive. Countries like US and UK started conducting various studies to determine the proportion of people who were vaccinated but still either got severely ill or died due to the covid. The Committee further notes the research studies that recommended delay in the second dose of the AstraZeneca vaccine beyond the earlier recommended 4 weeks. This was also endorsed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Committee. In May, 2021, the COVID Working Group chaired by Dr N K Arora also recommended extension of the gap between the first and second doses of COVISHIELD vaccine to 12-16 weeks. The earlier gap between the two doses of COVISHIELD vaccine was 6-8 weeks. The Committee, in this regard, recommends the Government to find out scientifically, the reasonable gap between the two doses of the vaccine on the gap between the 2<sup>nd</sup> and precautionary booster dose in the interest of public health otherwise common masses apprehend that Government is allowing adjustment of time gap between two doses of vaccine to clear the stock of vaccine manufacturers.

6.43 The Committee feels that with the huge repository of vaccination data in the country, India should have been at the forefront of conducting better assessment of the vaccine efficacy in its population. The Committee believes that any change in the national vaccination policy should have been substantiated by real-life evidences and concrete research in the country itself. The Committee therefore, recommends the Ministry to conduct more research on optimising the dosage interval and accordingly approach its vaccination policy.

6.44 The Committee further recommends that there is a need to develop a mechanism that in case of future outbreaks of the pandemic, the research infrastructure is put into action and the vaccine policy is accordingly modified for better results. The Committee

**again emphasizes that the preparedness of vaccination strategies requires much more clinical research so that the rapid response care strategies are adopted.**

#### **NEED OF CHANGE IN VIALS SIZE**

**6.45 The Committee has also been apprised by the State Governments that due to the bigger size of 20 doses in the Corbevax vaccine, it is becoming difficult for the vaccination Centres to use them. The Committee, therefore, recommends that the vaccines should be made available in smaller packs of 5 doses each to ensure the best usage of vaccine and prevent wastage.**

#### **ENHANCEMENT IN THE HONORARIUM OF AWWs/AWHs AND ASHAS**

6.46 The Ministry of Women and Child Development submitted that AWWs/AWHs being honorary workers are paid a monthly honorarium as decided by the Government from time to time. Government of India with effect from 01.10.2018 has enhanced the honorarium of AWWs at main AWCs from Rs. 3000/- to Rs. 4500/- per month; AWWs at mini AWCs from Rs. 2250/- to 3500/- per month; AWHs from Rs. 1500/- to Rs. 2250/- per month; and introduced performance linked incentive of Rs. 250/- per month AWHs. Further, modified guidelines have been issued for performance linked incentive @Rs. 500/- per month to Anaganwadi Workers with effect from 01.05.2021. In addition, States/UTs are also paying additional monetary incentives/honorarium to these functionaries from their own resources.

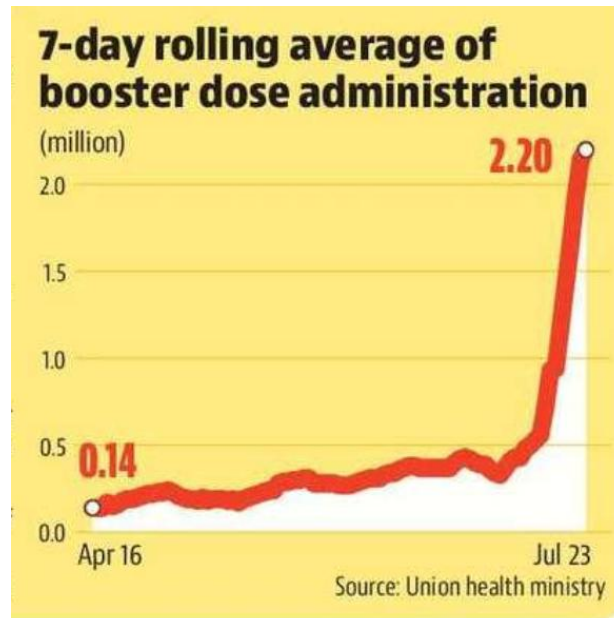
6.47 The Committee in its 126<sup>th</sup> Report on the Demand for Grants on the Department of Health and Family Welfare applauded ASHA and other frontline health workers for their role as foot soldiers in India's fight against the pandemic. The Committee has noted that the ASHA workers have proved pivotal in connecting the weaker and marginalized community to a host of health services.

6.48 The Committee notes that the country's frontline health workers ASHAs were one of the six recipients of WHO's Global Health Leaders Award-2022 that recognises leadership, contributions to advancing global health and commitment to regional health issues. As per WHO, ASHAs were conferred the honour for their crucial role in linking the community with the health system, to ensure those living in rural poverty can access primary health care services, as shown throughout the COVID-19 pandemic.

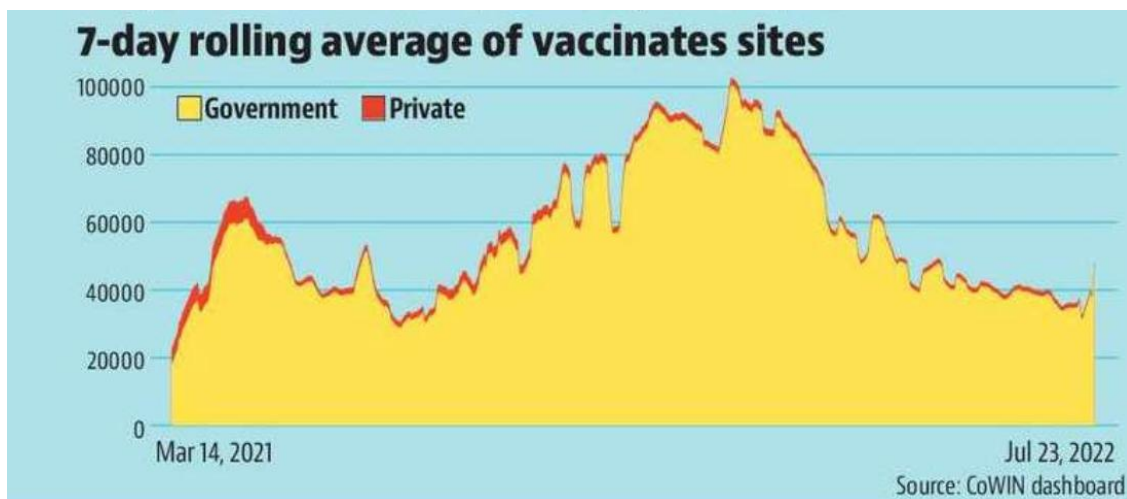
**6.49 The Committee applauds the Anganwadi Workers (AWWs), Anganwadi Helpers (AWHs) and Accredited Social Health Activist (ASHAs) who were extensively involved in COVID-19 awareness drive in the community. The Committee notes that ASHAs, AWWs and AWHs acted as the frontline workers during the pandemic and were responsible for spreading awareness about Covid-19 and safety protocols. The ASHAs were also tasked with identifying as well as tracking COVID-19 positive cases and carrying out vaccination drive. ASHAs, AWWs and AWHs have played an important role in community surveillance as has also been applauded by WHO, however, these frontline workers remain unrewarded. The Committee accordingly recommends the Ministry of Health and Family Welfare and the Ministry of Women and Child Development to ensure timely payment of wages along with other social security benefits. The Committee further recommends the Government to consider incentives and financial protection for the ASHAs, AWWs and AWHs workers under different financial packages.**

## COMPLACENCY IN ADMINISTRATION OF BOOSTER DOSES

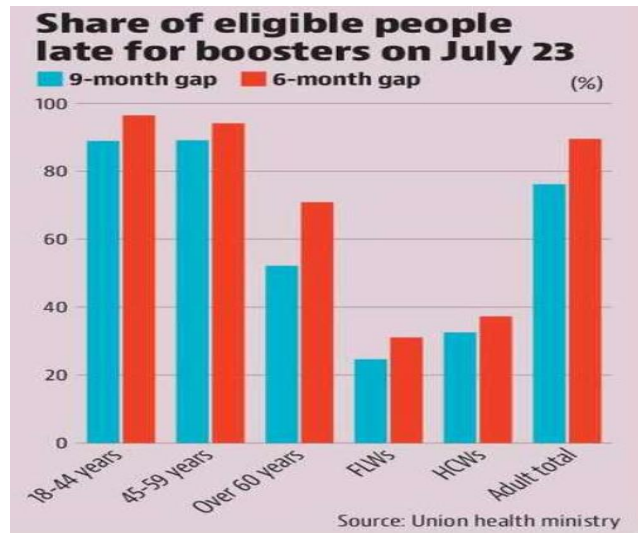
6.50 Attention of the Committee has also been drawn to the fact that there has been a considerable increase in the administration of the booster doses since the dose was made free. As per the estimates of the Government, the 7 day rolling average of booster dose administration increased from 0.14 million in April 16 to 2.20 million on 23rd July, 2022. The same is graphed as under:



6.51 Attention of the Committee is also drawn to fewer vaccination sites for administering booster doses. The same has been graphed as under:



6.52 Attention of the Committee is also drawn to the fact that there has been complacency about taking the booster dose in the public. The Committee is given to understand that even among the health care workers almost 37.3% have missed their shots at a six month gap. The absolute number of healthcare workers who are late for boosters is 2.97 million. 24.6% of eligible frontline workers are late for boosters by more than nine months. The same is graphed as under:



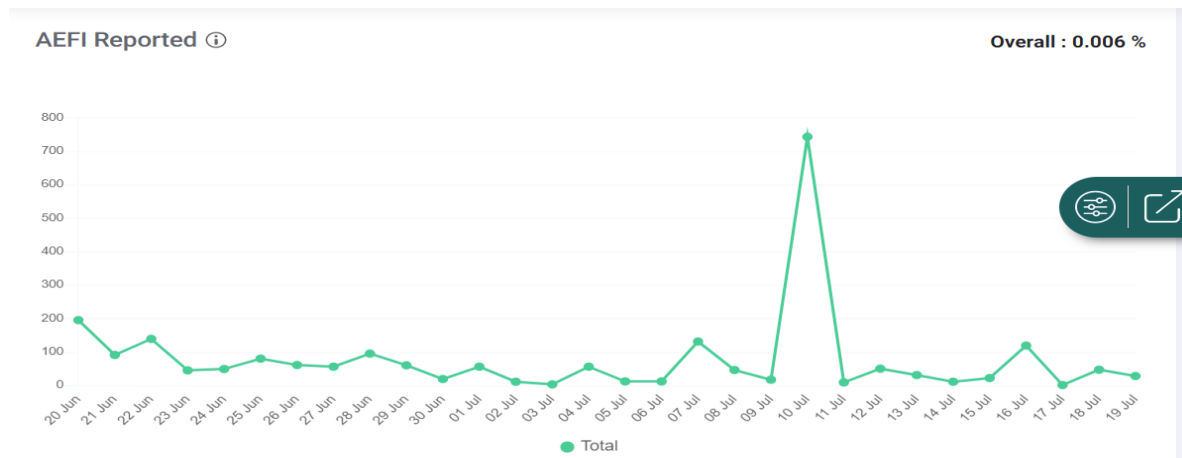
**6.53** The Committee notes that administration of free booster doses has enhanced the booster dose uptake. However, the Committee notes that this free precautionary dose window is only for 75 days. The Committee strongly recommends the Ministry to extend the 75 days window and make the precautionary dose free for all so that complete vaccination of all can be ensured.

**6.54** The Committee further notes that the ease of access to vaccination site also has a major role to play in increase in vaccination rate. The Committee strongly recommends the Ministry to increase the Government Covid Vaccination centres across all the States/UTs. The Committee is also concerned at the general prevalence of complacency in the healthcare workers as well as the public towards booster doses. The Committee strongly recommends the Ministry to work towards increasing awareness regarding the precautionary dose among the public, particularly among the immune-compromised and people with co morbidities.

**ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)**

**6.55** The Ministry of Health and Family Welfare submitted that as per the AEFI Surveillance Operational Guidelines and the Operational Guidelines for COVID 19 vaccinations, all suspected minor, severe and serious AEFI cases reported following administration of all vaccines (including routine immunization and COVID 19 vaccines) should be reported to the health system. Adverse events (minor, severe and serious) following COVID 19 vaccinations can be reported by the vaccinator and the District Immunization Officer through the COWIN portal. It is important to note that all reported events may not be caused due to the vaccine. The severe and serious AEFIs cases which are reported in COWIN are further investigated by the district AEFI committee through the District Immunization Officer.

**6.56** As per the data furnished by the Ministry of Health and Family Welfare, the total number of Adverse Event Following Immunization (AEFI) is graphed as under:



**6.57** The Committee notes that on 19<sup>th</sup> July, 2022, a total of 28 AEFI were reported across the country and total AEFI is reported to be 0.006% of the total cases. The Committee observes that under-reporting and poor quality data collection may be the reason behind reporting of such less number of AEFI. However, the Committee takes note of the unusual peak in AEFI on 10<sup>th</sup> July, 2022 where 743 AEFI cases were reported. The Committee would like to be apprised of the reason behind this sudden rise in the cases and the vaccines that caused the adverse reaction.

**6.58** The Committee notes that mild side effects after administering of the vaccines are usually reported as the body requires time to adjust to the vaccination dose. However, the Committee feels that the Ministry must ensure that possible adverse effects are communicated to the people followed by timely treatment. Attention of the Committee is also brought to the death of a patient post covid-19 vaccination. The Committee notes that in the concerned case, the AEFI Committee released its assessment Report after almost seven months. The Committee strongly recommends the Ministry to ensure that appropriate investigation must be done and AEFI Committee must expedite its examination of each adverse cases.

**6.59** The Committee also notes that COVID-19 vaccination is voluntary and presently there is no mechanism of compensation to beneficiaries or liability of vaccine manufacturer in case of any Adverse Event Following Immunization. The Committee, therefore, strongly recommends the Ministry to create a clear framework of vaccine liability for manufacturer in case of AEFI so that adequate compensation can be provided to the aggrieved individuals.

**6.60** The Committee also notes the findings of various research studies that have indicated the prevalence of long Covid among individuals infected with Covid. Even after the infection has passed, individuals have been reported to experience lingering symptoms. The Committee observes that there is a need to monitor and conduct surveillance of post covid complications. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to frame a treatment protocol and make specific guidelines for managing post Covid complications and related health problems arising due to the initial infection. The Ministry must also work towards sensitizing the Indian Health Public System to deal with such cases of long Covid. The Committee further recommends the Ministry to ensure medical support for Long COVID sufferers and train the healthcare workers for managing patients with Long COVID.

## **NEED OF AN ENHANCED ROLE OF AYUSH IN THE MITIGATION OF THE PANDEMIC COVID-19**

6.61 The Committee is given to understand that AYUSH can play an important role in realizing the dream of ‘New India’ by providing quality healthcare and medical care for its citizens. With the fear of subsequent waves still looming around, there is a strong need to promote the traditional system of medicines and Yoga as a way of life. Ayush with its preventive and promotive aspects can go a long way in preparing the individuals for future health uncertainties,

6.62 While examining the Demand for Grants 2022-23 of the Ministry of Ayush, the Committee noted that the Ministry had conducted clinical studies on AYUSH-64 in the management of asymptomatic and mild to moderate cases of COVID-19 involving 500 participants. The outcomes of these studies demonstrated early clinical recovery and reduced duration of hospital stay without any progression of the disease to severe or critical stage of COVID-19. Also, there was improvement in Quality of life (QoL) parameters. AYUSH-64 was found to be well tolerated and safe. A molecular docking study conducted at ICMR National Institute of Nutrition, Hyderabad demonstrated its anti-viral activity against SARSCoV-2.

### **AYUSH response in COVID 19 pandemic**



6.63 The Committee in its 136<sup>th</sup> Report had appreciated the efforts of the Research Councils in development of new drugs especially repurposed Ayush 64 in management of Covid-19. The Committee reiterates its recommendation that AYUSH must continue emphasis on evidence based scientific research and drug development process entailing pre clinical as well as clinical trials. The Committee further recommends the Ministry of Ayush to work towards building inter-ministerial linkages and collaborate with other Departments for undertaking clinical studies on newer drugs.

6.64 The Committee believes that in the wake of global health crisis and the threat of emerging viruses, Ayush system can be utilized as an effective means to tackle the challenges associated with health sector. The Committee strongly recommends the adoption of an inclusive and integrated health care policy. The Committee accordingly urges the Government to continue making efforts in integrating Ayush in the health sector.

**6.65** The Committee recognizes the services of AYUSH doctors in providing the first line of treatment especially in the rural areas. The Committee further commends the contribution of AYUSH manpower in offering their services during the pandemic.

#### **INCLUSION OF MARGINALIZED SECTION IN THE VACCINATION DRIVE**

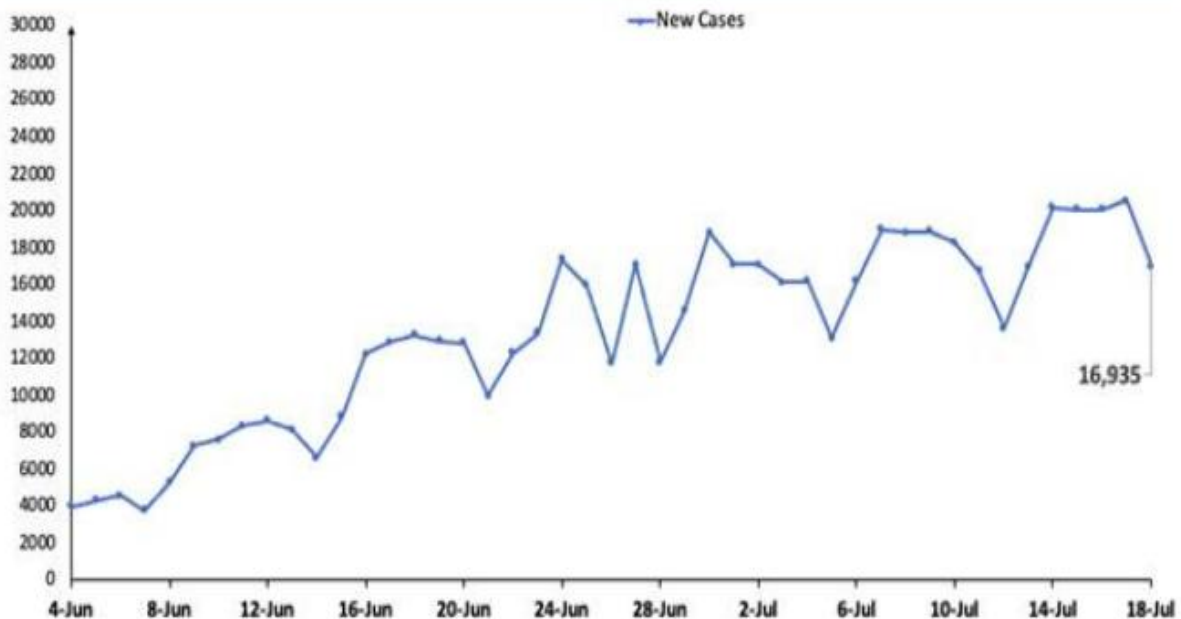
**6.66** The Committee notes the economic impact of the pandemic and the mass migration of the workforce from the cities to the villages. The Committee notes that the migrant workers due to the nature of their jobs that demand rapid movement may have been excluded from the vaccination drive. The Committee, therefore, recommends the Ministry of Health and Family Welfare to ensure that the migrant workforce is administered both the doses of the vaccine along with the precautionary doses. The Committee also urges the Ministry to ensure that the poor vulnerable section of the society, due to the absence of relevant identification cards or documents does not remain neglected. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to ensure free and universal vaccination for all.



## CHAPTER VII

### PANDEMIC IS FAR FROM OVER

7.1 As per the estimates of the Ministry of Health and Family Welfare, India's daily new Covid-19 cases stand at 16,935 (as on 18<sup>th</sup> July, 2022). The Committee notes that the hospitalization rate has been low and the Omicron sub-variant BA.2 is the dominant variant in the country. As per the Ministry the trend in new cases between 4<sup>th</sup> June and 18<sup>th</sup> July, 2022 has been as follows:



7.2 The Committee notes that the present trend of Covid-19 reflects the need for adopting a new approach to the pandemic for its total eradication. With waning immunity in the population, the susceptibility to the infection is bound to increase. The Committee is at distress to observe the lack of Covid Appropriate Behaviour (CAB) in the general public. People have stopped wearing masks and social gathering have also increased. The Committee further notes that though the cases are comparatively less than the earlier Covid waves but the fear of subsequent waves still persists if the CAB is not adhered to. The Committee, therefore, strongly recommends the Ministry to promote better communication in driving the benefits of vaccines to the general public as vaccine is the only last hope to mitigate the pandemic Covid-19.

7.3 The Committee further believes that any increase in the Covid cases must not be ignored and the public must not let the guard down against the pandemic. Over the past two years, the Ministry has been following, "Tracing, Tracking, Testing, Treating and Technology (5Ts)" to contain the pandemic. However, with the mutating Covid-19 variants, the Ministry must adopt newer strategies against the evolving virus. The Committee accordingly recommends the Ministry to revise the indicator to track the Covid-19 situation in the country. The Ministry must closely monitor clusters where any Covid incidence cases are reported. The Committee also recommends the Ministry to expand the genomic surveillance facilities in the country upto far flung areas so that the emergence of any new variant is tracked faster. The Ministry should strengthen the



network of labs under NCDC-IDSP upto the rural areas so that any newer clinical outcomes are translated to better covid management policies.

**7.4** The Committee also recommends the Ministry to conduct studies on whether there is a need to administer Covid vaccine yearly. The Committee further recommends the Ministry to undertake in depth R&D project to explore the possibility of manufacturing one-time single dose vaccine for all variants of corona virus. Moreover, the Committee emphasizes that R&D activities under PPP model should also be carried out to explore drugs development to treat Covid Patients with due clinical trials keeping in view the health safety of the patients. The Ministry must adopt a scientific view backed by research evidence to address major issues regarding Vaccine distribution. The Committee believes that the Ministry must be very pragmatic and strategic in administrating the precautionary dose of vaccines. However, the Ministry must continue accelerating its efforts towards administrating booster doses specifically to the high-risk population groups. The Committee believes that booster dose is essential to provide additional protection particularly to those with comorbidities. The Committee also believes that research outcomes with respect to efficacy of booster doses must be shared with the scientific community as well as the general public.

**7.5** Attention of the Committee has also been drawn to a study that suggests Hybrid immunity has been associated with higher levels of neutralising antibodies and greater protection against infection than vaccines. The Committee strongly recommends the Ministry to adopt a dynamic response strategy keeping in view the results of such studies.

#### **ESTABLISHING A ROBUST RESEARCH INFRASTRUCTURE IN THE COUNTRY**

**7.6** The Committee in its 135<sup>th</sup> Report on the Demands for Grants 2022-23 (Demand No. 47) of the Department of Health Research had examined the Schemes of the Department, particularly, "Establishment of Viral Diagnostic & Research Laboratories (VRDL) to manage epidemics and national calamities". The Committee had emphasized on the need of establishing VRDLs across States and strengthen the bio-safety network to tackle any future outbreaks. The Committee accordingly reiterates its recommendation that the Ministry must continue its efforts towards expansion of testing labs network in the country. The Ministry must aim towards -"One VRDL in each District" by 2026 and ensure that trained manpower is available in these laboratories.

**7.7** The Committee in its 135<sup>th</sup> Report had also strongly advocated for the need of BSL-3 and BSL-4 labs in the country. The Committee notes that a strong network of modern high tech labs with sophisticated diagnostic techniques is crucial to strengthen the bio-safety ecosystem in the wake of emerging new virus. Lack of adequate BSL Labs in the country increases the risk of such viral outbreaks. The Committee accordingly recommends the Ministry to establish one BSL-IV lab in each of the four zones. The Committee further believes that for regular and effective surveillance of any kind of infections or disease in the country, the Ministry must establish BSL-II facilities in different regions of the country. The Ministry must also start new mobile BSL-III labs in the country and ensure that all the zones of the country have a well established network.

**7.8** The Committee further notes that under the PM-ABHIM Scheme, existing 5 VRDLs are being upgraded to BSL-III labs. The Committee would like to be apprised of the status of these labs and the Ministry must accelerate its efforts and ensure that the labs are upgraded within the set timeline. The need of the hour is to focus and emphasize on the state of the art laboratory infrastructure and have a robust research environment in

**order to understand the various kinds of infections/ viruses and also to ensure bio security of the country.**

#### **75 days – ‘COVID Vaccination Amrit Mahotsava**

7.9 On 13<sup>th</sup> July, 2022, the Government of India announced a 75 day window starting from 15th July, 2022 wherein all the adults can get free booster doses at all Government Vaccination Centres. This special vaccination drive is a part of the celebration for Azadi ka Amrit Mahotsav and free booster doses to all citizens above 18+ will be provided.

**7.10 The Committee appreciates the Government's move for linking Azadi ka Amrit Mahotsav with vaccine drive, thereby, announcing a 75 day window starting from 15th July, 2022 wherein all the adults will get free booster doses at all Government Covid Vaccination Centres. In this regard, the Committee recommends the Government apparatus/NGO/Civil Society to associate with vaccination drive on auspicious occasion of Azadi Ka Amrit Mahotsav and achieve the intended targets. The Committee hopes that this Vaccination Amrit Mission leads to mass mobilization and mass vaccination among the eligible beneficiaries.**

#### **Need of restoring Ecological Balance in the world**

**7.11 The Committee observes that the pandemic through the devastating impact it ravaged across the rungs of the society, shed light on the importance of ecological balance in the world. The Committee notes that in this age of globalization and rapid urbanisation, humans are becoming more detached from their environment. Nature is the essence of human life and human-nature relationship does have an impact on human's health.**

**7.12 The Committee notes that the increase in anthropogenic activities and augmented human interventions in the ecosystem has had an adverse impact on the environment. The impact of Global warming and Climate Change are visible throughout the world, especially in developing countries. Pollution in all form-air, water, noise etc have become quite common. The Committee believes that there is a need to restore the ecological balance and let nature take its course. The Committee therefore, strongly emphasizes on the need to adapt a living and lifestyle which is in harmony with nature so that humanity is better prepared for dealing with any uncertainties in the future.**

**7.13 The Committee notes that the former President of India, Shri Ram Nath Kovind, has also highlighted the importance of economical balance in the world. The former President of India's in his Speech in the farewell function on 23rd July, 2022 stated the following:**

*"In the year 2020, in a matter of few days, our world changed like never before. After nearly hundred years, a pandemic jolted the entire humanity. It has been an unprecedented tragedy in our times, and the whole world is still struggling with it. At this stage, one can only hope that the world will draw the right lessons from it. The chief lesson is that we human beings have forgotten that we are part of nature. The reality is that we are neither separate from nature, nor we are above it. The outbreak of the pandemic was partly linked with the disruption in ecological balance. The last two years have also reminded us that we are after all one human family and our survival depends on mutual cooperation. India's efforts in combating COVID have been appreciated worldwide. With everyone's efforts,*

*we have achieved the target of 200 crore vaccinations in just 18 months. During the Corona period, we had provided free ration to 80 crore people."*

**7.14** The Committee notes that India's response strategy against the pandemic had many shortfalls and the country struggled to minimize the impact of the pandemic Covid-19. Many experts have opined that the Covid situation and its subsequent waves could have been handled in a better way. However, there is no denying the fact that India despite its large population and fragile healthcare infrastructure was successful in adapting to the uncertainties that the pandemic ravaged. The Committee appreciates the up scaling of the testing infrastructure in record time and notes that India has huge potential to deliver healthcare services to the last mile. India must continue its journey towards ushering new reforms in its health sector through its exemplary inclusive schemes and initiatives and expansion in the health Budget. Hon'ble President Smt. Droupadi Murmu in her Speech on her assumption of office as President of India on 25<sup>th</sup> July, 2022 also commended the capability India showed during the pandemic which is quoted as under:

*"The kind of capability that India has shown in combating the global crisis of Corona pandemic has enhanced India's credibility all over the world. We Indians not only faced this global challenge with our efforts but also set new standards for the world. Just a few days ago, India has set a record of administering 200 crore doses of corona vaccine. The patience, courage and cooperation shown by the people of India in this entire battle is a symbol of our growing strength and sensitivity as a society. India not only took care of itself in these difficult situations but also helped the world. In the atmosphere created by the Corona pandemic, today the world is looking at India with a new confidence. The international community has high hopes from India for ensuring global economic stability, ease of supply chain and peace."*

## **CONCLUSION**

**7.15** The Committee notes that the pandemic has brought in open the need of scaling up the vaccine manufacturing ecosystem in the country and investing in the research and development infrastructure in the country. With the future variants being inevitable, the country must prepare better vaccination strategies. The Committee further believes that a resilient vaccination strategy will require concrete clinical research which is currently being carried out in the country. The Ministry must also focus on development of newer vaccine candidates and develop rapid response care strategies for better mitigation of the future uncertainties.

**7.16** The Committee further feels that there is a need to learn from Covid experience and implement the health system reforms in the country. The Committee further reemphasizes that India must operationalize an effective, functional, transparent and accountable system for reporting severe adverse events.

**7.17** The Committee also believes that there is a need to expand democracy to promote people's health and include equitable centre-state relations and ensure more transparency in decision making and data management. The Committee further recommends that the Government must ensure robust planning at all levels along with taking special measures to address gender and social inequities.

**7.18** The Committee notes that during the pandemic, Covid related drugs were in short supply and rampant black-marketing led to selling of drugs at exorbitant prices. The Committee further notes the disruption of essential health care services during the pandemic. The Committee strongly recommends that the Government must take special initiatives to introduce comprehensive drug price control mechanisms to cover all essential medicines and ensure that such hike in the medicine prices especially at the time of a medical crisis is strictly monitored. The Committee further recommends the Ministry to streamline the routine public health care services and ensure non-Covid health services are restored to pre-pandemic level.

**7.19** The Committee also notes the shortfall of healthcare workforce in India and recommends the Ministry to ensure that regular recruitment is carried out to fill all the vacant posts in the Medical Colleges and Hospitals. The Committee also recommends the Ministry to continue its efforts to expand the capacity of public health services in rural and urban areas through adequate, massive increase in central government expenditure on health.

**7.20** The Committee in its Report has extensively examined the subject, "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID-19" and identified various issues and challenges that are yet to be resolved. The Committee emphasizes the Ministry to ensure that the set targets of complete vaccination are achieved and any existing disparity in vaccine distribution is addressed at the earliest. The Committee hopes that the Ministry sees Covid-19 as an opportunity to revamp the public healthcare infrastructure in the country and usher in new reforms. The Committee strongly advocates the imperative essentiality of increasing Government health expenditure and investments in research and development. The Ministry must also work towards forging better public private partnerships for ensuring last mile delivery of healthcare services.

## **RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE**

### **RESURGENCE OF PANDEMIC COVID-19**

**The Committee observes that the origin of the virus still remains obscure and more studies need to be conducted to shed light on the origins of the SARS-CoV-2 virus. The Committee strongly believes that identification of the true source of the virus is crucial for establishment of new zoonotic reservoirs so that future reinfections and diseases in animals as well as humans are prevented. Moreover, the information is crucial to reduce any future risks due to the emergence and transmission of the zoonotic diseases like the recent outbreak of Monkeypox. The Committee is of the opinion that the large scale fatalities and the devastating impact of Covid-19 pandemic necessitate the need of being better prepared for possible future outbreaks viz the menace and management of Monkeypox. The Committee strongly believes that it is incumbent upon global scientists to accelerate its efforts in identifying novel pathogens and establish a robust surveillance mechanism for faster detection of the pathogens. In this regard, it becomes all the more important to identify the origin of the SARS-CoV-2 virus and investigate its origin along all the possible pathway of emergence.**

**(Para 1.9)**

**The Committee takes into account that there is still lack of concrete evidence on whether the corona virus reached humans via a laboratory incident. Nevertheless, the Committee understands that if the origin of corona virus is allowed to remain a mystery, it will have colossal consequences over Bio-safety and Bio-security of the world. The Committee, therefore, strongly recommends the Government to reckon its diplomacy to appeal to the comity of nations to conduct more studies to identify the origin of Covid-19 and penalize the culprits at the International platform. The Committee further feels that the increasing number of emerging virus highlights the necessity of establishing a robust mechanism for systematic investigation of the origin and the route of transmission of the pathogens. The Committee accordingly recommends the Ministry to develop a healthcare framework in the country for investigating and managing future outbreaks more effectively. In this regard, the Committee strongly believes that the recently constituted Task Force Team led by Dr. VK Paul will track the Monkeypox situation and provide guidance to the Government on the expansion of diagnostic facilities in the country and combat the menace of Monkeypox.**

**(Para 1.10)**

### **RESURGENCE OF PANDEMIC COVID-19**

**The Committee observes that India is one of the countries with the heaviest burden of Covid-19 cases in the world. The enormity of the population of the country posed a major challenge in the face of this unprecedented pandemic. With the fragile health infrastructure and the huge shortage of the healthcare workers, the country witnessed itself reel under tremendous pressure. The Committee notes that the Government could not accurately anticipate the gravity of the possible resurgence of pandemic and its subsequent waves. The Committee believes that even when the trajectory of COVID-19 cases in the country registered a decline in the aftermath of first wave, the Government should have continued its efforts to monitor the resurgence of COVID-19 situation and its possible outrage in the country. The Committee notes that the Ministry has been**

cautioning States to maintain the vigil and chalk out situation and strategy & plan for any exigencies that may arise due to resurgence of COVID-19 in their respective States, however, the Committee is unhappy to note that many States were unable to cope up with the arising uncertainties and medical emergencies in the wake of the pandemic resurgence of Covid-19 during the second wave that caused more than 5 lakh registered deaths.

(Para 1.18)

#### **WAVES OF PANDEMIC OF COVID-19**

The Committee takes into consideration the anticipation and conclusion of virologists and microbiologists that virus will continue to evolve and possibly mutate into a more virulent and transmissible variant and so has been evident by the subsequent Covid waves across the world. The Committee, therefore, strongly advises the Government that there is an urgent need to expand the genome sequencing machinery in the country to keep a track of mutating variants.

(Para 1.31)

The Committee notes that Indian SARS-CoV-2 Consortium on Genomics (INSACOG) is a consortium of 38 laboratories which monitors the genomic variations in the SARS-CoV-2. INSACOG, in its Bulletin dated June 20, 2022 has submitted that the total number of samples sequenced is 256,599. The Committee feels that considering the high number of total covid cases in the country, the number of samples sequenced is very low. The Committee, therefore, is of the firm view that genome sequencing is part of an effective virus containment strategy and facilitates better surveillance thereby entailing necessity for better policy formulation on Covid-19 management. Keeping into account the fact that India lags behind in genome sequencing and has sequenced very less number of samples when compared to other countries. The Committee strongly believes that there is a need to augment the genome sequencing facilities in the country. The Committee, accordingly, recommends the Ministry to intensify its efforts with regard to genome sequencing of the SARS-CoV-2 genome and ensure that the mutating variants are monitored efficiently and regularly. This is essential to understand the characteristics and complexity of the virus along with its ramifications and the conclusion so arrived must be scientifically utilized for vaccines development based on empirical facts and data with due clinical trials.

(Para 1.32)

The Committee, in its 123<sup>rd</sup> Report, had analyzed the role of NCDC-IDSP and emphasized on the need to revitalize the enshrined role and responsibility of NCDC for effective control of the disease along with strengthening of the Central Surveillance Unit (CSU), State Surveillance Units (SSU) and District Surveillance Units (DSU). The Committee notes that NCDC-IDSP undertakes crucial tasks related to surveillance and conducts epidemiological investigation. The Committee strongly recommends that the sequenced data must be shared with the NCDC at the earliest. The Ministry must make efforts to strengthen the Integrated Disease Surveillance Programme (IDSP) at the National Centre for Disease Control (NCDC) so that the data provided by the sequencing laboratories are timely investigated and correlated with the field data trends.

(Para 1.33)

The Committee appreciates Government's efforts that the Covid-19 testing infrastructure in the country has come a long way since the detection of the first Covid case in January, 2020. Initially the Covid testing facility was available only at NIV Pune and gradually the testing facilities were expanded to other laboratories across the country.

**The Committee considers that the usage of highly specific molecular diagnostic tests is crucial for identifying the active cases and managing the risk of contamination. The Committee, in this regard, commends ICMR's push for a variety of other tests such as TrueNAT and CBNAAT systems which were used for comprehensive screening and confirmation of COVID- 19 cases.**

**(Para 1.37)**

**The Committee takes into account that earlier diagnosis of the virus followed by timely isolation of the infected persons is extremely important in the pandemic management. The Committee, however, strongly believes that providing large scale testing facilities with faster results that correspond to the increased transmission rate of the virus should have been a crucial part of Covid management policy. The Committee observes that owing to the initial delayed action in the aftermath of outbreak of Pandemic by the Healthcare system to adapt to the rapidly increasing cases, there were considerable procrastination in getting the results of Covid Test and thereafter unbound spree of transmission went unchecked and uncontrolled. Incidents of results getting delayed by more than a week were also reported thereby leaving infected persons in lurch. The Committee observes that the people had to reluctantly approach private facilities for RT-PCR Tests which charged heavily. The Committee is concerned to note that there existed a visible divide in the testing infrastructure in the rural and the urban areas, thereby forcing covid infected persons to run from pillar to posts.**

**(Para 1.38)**

**The Committee regrets the non-responsive attitude of the Government towards enhancing the health infrastructure in the aftermath of the receding first Covid-19 wave. With trends of Pandemic Covid-19 witnessing a steady decrease, the Government laid its guard down and failed to maintain the momentum of Covid case management attained during the first wave. The Committee expresses its disappointment over the lackadaisical approach of the Government machinery to testing of Covid cases with the fall in its trends and further ease in restrictions across the country. Both of these could be attributed to the tsunami of covid cases which was followed by enormous fatalities during the second wave and the Government agencies remained perplexed and witness to the deteriorating situation that went out of control.**

**(Para 1.39)**

#### **MISMANAGEMENT OF OXYGEN SUPPLY DURING THE SECOND WAVE**

**The Committee finds that with the increase in the number of covid positive cases in the country, there was a severe pressure on the health infrastructure from the smallest to the large private hospitals. There were several instances of families of patients pleading for oxygen and waiting in queues for oxygen cylinders. Media relayed stories of hospitals running out of oxygen and making desperate appeals when hospitals were reportedly left with only few hours of oxygen supply. In April, 2021, the Delhi High court slammed the Delhi Government for alleged mismanagement in distribution of medical oxygen. The High Court in May, 2021 also asked the Central Government to divert the unutilized tankers of oxygen to Delhi from States where the Covid-19 situation was improving.**

**(Para 1.47)**

**The Committee reiterates its observations/recommendations made while examining the Covid situation in 2020. The Committee in its 123<sup>rd</sup> Report had warned the Government of the possible shortage of the Oxygen Cylinders and supply of Oxygen in the hospitals. The Committee is disappointed to note that the Ministry in its submission in 2020 had assured that the country is self sufficient in Oxygen and Oxygen Cylinders; however, their hollow claim was brutally exposed during the second wave. The Committee recalls its recommendation made in the 123<sup>rd</sup> Report where the Committee had strongly recommended the Government for encouraging adequate production of oxygen and ensuring its supply in the hospitals. Notwithstanding, the Government failed to manage the even distribution of oxygen in the States and amidst the skyrocketing demand, the Government could not maintain a steady flow of oxygen leading to an unprecedented medical crisis. The Committee notes that poor logistic management and failure of the Government in ensuring a quick response from the healthcare system speaks volume of the utter chaos in the Government machinery especially during the second wave. A poor monitoring of the oxygen generation capacity and availability of Medical Oxygen, Oxygenated and Ventilator beds in the hospitals further aggravated the situation.**

**(Para 1.48)**

**The Committee observes that in the Statement laid in the house in the 256<sup>th</sup> Session of the Rajya Sabha, the Minister of Health and Family Welfare submitted that as on 4<sup>th</sup> April, 2022, States/UTs reported a total of 5,21,358 deaths due to COVID-19 in the country. The Ministry submitted that the Government of India maintains data of total cases and deaths due to COVID-19 reported and updated by States/UTs on a regular basis. The Committee wonders that in response to the Union Government's request to States/UTs to furnish the details of Covid deaths owing to the lack of oxygen, 20 States/UTs responded and none of these State/UTs have reported confirmed death due to oxygen shortage.**

**(Para 1.49)**

**The Committee is disturbed at the unfortunate denial of the Ministry of Health and Family Welfare regarding Covid Deaths due to Oxygen shortage in the country. The Committee takes into account the media reports that there were many deaths due to Oxygen shortage in the hospitals; however, the sheer negligence of the fact shows the absence of empathy in the Government parlance. The Committee notes that there were no definite guidelines for identifying the deaths due to inadequate supply of oxygen. Oxygen shortage is not noted as a cause of death in the medical records and most of the deaths were attributed to co-morbidities. The Committee is disappointed at this utter ignorance by the Government and strongly recommends the Ministry of Health and Family Welfare to examine the number of deaths due to oxygen shortage especially during the second wave of Covid. The Ministry, in coordination with the States, must audit the deaths due to oxygen shortage and enable robust documentation of the covid deaths that will infact generate the responsive and responsible sense of government and cautious formulation of policy and combat situational health care emergency. The Committee further expects more transparency and more accountability from the Government agencies. The Ministry must meticulously examine the oxygen stricken Covid deaths and ensure that proper compensation is accorded to the families of the victims.**

**(Para 1.50)**



During its deliberations with the Ministry, the Committee noted that the PSA plants were being established in each district hospitals. The Committee observes that setting up Pressure Swing Adsorption (PSA) and ensuring its proper operation and maintenance incurs high costs. The Committee is concerned that the plants may be left unused when the Oxygen demand is low. The Committee, therefore, recommends the Government to ensure that the PSA set up is utilized optimally and any wastage of the resources is avoided. The Government must accordingly devise a system to make Oxygen readily available to the hospitals and strengthen the infrastructure for transporting oxygen to the Government and private Hospitals within the desirable span of time.

(Para 1.51)

The Committee is of the view that technical expertise is required for operation of PSA plants. The Committee, therefore, recommends the Ministry to ensure that the required technical staff is available at the district hospitals and no unwarranted incident take place once the PSAs are installed in the hospitals. The Committee further recommends the Ministry to ensure that efficient Oxygen Management Protocols (OMP) are followed in all the hospitals and oxygen is scientifically administered and managed for optimum medical utilization in public and private hospitals.

(Para 1.52)

#### **CHALLENGES AND LEARNINGS FROM THE SECOND WAVE OF THE PANDEMIC**

The Committee understands that the second wave of Covid-19 put the Indian healthcare system and the diagnostic infrastructure under insurmountable pressure, thereby, emphasized on the need for strengthening mitigation strategies. The Committee appreciates that the Government has upgraded testing infrastructure in the country; however, the number of testing facilities still remains low in proportion to its population.

(Para 1.54)

The Second wave was undoubtedly marred by high cases, increased deaths, shortage of oxygen and beds in hospitals, reduced supplies of medicines and other important drugs, disruption of essential health care services, hoarding and black marketing of cylinders and medicines etc. The Committee is of the considered view that had the Government been successful in identification of the more virulent strain of virus in the population at an early stage and suitably implemented its containment strategy, the repercussions would have been less grave and many lives could have been saved.

(Para 1.55)

The Committee also takes note of the constant rise in covid cases during the Kumbh Mela, Tablighi Jamaat in New Delhi and election campaigns in the West Bengal. The Committee notes that large gatherings with no social distancing are synonymous with hotspots of Covid. The Committee notes that managing a large crowd along with following covid protocols poses a challenge to the administration. Such massive gatherings on several social, political and religious occasions were also a major causing factor for the second covid wave. With covid fatigue hitting in among the citizens, the Government also raised celebratory flag and presumed that the whole situation was under control.

**However, a devastating second covid wave exposed all the false claims of the Government and resulted into large scale casualties.**

**(Para 1.56)**

### **THIRD WAVE OF COVID-19**

**The Committee notes that the rate of spread of Omicron is higher than its previous delta variants. Omicron has led to a rise in the number of covid cases in India particularly among the young population. However, the rate of hospitalization and the severity of infection remained low compared to second wave that was fuelled by the Delta variant. The Committee is of the opinion that since many cases were mild and asymptomatic, there are more chances of cases remaining undetected and not making it to the official registry. The Committee understands that the death rates have been lower in the third wave; however, the Government must continue taking effective measures for enforcing Covid-Appropriate Behavior (CAB). The Committee further feels that a strict testing regime in the airports for international flights should have been followed and patients testing positive should have been immediately isolated. With the uncertainty brewing around newer and more virulent strains of the virus, it is imperative to generate public awareness to wear a mask and follow all the covid protocols.**

**(Para 1.63)**

### **NEW WAVE OF COVID-19 IN THE FUTURE**

**The Committee notes that although the Covid-19 cases have been on a slow rise, fear of transmission of a more virulent strain of Sars-Cov-2, still persists. The Committee notes that the recent surge in cases reveals that Covid is here to stay and will become endemic. The Committee strongly recommends the Ministry to take note of any fresh surge in the Covid cases and conduct sequencing of adequate number of samples so that new Variants of Interest (VoI) and Variants of Concern (VoC) can be identified at the earliest. The Ministry must also ensure that adequate number of samples are tested so that Covid cases are well reported and documented. The Committee also recommends the Ministry to be prepared for any eventualities of more virulent strain of Sars-Cov-2 virus and carry out mock drills to identify any gap in the covid containment policy of the Government. The Ministry must also explore options to study sewage samples for early prediction of any possible outbreak of Covid waves in future and thereby formulate dynamic strategy to mitigate the resurgence.**

**(Para 1.66)**

**The Union Government must coordinate with the States and assess the requirement of medicines, kits, oxygen etc so that shortage in supplies is averted in case of future outbreak. The Committee strongly recommends that the Ministry must closely monitor the trajectory of Covid in the country so that the system is better prepared to manage future resurgence of the virus, if any.**

**(Para 1.67)**

### **VACCINE RESEARCH AND DEVELOPMENT**

**The Committee emphasizes that the Government must incentivise multi-disciplinary research and efforts towards enhancing the research infrastructure in the country. The Committee recommends to promote collaborative studies among National**

and International Institutes and develop a roadmap for creating a vibrant research environment in the country.

(Para 2.6)

The Committee observes that the provisions for emergency use authorisation is absent in New Drugs and Clinical Trials Rules, 2019 and under Drugs and Cosmetics Act, 1940. It is regretful to note that the vaccines have been given EUA without any specific provision in the Indian drug rules and regulations. The laws in other countries are very clearly defined which made the granting of approvals of vaccine and drugs during the pandemic very transparent. However in India, the information regarding the protocol followed and the clinical trial data of the vaccines remained shadowed for a long time.

(Para 2.17)

The Committee is of the firm opinion that the procedure followed behind granting emergency or restricted approvals to drugs and vaccines must be clearly defined in the laws. Ambiguity on the vaccines trials as well as the procedure followed for EUA reflects greatly on the need of making amendments to the Indian Laws. The Committee accordingly recommends the Ministry to make specific provisions for EUA in the Indian drug laws. The Committee also notes the lack of clarity in the procedure followed for granting the approval for administering the booster doses. The Committee would like to be apprised on the protocol followed and the laws under which the approval was granted. The Committee feels that meticulous scientific findings must form the basis for any major changes in the course of the vaccination policy. The Committee further recommends the Ministry of Health and Family Welfare to carry out rigorous assessments of laboratory and clinical trial data before granting any future Emergency Use Authorization for vaccines. The Ministry must also share the data on quality, safety, production of protective antibodies and efficacy of the vaccines in the public domain.

(Para 2.18)

The Committee appreciates the efforts of the Department of Health Research and the Department of Biotechnology that have been at the forefront of the vaccine research and development in the country. The Committee time and again has emphasized on the need for strengthening the research ecosystem in the country. The Committee further believes that both the Departments must also work towards strengthening the clinical trials ecosystem in the country along with data transparency. The Committee understands that vaccine development faces a slew of challenges ranging from procuring the raw material to conducting human trials. However, the present situation necessitate development of effective interventions so that the future outbreaks as the like of Covid-19 are mitigated. The Committee strongly recommends the Ministry to strengthen the end-to-end vaccine development programme and extend support to vaccine candidates which are at different stages of development.

(Para 2.23)

The Committee also appreciates, "Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission" which was announced as part of the third stimulus package. The Committee recommends Ministry of Health and Family Welfare and the Department of Biotechnology to continue work towards development of vaccines and ensure that the vaccines are introduced in the market for free use.

(Para 2.24)

**The Committee strongly feels that there is an urgent need to develop vaccines that are effective against all the variants of concerns that have been discovered so far and also the future newer variants. The Committee recommends the Ministry to take initiatives to develop a universal covid vaccine that is effective against all the variants. The Ministry should encourage research collaboration between ICMR and other research Institutes in the country.**

**(Para 2.25)**

#### **VACCINES BEING ADMINISTERED IN THE COUNTRY**

**The Committee observes that the country's first indigenous vaccine- Covaxin works on inactivated virus platform. With the constant mutation in the virus, there is an urgent need to evolve strategies for development of second-generation vaccines. The Committee, accordingly recommends the Ministry to encourage vaccine development on other newer and more efficient platforms and also evaluate the efficacy of the existing Covid-19 vaccines. The Ministry must make continuous efforts in developing vaccines that are variant neutral and whose efficacy remains unchanged against other strains of virus. The Committee reiterates its recommendation that all the Ministries concerned must collaborate with other National and International Institutes on vaccine research and development front and benefit the nation with latest innovation.**

**(Para 2.29)**

**The Committee appreciates that the scientific community around the world sprung into action and developed Covid-19 vaccines in record time. It is a well established fact that the Indian pharmaceutical companies have a worldwide presence and have the ability to produce vaccines on a large scale. Taking into account that the company that produces the largest number of vaccines in the world is an Indian company, the Committee observes that India has huge potential in supplying the global demand of vaccines, however, the Committee discovers that there is a gigantic scope for more innovation and research in the sector. The Committee, therefore, strongly recommends that the Government should look forward for strengthening the research ecosystem so that vaccines on newer and more scientific platforms are developed. The Committee, accordingly, recommends the Government to increase the budget of Health Research and ICMR so that newer innovations see the light of the day. India should not just focus on being a mass producer of vaccines but also aim at creating a niche space for the Indian Research fraternity in the vaccine and drugs development sector.**

**(Para 2.30)**

#### **INDIA COVID-19 EMERGENCY RESPONSE AND HEALTH SYSTEM PREPAREDNESS PACKAGE**

**The Committee is of the view that the funds allocated for Covid-19 management should have been judiciously distributed among the States so that the financial burden of the poorer States is aptly managed. The Committee recommends the Government to ensure that adequate funds are reserved for purchasing and administering of vaccine doses. The Ministry may submit the expenditure profile of the Rs. 35,000 crore funds allocated for vaccination other emergency response and Health System preparedness packages and allocation from PM Covid Care Funds. The Committee again emphasizes that the Ministry must ensure equitable distribution of funds among the States.**

**(Para 2.34)**

As per the information submitted by the Ministry, a large percentage of the fund has already been transferred to the States, however, the Committee is apprehensive about the utilization of the funds under the Emergency Covid Response Package (Phase I & II). The Committee accordingly recommends the Ministry to monitor the utilization of the funds by the States and ensure that adequate infrastructure is available in the States. The Centre along with the States must ensure that the allocated Covid fund is utilized for implementation of IT, training and capacity building of human resources besides vaccine administration. The Committee, therefore, strongly recommends the Ministry to follow up with the States to ensure that the funds are optimally utilized by the States and seek utilization certificate from the States/UTs.

(Para 2.35)

The Committee expresses its deep concern over the practice of releasing grants on the last day of the financial year. The Committee has time and again recommended the Government to adopt financial prudence and avoid last minute disbursement of funds. However, such poor financial management speaks volume of the lack of communication between the Union Government and the UT. The Committee recommends the Ministry to frame guidelines of financial prudence in consultations with the States and ensure that the guidelines are judiciously followed. The Ministry of Health and Family Welfare must act as a facilitator and guide the States to ensure optimum utilization of the funds. The Committee, therefore, recommends the Ministry to adopt prudent fiscal analysis and devise a feasible roadmap so that such instances of poor financial mismanagement are not repeated.

(Para 2.37)

## VACCINE PROCUREMENT AND DISTRIBUTION

The Committee notes that procurement and delivery of vaccines for catering to the targeted group of people requires huge amount of financial resources. The Committee observes that a robust assessment of the logistic requirements and streamlining of the procurement process is crucial in ensuring the supply chain of the vaccines in the country. As the beginning of the National Covid Vaccination Program, much confusion prevailed on the Government's vaccine procurement policy. The Committee takes into account that some States raised objection to the provision of Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy due to the financial constraints in the procurement of the vaccine that disturbed the vaccine demand supply continuum. States complained about acute shortage of vaccines in the third phase of vaccination, i.e. 18-44 age Group while vaccination was the only real weapon or the last hope to combat Covid-19. The Committee is of the opinion that the Centre's erstwhile policy of not providing free vaccines to age group of 18-44 years was devoid of any justification and generated hue and cry amongst vaccine willing citizens.

(Para 3.10)

The Committee takes note that the Indian Government did not make any upfront payments or signed any prepurchase agreement with the vaccine manufacturers during the developmental phase of vaccines. The need of such agreement was felt when the vaccine supply could not match the vaccine demand from the States. The Committee notes that as most of the vaccine centres used to get full to its capacity at quick pace, booking a slot on Cowin became herculean task at the early stage. The Committee is of the view that the Government should have taken steps to enhance vaccine capacity in the country and

procure additional vaccine doses. The Committee believes that a better assessment of the vaccine requirement in the country could have accelerated the vaccination drive. However, absence of a micro-level planning greatly impacted the supply chain of vaccines.

(Para 3.11)

The Committee further notes that the Procurement Policy was modified from time to time to overcome the limitation of each Procurement Process. However, the Committee is of the view that there exists a huge disparity between the States and many economically weaker States were incapable of managing such intricate vaccine logistic requirements on their own. With the change in the guidelines of the procurement policy, the Central Government could negotiate with the vaccine manufacturers and settle on a fair and better price. The Committee recommends the Ministry to make elaborate arrangements for ensuring procurement in emergency situations.

(Para 3.12)

The Committee further recommends the Ministry to seek technical as well as financial assistance so that procurement planning strategy can be further strengthened for future such emergencies.

(Para 3.13)

#### **DISTRIBUTION PLAN AND ITS SPECIFIC COURSE OF ACTION FOR VACCINATION FOR COVID-19**

The Committee notes that a robust cold chain infrastructure forms the crux of the National Vaccination Programme. Under the Universal Immunisation Programme, the Government has been providing vaccination for other diseases to the citizens. However, considering the large scale of Covid vaccination program, there was an urgent need to provide adequate cold chain equipments to the States so that the vaccines were smoothly distributed and rolled out upto the last corner of the country. The Committee is of the view that the vaccines need to be stored in refrigerated conditions and the temperature has to be monitored on a real time basis. Insulated vaccines vans are required for transportation of the vaccines across the country within stipulated timeframe. The Ministry, therefore, must assess the ground requirements of the cold chain supply and ensure that adequate number of insulated vans and cold chain equipments are available. The Committee points out that since adequate cold chain infrastructure is absent in many rural parts of the country, therefore, the Ministry must make concerted efforts to address future challenges arising from newer variants and newer diseases, keeping a vigil on assured adequate vaccine cold-chain supply. The Committee emphasizes that the Ministry must accordingly work towards establishing an efficient network of cold chain logistics for ensuring efficient last mile-delivery of the vaccines in required environment.

(Para 3.18)

The Committee also notes the five levels of vaccine stores and recommends the Ministry to ensure that vaccine store at each level fulfil the requisite criteria for adequate storage of vaccines. The Ministry along with the States must ensure that the personnel are well trained to manage the vaccines at these cold chain points. Any damage to the vaccines

at any level must be taken very seriously and all efforts must be made to ensure that the vaccines are transported at desired temperature.

(Para 3.19)

The Committee notes that the use of modern cold chain equipments for storing and transportation of vaccines at the recommended temperature is the keystone for maintaining the quality and efficacy of the vaccines, however, the Committee finds that there is huge scope for improvement in the cold chain equipments in the country. The Committee points out that there is a need to upgrade the cold chain equipments in many States and adopt modern refrigerant technology so that the vaccines can be better monitored. The Committee also notes that use of eVIN has facilitated real time monitoring of the vaccines in the States. The Committee strongly recommends the Ministry to make eVIN functional in all the States and UTs and build technical capacities so that the cold chain handlers as well as the Programme Managers have a complete overview of the vaccine supply and consumption pattern.

(Para 3.25)

The Committee takes into account the fact that the lack of ultra cold chain vaccine infrastructure in the country has limited the choice of vaccines. The m-RNA vaccines from Moderna, Pfizer etc that need a temperature of -70 to -80 C for storage could not be explored as vaccine options in India when these were some of the first vaccines that were given EUA in the western countries. The Committee believes that a poor cold chain infrastructure not only limits the choice of the vaccines but also increases the risk of vaccines wastage.

(Para 3.26)

The Committee also notes that in regions with difficult geographical terrain and poor connectivity, digitization of vaccine stock inventory and its storage temperature may not be possible. The Committee is concerned especially for States like Uttarakhand, Himachal Pradesh and the North Eastern States where road as well as network connectivity is very poor. Ensuring a robust vaccine distribution mechanism and monitoring the temperature while ensuring last mile delivery of the vaccines may be a challenge in such areas. The Committee, accordingly, recommends the Ministry to coordinate with the States and encourage use of modern technologies, Drones, Helicopters for the robust distribution of the vaccines.

(Para 3.27)

The Committee observes that the price of Indian vaccines compared to the foreign vaccines is less, however, the Committee observes that mRNA vaccines because of their high potency have been greatly explored over the conventional vaccine platforms such as subunit, killed and live attenuated virus etc. The Committee is given to understand that mRNA vaccines provide greater flexibility in comparison to other vaccine platforms. With the virus constantly mutating and increasing risk of vaccine escape, mRNA vaccines provide a better alternative and more flexibility. The potential for low cost manufacture of the mRNA vaccines is also a major advantage. The Committee, accordingly, recommends

**the Ministry to explore such versatile vaccine platforms in the country and work towards producing cost effective indigenous mRNA vaccines.**

**(Para 3.32)**

**The Committee notes that the bargaining powers of the vaccine manufacturers are high due to the high demand of the vaccines, however, the Ministry through bulk negotiations have settled at a fair price for free administration of the vaccines in the Government facilities. The Committee further notes that the vaccine manufacturers fix the price of vaccine for procurement by Private Hospitals and these private hospitals subsequently charge high price for administering the vaccines. The Committee strongly recommends the Ministry and the States to strictly monitor the exorbitant rates being charged by the private hospitals.**

**(Para 3.33)**

**The Committee further notes that with the increase in the number of vaccine candidates in the market, the private hospitals as well as the Government will be at a better position to negotiate the price. The Ministry must accordingly ensure that the vaccines prices are negotiated on favourable terms and the demand supply gap is adequately abridged.**

**(Para 3.34)**

## **BOOSTER DOSES**

**The Committee notes that Booster or Precautionary doses commenced for all adults at Private vaccination Centres from April, 2022. The Committee would like to be apprised of the evidence based research and the clinical trials conducted in the country that necessitated the administering of booster doses in the country. The Committee would like to be informed on the reasons for the change in the vaccination policy of the Government and inoculating the citizens with the precautionary dose of the same vaccine. The Committee also notes that some reports suggest that a booster dose of a vaccine of a different platform could be better than a vaccine of the same platform. The Committee feels that such proposition requires deep research and any implementation of such suggestion must be substantiated by in-depth research data, scientific interpretations and clinical trials.**

**(Para 3.37)**

**Attention of the Committee is also drawn to the study of CMC Vellore on the inter-mixing of doses of Covishield and Covaxin which claims to provide better immunity. Media Reports have suggested that the CMC Vellore study reveals that heterologous immunisation provides better results than homologous vaccination. However, no official information or updates have been provided by the Ministry of Health and Family Welfare in the public domain. The Committee would like to be apprised on the findings of the aforementioned research study. The Committee further recommends the Ministry to encourage such studies on the potency and efficacy of the vaccines and ensure that bureaucratic hurdle and inordinate delays do not stall the findings of the research.**

**(Para 3.38)**



**The Committee reiterates that research studies that provide data on the efficacy of vaccines must be encouraged. The results of such study can help the Government in developing a better containment strategy and effective vaccine administration policy. The Ministry must expedite the decisions on such studies and its vaccine policy must be guided by scientific evidence and amended accordingly. The Committee further recommends the Ministry to commission epidemiological and vaccine effectiveness studies so that strong evidence on the vaccines efficacy is generated and guaranteed so as to alley the apprehension and hesitancy against the booster dose.**

**(Para 3.39)**

**Attention of the Committee has also been brought to the concerns of few States that have sought the Union Government's permission to use the available vaccines for booster doses for the 18-59 age group. The Committee recommends the Ministry to address the concerns of the States and allow them to use the available doses for booster doses if full vaccine coverage in the adult population has been achieved. The Committee further recommends the Ministry to ensure that any excess stock of vaccines is not wasted so that country achieves 100% vaccination of its citizens.**

**(Para 3.40)**

#### **UNFOLDING OF THE NATIONAL COVID-19 VACCINATION PROGRAMME**

**The Committee is of the view that a robust implementation of the five principles will ensure the success of the National Vaccination Program. The Committee recommends the Ministry to ensure participation of the key officers from State to the Block level along with active participation of the masses. The Committee also recommends the Ministry to ensure that diversion of healthcare forces to manage Covid-related uncertainties must not cause any disruption in the delivery of primary health care services. The Committee further recommends that that past experiences of universal immunization and elections must be utilized in smooth implementation of the National Vaccination Program. At the same time, every effort should be made so that there is no compromise on scientific and regulatory rules and norms.**

**(Para 4.5)**

**The Committee takes note that undertaking covid vaccination drive at such a large scale requires huge capacity and financial resources which many States may lack. The Committee, therefore, is of the firm view that the Government should generously equip the State Government with technical import and financial assistance. In all circumstances, The Centre had to take a lead role in devising policies to substantially mitigate the impact of the pandemic. The Committee understands that mass vaccination for a country as vast and as diverse as India poses a big challenge. The Central Government adopted a targeted vaccination strategy by according the highest priority to the group at the highest risk. The Committee, in its 123<sup>rd</sup> Report, had pointed out that smart vaccination might be used as an immediate strategy so that the whole population should be vaccinated. The Committee agrees that for a country as heterogeneous as India a smart vaccination strategy was the need of the hour. However, the Committee observes that the response of the Union Ministry of Health and Family Welfare on the vaccine front was delayed at the initial stage. In India, mass vaccination started in June, 2021 when vaccination was made free for**

persons aged 18 and above. The Committee notes that repercussions of the delay in the vaccination program were evident in the high fatality during the second wave.

(Para 4.11)

The Committee notes that in countries like the USA, mass vaccination started in December, 2020 whereas in India, the first phase of the vaccination drive started in January, 2021 with the healthcare workers getting the shots. The beginning of the vaccination drive had been slow owing to the exclusion of the other groups. Vaccination was made free at all Government Centers for people above 18 years from 21<sup>st</sup> June, 2021.

(Para 4.18)

As per the vaccination trend, the Committee observes that the vaccination rate has not been steady and the vaccination reached its peak in September 2021. The Committee understands that although the one size fits all approach does not bear fruit and the situation in India cannot be compared to other countries considering the large scale of the vaccination drive, however, the Committee strongly believes that India has immense potential and is home to the best of the brains in the world. The country must emulate the best of the practices from the western world and be the harbinger of innovation not only in its public policies but also in its approach to ameliorate the health sector. The Committee emphasizes that, had the vaccination drive been carried out in full swing as was done in the western countries; the country would have been at a better position to face the subsequent Covid waves. However, the exclusion of a large population from the program during the initial period aggravated the health inequities. The Committee strongly believes that the vaccination has to be made free and universal. The Committee accordingly recommends the Ministry to ensure adequate supply of vaccines so that the target of universal free covid vaccination is achieved.

(Para 4.19)

#### CoWIN App

The Committee appreciates the Ministry's initiatives in developing a digital system, "CoWin" to monitor vaccine administration in the country. The Committee notes that a platform was crucial for rolling out of the country wide vaccination program and the Co-WIN app formed the backbone of the country's vaccination drive. However, some technical glitches were reported in the app and some issues were raised during beneficiary registration on the COWIN App. The Committee is of the view that enabling a strong IT framework through Cowin Platform and imparting necessary training to all the stakeholders was crucial for success of the vaccination Program.

(Para 4.24)

The Committee observes that tracking of the vaccine transporting vehicles is crucial for ensuring the timely supply of the vaccines. The Committee appreciates the efforts of the Karnataka Government and recommends that all the States must also use such vaccine vehicle live tracking app for better vaccine management on a real time basis.

(Para 4.25)

The Committee understands that there exists a huge digital divide between the rural and the urban population. With poor accessibility and connectivity, many areas of

the country still remain disconnected from the digital ecosystem. The Committee notes that rural areas tend to be neglected as the level of awareness is very poor. The Committee recommends the Ministry to take effective measures to ensure that the rural areas especially the tribal areas are also included in the vaccination drive. The Committee notes that in the absence of internet connectivity, entering data in the app is a challenge. The Committee accordingly, recommends the Ministry to ensure that the data collected in the physical form is uploaded in the Cowin app at the earliest. The Committee is of the view that the Ministry must aim towards an inclusive vaccination policy and the vaccination drive must include the marginalized and the vulnerable population of the country too.

(Para 4.26)

The Committee also notes that through CoWin the Ministry has been successful in administering 2 billion Covid doses and CoWin holds a huge repository of the vaccination data. However, various stakeholders during the discussion highlighted the absence of any data on the efficacy of the vaccine. The Committee accordingly notes that even with an outstanding CoWin data system, the country has no extensive records of after immunisation effects in its population. The Committee strongly recommends the Ministry to facilitate linkages between CoWin and other data systems and share the data in the public domain. The Committee is of the opinion that building inter-operable data systems that ensure real time data exchange can provide a better assessment of the efficacy of the vaccines. The Committee further feels that this digital ecosystem can be aptly utilised for not only monitoring the vaccine supply chain but also promoting concrete research and formulating better policy decisions.

(Para 4.27)

#### **VIEWS OF STATE GOVERNMENTS/ THE DEPARTMENTS/MINISTRIES AND OTHER STAKEHOLDERS**

The Committee takes into account that DBT strengthened the Regional Scientific Co-operation and looked forward in taking a lead role in ensuring that the indigenous vaccines undergo rigorous clinical trials in the neighbouring countries. The Committee, in this regard, recommends the Ministry to collaborate with research bodies and apex institutes of the neighbouring countries so that regional cooperation is further strengthened and scientific fervour is promoted in India and the neighbouring countries. The Committee also recommends the Ministry of Health and Family and the Department of Biotechnology to work towards upgrading the clinical trials infrastructure in the country.

(Para 5.4)

The Committee appreciates the PACT (Partnerships for Accelerating Clinical Trials) programme and recommends the Department of Biotechnology and the Department of Health Research to launch various programs for studying other diseases alongwith their drug and vaccine development. The Committee also recommends the Ministry of Health and Family Welfare and the Department of Health Research to collaborate on development of Indian Covid-19 vaccines.

(Para 5.5)

The Committee appreciates, "Mission Covid Suraksha-The Indian Covid-19 Vaccine Development Mission" which is aimed at accelerating indigenous Covid 19 vaccine development efforts. The Committee hopes that the Mission is successful in

developing more indigenous vaccines that are affordable and easily accessible. The success of the Mission can break the barrier of shortage in vaccine supply, thus ensuring vaccines for all and promoting vaccine equity across the world.

(Para 5.6)

The Committee is of the firm opinion that India should ensure adequate availability of vaccines in the country alongwith expanding its collaboration with other countries under "Vaccine Maitree". The Committee believes that India's vaccine diplomacy would promote vaccine equity i.e. global equitable vaccine distribution among the less developed Asian, African and Latin American countries.

(Para 5.7)

#### **Ministry of AYUSH**

The Committee understands the piloted role of Ministry of Ayush in National Covid-19 vaccination programme as the Ministry provided pool of Healthcare workers as vaccinator. The Committee recommends that the Ayush institutional structure must be massively utilised as platform for dissemination of IEC activities, thus enhancing public awareness for mitigation of Covid-19.

(Para 5.8)

#### **DEPARTMENT OF PHARMACEUTICALS, MINISTRY OF CHEMICALS & FERTILIZERS**

The Committee recommends the Government to lay special emphasis on the strengthening of the end-to-end vaccine supply chain and logistics systems. The Ministry of Health and Family Welfare in coordination with the States must ensure strengthening of the cold-chain infrastructure and fair distribution of the vaccines to all the States/UTs.

(Para 5.10)

#### **MINISTRY OF PANCHAYATI RAJ**

Taking into account the Urban-Rural vaccination gap, the Committee is of the view that the existing infrastructure of Panchayati Raj can be optimally reckoned for dissemination of IEC for creating public awareness regarding the benefits of vaccine.

(Para 5.13)

The Committee, in this regard recommends that the Panchayati Raj Institutional arrangement and grass root local bodies must be massively utilized for mass rural vaccination. The Ministry must also utilize the State machinery to increase the uptake of the precautionary dose in the rural areas.

(Para 5.14)

#### **STUDY VISIT TO JAMMU AND KASHMIR AND CHANDIGARH**

The Committee hopes that the UT of J&K would achieve the set target under its vaccination drive through coveted IEC mechanism. The Ministry of Health and Family

**Welfare must monitor and guide the UT for effective management of covid cases in the UT of J&K.**

**(Para 5.19)**

#### **VIEWS OF THE STATE GOVERNMENT OF HARYANA ON THE SUBJECT**

**The Committee is of the view that the Ministry of Health and Family Welfare must ensure that appropriate accountability and review mechanisms are established in each State and adequate training is provided for ensuring smooth roll out of the vaccination drive. The Committee further recommends the use of Information Education and Communication (IEC), Interpersonal communication (IPC) strategies to generate awareness among the community to counter vaccine hesitancy in the States.**

**(Para 5.27)**

**The Committee, in this regard, commends the role of Government of Haryana for conducting special sessions to cover homeless population, prison inmates, specially-abled, etc. The Committee recommends the Ministry to ensure that the vulnerable and marginalized groups are not excluded from the vaccination drive.**

**(Para 5.28)**

#### **VIEW OF THE UT OF CHANDIGARH**

**The Committee appreciates the involvement of residential welfare association, Market Committees, NGOs, Management committees of various Temples, Gurudwaras & Mosques in the National Covid-19 vaccination programme to ensure the success of the vaccination drive in the UT of Chandigarh. The Committee recommends the other State Governments to follow suite and also conduct special vaccination campaign for elderly, differently-abled persons, bed-ridden beneficiaries and people without any identification Card.**

**(Para 5.35)**

#### **STUDY VISIT TO GUWAHATI, BENGALURU AND MUMBAI**

**The Committee emphasizes on the need of expanding "Har Ghar Dastak" Programme across the country. The Committee further desires that other State Governments must follow the Covid-19 mitigation strategy of the Government of Assam where funds raised under Corporate Social Responsibility have been utilized to strengthen the public health infrastructure in the State that is being optionally utilized in Vaccination drive in the State.**

**(Para 5.41)**

#### **VIEWS OF THE STATE GOVERNMENT OF MANIPUR ON THE SUBJECT DURING THE STUDY VISIT OF COMMITTEE TO GUWAHATI**

**The Committee appreciates the utilization of eVIN in the State of Manipur, however, the Committee notes that collection of real time information may be difficult in many geographically tough terrain of the State thereby necessitating further improvement**

**in Vaccine logistic management. The Committee, further recommends the State to ensure that vaccine centres and cold chain points are well integrated in the eVIN.**

**(Para 5.43)**

#### **VIEWS OF THE STATE GOVERNMENT OF ARUNACHAL PRADESH ON THE SUBJECT DURING THE STUDY VISIT OF THE COMMITTEE TO GUWAHATI**

**The Committee takes note of the CVC linked outreach session, Alternate Vaccine Delivery mechanism being followed in the State of Arunachal Pradesh for transporting vaccine. The Committee strongly recommends the State Government to ensure the last mile delivery of vaccines especially in the remotest area of the State. The Committee appreciates the use of First Expiry First Out (FEFO) concept in the State where vaccine vials with early expiry are used first. However, the Committee recommends the State Government to ensure that the temperature of the vaccines are maintained accurately and avoid any wastage of vaccine. The Committee further recommends the Ministry to ensure that FEFO is followed in all the States so that vaccine vials are not wasted due to expiry of the vaccines.**

**(Para 5.49)**

#### **VIEWS OF THE STATE GOVERNMENT OF MAHARASHTRA**

**The Committee commends the role of the State Government of Maharashtra where the Pandemic Covid-19 has shown heinous expression resulting into large number of deaths, however, the SMART (Specific, Measureable, Achievable, Relevant and Time Bound) monitoring of the implementation of vaccination programme led to effective management of the Pandemic. The Committee appreciates the vaccine distribution plan of Government of Maharashtra which was formulated through meticulous planning and prioritization of areas based on consideration of the number of active Covid cases and micro analysis of vaccination data. The committee further applauds the specific strategy for Covid-19 Management in 'Dharavi' -Asia's largest slum area in Mumbai. The Committee recommends the Ministry to undertake case study of 'Dharavi' Model of Covid Management to arrive at the managerial skill, planning & strategic course of action for combating any possible pandemic in the country.**

**(Para 5.55)**

#### **VIEWS OF THE OTHER STATES/UTS ON THE SUBJECT**

**The Committee appreciates the steps taken by the State Government of Meghalaya for ensuring the vaccination Status of the shopkeepers and their staff that are being displayed in all the shops. The Committee further recommends the State to ensure that the information regarding vaccine availability and other logistics are reflected on a real time basis for better vaccine distribution and management in the State.**

**(Para 5.62)**

**The Committee notes the submission of the State Government of West Bengal where instances of shortage in supply of syringes have been reported. The Committee, accordingly, recommends the Ministry of H&FW to work in tandem with the State Government and ensure that such instances are avoided for making the vaccination drive a success in the State. The Committee strongly recommends the State Government to**

manage the logistics of the vaccine distribution system and in case of shortage in supply of any related equipment timely communication to the Union Government should be ensured.

(Para 5.66)

The Committee understands that far flung and remote islands of the UT of Andaman & Nicobar have poor network connectivity and live data entry may be a herculean task. The Committee recommends the UT to ensure that the entries are logged as soon as the network connectivity is restored so that national data on the vaccination is compiled without delay.

(Para 5.73)

The Committee takes notes of the best practices adopted while implementing national Vaccination Programme in Madhya Pradesh especially for Cold Chain and vaccine management. The Committee recommends the adoption of the best practices during execution of Vaccination drive by other States too.

(Para 5.76)

The Committee applauds the role of UT Government of Dadra and Nagar Haveli for vaccinating all eligible beneficiaries for 1<sup>st</sup> dose. However, the Committee recommends the Central Government to address the concerns of the UT of Dadra and Nagar Haveli and Daman & Diu by rectifying the total population of UT.

(Para 5.80)

The Committee applauds the proactive response of the State Government of Kerala in covid case management. The State was very efficient in minimizing the impact of the first wave of the pandemic and the State Health machinery was never stretched to its limits. Various State interventions were planned at the outset of the pandemic itself which helped the State to manage the pandemic efficiently. The robust Institutional arrangement and timely & effective measures further helped in delaying the peak.

(Para 5.89)

The Committee appreciates the novel approaches adopted by the State Government of Kerala to manage the pandemic. The State Healthcare system did a commendable job to ensure that the covid cases are timely tracked and contained. The Committee takes notes that the State of Kerala had a robust monitoring system and a well planned infrastructure in the form of Domiciliary Care Centre, Covid first line treatment Centre, Covid second line treatment centre and Covid hospital. The Committee strongly feels that a strong primary health care network along with trained grass root healthcare workers was crucial for containing the pandemic. The containment strategies and efficient planning adopted by the State helped the State in averting the medical emergency due to shortage of medical oxygen and beds in the hospitals. The Committee further acknowledges the hub and spoke model adopted by the State for efficient management of Oxygen in the State. The Committee notes that timely mapping of hospitals through software as done by the State of Kerala should have been adopted by the other States for better management of Oxygen across hospitals.

(Para 5.90)

The Committee feels that the pandemic has given us the opportunity to plug the loopholes of the Indian Healthcare System and shifted the focus on the need of ushering change in the healthcare sector. The Committee observes that the State Government of Kerala adopted many novel approaches in its fight against the pandemic. The Committee strongly recommends the Ministry of Health and Family Welfare to study the Kerala Model and other novel approaches adopted by other States. The Committee recommends that the Ministry must co-ordinate and play pivotal role in exchanging of new ideas and new learning during the pandemic and related strategic management and ensure implementation of the successful models viz. the Kerala Model in other States and strengthen healthcare delivery system to meet any future medical emergency.

(Para 5.91)

#### **VIEWS OF VARIOUS STAKEHOLDERS ON THE SUBJECT**

The Committee finds that Jan Swasthay Abhiyan (JSA) has suggested useful course of action for strategic management of Pandemic Covid-19 that *inter-alia* include report of Serious Adverse Events (SAE) following Covid vaccine, assurance of affordable Medicine, Strengthening of public health sector & health manpower and promotion of PPP Model in health reforms. The Ministry of Health and Family Welfare may examine the suggestions at length for better health management in the country.

(Para 5.96)

#### **CHALLENGES IN COVID-19 MITIGATION AND MANAGEMENT**

The Committee is disappointed to note that the Government Health Expenditure as a percentage of Current Health Expenditure is only 27% and the Out of Pocket Expenditure as percentage of the Current Health Expenditure is 62.7%. The Committee while examining the Demands for Grants of the Ministry has repeatedly recommended for increase in Public investments in the health sector.

(Para 6.4)

The Committee in its 134<sup>th</sup> Report on the Demand for Grants of the Department of Health and Family Welfare had noted that BE of 2022-23 was just a 0.2% increase over RE 2021-22. The Committee had noted that despite the pandemic necessitating high investments in health sector, the Government had failed to increase the Health Budget. As per National Health Accounts Data 2017-18, the Government Health Expenditure as percentage of GDP is 1.35%. The Committee further recalls that under National Health Policy, the GHE was targeted to increase to 2.5% of GDP by 2025.

(Para 6.5)

The Committee reiterates its recommendation that the Government must increase its investment in public health systems and public health research. Indian States like Kerala that have a robust healthcare infrastructure were at a far better position to anticipate the uncertainties of the pandemic. The quick response strategy of the State reflected the advantages of a strong public healthcare infrastructure. The Committee in its 126<sup>th</sup> Report on Demands for Grants 2021-22 had explicitly recommended the Government for increasing its health expenditure to 2.5 % of GDP in the next two years and to 5% by 2025. The Committee accordingly reiterates its recommendation that the Ministry must set higher targets and ensure that the Government Health Expenditure is



increased to 5% of GDP. The Committee further recommends the Ministry to nudge the States with Health Budget less than 8% of the State's GDP to increase the State Government's investment in the health sector.

(Para 6.6)

### **Gender Gap in Vaccination**

The Committee regrets that women remain the most affected group in any calamity. Women have long been denied basic rights and gender inequities are very high, especially in economically weaker and poorly accessible regions. The Committee notes that as per the Government official data a total of 1.99 billion doses have been administered in the country till mid July, 2022. Out of the total doses, 988 million doses have been given to Males and 950 million doses to women leading to a difference of over 38 million doses.

(Para 6.11)

The Committee notes the success of vaccination drive is correlated to registration on Cowin and easy access to the health care centre for vaccination. However, with women having no access to internet or any digital tool and her high dependence on the male member of the family for any information further widens the gender gap in vaccination. The Committee further notes that rumours, such as the impact of vaccination on menstruation etc further leads to lower willingness to be vaccinated. The Committee strongly recommends the Ministry to conduct more awareness campaigns especially in region with poor rate of vaccination among women. The Ministry must make all out efforts to bridge this gender gap in vaccination.

(Para 6.12)

### **RURAL-URBAN VACCINE DISPARITY**

The Committee observes that the vaccination rate was very poor in the rural areas in the beginning of the vaccination drive. Internet connection and a mobile phone was the foremost requirement for registering oneself in the Cowin App and walk-in Covid vaccination had not yet started. Rural areas with poor digital literacy did not see an uptake in the vaccination drive. The Committee further notes that many villages across India do not have access to pucca roads, electricity and drinking water. These regions are rendered inaccessible either due to their rough geographical terrain or precarious security situation. With regions devoid of electricity, maintaining the temperature of the vaccines especially in inhospitable terrain is a difficult challenge.

(Para 6.13)

The Committee accordingly recommends the Ministry to open more vaccination centres in the rural areas. The Ministry must also explore use of newer refrigeration technology, such as "solar direct drive" that resolves the battery powered vaccine refrigerator problems and ensure that vaccines are made available in such remote areas. The Committee reiterates its recommendation that the Ministry must use modern technology and equipments to expedite the delivery of vaccines. The use of drone by the State Government of Maharashtra for delivering vaccines is a good example of making vaccines easily available in difficult terrains. The Committee recommends the Ministry to

**deploy helicopters, boats, motor bikes and every possible means of transport to achieve last mile delivery of vaccines.**

**(Para 6.14)**

### **VACCINE HESITANCY**

**The Committee agrees that a lot of misconceptions about the vaccines have given rise to vaccine hesitancy in the Indian population. With Covid vaccines getting the Emergency use authorization amidst the lack of information in the public domain, a certain sense of doubt prevailed in the people's mind. The Committee also notes that several instances of vials of vaccines getting wasted due to people not turning up to the vaccination centres have been reported. The vaccines have to be maintained at the recommended temperature and the vials of vaccines have to be used and discarded within hours of being opened.**

**(Para 6.16)**

**Vaccine hesitancy has also been recognised as one of the reason behind low vaccine coverage in certain areas leading to regional disparities in Vaccine Distribution Plan. The Committee therefore believes that there is an urgent need to provide correct information on vaccines and address the issue of vaccine hesitancy. The Committee accordingly recommends the Ministry to feature strong community engagement strategies in the vaccination Programme along with social media engagement. The Ministry must also explore involving celebrities and influential community voices for increasing the outreach of the vaccination programme.**

**(Para 6.17)**

**The Committee strongly urges the Ministry to disseminate information and spread public awareness regarding the safety and efficacy of the vaccines. The Committee further recommends the Ministry to continue conducting various Communication strategy activities especially in rural areas and areas with poor accessibility. The Committee also recommends the Ministry to conduct at-home inoculations especially for the aged and people with special need.**

**(Para 6.18)**

### **VACCINE EQUITY**

**The Committee was given to understand that the Indian Government had targeted vaccination for the entire adult population by December, 2021, however, the Government failed to achieve its targets set for the total vaccination drive. Attention of the Committee has also been brought to instances of vaccine shortage in few States, thereafter, the States were forced to divert stock meant for the 18-44 age group to the 45 plus group for their second dose. The Committee, therefore, strongly recommends the Government to refresh its target of 100% vaccination of the Indian population along with booster doses and make concerted efforts to achieve the targets.**

**(Para 6.20)**

**The Committee further notes that there exists a huge economic divide in the world and the pandemic has further widened the divide between the rich and the poor countries.**

With the development of vaccines, the western countries started stockpiling of the vaccines and were the first to provide booster doses to its citizens while the low and middle income countries struggled to administer even the first dose of the vaccine. The Committee, therefore, recommends the Government to revisit its vaccine diplomacy and take a lead role at international fora to ensure that the third world countries get adequate doses of vaccines. The Committee believes that global vaccination is very crucial for minimizing the possibility of any future outbreaks of pandemic due to resurgence of mutated virus in any other country. The Committee, in this regard strongly advocates equitable global distribution of vaccines.

(Para 6.21)

The Committee agrees that the Government should have employed a better pricing mechanism for controlling the price of the vaccines. The prices of the vaccines in the Private Hospitals and vaccination centres were very high allowing high profiteering by the vaccine manufacturing firms and the Private hospitals.

(Para 6.25)

The Committee further notes that the vaccine manufacturing firms slashed the prices of vaccines for private hospitals to Rs 225 per dose in April, 2022. During the peak of the pandemic, the Covid vaccines were being administered at Rs. 900-1400 in the Private hospitals. The Committee understands the demand-supply economics and believes that private firms have to be allowed to make some profit so that investment can be made in research & development and increasing the production capacity. However, the Committee fails to understand such high fluctuations in the prices of the vaccine that leave enormous space for vaccine manufacturing firms to earn exorbitant profits on the production of vaccines.

(Para 6.26)

## **WAIVER OF INTELLECTUAL PROPERTY PROTECTION FOR COVID VACCINES AND OTHER COVID-19 DIAGNOSTICS AND THERAPEUTICS**

Attention of the Committee has also been drawn to the proposal of temporary waiver of Intellectual property protection for covid vaccines and other COVID-19 diagnostics and therapeutics at WTO. The Committee believes that exclusive control over vaccines via patents can pose a hurdle in ensuring vaccine access to countries that lack the vaccine manufacturing capacity. The looming fear of future resurgence and more virulent viruses persists and global eradication of the Covid is crucial for halting this pandemic. The Committee, therefore, believes that transfer of technology and waiver will significantly bridge the large demand supply gap as the vaccines will be produced without authorization from the patent holder. The Committee strongly believes that for ensuring vaccine equity, there is a need to expand the vaccine manufacturing capacity across the globe and waive the Intellectual Property Protection (IPP) for Covid-19 vaccines. This can help countries in scaling up the production of vaccines and make vaccines more affordable and accessible to everyone. The Committee, however, also believes that special emphasis will have to be laid on ensuring safety and quality standard for mass vaccine manufacturing. The Committee further notes that the move to waive Intellectual Property Protections (IPP) must not disincentivize the Pharmaceutical companies to invest on

**vaccine research rather the Industry and the countries across the world must unite and work together to expand the global vaccine manufacturing capacity.**

**(Para 6.27)**

**The Committee accordingly urges the Government to continue making efforts for waiver of IP Protection for Covid vaccines and other COVID-19 diagnostics and therapeutics so that the vaccines are produced on a large scale and 100% vaccination of the world population is achieved.**

**(Para 6.28)**

#### **REVAMPING OF PUBLIC SECTOR VACCINE MANUFACTURING UNITS**

**The Committee understands that ensuring a consistent supply of vaccine during the pandemic Covid-19 posed a major challenge, thereby, arising an urgent need to accelerate the Covid-19 vaccination drive. However, the Committee laments that the public sector vaccine units were not reckoned to service in times of crisis and their contribution to the Covid-19 vaccine production remained negligible in the fight against the pandemic Covid-19.**

**(Para 6.30)**

**The Committee has been given to understand that in 2008, the vaccine production in CRI, PII and the BCG Vaccine Laboratory (BCGVL), Chennai were halted for non-compliance with Good Manufacturing Practices (GMP). The Committee observes that although the licenses were restored in 2010; however these vaccine units continued to remain underutilised. The Committee strongly believes that revival of these units is imperative to bridge the gap between vaccine demand and supply and to make vaccines more affordable and accessible. The Committee further notes that the Madras High Court in May 2021 had asked the Central Government as to what steps were being taken to revive the existing Vaccine Institutes owned by the Government. The Supreme Court in December, 2021 had also sought the response of the Central Government on its policy to revamp public sector vaccine manufacturing units. The Committee, accordingly, strongly recommends the Ministry of Health and Family Welfare to revive the existing vaccine manufacturing units and issue production licences to the GMP compliant vaccine manufacturing units.**

**(Para 6.31)**

**The Committee, in this regard, would like to be apprised of the total number of Public Sector Vaccines Units that are owned by the Central Government and the State Governments. The Committee must also be informed about the financial status and the annual Budget that has been allocated to these Public Sector Manufacturing Units over the past four years. The Committee recommends the Ministry to monitor the revival of these units and henceforth, furnish quarterly Reports to the Committee. The Committee desires that the Ministry of Health and Family Welfare must forward the revival plan alongwith financial requirement to the Ministry of Finance for approval at the earliest.**

**(Para 6.32)**

**The Committee further notes that India has been advocating the waiver of Intellectual Property rights of Covid vaccines at the global level, however, the Committee**

is perplexed to note that the Government has taken no major initiative to waive the Intellectual Property Rights for the indigenous vaccine Covaxin which was developed in collaboration with ICMR. The Committee strongly recommends to examine the possibility of technology transfer of Covaxin to the Public Sector Units and start its production in these Units.

(Para 6.33)

The Committee notes that the National Disaster Management Guidelines, Management of Biological Disasters contained comprehensive guidelines for undertaking biosafety and biosecurity measures. It aimed to strengthen the existing regulatory framework so that the country adopts a resilient response strategy in the wake of any imminent biological disaster. The Committee believes that had the Ministry implemented the guidelines and addressed the gap that was highlighted in the Report, the country would have been better prepared to tackle the pandemic. The Committee further notes that if the Government had implemented the National Vaccine Policy, 2011 in letter and spirit, the issues of vaccine-security, management, regulatory guidelines, vaccine research & development and product development could have been dealt in a better manner. The Committee recommends the Ministry to assess the functional status of National Disaster Management Guidelines, 2008 and National Vaccine Policy, 2011 and apprise the Committee of the initiatives being taken for implementation of these policies at the ground level to achieve the set objectives in these guidelines/policy.

(Para 6.35)

The Committee observes that vaccination has caused a phenomenal mitigating impact on the continuum of the pandemic Covid-19. The Committee notes that the vaccine effectiveness in Preventing Mortality is very high and the death among the non- vaccinated has been the highest during the second and the third wave. The Committee, therefore, strongly recommends the Government to continue with National Covid-19 control Plan through massive vaccination drive so as to mitigate the causation factor of mutating variants of Covid-19.

(Para 6.37)

The Committee further points out the unrealistic target set by the Government for completion of the vaccination drive in the country by December 2021. Various studies have been conducted across the world on the additional deaths that would have been averted had the vaccination coverage targets been achieved by the country. With the waning of vaccine efficacy in the population and the risk of emerging mutated variants across the world, the success of the vaccination Program is a keystone of the Covid mitigation policy. The Committee, therefore, accordingly recommends the Ministry to focus not only on the vaccine supply side barrier but also on the demand side barriers so that vaccination targets are achieved. The Committee also recommends the Ministry to take necessary measures to increase the uptake of precautionary doses so that the mortality rate is lowered given the rise in fresh infections. The Committee cautions the Government against mutating variants of Covid-19 and strongly recommends to have the vigil for total elimination of virus through resilient mitigation policy and effective mass vaccination Program.

(Para 6.38)

The Committee further notes that geographically tough terrain with poor connectivity may not permit live data entry of vaccination, hence back log entry option or off line mode of entry must be permitted so that the extent of actual vaccination coverage can be observed and any possible gap for vaccination is abridged.

(Para 6.39)

#### **NEED OF STRONG PUBLIC-PRIVATE PARTNERSHIP IN THE HEALTH SECTOR**

The Committee understands that the Government with its limited resources, faces a far big challenge to bring in structural changes in the Public Health System. It is a well established fact that there is an urgent need to augment and develop the health ecosystem in the country to keep the health index of the whole population to global standard. The Committee believes that Public Private Partnership in the Health Sector can facilitate bridging of the gaps in the healthcare infrastructure and ensure an efficient delivery of healthcare services upto lower rungs of the society. The Committee, taking a clue from the success of the PPP model in various sectors such as infrastructure, tourism, education recommends the Government to adopt a similar model in the health sector. The Committee finds that the Public Private Partnership in Health Sector is still an unexplored area and therefore, can prove momentous in increasing the reach of healthcare facilities. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to collaborate with the Private Sector on novel Projects related to the Health. The Business Houses and Companies must be encouraged to devote a substantial part of their CSR funding in the Health Sector to build necessary health infrastructure.

(Para 6.40)

The Committee also recommends the Government to launch new Schemes and initiatives that incentivises the Private Sector to bring in the funding and the expertise in the health sector. The Government must leverage the key resources of the Private sector and take full advantage of the expertise, finances, technology and human resource that the PPP model offers in combating National emergency situation in health sector like the pandemic Covid-19.

(Para 6.41)

#### **NEED OF CHANGE IN VACCINATION POLICY**

The Committee is of the opinion that the effectiveness studies of the vaccines on the newer variants of the virus should have been conducted by the research bodies in India along with the beginning of the vaccination drive. Countries like US and UK started conducting various studies to determine the proportion of people who were vaccinated but still either got severely ill or died due to the covid. The Committee further notes the research studies that recommended delay in the second dose of the AstraZeneca vaccine beyond the earlier recommended 4 weeks. This was also endorsed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Committee. In May, 2021, the COVID Working Group chaired by Dr N K Arora also recommended extension of the gap between the first and second doses of COVISHIELD vaccine to 12-16 weeks. The earlier gap between the two doses of COVISHIELD vaccine was 6-8 weeks. The Committee, in this regard, recommends the Government to find out scientifically, the reasonable gap between the two doses of the vaccine on the gap between the 2<sup>nd</sup> and precautionary booster

dose in the interest of public health otherwise common masses apprehend that Government is allowing adjustment of time gap between two doses of vaccine to clear the stock of vaccine manufacturers.

(Para 6.42)

The Committee feels that with the huge repository of vaccination data in the country, India should have been at the forefront of conducting better assessment of the vaccine efficacy in its population. The Committee believes that any change in the national vaccination policy should have been substantiated by real-life evidences and concrete research in the country itself. The Committee therefore, recommends the Ministry to conduct more research on optimising the dosage interval and accordingly approach its vaccination policy.

(Para 6.43)

The Committee further recommends that there is a need to develop a mechanism that in case of future outbreaks of the pandemic, the research infrastructure is put into action and the vaccine policy is accordingly modified for better results. The Committee again emphasizes that the preparedness of vaccination strategies requires much more clinical research so that the rapid response care strategies are adopted.

(Para 6.44)

#### **NEED OF CHANGE IN VIALS SIZE**

The Committee has also been apprised by the State Governments that due to the bigger size of 20 doses in the Corbevax vaccine, it is becoming difficult for the vaccination Centres to use them. The Committee, therefore, recommends that the vaccines should be made available in smaller packs of 5 doses each to ensure the best usage of vaccine and prevent wastage.

(Para 6.45)

#### **ENHANCEMENT IN THE HONORARIUM OF AWWs/AWHs AND ASHAs**

The Committee applauds the Anganwadi Workers (AWWs), Anganwadi Helpers (AWHs) and Accredited Social Health Activist (ASHAs) who were extensively involved in COVID-19 awareness drive in the community. The Committee notes that ASHAs, AWWs and AWHs acted as the frontline workers during the pandemic and were responsible for spreading awareness about Covid-19 and safety protocols. The ASHAs were also tasked with identifying as well as tracking COVID-19 positive cases and carrying out vaccination drive. ASHAs, AWWs and AWHs have played an important role in community surveillance as has also been applauded by WHO, however, these frontline workers remain unrewarded. The Committee accordingly recommends the Ministry of Health and Family Welfare and the Ministry of Women and Child Development to ensure timely payment of wages along with other social security benefits. The Committee further recommends the Government to consider incentives and financial protection for the ASHAs, AWWs and AWHs workers under different financial packages.

(Para 6.49)

#### **COMPLACENCY IN ADMINISTRATION OF BOOSTER DOSES**

The Committee notes that administration of free booster doses has enhanced the booster dose uptake. However, the Committee notes that this free precautionary dose window is only for 75 days. The Committee strongly recommends the Ministry to extend

the 75 days window and make the precautionary dose free for all so that complete vaccination of all can be ensured.

(Para 6.53)

The Committee further notes that the ease of access to vaccination site also has a major role to play in increase in vaccination rate. The Committee strongly recommends the Ministry to increase the Government Covid Vaccination centres across all the States/UTs. The Committee is also concerned at the general prevalence of complacency in the healthcare workers as well as the public towards booster doses. The Committee strongly recommends the Ministry to work towards increasing awareness regarding the precautionary dose among the public, particularly among the immune-compromised and people with co morbidities.

(Para 6.54)

#### **ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)**

The Committee notes that on 19<sup>th</sup> July, 2022, a total of 28 AEFI were reported across the country and total AEFI is reported to be 0.006% of the total cases. The Committee observes that under-reporting and poor quality data collection may be the reason behind reporting of such less number of AEFI. However, the Committee takes note of the unusual peak in AEFI on 10<sup>th</sup> July, 2022 where 743 AEFI cases were reported. The Committee would like to be apprised of the reason behind this sudden rise in the cases and the vaccines that caused the adverse reaction.

(Para 6.57)

The Committee notes that mild side effects after administering of the vaccines are usually reported as the body requires time to adjust to the vaccination dose. However, the Committee feels that the Ministry must ensure that possible adverse effects are communicated to the people followed by timely treatment. Attention of the Committee is also brought to the death of a patient post covid-19 vaccination. The Committee notes that in the concerned case, the AEFI Committee released its assessment Report after almost seven months. The Committee strongly recommends the Ministry to ensure that appropriate investigation must be done and AEFI Committee must expedite its examination of each adverse cases.

(Para 6.58)

The Committee also notes that COVID-19 vaccination is voluntary and presently there is no mechanism of compensation to beneficiaries or liability of vaccine manufacturer in case of any Adverse Event Following Immunization. The Committee, therefore, strongly recommends the Ministry to create a clear framework of vaccine liability for manufacturer in case of AEFI so that adequate compensation can be provided to the aggrieved individuals.

(Para 6.59)

The Committee also notes the findings of various research studies that have indicated the prevalence of long Covid among individuals infected with Covid. Even after the infection has passed, individuals have been reported to experience lingering symptoms. The Committee observes that there is a need to monitor and conduct surveillance of post covid complications. The Committee, accordingly, recommends the Ministry of Health and



**Family Welfare to frame a treatment protocol and make specific guidelines for managing post Covid complications and related health problems arising due to the initial infection. The Ministry must also work towards sensitizing the Indian Health Public System to deal with such cases of long Covid. The Committee further recommends the Ministry to ensure medical support for Long COVID sufferers and train the healthcare workers for managing patients with Long COVID.**

**(Para 6.60)**

#### **NEED OF AN ENHANCED ROLE OF AYUSH IN THE MITIGATION OF THE PANDEMIC COVID-19**

**The Committee in its 136<sup>th</sup> Report had appreciated the efforts of the Research Councils in development of new drugs especially repurposed Ayush 64 in management of Covid-19. The Committee reiterates its recommendation that AYUSH must continue emphasis on evidence based scientific research and drug development process entailing pre clinical as well as clinical trials. The Committee further recommends the Ministry of Ayush to work towards building inter-ministerial linkages and collaborate with other Departments for undertaking clinical studies on newer drugs.**

**(Para 6.63)**

**The Committee believes that in the wake of global health crisis and the threat of emerging viruses, Ayush system can be utilized as an effective means to tackle the challenges associated with health sector. The Committee strongly recommends the adoption of an inclusive and integrated health care policy. The Committee accordingly urges the Government to continue making efforts in integrating Ayush in the health sector.**

**(Para 6.64)**

**The Committee recognizes the services of AYUSH doctors in providing the first line of treatment especially in the rural areas. The Committee further commends the contribution of AYUSH manpower in offering their services during the pandemic.**

**(Para 6.65)**

#### **INCLUSION OF MARGINALIZED SECTION IN THE VACCINATION DRIVE**

**The Committee notes the economic impact of the pandemic and the mass migration of the workforce from the cities to the villages. The Committee notes that the migrant workers due to the nature of their jobs that demand rapid movement may have been excluded from the vaccination drive. The Committee, therefore, recommends the Ministry of Health and Family Welfare to ensure that the migrant workforce is administered both the doses of the vaccine along with the precautionary doses. The Committee also urges the Ministry to ensure that the poor vulnerable section of the society, due to the absence of relevant identification cards or documents does not remain neglected. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to ensure free and universal vaccination for all.**

**(Para 6.66)**

## **PANDEMIC IS FAR FROM OVER**

**The Committee notes that the present trend of Covid-19 reflects the need for adopting a new approach to the pandemic for its total eradication. With waning immunity in the population, the susceptibility to the infection is bound to increase. The Committee is at distress to observe the lack of Covid Appropriate Behaviour (CAB) in the general public. People have stopped wearing masks and social gathering have also increased. The Committee further notes that though the cases are comparatively less than the earlier Covid waves but the fear of subsequent waves still persists if the CAB is not adhered to. The Committee, therefore, strongly recommends the Ministry to promote better communication in driving the benefits of vaccines to the general public as vaccine is the only last hope to mitigate the pandemic Covid-19.**

**(Para 7.2)**

**The Committee further believes that any increase in the Covid cases must not be ignored and the public must not let the guard down against the pandemic. Over the past two years, the Ministry has been following, "Tracing, Tracking, Testing, Treating and Technology (5Ts)" to contain the pandemic. However, with the mutating Covid-19 variants, the Ministry must adopt newer strategies against the evolving virus. The Committee accordingly recommends the Ministry to revise the indicator to track the Covid-19 situation in the country. The Ministry must closely monitor clusters where any Covid incidence cases are reported. The Committee also recommends the Ministry to expand the genomic surveillance facilities in the country upto far flung areas so that the emergence of any new variant is tracked faster. The Ministry should strengthen the network of labs under NCDC-IDSP upto the rural areas so that any newer clinical outcomes are translated to better covid management policies.**

**(Para 7.3)**

**The Committee also recommends the Ministry to conduct studies on whether there is a need to administer Covid vaccine yearly. The Committee further recommends the Ministry to undertake in depth R&D project to explore the possibility of manufacturing one-time single dose vaccine for all variants of corona virus. Moreover, the Committee emphasizes that R&D activities under PPP model should also be carried out to explore drugs development to treat Covid Patients with due clinical trials keeping in view the health safety of the patients. The Ministry must adopt a scientific view backed by research evidence to address major issues regarding Vaccine distribution. The Committee believes that the Ministry must be very pragmatic and strategic in administrating the precautionary dose of vaccines. However, the Ministry must continue accelerating its efforts towards administrating booster doses specifically to the high-risk population groups. The Committee believes that booster dose is essential to provide additional protection particularly to those with comorbidities. The Committee also believes that research outcomes with respect to efficacy of booster doses must be shared with the scientific community as well as the general public.**

**(Para 7.4)**

**Attention of the Committee has also been drawn to a study that suggests Hybrid immunity has been associated with higher levels of neutralising antibodies and greater**

protection against infection than vaccines. The Committee strongly recommends the Ministry to adopt a dynamic response strategy keeping in view the results of such studies.

(Para 7.5)

#### **ESTABLISHING A ROBUST RESEARCH INFRASTRUCTURE IN THE COUNTRY**

The Committee in its 135<sup>th</sup> Report on the Demands for Grants 2022-23 (Demand No. 47) of the Department of Health Research had examined the Schemes of the Department, particularly, "Establishment of Viral Diagnostic & Research Laboratories (VRDL) to manage epidemics and national calamities". The Committee had emphasized on the need of establishing VRDLs across States and strengthen the bio-safety network to tackle any future outbreaks. The Committee accordingly reiterates its recommendation that the Ministry must continue its efforts towards expansion of testing labs network in the country. The Ministry must aim towards -"One VRDL in each District" by 2026 and ensure that trained manpower is available in these laboratories.

(Para 7.6)

The Committee in its 135<sup>th</sup> Report had also strongly advocated for the need of BSL-3 and BSL-4 labs in the country. The Committee notes that a strong network of modern high tech labs with sophisticated diagnostic techniques is crucial to strengthen the bio-safety ecosystem in the wake of emerging new virus. Lack of adequate BSL Labs in the country increases the risk of such viral outbreaks. The Committee accordingly recommends the Ministry to establish one BSL-IV lab in each of the four zones. The Committee further believes that for regular and effective surveillance of any kind of infections or disease in the country, the Ministry must establish BSL-II facilities in different regions of the country. The Ministry must also start new mobile BSL-III labs in the country and ensure that all the zones of the country have a well established network.

(Para 7.7)

The Committee further notes that under the PM-ABHIM Scheme, existing 5 VRDLs are being upgraded to BSL-III labs. The Committee would like to be apprised of the status of these labs and the Ministry must accelerate its efforts and ensure that the labs are upgraded within the set timeline. The need of the hour is to focus and emphasize on the state of the art laboratory infrastructure and have a robust research environment in order to understand the various kinds of infections/ viruses and also to ensure bio security of the country.

(Para 7.8)

#### **75 DAYS – ‘COVID VACCINATION AMRIT MAHOTSAVA**

The Committee appreciates the Government's move for linking Azadi ka Amrit Mahotsav with vaccine drive, thereby, announcing a 75 day window starting from 15th July, 2022 wherein all the adults will get free booster doses at all Government Covid Vaccination Centres. In this regard, the Committee recommends the Government apparatus/NGO/Civil Society to associate with vaccination drive on auspicious occasion of Azadi Ka Amrit Mahotsav and achieve the intended targets. The Committee hopes that

**this Vaccination Amrit Mission leads to mass mobilization and mass vaccination among the eligible beneficiaries.**

**(Para 7.10)**

## **NEED OF RESTORING ECOLOGICAL BALANCE IN THE WORLD**

**The Committee observes that the pandemic through the devastating impact it ravaged across the rungs of the society, shed light on the importance of ecological balance in the world. The Committee notes that in this age of globalization and rapid urbanisation, humans are becoming more detached from their environment. Nature is the essence of human life and human-nature relationship does have an impact on human's health.**

**(Para 7.11)**

**The Committee notes that the increase in anthropogenic activities and augmented human interventions in the ecosystem has had an adverse impact on the environment. The impact of Global warming and Climate Change are visible throughout the world, especially in developing countries. Pollution in all form-air, water, noise etc have become quite common. The Committee believes that there is a need to restore the ecological balance and let nature take its course. The Committee therefore, strongly emphasizes on the need to adapt a living and lifestyle which is in harmony with nature so that humanity is better prepared for dealing with any uncertainties in the future.**

**(Para 7.12)**

**The Committee notes that the former President of India, Shri Ram Nath Kovind, has also highlighted the importance of economical balance in the world. The former President of India's in his Speech in the farewell function on 23rd July, 2022 stated the following:**

***"In the year 2020, in a matter of few days, our world changed like never before. After nearly hundred years, a pandemic jolted the entire humanity. It has been an unprecedented tragedy in our times, and the whole world is still struggling with it. At this stage, one can only hope that the world will draw the right lessons from it. The chief lesson is that we human beings have forgotten that we are part of nature. The reality is that we are neither separate from nature, nor we are above it. The outbreak of the pandemic was partly linked with the disruption in ecological balance. The last two years have also reminded us that we are after all one human family and our survival depends on mutual cooperation. India's efforts in combating COVID have been appreciated worldwide. With everyone's efforts, we have achieved the target of 200 crore vaccinations in just 18 months. During the Corona period, we had provided free ration to 80 crore people."***

**(Para 7.13)**

**The Committee notes that India's response strategy against the pandemic had many shortfalls and the country struggled to minimize the impact of the pandemic Covid-19. Many experts have opined that the Covid situation and its subsequent waves could have been handled in a better way. However, there is no denying the fact that India despite its large population and fragile healthcare infrastructure was successful in adapting to the uncertainties that the pandemic ravaged. The Committee appreciates the up scaling of the**

testing infrastructure in record time and notes that India has huge potential to deliver healthcare services to the last mile. India must continue its journey towards ushering new reforms in its health sector through its exemplary inclusive schemes and initiatives and expansion in the health Budget. Hon'ble President Smt. Droupadi Murmu in her Speech on her assumption of office as President of India on 25<sup>th</sup> July, 2022 also commended the capability India showed during the pandemic which is quoted as under:

*"The kind of capability that India has shown in combating the global crisis of Corona pandemic has enhanced India's credibility all over the world. We Indians not only faced this global challenge with our efforts but also set new standards for the world. Just a few days ago, India has set a record of administering 200 crore doses of corona vaccine. The patience, courage and cooperation shown by the people of India in this entire battle is a symbol of our growing strength and sensitivity as a society. India not only took care of itself in these difficult situations but also helped the world. In the atmosphere created by the Corona pandemic, today the world is looking at India with a new confidence. The international community has high hopes from India for ensuring global economic stability, ease of supply chain and peace."*

(Para 7.14)

## CONCLUSION

The Committee notes that the pandemic has brought in open the need of scaling up the vaccine manufacturing ecosystem in the country and investing in the research and development infrastructure in the country. With the future variants being inevitable, the country must prepare better vaccination strategies. The Committee further believes that a resilient vaccination strategy will require concrete clinical research which is currently being carried out in the country. The Ministry must also focus on development of newer vaccine candidates and develop rapid response care strategies for better mitigation of the future uncertainties.

(Para 7.15)

The Committee further feels that there is a need to learn from Covid experience and implement the health system reforms in the country. The Committee further reemphasizes that India must operationalize an effective, functional, transparent and accountable system for reporting severe adverse events.

(Para 7.16)

The Committee also believes that there is a need to expand democracy to promote people's health and include equitable centre-state relations and ensure more transparency in decision making and data management. The Committee further recommends that the Government must ensure robust planning at all levels along with taking special measures to address gender and social inequities.

(Para 7.17)

The Committee notes that during the pandemic, Covid related drugs were in short supply and rampant black-marketing led to selling of drugs at exorbitant prices. The Committee further notes the disruption of essential health care services during the

**pandemic. The Committee strongly recommends that the Government must take special initiatives to introduce comprehensive drug price control mechanisms to cover all essential medicines and ensure that such hike in the medicine prices especially at the time of a medical crisis is strictly monitored. The Committee further recommends the Ministry to streamline the routine public health care services and ensure non-Covid health services are restored to pre-pandemic level.**

**(Para 7.18)**

**The Committee also notes the shortfall of healthcare workforce in India and recommends the Ministry to ensure that regular recruitment is carried out to fill all the vacant posts in the Medical Colleges and Hospitals. The Committee also recommends the Ministry to continue its efforts to expand the capacity of public health services in rural and urban areas through adequate, massive increase in central government expenditure on health.**

**(Para 7.19)**

**The Committee in its Report has extensively examined the subject, "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID-19" and identified various issues and challenges that are yet to be resolved. The Committee emphasizes the Ministry to ensure that the set targets of complete vaccination are achieved and any existing disparity in vaccine distribution is addressed at the earliest. The Committee hopes that the Ministry sees Covid-19 as an opportunity to revamp the public healthcare infrastructure in the country and usher in new reforms. The Committee strongly advocates the imperative essentiality of increasing Government health expenditure and investments in research and development. The Ministry must also work towards forging better public private partnerships for ensuring last mile delivery of healthcare services.**

**(Para 7.20)**

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# MINUTES

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## VI

### SIXTH MEETING

The Committee met at 11.00 a.m. on Tuesday the 12<sup>th</sup> January, 2021 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

#### MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

#### RAJYA SABHA

2. Dr. L. Hanumanthaiah
3. Shri K. Somaprasad
4. Dr. Subramanian Swamy
5. Shri Suresh Prabhu

#### LOK SABHA

6. Shri Arjunlal Meena
7. Dr. Pritam Gopinath Munde
8. Dr. Mahendrabhai Kalubhai Munjapara
9. Adv. Adoor Prakash
10. Dr. Mahesh Sharma
11. Dr. Sujay Radhakrishna Vikhepatil
12. Shri K. Navaskani
13. Dr. Bharati Pravin Pawar
14. Shri Haji Fazlur Rehman
15. Dr. D.N.V. Senthilkumar S.
16. Shri Anurag Sharma
17. Dr. Krishna Pal Singh Yadav

#### SECRETARIAT

- |                           |                     |
|---------------------------|---------------------|
| 1. Shri J. Sundriyal      | Joint Secretary     |
| 2. Shri V.S.P. Singh      | Director            |
| 3. Shri Bhupendra Bhaskar | Additional Director |
| 4. Smt. Harshita Shankar  | Under Secretary     |

#### LIST OF WITNESSES

##### Representatives of Department of Health & Family Welfare

1. Shri Rajesh Bhushan, Secretary
2. Shri Manjohar Agnani, Additional Secretary
3. Shri Lav Agarwal, Joint Secretary

##### Representatives of Department of Health Research

Prof. Balram Bhargava, Secretary, DHR cum DG, ICMR



## **Representative of Drug Controller General of India**

Dr. V.G. Somani, DCGI

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them about the agenda of the meeting i.e hearing the Health Secretary on the Subject "Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19. He pointed out that considering the much needed vaccination drive, the Committee may examine the distribution plan of vaccine across the country; methods/modalities of vaccination; network of physical distribution of vaccine; the efficacy of vaccine in controlling the new strain of Corona Virus. To examine all the aspects of Vaccine Development, Distribution Plan and Mitigation Management of Covid-19, the Secretary, Department of Health and Family Welfare and Secretary, Department of Health Research were to apprise the Committee on the subject.

### **Oral evidence of stakeholders on the "Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19":**

3. The Committee, at first, heard the views of Shri Rajesh Bhushan, Secretary, Department of Health and Family Welfare. He made a presentation which inter alia included the following points:-

(i) Out of 9 crore Covid-19 cases world over, India accounts for 1.05 crore cases and USA has 2.13 crore cases. While out of 19.40 lakh death globally, India accounts for 1.51 lakh people who lost their lives due to Covid. Globally, the recovery rate is 71% and for India, the corresponding figure stands at 96%.

(ii) As on 11<sup>th</sup> January, 2021, total number of Covid-19 cases in India was 1.05 crores and the total number of active cases was 2.23 lakh and the total number of tests conducted was 18.2 crores. Only two States in India- Kerala and Maharashtra have active Corona cases of over 50,000.

(iii) Constitution of two Committees by the Prime Minister to tackle the unprecedented Covid-19 situation in the country; (a) Task Force on Encouraging Research and Development in Drugs, Pharmaceuticals and Vaccines headed by Principal Scientific Advisor to the Government of India, Shri K Vijay Raghavan constituted in May, 2020 with the aim to encourage Research and Development and manufacturing of vaccines in India, (b) NEGVAC (National Expert Group on Vaccine Administration) headed jointly by Member (Health), NITI Aayog Dr. V. K. Paul and Secretary MH&FW constituted in August 2020 with the aim to form prioritization groups for vaccination and to work out other modalities in vaccine management and distribution.

(iv) Two vaccines developed in the country namely- Covishield (developed by Oxford and manufactured by Serum Institute of India) and Covaxin which is a completely indigenous vaccine developed by Bharat Biotech. Both these vaccines have been granted emergency use authorization. Safety and Immunogenicity of both the vaccines are established.

(v) Four more vaccines in the pipeline in the country viz.; Vaccine by the company Zydus Cadila; Vaccine by Biological.E Company; Vaccine developed by Pune based company Gennova and Russian vaccine Sputnik-V, (In India, it would be manufactured by Dr. Reddy's Labs).

(vi) Indian vaccines are more economical and affordable compared to foreign vaccines. Close collaboration with States/UTs for vaccine roll-out preparedness. 26 virtual trainings and meetings have been done with the State Governments to discuss operational and communication guidelines. A total of 2,360 Master Trainers have been trained who further are training 61,000 individuals who are known as Program Managers. Two lakh vaccinators who will actually vaccinate people have been trained and 70 thousand other vaccination team members have been trained. The entire vaccination programmes will be based on the five principles namely; Ensure People's Participation; experience of elections and universal immunization programme; no compromise of existing healthcare services, especially, national programs and primary healthcare; no compromise on scientific and regulatory norms; orderly and smooth implementation driven by technology.

(vii) Sequential rollout of Covid-19 vaccine: - In the first phase, healthcare workers of both the private and public healthcare facilities would be vaccinated. Healthcare workers not only include doctors and nurses but also sanitation workers, technicians, DEOs, ambulance drivers, clerks, assistants and every individual associated with healthcare facilities. Total figure of healthcare workers in the country is almost 1 crore. After this, frontline workers i.e. State Police, Central Police, Armed Forces, Civil Defence, Disaster management employees would be vaccinated. In the third phase, people above the age of 50 years would be vaccinated. In this category, there are sub-groups as well; initially people above 60 years of age would be vaccinated, then people falling in the age bracket of 50-60 years would be vaccinated and then people below 50 years of age who are having co-morbidities would be vaccinated. A total of 3 crore people who fall into those categories would be vaccinated in the first two phases and the entire cost of vaccinating these people would be borne by the Central Government.

(viii) Development of digital platform called CoWIN by the Government using which data of vaccine like vaccine movement information, storage information, dose information etc. can be recorded, monitored, updated. The platform will also track the recipient of the vaccination dose and inform them about the timings and place to get the second dose of vaccine which needs to be taken after 28 days of taking the first dose. After the successful vaccination, the platform will also generate an electronic certificate and send it on the registered mobile number.

(ix) Two Committees to be formed; to supervise the entire programme at the State level, namely: State's Steering Committee, chaired by Chief Secretary of the State to monitor coordination issues with other Departments of the State. State Task Force, chaired by Principal Secretary Health, will look at actual administration related issues of the vaccination programme. Apart from this, there will be a District Task Force headed by the District Collector with the aim to monitor functioning of vaccination booths and availability of vaccines. Also, Block Task Force has also been formed headed by Block Development Officer with the aim to monitor the vaccination programme at the block level.

(x) Ensuring sufficient number of cold chain points and also uninterrupted supply of syringes and other logistics in the country. A 24X7 helpline in two languages English and Hindi has been opened by the Central Government, similar help lines have also been opened by various State Governments in their respective local languages.

4. The Members of the Committee raised following issues:-

- (i) Concerns over hurried clearance for the "Covishield" vaccine;
- (ii) Covaxin vaccine given approval before the completion of Phase III trials;
- (iii) Time required to vaccinate at least, 50 per cent of the Indian population, if not the entire population;
- (iv) Tracking of effect of the vaccine on the person on whom the vaccination has been jabbed; effectiveness of the vaccine against the new strains of the virus; side-effects of the vaccine known or not; effect on the vaccine if kept in the deep freezer which generally has temperatures below 2 degree Celsius; duration of the effectiveness of the vaccines;
- (v) Liability of the vaccine manufacturer in case the recipient of the vaccine develops certain health complications;
- (vi) Mechanism for administering the vaccine to the physically handicapped people;
- (vii) Variation in the price of vaccines; price of vaccines for the people not belonging to any of the prioritized groups;
- (viii) Vaccination centers should have ICU facilities and the provision of stabilizers to address any untoward incident due to the side-effects;
- (ix) Government studies on the impact of vaccines being administered in foreign countries like United States and United Kingdom;
- (x) Easy availability of these vaccines to the rural population;
- (xi) Mechanism for distribution and administration of vaccines to the poor and the deprived sections of the society free of cost or at a very nominal rate;
- (xii) Choice between different vaccines available or not;
- (xiii) T-cell and B-cell assessment post vaccination;
- (xiv) Safety measures to be taken while vaccinating pregnant women;
- (xv) Prioritization of Covid-19 hotspots States like Kerala in vaccine distribution;
- (xvi) Exemption of vaccines from GST;
- (xvii) Stock of vaccines to supply without any interruption to all the States;
- (xviii) Decision on giving approval foreign vaccines like Pfizer;
- (xix) Measures taken to rein in the fake apps or fake versions of CoWIN;
- (xx) Exploring the research to improve the curative technology to cure already infected people;
- (xxi) Monitoring of post-covid complications being seen in various Covid recovered people;
- (xxii) Authority of State Governments to choose the vaccine whichever they feel right to administer their population;
- (xxiii) Inclusion of private hospitals in the vaccination programme;
- (xxiv) Number of patients infected with the new strains of the Corona virus;
- (xxv) Vaccination of MPs; and
- (xxvi) Vaccination mandatory or voluntary.

5. The Secretary, Department of Health and Family Welfare replied to the queries of the members. He submitted that the Covaxin vaccine was given accelerated approval as per the New Drugs and Clinical Trial Rules, 2019. Based on such approvals, WHO pre-qualified drugs can be used by countries which do not have regulatory frameworks. He further informed that no vaccine in India is available or would be available in private market in the coming months. All these vaccines have only been given emergency use authorization and market authorization would be given at the later stage. He further said the vaccination is not mandatory and is completely voluntary. As regards price of the vaccine, he informed the Committee that the price

of vaccine for the remaining population would be decided once 60-70% people are vaccinated in the first and second phase. Also, CoWIN platform would send SMS in 12 different languages to inform the people about their vaccination schedule for both the doses. It would also send a reminder to the individual before the second dose. After successful vaccination, it would also generate and send a certificate. If the person is not in possession of a smart phone, then the responsibility to intimate the individual is upon the Medical Officer in the Block Development Office.

6. Responding to the queries of the Committee, Shri V.G. Somani, DCGI informed the Committee that Covaxin underwent pre-clinical studies on mice, rats and rabbits. Moreover, it also went through Challenge Studies on two animal species, that is, hamster and rhesus macaques. Phase-I trial of Covaxin was done on 375 people, none of them reported any complications. Phase II trials were conducted on 380 people. 22,500 people were given the first dose of the vaccine in Phase III. The solicited reaction of Covaxin is only 15% which is significantly lower than the solicited reactions of Pfizer and Moderna which are 75% and 65%. He further informed the Committee that Covaxin has seen 8 folds rise in neutralising anti bodies. Its neutralising anti bodies were tested for three elements namely; spike protein, receptor binding domain and Nucleocapsid protein.

7. The Committee, thereafter, heard the views of Prof. Balram Bhargava, Secretary, Department of Health and Research. He submitted that the data regarding the versatility i.e. the effectiveness on the mutation strain of the said vaccines is not available. He further informed the Committee that the Covaxin is being tested for its effectiveness on the newly discovered strain in the UK. The total number of people infected with the UK strain is 96 (as on January, 12) and every person coming from UK is being monitored and tested. Also, genome sequencing of the positive cases is being done. The decision to give the second dose after 28 days is backed by the available data. He further submitted that if a woman gets pregnant after the first dose, she would be kept under close watch. As regards effectiveness of the vaccine, he informed the Committee that as per the data available, the vaccines would be equally effective if it is stored below 2 degree Celsius. He also admitted before the Committee that some people have experienced post Covid weakness and complications. People who experience rise in serum ferritin or D-Dimer are given anti-coagulation. He further apprised the Committee that in the clinical trials of Covishield which were done on mice in UK, no Pneumonia cases were reported and high immunogenicity was recorded. Phase-I trials were done on 1077 people, Phase-II trials were done on 560 people and finally Phase-III trials were done on 11,636 people in UK and Brazil. To establish vaccine's equivalency, Phase-III trials were done on 1,600 people in India.

8. The Chairman thanked the witnesses for clarifying various doubts and issues raised by the members of the Committee.

9. A verbatim record of the proceedings of the meeting was kept.

10. The Committee then adjourned at 1:15 p.m.

### **XIII**

#### **THIRTEENTH MEETING**

The Committee met at 03.00 p.m. on Tuesday the 10<sup>th</sup> August, 2021 in Committee Room-A, Parliament House Annexe, New Delhi.

#### **MEMBERS PRESENT**

1. Prof. Ram Gopal Yadav - Chairman

#### **RAJYA SABHA**

2. Shri AK. Antony
3. Dr. L. Hanumanthaiah
4. Shri Suresh Prabhu
5. Dr. Subramanian Swamy
6. Shrimati Sampatiya Uikey

#### **LOK SABHA**

7. Ms. Ramya Haridas
8. Amol Ramsing Kolhe
9. Dr. Sanghmitra Maurya
10. Arjunlal Meena
11. Shrimati Pratima Mondal
12. Shri K. Navaskani
13. Adv. Adoor Prakash
14. Shri Haji Fazlur Rehman
15. Dr. Rajdeep Roy
16. Dr. DNV Senthilkumar. S
17. Shri Anurag Sharma
18. Dr. Mahesh Sharma
19. Dr. Sujay Radhakrishna Vikhepatil
20. Dr. Krishna Pal Singh Yadav

#### **SECRETARIAT**

- |                           |                     |
|---------------------------|---------------------|
| 1. Shri Puneet Kumar      | Joint Secretary     |
| 2. Shri V.S.P. Singh      | Director            |
| 3. Shri Bhupendra Bhaskar | Additional Director |
| 4. Smt. Harshita Shankar  | Under Secretary     |

#### **WITNESSES**

##### **(i) Department of Health and Family Welfare**

1. Shri Rajesh Bhushan, Secretary (Health)
2. Smt. Arti Ahuja, Addl. Secretary
3. Ms. Anu Nagar, Joint Secretary

**(ii) Department of Health Research (DHR)/ Indian Council of Medical Research, New Delhi**

1. Prof. Balram Bhargava, Secretary (DHR)
2. Dr. Samiran Panda, Scientist 'G', ICMR
3. Dr. Nivedita Gupta, Scientist 'F', ICMR

2. At the outset, the Chairman welcomed the Members to the meeting of the Committee and informed them that the Committee would hear the views of Secretaries, Department of Health and Family Welfare and Department of Health Research on the challenges faced during the Second Wave of Covid-19, preparedness to combat and handle the impact of predicted Third Wave of Covid-19 and progress made under vaccination drive in the country' as part of the consideration of the subject "Vaccine Development, Distribution Plan and Mitigation of Pandemic Covid-19". Welcoming the witnesses, thereafter, he asked them to apprise the Committee about the challenges posed by the second wave of COVID-19, the lessons learnt by the Government in the aftermath of the second wave, the status of vaccination drive in the country and the strategy chalked out to contain the possible threat of third wave, the status of development of other vaccine candidates, etc. He also asked them to explain as to what were the factors that caused second wave; whether the second wave could have been avoided with prompt and timely action on the part of the Government; the reasons for the severity of the second wave as compared to the first wave, etc.

3. The Secretary, Department of Health and Family Welfare sought the permission of the Chairman of the Committee to make a power points presentation containing 30 slides, however, the Chairman refused the permission by saying that discussion on important bill was going on in the House and therefore Members would ask questions/seek clarifications based on the hard copy of the presentation which was already with them. Thereafter, members asked questions one by one which were as follows:-

- (i) The reasons for the number of new cases stagnating at around 40 thousand per day and not going down further and also for Kerala, despite being the most literate State, having over 40 percent of the total Covid infections;
- (ii) Expressing apprehensions on the authenticity of figures about the testing and positive cases as given in the power point presentation, it was enquired whether there was any method to verify these figures;
- (iii) Probable causes for the high number of cases in the State of Kerala which otherwise has a sound healthcare infrastructure at the village, *taluka* and district level; whether necessary arrangements would be made to provide enough vaccines to Kerala;
- (iv) Whether the number of deaths caused due to Covid has been accounted for properly by all the States and if not, what is the number of actual deaths; whether Government would provide compensation to the families of those who lost their lives due to Covid notwithstanding the fact that their death is recorded or not; the arrangements of health infrastructure, if any, made in the wake of the third wave;
- (v) The reasons why movement of people from States with high infection rate to States with low infection rate is not being checked so as to contain the spread of

infection; cases of overcharging of fees by private hospitals from Covid patients need to be investigated;

- (vi) Need to ramp up vaccination but allotting more vaccines particularly to States experiencing high numbers of cases like Kerala and Maharashtra, also timeline for availability of vaccines in the open market, the requirement of third dose to further boost the immune response and steps taken to prevent vaccine wastage;
- (vii) Unreliability of RT-PCR report in declaring deaths owing to Covid-19 as RT-PCR report is generally negative after one week of infection and hence deaths are not counted as Covid-19 deaths; problems encountered in receiving death certificate due to Covid which makes it impossible to receive compensation under various schemes for family/children of the deceased;
- (viii) Differing opinions of experts regarding the effectiveness and suitability of different vaccines;
- (ix) Establishing labs at district and block level for better testing to get more accurate picture of positive cases and thus limit the number of deaths;
- (x) Disproportionately high prices of ICU beds and other medical equipments listed in the GEM portal and the need to regulate the pricing mechanism;
- (xi) Whether any study is being done to find out the reasons as to why Mucormycosis infection occurred as several reasons are being discussed; the need to involve MPs (Members of Parliament) in the vaccination programme;
- (xii) Concern regarding children as the probable third wave is expected to be more severe on them; confusion/concern regarding opening of educational institutes;
- (xiii) Testing of newly established Pressurized Swing Adsorption (PSAs) for malfunctions under prolonged use and issues like fall in pressure and purity of oxygen in PSA Oxygen Generation Plants particularly when more patients on ventilators are added to it; whether integration of liquid oxygen tank with the PSA plant can be done;
- (xiv) Delay in installation of Pressure Swing Absorption Oxygen Plants in Jayanagar, West Bengal which was to be installed by National Highway Authority of India;
- (xv) Importance of sero-survey and genome sequencing in combating the future waves of pandemic Covid-19;
- (xvi) Moratorium on loan amount and a special loan scheme with low interest rate to support pandemic affected families and small-scale industries/businesses should be considered;
- (xvii) Timeline for vaccination trials and subsequent availability of vaccines for children;
- (xviii) Effectiveness of drugs like Remdesivir in combating multisystem inflammatory syndrome in children where all the children tested were RTPCR negative but their Covid antibodies were positive; affordability and availability of alternative drug IV Immunoglobulin for treatment of Covid amongst children;

- (xix) Confusion amongst people regarding changing interval between two doses of vaccines;
  - (xx) Lack of skilled and trained manpower to operate newly established oxygen plants, ventilators etc;
  - (xxi) Promotion to research regarding treatment of Covid-19 not only in Allopathy but also in Ayurveda and Homeopathy as adjuvant therapy and
  - (xxii) Steps taken to combat misinformation about efficacy of vaccines and to address vaccine hesitancy; etc.
4. The Chairman then asked the Secretary to submit a written response to the queries raised/ clarifications sought by Members within a week.
5. A verbatim record of the proceedings of the meeting was kept.

**(The witnesses then withdrew)**

6. \*\*\*
7. The Committee then adjourned at 4:35 p.m.

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*\* Pertains to other matter*



## VII

### SEVENTH MEETING

The Committee met at 03.00 p.m. on Friday the 22<sup>nd</sup> January, 2021 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

#### MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

#### RAJYA SABHA

2. Dr. L. Hanumanthaiah
3. Shri K. Somaprasad
4. Dr. Subramanian Swamy
5. Shri Suresh Prabhu

#### LOK SABHA

6. Shri Arjunlal Meena
7. Dr. Pritam Gopinath Munde
8. Dr. Mahendrabhai Kalubhai Munjapara
9. Shrimati Pramita Mondal
10. Dr. Subhas Sarkar
11. Dr. Sujay Radhakrishna Vikhepatil
12. Dr. Krishna Pal Singh Yadav

#### SECRETARIAT

- |    |                         |                     |
|----|-------------------------|---------------------|
| 1. | Shri Pradeep Chaturvedi | Joint Secretary     |
| 2. | Shri V.S.P. Singh       | Director            |
| 3. | Shri Bhupendra Bhaskar  | Additional Director |
| 4. | Smt. Harshita Shankar   | Under Secretary     |

#### LIST OF WITNESSES

##### Team of Principal Scientific Advisor to the Government of India

1. Prof. K. Vijay Raghavan, Principal Scientific Advisor to the Government of India
2. Dr. Arabinda Mitra, Scientific Secretary, Government of India
3. Dr. Shailja V. Gupta, Senior Adviser/ Scientist 'H, Government of India

##### Team of All India Institute of Medical Science (AIIMS), New Delhi

1. Dr. Randeep Gulleria, Director, AIIMS, New Delhi
2. Shri Subhasish Panda, Deputy Director

2. At the outset, the Chairman welcomed the Members of the Committee to the meeting and recapitulated that the Committee had undertaken the Subject "Vaccine Development,

Distribution Management and Mitigation of Pandemic Covid-19" for examination and Report. He informed members that in the previous meeting the Committee had heard the views of the Secretaries of Department of Health and Family Welfare and Department of Health Research on the subject and deliberated on the production, approval, methods and modalities of distribution plan of the vaccine, network of physical distribution of vaccine, efficacy of vaccine in controlling the new strain of Corona virus, etc. He further informed the members that continuing with its deliberations, the Committee would hear the views of Principal Scientific Advisor to the Government of India and Director, AIIMS (New Delhi) on the subject.

### **Oral evidence of stakeholders on the "Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19":**

3. At the outset the Chairman welcomed Principal Scientific Adviser and his team and also Director AIIMS to the meeting of the Committee and asked them to apprise the Committee of the stages of development of the vaccine, challenges faced in its innovation, the methods of its scientific validation etc. He asked Principal Scientific Advisor to the Government of India to make his presentation first after introducing his team of officials. During his presentation to the Committee he highlighted the following points:-

- i. The PMO constituted a Vaccine Task Force consisting of Secretary (Health), Secretary (Biotechnology), ICMR, CSIR, Department of IT, Department of Telecom, Drug Controller and Director General Health Services for focused research and development of CORONA vaccine and other science and technology related issues on April 14, 2020 co-chaired by Dr. VK Paul and Prof. K. Vijay Raghavan. A total of 14 meetings of this Task Force were held. The idea behind this task force was to get all the views on scientific aspects to these people, so that they can use this advice in their own specific roles, in a way they saw appropriate, as they were heads of their departments. Coming to the vaccine development initiatives The Bharat Biotech International's Covaxin has been developed indigenously using a virus strain, isolated by the Indian Council for Medical Research at the National Institute of Virology. Its clinical trials are ongoing at phase III. An emergency use authorization of it has been granted. The Serum Institute of India developed "Covishield" in partnership with Oxford University AstraZeneca. And for this vaccine candidate, the emergency use authorization was granted on the basis of international trial data and bridging trial data in India. There are other vaccine candidates in development by these companies. There are also other companies which were working on vaccine development.
- ii. Underlining the challenges in development of the vaccine he pointed out that India had not done many phase 1,11 and Phase 111 clinical trials and hence setting up the whole sequence, in the midst of the pandemic was a challenge. Identifying clinical trial sites, putting in place networks to get harmonized clinical trials protocols and to partner with medical colleges for trials were some of the key challenges. We had only one drug testing and certification laboratory at Kasauli but now its number was being increased. Access to resources was also a major challenge because vaccine development was very expensive. Explaining the trial stage he stated that during trials, the vaccine is administered to healthy people and thus safety of such people is of key concern. To establish safety in phase-I clinical trials, immune response is monitored in monkeys or ferrets after administering them with vaccine.

- iii. Another Pharma company Zydus Cadila has got permission to conduct its phase III trials. They have a DNA vaccine candidate that has completed phase II trials. Hyderabad based Biological-e has tied up with Johnson & Johnson to manufacture a single-dose vaccine. The company is collaborating with other companies to make other vaccines against the receptor binding domain of the virus. Dr. Reddy's has tied up with Sputnik Vaccine on phase II. Genevo Pharmaceuticals is another pharma company which has collaborated with a USA company to develop an mRNA vaccine. And, there are many other smaller companies engaged in vaccine development candidates. India, that has got a great reputation for a vaccine manufacturing hub is embarked on vaccine development.
  - iv. Generally, it takes about four-five years for developing a vaccine. But in view of the urgency that arose due to the pandemic the parallel processes involved in vaccine development and other regulatory processes have been ramped up. He further said that unlike other vaccines which are manufactured using a part (RNA or DNA) of the virus, the Covaxin is manufactured using complete inactivated virus. Therefore, Covaxin theoretically is better placed in raising immunity against various variants of the Corona virus.
  - v. Another important part of testing is the Genome Sequencing. CSIR's Institute of Genomics and Integrative Biology along with National Institute of Biomedical Genomics, Department of Biotechnology and Center for Cellular and Molecular Biology have done a wonderful job in sequencing genes of the virus.
4. The Committee then heard the views of Dr. Randeep Gulleria, Director, AIIMS, New Delhi. He submitted that the Phase-III trials of the Covaxin vaccine are still not complete but the limited data suggests that the vaccine is safe. It is efficacious and has been tried out mainly on Indians. On the other hand the trials of Covishield were mainly done in the UK and Brazil population and for determining its efficacy on Indians, only the bridging studies were conducted. He further informed the Committee that as far as the vaccine distribution is concerned, that decision is taken by the respective State Governments. The State Government decides which vaccine would be sent to which hospital.
5. During the course of the meeting, the members raised certain queries which are as follows:-
- i. Guidelines or protocols to be followed after taking the first shot of the vaccine or in the event of any adverse reaction;
  - ii. Measures taken by the Government to avoid wastage of the doses;
  - iii. Monitoring and maintenance of various States Government's cold chain systems;
  - iv. Period for which the vaccine would be effective;
  - v. Measures taken to address apprehensions and hesitancy of people regarding vaccines and tackling misinformation and fake news regarding vaccine;
  - vi. Chances of adverse side effects of vaccines and provisions for compensation to the victim in case of adverse side-effects;
  - vii. Emergency authorization given to Covishield which is a foreign vaccine;
  - viii. Trials of intra-nasal vaccines and its basic formation;
  - ix. Tackling misinformation and fake news regarding vaccine;
  - x. Availability of vaccines to economically weaker sections free of cost;
  - xi. New strategies and initiatives for vaccination and immunization in light of the current pandemic;

- xii. Making retired sportspersons and actors brand ambassadors of the vaccination drive to instill confidence amongst the masses with respect to the vaccines;
- xiii. Establishment of public sector vaccine manufacturers and research units; and
- xiv. Need of two doses in the current vaccination drive and duration between the doses & the quantity of the second dose.

6. Responding to the queries raised by the members, Prof. K. Vijay Raghavan informed the Committee that regarding guidelines for vaccination, vaccine manufacturing companies have come up with detailed fact sheets of Do's and Don'ts in case of adverse reactions. He further informed the Committee that the immunity after the vaccination would at least last for 8 months. On nasal vaccines he said that the dose quantity and effect of such vaccines are difficult to quantify because there is a lot of variability associated with nasal vaccines. However research is being done on such vaccines and Bharat Biotech is developing a nasal vaccine. He further informed the Committee that an Indian Startup is developing a room temperature storable vaccine. Vaccines like the Nasal vaccines are easy to administer, can be bought and administered by the person himself possibly at room temperature.

7. On preparedness for future health emergencies, Prof. K. Vijay Raghavan submitted that next pandemic might happen with equal probability or low probability. With vagaries of climate change and other kinds of human-animal contact, the chances are only increasing. He said that India has learnt a lot both from the domestic experience and from the rest of the world. On the issue of requirement of two doses of vaccine, he informed that this is due to population effect and an individual effect. A doze gives an individual a certain immune response. And, in a population, there can be some which have a very low immune response while others might have a modest immune response. So, the second dose takes care of those people and protects them. But, the second dose also increases the first response substantially. So, if population level immunity is desired, which is what the purpose of the vaccination drive is, two doses are needed. He further informed the Committee that the companies which are making vaccine are responsible for providing indemnity care to recipients of their vaccine.

8. On chances of contracting virus even after vaccination, Prof. K. Vijay Raghavan submitted that once a person gets vaccinated, he is not immune to infection; however, the progression of the disease would be mitigated enormously. So, if people are tested after vaccination, virus could still be found in his body. Some vaccines are very good; not only do they stop the progression of the disease but they also greatly lower transmission. So, suppose, if someone gets infected and they are vaccinated, the disease would not progress but they might transmit. But some vaccines would mitigate the replication of the virus if the transmission is low.

9. Regarding a specific query on whether the people who are on blood thinners must get vaccinated, Dr. Randeep Guleria clarified that ecosprin, clopidogrel are classified as anti-platelets and warfarin, heparin as anti-coagulants. People who take anti-platelets can be vaccinated; however, people who take anti-coagulants need to be careful.

10. The Chairman thanked the witnesses for clarifying various doubts and issues raised by the members of the Committee.

11. A verbatim record of the proceedings of the meeting was kept.

12. The Committee then adjourned at 4:45 p.m.

### III

#### THIRD MEETING

The Committee met at 3.00 p.m. on Thursday, the 9<sup>th</sup> December, 2021 in Room No.-63, First Floor, Parliament House, New Delhi.

#### MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

#### RAJYA SABHA

2. Dr. L. Hanumanthaiah
3. Shri Suresh Prabhu
4. Shri A.D. Singh
5. Dr. Kanimozhi NVN Somu
6. Dr. Subramanian Swamy
7. Shrimati Sampatiya Uikey

#### LOK SABHA

8. Shri Maddila Gurumoorthy
9. Ms. Ramya Haridas
10. Dr. Sanghmitra Maurya
11. Shrimati Pratima Mondal
12. Dr. Pritam Gopinath Munde
13. Shri K. Navaskani
14. Dr. Sujay Radhakrishna Vikhe Patil
15. Dr. Rajdeep Roy
16. Dr. DNV Senthilkumar. S
17. Shri Anurag Sharma
18. Dr. Krishna Pal Singh Yadav

#### SECRETARIAT

1. Shri J. Sundriyal Joint Secretary
2. Shri V.S.P. Singh Director
3. Shri Bhupendra Bhaskar Additional Director
4. Smt. Harshita Shankar Under Secretary

#### WITNESSES

#### Ministry of Health and Family Welfare

1. Shri Rajesh Bhushan, Secretary (Health)
2. Prof. Balram Bhargava, Secretary (DHR)
3. Shri Lav Agarwal, Joint Secretary
4. Dr. Samiran Panda, Additional DG (ICMR)

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them about the agenda of the meeting i.e. to examine "Challenges posed by Omicron variant of Covid-19, the strategy adopted and measures taken to combat the same" as part of the examination of the subject "Vaccine Development, Distribution Management and Mitigation of Pandemic COVID-19. He further informed the Committee that on 26<sup>th</sup> November, WHO's Technical Advisory Group on SARS-CoV-2 Virus Evolution designated the new variant of Coronavirus 'Omicron', first reported by South Africa, as a variant of concern. The Omicron now had gained a foothold in Asia, Africa, the Americas, the West Asia and Europe. Several cases of the new variant had been reported in India as well. In view of this, the Secretary, Department of Health and Family Welfare and Secretary, Department of Health Research were invited to apprise the Committee on the subject.

3. The Committee, at first, heard the views of Shri Rajesh Bhushan, Secretary, Department of Health and Family Welfare. He made a presentation which inter alia included the following points:-

- i. According to WHO, the Covid-19 was a cause of concern with daily incidence of more than 6 lakh cases. Several countries like UK, France and Italy had faced multiple Covid surges and were witnessing high number of daily Covid cases due to laxity in public health and social measures;
- ii. The situation in India was significantly better with less than 10 thousand daily cases. Kerala was the only State in India to have more than ten thousand active cases and accounted for almost 44% of active cases in the country. There were ten States having active cases between 1-10,000;
- iii. More than 130 crore Covid vaccine doses had been administered thus far and almost 53% of the adult population have received both the doses of the vaccine; nation-wide Covid-19 vaccination campaign "हर घर दस्तक" has been launched to boost awareness, mobilization and vaccination of all eligible beneficiaries with first dose and all due beneficiaries with second dose off Covid-19 vaccines through House to House visit;
- iv. 108 countries had entered into agreement with India for mutual recognition of vaccination certificates;
- v. The Omicron variant was first reported in Gauteng, South Africa on November 24 and on 26<sup>th</sup> November the WHO declared it variant of concern; as of 08 December, 2021, 57 countries were infected with Omicron and there were 2,303 Omicron cases worldwide;
- vi. On 28<sup>th</sup> November, India released an International travel advisory (w.e.f 01 December, 2021) for travelers coming to India. Travelers coming from Countries 'at risk' to follow additional measures, including post-arrival RT-PCR test. In India, there were 23 cases of Omicron and the first case was reported in Karnataka;
- vii. Omicron had close to 50 mutations with 26-32 mutations happening only in the spike. It is not yet clear whether Omicron was more transmissible compared to other variants and whether infection with Omicron caused more severe disease;
- viii. Current Public Health Measures such as masks, hand hygiene, physical distancing, improving ventilation of indoor spaces, avoiding crowding spaces and getting vaccinated remain effective against all variants of concerns;

- ix. PCR diagnostics continue to detect COVID-19 infection, including Omicron infection and clinical management for patients with severe COVID-19 remains unchanged. Impact of vaccines on Omicron was not yet known as evidence was still evolving.
4. Thereafter, Secretary, Department of Health Research apprised the Committee on the subject and highlighted that testing protocol for Omicron remained unchanged and all the current tests that were being used for other variants of Covid-19 would be working for identifying the patients with Omicron. The treatment protocol and the medications that are already approved by the National Task Force, the Joint Monitoring Group, Ministry of Health, too remains unchanged and the same medicines will be used for treating Omicron cases as well. He also added that ICMR was taking up a research to ascertain the efficacy of current vaccines that are being administered in the country against the Omicron, for this ICMR needed to grow the virus in the culture medium. Typically, it would take about five to seven days to grow the virus. If it was successful, then, using blood from people who had been vaccinated, the efficacy of vaccines against Omicron would be determined.
5. Thereafter, the Chairman and the members of the Committee raised certain issues/queries on the subject which are as follows:-
- i. Effectiveness of vaccines against deaths; need for booster shot; time frame within which the Government intended to finish first and second dose of vaccination to the entire eligible adult population; requirement of vaccination for children, vulnerability of the below 18 population with respect to Omicron and confusion among the public with regards to the gap between the first and second dose of the vaccine;
  - ii. Reasons behind higher Covid cases in relatively better educated regions in the country;
  - iii. Need to check the 14 days travel history of travelers coming to India and steps taken to monitor people who are home quarantined;
  - iv. Veracity of the vaccination data with respect to the State of Bihar;
  - v. Effect on death rate as the number of cases were rising worldwide and whether any change observed in the delta variant;
  - vi. Effectiveness of conventional RT-PCR compared to the rapid RT-PCR; high cost of RT-PCR testing and inadequate arrangements at the airports;
  - vii. Possibility of relation between Omicron and biological warfare;
  - viii. Preparation for worst case scenarios;
  - ix. Independent assessment by bodies like ICMR on evasion of vaccines by Omicron; identification of onummi-elpoep desimorpmoc;
  - x. Alternate seating in flights which are coming from at-risk countries;
  - xi. Study to ascertain reasons behind developing of high positivity rate clusters in several States;
  - xii. Need to have a proactive strategy to deal with newer variants of Covid-19;
  - xiii. Initiatives to stop spread of misinformation and fear amongst masses with regards to Omicron;
  - xiv. Avoiding of imposition of lockdown to counter the spread of Omicron, considering poor financial health of certain sections of the society and overall economic cost involved; and

- xv. Adequacy of testing and tracking infrastructure and need to maintain and boost it in light of the higher transmissibility associated with the Omicron.
6. The Secretary Department of Health and Family Welfare, Department of Health Research and Additional DG (ICMR) thereafter, responded to some of the queries of the Chairman and the members as enumerated below:
- i. Regarding the effectiveness of RT-PCR and rapid RT-PCR test, Secretary DHR stated that rapid RT-PCR machines like TrueNAT can take limited number of samples but they give the results in 90-minutes. He said that RTPCR and rapid RT-PCR both are identical and there was no difference in results. In terms of percentage positivity and percentage sensitivity, they were perfect. He further stated that Rapid Antigen Test gives faster results and takes only 15-minutes to test, but it only gives positive results;
  - ii. Answering the query regarding the need for booster doses, Secretary DHR elaborated that the senicav that were being administered weesaesid er-senicav gniyfidom. T yeh would esaesid tneverp ton , but severity would be low. Also, t erehwa ot atad ssel s troppusthe claim for ereht esuaceb tmemom eht ta esod lanoitiddawer morf selpmaxe e ah elpoep erehw learsld esod driht a deviecer but detcefni tog llits. Regarding giving additional dose to immuno-compromised people, he informed the Committee that the vaccination involved not only esnopser ydobotna , but also esnopser ralullec, T- llec esnopser lasocum dna esnopser and these things derusaem eb tonnac. However, the issue was being discussed ht nie National Technical Advisory Group on Immunization in India (IGATN), onummi rehtehw - eb dluohs elpoep desimormcor should not be esod lanoitidda na nevig. Replying to the query regarding confusion among the public w.r.t the gap between the first and second dose of the vaccine, he informed the Committee that the gap between the two doses of Covaxin remained the same i.e. 28 days. However, in respect of Covishield, as per the current data, interval between the two doses was of 12 weeks;
  - iii. Adding to the query of booster shots for immuno-compromised people, the Secretary Department of Health and Family Welfare informed the Committee that the Department did not have a list of immuno-compromised people. Nowhere in the country such a list is maintained.
  - iv. Replying on devising a proactive strategy to counter new variants of Covid-19, Secretary Department of Health and Family Welfare stated that, there were two ways of doing it. First to do testing which was higher than the threshold prescribed by the WHO, so that very quickly, one can come to know when the cases are flaring up. Second the INSACOG (Indian SARS-CoV-2 Consortium on Genomics or Indian SARS-CoV-2 Genetics Consortium) network which indicated whether the virus was mutating. Once it was known that the virus had mutated, and, the particular region where the mutation occurred, that geographical area can be focused upon. So, more testing and genome sequencing can be the two parts of a proactive strategy.
  - v. Answering to the query on probable variation in the Delta variant, Additional DG (ICMR) said that the predominant circulating strain in India, as yet, was Delta. Regarding increased chance of children getting infected with Omicron, he informed the Committee that this was determined by the contact metrics in any population group, be it adult, adolescent or children. So, children do not have any excess possibility or increased chance of getting infected with Omicron.
  - vi. Responding to the query on Kerala's paradox of high Covid cases, Additional DG (ICMR) said that hypothetically, it could be related to the reverse behaviour. It may be



case that those who are doubly-vaccinated think that as they are protected, they can let the guard down and since these vaccines did not prevent acquisition of infection, this trend was being seen. He further stated that viruses try to escape the immune pressure but at the same time, they become more transmissible. If any transmissible variant -- for example, omicron -- kills its host, it cannot remain transmissible. So, increased transmissibility does not go hand in hand with fatality.

7. The Chairman then directed the Department to send written replies to the queries raised by the Members within a week.
8. A verbatim record of the proceedings of the meeting was kept.
9. The Committee then adjourned at 4:15 p.m.

## VII

### SEVENTH MEETING

The Committee met at 3.00 p.m. on Monday, the 4<sup>th</sup> April, 2022 in Committee Room-A, Ground Floor, Parliament House Annexe, New Delhi.

#### MEMBERS PRESENT

1. **Prof. Ram Gopal Yadav** - **Chairman**

#### RAJYA SABHA

2. Dr. L Hanumanthaiah
3. Shri Suresh Prabhu
4. Dr. Santanu Sen
5. Shri A.D. Singh
6. Dr. Kanimozhi NVN Somu
7. Dr. Subramanian Swamy

#### LOK SABHA

8. Dr. Chandra Sen Jadon
9. Dr. Sanghamitra Maurya
10. Shrimati Pratima Mondal
11. Shri K. Navaskani
12. Dr. Sujay Radhakrishna Vikhe Patil
13. Dr. DNV Senthilkumar S.
14. Dr. Mahesh Sharma
15. Dr. Krishna Pal Singh Yadav
16. Dr. Lorho S. Pfoze

#### SECRETARIAT

- |                           |                     |
|---------------------------|---------------------|
| 1. Shri Mahesh Tiwari     | Joint Secretary     |
| 2. Shri Shashi Bhushan    | Director            |
| 3. Shri Bhupendra Bhaskar | Additional Director |
| 4. Shri Praveen Kumar     | Deputy Secretary    |
| 5. Smt. Harshita Shankar  | Deputy Secretary    |

#### WITNESSES:

#### SAMA - Resource Group for Women and Health

1. Dr. Sarojini Nadimpally, Executive Director
2. Ms. Priyam Lizmary Cherian
3. Ms. Neelanjana Das

#### National Institute of Public Finance and Policy (NIPFP)

1. Dr. Mita Choudhury, Associate Professor, National Institute of Public Finance and Policy (NIPFP), New Delhi

## **Ministry of Women and Child Development**

1. Ms. Preeti Pant, Joint Secretary
2. Capt. Prabhanshu Srivastav, Deputy Secretary

## **Department of Biotechnology**

1. Dr. Rajesh S. Gokhale, Secretary
2. Dr. Alka Sharma, Scientist-H
3. Dr. Onkar Tiwari, Scientist-E
4. Dr. Kamakshi Chaithri, Scientist-C

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them about the agenda of the meeting i.e. to examine various aspects of changing landscape of Covid-19 in India and the world, vaccination of children in 12-14 age group, issues associated with vaccination of lactating and pregnant women, challenges being faced at the ground level during vaccination, need for the third dose/booster dose and other related aspects as part of examination of the subject "Vaccine Development, Distribution Management and Mitigation of Vaccine Pandemic Covid-19". In this regard, the Chairman informed the members that the Committee would be hearing the views of Ministry of Women & Child Development and Department of Biotechnology and two other organizations on the said subject.

3. The Committee, at first, heard the views of Executive Director, SAMA-Resource Group of Women. The deposition to the Committee included following points:-

- i. Covid-19 had a debilitating impact on the health and lives of the people, particularly, on the marginalised communities; additionally many people were still suffering with post-COVID complications, with an estimation that over one crore COVID survivors in India might have long COVID, accordingly healthcare workers and the doctors should be trained to deal with it;
- ii. Lack of regulation of rates for medicines, hospitalization, testing, medical devices and vaccine in private sector created inequities in access to healthcare services resulting in marginalized sections of the society bearing the brunt of Covid-19 pandemic, therefore, prices should be regulated even in the private sector;
- iii. Insufficient allocation of budget for health in the Union Budget 2022-23; significant decline in provision for insurance under Pradhan Mantri Gareeb Kalyan scheme; similarly inadequate financing of ICMR in the Union Budget 2022-23;
- iv. Stressed on participation and contribution of public sector units for the manufacturing of vaccines not just for Covid-19 but also for other illnesses;
- v. Waiver of certain intellectual property provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement for easy access to patented technologies by Indian companies for vaccine and medicine production;
- vi. Lack of information, clarity and transparency on the process of collection of data regarding Adverse Events Following Immunization, (AEFI); provision of compensation for both long and short term adverse effect post vaccination;
- vii. Vaccination for children should have been rolled out only after complete risk-benefit analysis;
- viii. Gender gap in vaccination due to underlined gender inequality, difference in access and control over resources and access to smart phones and internet;
- ix. Lack of clinical research and clinical trials regarding vaccination of lactating and pregnant women;

- x. Adequate remuneration for front line workers including ASHAs also compensating them for their extra efforts during Covid-19 pandemic;
  - xi. Effect of Covid-19 on the maternal health due to disruption in access to abortion services contraceptives and also menstrual and sanitary products during pandemic;
  - xii. Increase in violence against women, girls and also on other gender minorities during Covid-19;
4. Thereafter, Associate Professor, National Institute of Public Finance and Policy (NIPFP) presented her views on the subject and inter-alia highlighted the following key points:
- i. Relatively low health spending in India as a proportion to GDP when compared to major countries of the world; two-thirds of the health spending in the country is done by the State Governments rest one-third is done by the Central Government; wide variation within States regarding health spending with poorer States having weaker healthcare infrastructure resulting in sluggish testing and vaccination drive;
  - ii. Increase in healthcare spending by certain States post Covid-19;
  - iii. Covid virus has been mutating continuously thus making existing vaccines less effective;
5. During the course of the meeting, members raised the following queries:-
- a) Role of environment in human health as most of the new challenges in healthcare are having their genesis in environment for example rise in zoonotic diseases;
  - b) Inability of large proportion of India's population in affording healthcare services; need for promoting health insurance;
  - c) Swiftness in vaccine production to limit the spread of pandemic; taking adequate steps to achieve the vaccination targets regarding first dose, both doses and boosters shots, why has the vaccine not been made free all over India when Covid-19 is a notifiable disease?
  - d) Considering to implement successful models like Kerala model in other States for mitigating Covid-19;
  - e) Access to healthcare facilities in private hospitals by the poor populace;
  - f) Need for more research on new and upcoming variants of Covid-19 and development of effective vaccines;
  - g) Post-Covid complications faced by people suffering from long Covid and exploring healthcare system resilient enough to address these complications and adherence to best practices followed world-wide to fight long Covid complications;
  - h) Slow pace of vaccination in the states like Manipur and need to push the same;
  - i) Need to significantly boost public healthcare spending;
  - j) Regulation of prices of vaccines administered by private hospitals/organizations; increasing government run vaccination centres;
  - k) Lack of awareness regarding vaccines and the need to address vaccine hesitancy;
6. The Chairman then asked the representatives of both the organisations to submit written responses to the questions asked by the Members within seven days.

**(The witnesses then withdrew)**

7. The Committee thereafter heard the oral evidences of Secretary Department of Biotechnology and representatives of Ministry of Women and Child Development on vaccine development, efficacy and safety of vaccines, vaccination of pregnant and lactating women, issues involved and likely side-effects. The Chairman asked the Department of Biotechnology to apprise the Committee about the steps taken by the Department to increase investments in

research & development and manufacturing of COVID-19 Vaccines; details of "Mission COVID Suraksha Programme", its aim and objective; initiatives taken by the Department to make the vaccines accessible and affordable. The Chairman further asked the representatives of Ministry of Women and Child Development to explain their role in the vaccination programme; steps taken to boost vaccination coverage with respect to women, teenage girls and children, role of Anganwadi workers or helpers in the vaccination drive and challenges faced at the ground level and areas of concern.

8. The Secretary, Department of Biotechnology then made a presentation that inter-alia included the following important points:-

- i. The Department set up a DBT-BIRAC (Department of Biotechnology-Biotechnology Industry Research Assistance Council) research consortium to counter Covid-19 that focused on Diagnostics, Vaccines, Therapeutics and Other Interventions like ways to scale up manufacturing of PPE kits, ventilators etc;
- ii. The Department developed a Hub and Spoke Model through which testing activities were conducted in more than 30 centres across the country; mobile vans to facilitate testing in rural India;
- iii. Accelerating Indian Covid-19 vaccine development through "Mission Covid Suraksha"; the aim being the development of 5-6 Covid-19 vaccine candidates for licensure, introduction in the market;
- iv. Developing a network of GCP (Good Clinical Practice) Compliant Clinical trial sites;
- v. To enable accelerated Covid-19 related research and innovation, DBT developed Covid-19 bio-repositories;
- vi. Launched India-PACT (Partnerships for Accelerating Clinical Trials) programme for strengthening clinical trial research capacity in 14 neighboring and friendly countries;
- vii. Jointly established INSACOG (Indian Sars-Cov-2 Genomics Consortium) platform with MoF&HW, CSIR and ICMR to assess Sars-Cov-2 variants from Indian patients;

9. Thereafter, the Joint-Secretary of the Ministry of Women and Child Development presented views of the Ministry which included the following major points:-

- i. Timely and periodic, clear and detailed guidelines were issued by the Ministry for Anganwadi workers during the pandemic Covid-19 with an aim to mobilize and create awareness amongst workers;
  - ii. The Ministry also ensured that children in child care institutions were vaccinated and were taken care of during the times of pandemic;
10. During the course of the meeting, the members raised the following queries:-
- a. Need for better coordination with the *Anganwadi* workers to make the vaccination programme a success; providing special incentives to the *Anganwadi* workers for their work during Covid-19;
  - b. Reason for gender gap in vaccination inspite of *Anganwadi* workers playing a major role in vaccination drive; using different media channels like radio, TV, print to create awareness amongst women regarding vaccination;
  - c. High vaccine hesitancy in rural areas;
  - d. Steps taken by DBT to improve deficiency of funds due to which lab faced problems in genome sequencing essential for identifying mutation of COVID-19;
  - e. Need to develop healthcare systems and models which focuses on reducing Out of pocket expenditure and;
  - f. Need for booster doses.

11. The Chairman then asked the witnesses to submit a written response to the queries raised by the Members within seven days.
12. A verbatim record of the proceedings of the meeting was kept.
13. The Committee then adjourned at 5.02 p.m. to meet again at 3.00.m. on 05<sup>th</sup> April, 2022.

## VIII

### EIGHTH MEETING

The Committee met at 3.00 p.m. on Tuesday, the 5<sup>th</sup> April, 2022 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

#### MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

#### RAJYA SABHA

2. Shri Suresh Prabhu
3. Dr. Santanu Sen
4. Shri A.D. Singh
5. Dr. Kanimozhi NVN Somu

#### LOK SABHA

6. Shrimati Mangal Suresh Angadi
7. Shri Maddila Gurumoorthy
8. Dr. Chandra Sen Jadon
9. Dr. Amol Ramsing Kolhe
10. Dr. Sanghamitra Maurya
11. Shrimati Pratima Mondal
12. Dr. Pritam Gopinath Munde
13. Shri K. Navaskani
14. Dr. Rajdeep Roy
15. Dr. DNV Senthilkumar S.
16. Dr. Krishna Pal Singh Yadav
17. Dr. Lorho S. Pfoze

#### SECRETARIAT

- |                           |                     |
|---------------------------|---------------------|
| 1. Shri Mahesh Tiwari     | Joint Secretary     |
| 2. Shri Shashi Bhushan    | Director            |
| 3. Shri Bhupendra Bhaskar | Additional Director |
| 4. Shri Praveen Kumar     | Deputy Secretary    |
| 5. Smt. Harshita Shankar  | Deputy Secretary    |

#### WITNESSES:

##### Government of Maharashtra

1. Shri Manu Kumar Srivastava, Chief Secretary
2. Dr. Pradeep Vyas, Additional Chief Secretary
3. Shri Saurabh Vijay, Secretary, Medical Education and Drugs Department

##### Government of Karnataka

1. Shri Ravi Kumar P., Chief Secretary
2. Dr. Arundhati Chandrasekhar, Mission Director, NHM

## **Government of Kerala**

1. Dr. Rajan N. Khobragade, Principal Secretary (D/o Health and Family Welfare)

## **Jan Swasthya Abhiyan**

1. Dr. Abhay Shukla, National Co-Convener, Pune
2. Dr. Vandana Prasad
3. Dr. Gagandeep Kang, Virologist and Microbiologist, Christian Medical College, Vellore

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them the agenda of the meeting i.e. continuing to examine various aspects of changing landscape of Covid-19 in India vis-à-vis the disease ridden countries of the world; vaccination of children in 12-14 age group; issues associated with vaccination of lactating and pregnant women; challenges faced at the ground level during first and second wave of pandemic and the vaccination drive; need for the third dose/booster dose and other related aspects as part of examination of the subject "Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19". The Chairman informed the members that the Committee would be hearing the views of State Governments of Maharashtra, Karnataka and Kerala and also gets the opinion of domain experts- Dr. Gagandeep Kang, Virologist and Microbiologist, Christian Medical College, Vellore and Dr. Abhay Shukla, National Co-Convener of Jan Swasthya Abhiyan.

3. The Committee, at first, heard the views of the representatives of Government of Maharashtra. The Chief Secretary informed the Committee that the Additional Chief Secretary, Government of Maharashtra, handled the pandemic in Maharashtra during previous two years, and hence he would be making a brief presentation before the Committee . The submission to the Committee included following points:-

- i. As on 05<sup>th</sup> April, 2022, there were only 866 active cases of Covid-19 that are concentrated in ten Districts, and the weekly positivity rate was 0.4 per cent;
- ii. Impending threat of fourth wave or surge because of South-East Asian countries, however, in case of incidence of fourth wave of Covid-19, Maharashtra is capable of combating the same;
- iii. The State Government partnered with *CSIR - Institute of Genomics and Integrative Biology* for genome sequencing and was closely monitoring the situation for any newer variant;
- iv. With regard to vaccination of 18 plus population, the first dose coverage was 92.07 per cent and the fully vaccinated population is 74 per cent; in 15-18 year category, more than 60 per cent population was covered and in case of 12-14 year population, about 40 per cent population had been covered;
- v. Absence of vaccine vial monitor in the recently-introduced vaccine, Corbevax of Biological Evans company, gave a window of only four hours for the usage of 20 doses of vaccine, that often resulted in vaccine wastage;
- vi. The State Government is running *Mahatma Jyotiba Phule Jan Arogya Yojana*, under which the beneficiaries are decided based on the ration card colours and every resident of the State is eligible for it; also all the non-covid treatment was covered under this scheme during the pandemic times;
- vii. Certain category of health workers like private doctors and private health professionals who are not covered under the *Pradhan Mantri Garib Kalyan Package*, should be covered under this scheme;



- viii. Ensuring that home based testing results and their positivity are also taken into official count; and
- ix. Need for consensus and uniformity in certain policy decisions applicable for the entire country like application of lockdown, opening of schools and colleges and conduct of examinations.

4. Thereafter, the Committee heard the views of Chief Secretary, Government of Karnataka whose deposition to the Committee included the following important points:-

- i. As on 04<sup>th</sup> April, 2022, the State of Karnataka had 1,500 active cases, out of these, about 1,369 cases were in Bengaluru city alone;
- ii. During the third wave due to Omicron variant, the State registered largest number of cases, but still the third wave was easiest to handle due to less virulence of the variant; however, the delta variant, which led the second wave, was very difficult to handle ; one major problem was lack of Oxygen cylinders due to which many people lost their lives;
- iii. Another challenge the State faced during the second wave was - Mucormycosis and there was no medicine for it in the country thus the medicine was imported and the State Government provided it for free to the patients;
- iv. The State needs to find ways to utilise infrastructure and healthcare facilities like ICU, oxygenated beds, ventilators that was created during second wave;
- v. State Government gave an insurance of Rs. 30 lakh even to the private doctors in case of Covid-related deaths;
- vi. The State set up 5 labs for Genome Sequencing;
- vii. With regard to vaccination, 98 per cent of the 18+ population is covered, 80 per cent of the population of 15-18 year age group has been covered; and
- viii. 51% of vaccination for the population of 12-14 year age group was complete; on spot vaccination were being done, but still there was lot of hesitancy and people were not coming forward.

5. The Committee then heard the views of Principal Secretary, Department of Health and Family Welfare, Government of Kerala who gave a presentation before the Committee which included the following important points:-

- i. The impact of first wave of Covid-19 was minimal in Kerala;
- ii. During the Delta wave, the Oxygen management was done properly and at no point health infrastructure was overwhelmed as managerial, public health and clinical interventions were planned at the outset of pandemic itself;
- iii. The State was witnessing very low transmission rate, high case detection, high testing rate and low mortality rate;
- iv. The strategies to combat Covid-19 included Genome sequencing for surveillance, cluster identification under mobility monitoring, free treatment under universal health coverage and respiratory rehab unit for post Covid management;
- v. As on 31<sup>st</sup> March 2022, 100% first dose vaccination of front line workers and 60+ age group population; more than 90% second dose vaccination of these two categories; high vaccination rates in 45-59 and 18-44 age group population;
- vi. The State Government launched DISHA-24\*7 multipurpose communication network for effective knowledge sharing for empowering the public during the pandemic times; daily bulletins and regular Chief Minister's media briefing were also conducted;

- vii. The Government of India should allow precautionary dose for the 18+ population including people with co morbidities; similarly precautionary dose for those who have taken 2 doses abroad should also be allowed;
  - viii. Vaccines that protect against all the variant of concern should be developed by bodies like ICMR;
  - ix. Research whether Covid-19 vaccine should be administered yearly should be prioritized; if so covid-19 vaccination should be included in the Universal Immunization Programme; and
  - x. Cowin Data should be shared with States and UTs through APIs (Application Programming Interface).
6. Thereafter, the members raised certain queries which are as follows:-
- i. Maintenance of cold-chain for transportation of vaccines and how the hilly States could work on optimisation and maintenance of cold chains?;
  - ii. Responsibilities should be assigned and deaths during the second wave should be accounted;
  - iii. Vaccination drives involving public representatives in places of public gatherings like schools, colleges etc to reduce vaccine wastage; increasing vaccination may reduce the fatality rate;
  - iv. Steps taken to maintain and better utilise the health infrastructure created during the second wave;
  - v. Ensuring medicines and other life saving drugs are available at the earliest in case of fourth wave of Covid-19;
  - vi. Steps taken to contain the spread of Covid-19 in densely populated areas like Dharavi;
  - vii. Providing insurance cover under Pradhan Mantri Garib Kalyan Yojana to the doctors and medical staff of private hospitals;
  - viii. Need to conduct research on delayed effects of Covid-19 on recovered patients and
  - ix. More than establishing physical health infrastructure, there is need to develop more number of trained and skilled manpower resources as ultimately, human resource is the most important resource to fight any medical emergency.
7. Thereafter, National Co-Convener, Jan Swasthya Abhiyan gave a presentation in front of the Committee. His presentation included following major points:-
- i. Government must ensure transparent and effective monitoring of serious adverse events following Covid vaccination and a comprehensive mechanism for management of post-covid complications must be formulated;
  - ii. Profiteering by private vaccine manufacturers must be curbed and manufacturing of vaccines by public sector units should be revived and encouraged;
  - iii. Law for regulation of private hospitals during health emergencies should be formulated;
  - iv. Adequate remuneration and support for ASHA and other frontline health workers;
  - v. Urgent need to strengthen public health infrastructure and expanding human resource engaged in healthcare by increasing seats in medical institutions; attracting more youth to pursue career in medical sciences by making medical education more accessible and affordable and
  - vi. The Government must significantly increase public health expenditure and provide affordable Universal Health coverage to the entire eligible population.
8. Finally, the Committee heard the views of Dr. Gagandeep Kang who highlighted the following key points on the subject:

- i. India must develop a strategy to build a vaccine eco system to develop completely indigenous vaccines;
  - ii. Lack of efforts in sharing and making Covid data public; the CoWIN platform does not link to any other data system, which is why despite administering 1.6 billion doses of Covishield, India still lacks data on the effectiveness of the vaccine and
  - iii. Approvals and licensing to use drugs for clinical research and undertaking studies should be fast tracked during health emergencies.
9. The Chairman then asked the witnesses to submit a written response to the queries raised by the Members within seven days.
10. A verbatim record of the proceedings of the meeting was kept.
11. The Committee then adjourned at 4.51 p.m.

## XV

### FIFTEENTH MEETING

The Committee met at 3.00 p.m. on Monday, the 8<sup>th</sup> August, 2022 in Committee Room-A, Ground Floor, Parliament House Annexe, New Delhi.

#### MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

#### RAJYA SABHA

2. Dr. Santanu Sen
3. Shri A. D. Singh

#### LOK SABHA

4. Dr. Chandra Sen Jadon
5. Dr. Sanghmitra Maurya
6. Dr. Pritam Gopinath Munde
7. Shri K. Navaskani
8. Dr. Sujay Radhakrishna Vikhe Patil
9. Shri Haji Fazlur Rehman
10. Dr. Rajdeep Roy
11. Dr. DNV Senthilkumar S.
12. Shri Anurag Sharma
13. Dr. Mahesh Sharma
14. Dr. Krishna Pal Singh Yadav
15. Dr. Lorho S. Pfoze

#### SECRETARIAT

- |                           |                     |
|---------------------------|---------------------|
| 1. Shri Shashi Bhushan    | Director            |
| 2. Shri Bhupendra Bhaskar | Additional Director |
| 3. Shri Praveen Kumar     | Deputy Secretary    |
| 4. Smt. Harshita Shankar  | Deputy Secretary    |

2. At the outset, the Chairman welcomed the Members of the Committee and informed that the meeting has been convened to consider and adopt draft 137<sup>th</sup> Report on the subject "Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19" and \*\*\*.

3. The Committee, thereafter, took up for consideration the draft 137<sup>th</sup> and \*\*\* of the Committee. The Chairman informed the Committee that a total of 140 observations/recommendations were there in the draft 137<sup>th</sup> Report and \*\*\*. He invited views/suggestions/modifications, if any, from the Members in the draft reports. During the brief deliberation, \*\*\*. After a brief discussion, the Committee adopted both reports with some modifications.

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\* Pertains to other matter

4. The Committee, thereafter, decided that the aforementioned two Reports may be presented to the Rajya Sabha and simultaneously laid on the Table of the Lok Sabha on Wednesday, the 10<sup>th</sup> August, 2022. The Committee authorized its Chairman Prof. Ram Gopal Yadav, MP, Rajya Sabha and in his absence Dr. Anil Agrawal, MP, Rajya Sabha and in the absence of both members, Dr. Kanimozhi NVN Somu to present the Reports in Rajya Sabha. The Committee also authorized Dr. Rajdeep Roy, MP, Lok Sabha and in his absence Dr. Sanghamitra Maurya MP, Lok Sabha to lay the Reports on the Table of the Lok Sabha.

5. The Committee further decided that in case the Parliament gets adjourned sine die, the reports would be presented to the Hon'ble Chairman, Rajya Sabha during the inter-session period.

6. The Committee then adjourned at 3:18 p.m.

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# **ANNEXURE**

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## Annexure-1

### State/UT-wise details of Cold Chain Points and their storage capacity

S. No.	State	No. of CCP	SVS/RVS level		DVS level		Last CCP level	
			Available space (in ltr)	No. of doses can be stored*	Available space (in ltr)	No. of doses can be stored*	Available space (in ltr)	No. of doses can be stored*
1	A&N Islands	40	6,321	22,57,418	741	2,64,561	1,731	6,18,132
2	Andhra Pradesh	1,646	68,234	2,43,69,354	47,029	1,67,96,140	1,97,661	7,05,93,351
3	Arunachal Pradesh	196	10,401	37,14,589	8,404	30,01,374	8,332	29,75,660
4	Assam	799	34,659	1,23,78,235	21,325	76,16,099	93,605	3,34,30,384
5	Bihar	684	1,80,373	6,44,19,014	71,269	2,54,53,300	94,773	3,38,47,585
6	Chandigarh	53	4,842	17,29,371	1,664	5,94,150	3,638	12,99,371
7	Chhattisgarh	750	32,944	1,17,65,552	18,603	66,43,766	55,436	1,97,98,409
8	Dadra & Nagar Haveli	19	380	1,35,738	4,896	17,48,584	1,495	5,33,953
9	Daman & Diu	2	576	2,05,575	1,365	4,87,360	534	1,90,645
10	Delhi	631	6,724	24,01,392	13,417	47,91,749	64,940	2,31,92,821
11	Goa	41	4,542	16,22,282	2,189	7,81,677	3,930	14,03,711
12	Gujarat	2,295	54,806	1,95,73,637	40,939	1,46,21,137	1,66,576	5,94,91,494
13	Haryana	688	30,319	1,08,28,104	17,267	61,66,675	55,580	1,98,49,890
14	Himachal Pradesh	416	20,688	73,88,588	6,710	23,96,445	33,081	1,18,14,660
15	J&K (including Ladakh)	681	19,724	70,44,366	12,354	44,12,221	63,231	2,25,82,578
16	Jharkhand	281	55,909	1,99,67,331	20,091	71,75,188	31,735	1,13,33,759
17	Karnataka	2,900	56,104	2,00,36,990	40,933	1,46,18,776	3,05,681	10,91,71,633
18	Kerala	1,265	56,983	2,03,51,107	24,592	87,82,892	1,36,871	4,88,82,535
19	Lakshadweep	5	393	1,40,318	597	2,13,135	952	3,39,921
20	Madhya Pradesh	1,240	96,329	3,44,03,168	68,484	2,44,58,526	1,13,864	4,06,65,668
21	Maharashtra	3,318	1,54,044	5,50,15,828	75,416	2,69,34,399	2,90,851	10,38,75,471
22	Manipur	123	8,531	30,46,940	1,642	5,86,583	3,757	13,41,940
23	Meghalaya	189	12,043	43,00,972	7,106	25,37,757	8,658	30,92,043
24	Mizoram	85	6,304	22,51,542	2,147	7,66,899	4,851	17,32,613
25	Nagaland	123	4,473	15,97,348	1,690	6,03,420	7,504	26,79,848
26	Odisha	1,250	87,547	3,12,66,714	65,379	2,33,49,571	1,15,997	4,14,27,428
27	Puducherry	56	1,984	7,08,734	1,328	4,74,254	3,751	13,39,611
28	Punjab	753	31,473	1,12,40,226	21,599	77,14,042	59,522	2,12,57,726
29	Rajasthan	2,564	69,199	2,47,13,965	79,628	2,84,38,607	1,79,933	6,42,61,822
30	Sikkim	36	1,335	4,76,678	1,186	4,23,463	3,843	13,72,392
31	Tamil Nadu	2,600	88,414	3,15,76,440	51,017	1,82,20,369	1,82,842	6,53,00,726
32	Telangana	906	43,441	1,55,14,535	43,080	1,53,85,606	1,02,801	3,67,14,535
33	Tripura	162	8,617	30,77,533	3,173	11,33,247	12,981	46,36,104
34	Uttar Pradesh	1,309	1,65,112	5,89,68,586	1,46,518	5,23,27,872	1,93,344	6,90,51,443
35	Uttarakhand	373	11,580	41,35,682	12,709	45,38,896	58,712	2,09,68,539
36	West Bengal	947	1,93,715	6,91,84,023	97,230	3,47,25,095	1,50,237	5,36,56,166
37	<b>TOTAL</b>	<b>29,426</b>	<b>9,29,062</b>	<b>58,18,07,874</b>	<b>3,33,715</b>	<b>36,91,83,835</b>	<b>21,13,229</b>	<b>1,00,47,24,568</b>

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