STANDING COMMITTEE ON HEALTH AND WELFARE

Vaccine Development, Distribution Management And Mitigation Of Pandemic Covid-19

ONE HUNDRED THIRTY SEVENTH REPORT

The outbreak of Pandemic Covid-19 with mutating variants necessitated the detailed examination of 'Vaccine Development, Distribution Management and Mitigation Plan of Pandemic Covid-19'. During the examination, deliberations were held with officials from various organisations and State Governments, representatives of Department of Health and Family Welfare, Health Research, following such meetings and study visits, the Report was adopted in 2022.

CHAPTER 1 - RESURGENCE OF PANDEMIC COVID-19

The world witnessed the severe impact of Covid-19 pandemic that brought the global economy to a standstill. India faced one of the heaviest burdens of Covid-19 cases in the world. The enormity of the population of the country posed a major challenge in the face of the unprecedented pandemic. 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. Accordingly, it was observed that the government could not accurately anticipate the gravity of the possible resurgence of the pandemic and its subsequent waves and there were no definite guidelines for identifying the deaths due to inadequate supply of oxygen, it was also noted that the Government could not maintain a steady flow of oxygen which ultimately lead to an unprecedented medical crisis.

Challenges and learnings from the Second wave of the pandemic :

- **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.
- **Reliance on imported logistics** : Public health response could not be possible without development of indigenous capacities in terms of essential equipment, diagnostics and vaccine manufacturing capacities.
- Supporting States with adequate logistic
- **Black marketing of essential drugs** like Remdesivir
- 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
- **Need for large number of trained manpower**

Recommendations were made following detailed study of Reports by multiple Laboratories and study visits :

- **Strengthening the mitigation strategies** as the Indian health care system and the diagnostic infrastructure were under insurmountable pressure.
- **Development of a healthcare framework in the country** for investigating and managing future outbreaks more effectively in the light of increasing virus cases. Along with this, establishment of a robust mechanism for systemic investigation of the origin and route of transmission of the pathogens.
- **Availability of technical staff at the district hospitals** for the operation of PSA (pressure swing adsorption) and to ensure efficient oxygen management protocols in hospitals for medical utilization.
- **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
- Strict monitoring of International travelers in the community.
- Contact tracing of positive individuals & follow up for 14 days.

- **Genome sequencing of positive samples** through Laboratories in a prompt manner.
- Continued monitoring of areas where clusters of positive cases emerge.
- Further **strengthening of COVID-19 testing infrastructure** and ensuring early identification of cases through adequate testing across the States.
- Commissioning all PSA plants, ensuring sufficient logistics, drugs etc.
- 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 comorbidities.
- Ensuring adherence to COVID Appropriate Behaviour.
- To **take note of any fresh surge in covid cases** and conduct sequencing of adequate numbers of samples so that new variants of interest and variants of concern can be identified at the earliest. To closely monitor the trajectory of Covid in the country so that the system is better prepared to manage future resurgence of the virus.

CHAPTER 2 : VACCINE RESEARCH AND DEVELOPMENT

In the midst of an emergency situation, the world scientific community accelerated to come up with a vaccine for the SARS-CoV-2 virus. 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 deliberations discussed various issues regarding vaccine research and its status in the country.

There were enormous challenges in early stage vaccine development in India which the country came across.

There were three kinds of Committees, viz, (i) the Task Force on Focused Research on Corona Vaccine and other Science and Technology Issues (ii) National Expert Group on Vaccine Administration for Covid-19, NEGVAC (iii) the National Technical Advisory Group on Immunization which evaluate vaccines and decided whether or not to roll them into the immunization programme. 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, highest priority was accorded to this. Similarly, the regulatory response had to be rapid.

The Government must incentivise multidisciplinary research and efforts towards enhancing the research infrastructure in the country, collaborative studies among National and International Institutes must be promoted and a roadmap should be developed for creating a vibrant research environment in the country.

The main objective of development of vaccines 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. **Emergency Use Authorisation (EUA),** a regulatory mechanism to allow the use of vaccines to reduce the impact of life-threatening diseases. Provisions for emergency use authorisation were absent in New Drugs and Clinical Trials Rules 2019 and vaccines were given EUA without any specific provision in the Indian drug rules and regulations. Ambiguity on the vaccine trials as well as the procedure followed for EUA reflects greatly on the need of making amendments to the Indian Laws and specific provisions for EUA should be made in the Indian drug laws. **The Ministry of Health and Family Welfare should carry out rigorous assessments of laboratory and clinical trial data before granting any future Emergency Use Authorization for vaccines** and the data on quality, safety, production of protective antibodies of vaccines should be shared in the public domain.

Time and again the need of a strengthened research ecosystem in the country has been emphasised, and the Departments must work on strengthening the clinical trials ecosystem in the country along with data transparency. The present situation necessitates development of effective interventions so that future outbreaks are mitigated. **Initiatives must be taken to develop a universal covid vaccine that is effective against all the variants**.

The Indian pharmaceutical companies have a worldwide presence and have the ability to produce vaccines on a large scale supplying the global demand of vaccines, however, there is a gigantic scope for more innovation and research in the sector. The Government should look forward to strengthening the research ecosystem so that vaccines on newer and more scientific platforms are developed and the budget of Health Research and ICMR for newer innovations.

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.

The funds allocated for Covid-19 management should have been judiciously distributed among the States so that the financial burden of the poorer States could be aptly managed, Government must ensure that adequate funds are reserved for purchasing and administration of vaccine doses. **Adequate fund allocation** was emphasized for purchasing administering the vaccine doses and to ensure equitable distribution of funds among the states. The Ministry was further advised to look into the **utilization of funds by the states and ensure the fulfillment of adequate infrastructure in the states**. The Government was advised to frame guidelines and adopt financial prudence and avoid last minute disbursement of funds and to frame guidelines of financial prudence in consultations with the States to ensure that the guidelines are judiciously followed.

CHAPTER 3 - VACCINE PROCUREMENT AND DISTRIBUTION

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

Under the **National COVID Vaccination Program,** from 16th January to 30th April 2021, 100% of vaccine doses were procured by the 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.
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. The 'Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy' was in effect from 1st May 2021 to 20th June 2021. The aforesaid strategy was implemented in response to the suggestions of many State Governments to be permitted the flexibility to procure vaccines directly and administer them as per their own prioritization based on local requirements.

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, therefore the guidelines were revised as 'Revised Guidelines for implementation of National COVID Vaccination Program'.

Procurement and delivery of vaccines for catering to the targeted group of people required a huge amount of financial resources. **A robust assessment of the logistic requirements and streamlining of the procurement process was crucial in ensuring the supply chain of the vaccines in the country.**

A huge disparity between the states with respect to the procurement policy as many states were not able to manage 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 Ministry was advised to make **elaborate arrangements for ensuring procurement in emergency situations.**

Most of the vaccine centres used to get full to their capacity at a quick pace, booking a slot on Cowin became a herculean task at the early stage . The Government should have taken steps to **enhance vaccine capacity in the country and procure additional vaccine doses and a better assessment of the vaccine requirement in the country could have accelerated the vaccination drive**.

A **robust cold chain infrastructure** form 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 equipment to the States so that the vaccines were smoothly distributed and rolled out upto the last corner of the country. The vaccines need to be stored in refrigerated conditions and the temperature monitored on a real time basis. Insulated vaccine vans are required for transportation of the vaccines across the country within a stipulated time frame. The Ministry, therefore, must **assess the ground requirements of the cold chain supply and ensure that an adequate number of insulated vans and cold chain equipment are available.**

Electronic Vaccine Intelligence Network (eVIN), an innovative technological solution is aimed at strengthening the vaccine supply chain systems across the country. The use of eVIN has facilitated real time monitoring of the vaccines in the States, and must be made 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.

Taking into account the regions with difficult geographical terrains and poor connectivity , digitization of vaccine stock inventory and its storage may not be possible, therefore the Ministry was recommended to **coordinate with states and encourage the use of modern technologies, drones, helicopters for the robust distribution of vaccines.**

The **mRNA vaccines** because of their high potency, greater flexibility act as a better alternative in comparison to other vaccine platforms.Therefore, the Ministry must explore such versatile **vaccine platforms in the country and work towards producing cost effective indigenous mRNA vaccines.**

Attention has 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 Ministry should 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 Ministry must ensure that any excess stock of vaccines is not wasted so that the 100% vaccination of its citizens is achieved.

CHAPTER-4 UNFOLDING OF THE NATIONAL COVID-19 VACCINATION PROGRAMME

The Vaccination Programme of India against Covid-19 was 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 the National COVID-19 Vaccination Programme.

Sequential roll out of Covid-19 vaccination : 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

The vaccination programme was based on five principles :

- Ensure People's Participation
- Utilize experience of elections and universal immunization programme
- No compromise of existing healthcare services, especially, national programmes and primary healthcare.
- No compromise on scientific and regulatory norms
- Orderly and smooth implementation driven by technology

A **robust implementation of the five principles would ensure the success of the National Vaccination Program** and active participation of the key officers from State to the Block level

along with the masses. Also, past experiences of universal immunization and elections must be utilized in smooth implementation of the National Vaccination Program.

With an aim to make vaccination free and universal, an adequate supply of vaccines should be ensured so that the target of universal free covid vaccination is achieved.

CoWIN APPLICATION

The Government developed a digital platform called CoWIN where all the **data of vaccines, like vaccine movement information, storage information, dose information etc. could be recorded, monitored, and updated**. The platform tracked the recipient of the vaccination dose and informed 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.

With **poor accessibility and connectivity, many areas of the country still remain disconnected from the digital ecosystem** and many rural areas tend to be neglected as the level of awareness is very poor. Effective measures need to be taken to ensure that the rural areas especially the tribal areas are also included in the vaccination drive. In the absence of internet connectivity, entering data in the app was a challenge, accordingly, the Ministry should ensure that the data collected in the physical form is uploaded in the Cowin app at the earliest and 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.**

The country has no extensive records of after immunization effects in its population. The facilitation of linkages between CoWin and other data systems and sharing the data in the public domain was recommended. **Building interoperable data systems that ensure real time data exchange could provide a better assessment of the efficacy of the vaccines**.

CHAPTER-5 VIEWS OF STATE GOVERNMENTS/ THE DEPARTMENTS/MINISTRIES AND OTHER STAKEHOLDERS

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 views of the other Ministries and State Governments on the subject were also sought. Continuing with the examination of the subject, the Committee also undertook two study visits (i) to Srinagar and Chandigarh and (ii) to Guwahati, Bengaluru and Mumbai. On the basis of the deliberations, certain suggestions were made to the Government for implementation in the future.

The pandemic gave an 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 State Governments adopted many novel approaches in their fight against the pandemic and The Ministry of Health and Family Welfare was recommended to study the novel approaches adopted by the States. **The Ministry must coordinate and play a pivotal role in exchanging of new ideas and new learning during the pandemic and related strategic management and ensure implementation of the successful models in other States and strengthen the healthcare delivery system to meet any future medical emergency**.
The Ministry must **collaborate with research bodies and apex institutes of the neighboring countries so that regional cooperation is further strengthened** and scientific fervor is promoted in India and the neighboring countries.

The piloted role of the Ministry of Ayush in the National Covid-19 vaccination programme could not be understated as the Ministry provided a pool of Healthcare workers as vaccinators. The **Ayush institutional structure must be massively utilized as a platform for dissemination of Information, Education and Communication (IEC) activities**, thus enhancing public awareness for mitigation of Covid-19. 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. The Committee strongly recommends the State Government to ensure the last mile delivery of vaccines especially in the remotest area of the State.

CHAPTER- 6 CHALLENGES IN COVID-19 MITIGATION AND MANAGEMENT

The pandemic caused an unprecedented crisis and the Indian health infrastructure struggled to handle the emergency of such high proportions. Some of the challenges identified during the implementation of the National Vaccine Policy have been enumerated :

POOR GOVERNMENT EXPENDITURE ON HEALTH : 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. **An increase in public investments in the health sector in the systems and research was recommended. The Ministry must nudge the States with a 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 : 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%. **The Ministry must conduct more awareness campaigns especially in regions with poor rates of vaccination among women and efforts must be taken to bridge this gender gap in vaccination.**

RURAL-URBAN VACCINE DISPARITY : The vaccination rate was very poor in the rural areas in the beginning of the vaccination drive. 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. The Ministry must **open more vaccination centers in the rural areas and must use modern technology and equipment to expedite the delivery of vaccines** and must use modern technology and equipment to expedite the delivery of vaccines. The Ministry should **deploy helicopters, boats, motor bikes and every possible means of transport to achieve last mile delivery of vaccines.**

VACCINE HESITANCY : 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 Ministry must disseminate information and **spread public awareness regarding the safety and efficacy of the vaccines and to continue conducting various communication strategy activities in rural areas and areas with poor accessibility**. Further recommendation is to **conduct at-home inoculations** especially for the aged and people with special needs.

VACCINE EQUITY : 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, 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. Also, the Ministry is advised to **focus not only on the vaccine supply side barrier but also on the demand side barriers so that vaccination targets are achieved**. The Government should refresh its target of 100% vaccination of the Indian population along with booster doses and make concerted efforts to achieve the targets.

REVAMPING OF PUBLIC SECTOR VACCINE MANUFACTURING UNITS : 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 Covid19. The Ministry must **monitor the revival of the vaccine manufacturing units and henceforth, furnish quarterly Reports to the Committee**. The Ministry of Health and Family Welfare must forward the revival plan along with financial requirements to the Ministry of Finance for approval at the earliest.

NEED OF STRONG PUBLIC-PRIVATE PARTNERSHIP IN THE HEALTH SECTOR : The Government with its limited resources, faces a far bigger 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. **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.**

NEED OF CHANGE IN VACCINATION POLICY : 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. **The Government should find out scientifically, the reasonable gap between the two doses of the vaccine** and the gap between the 2nd 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 and 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 : ASHAs, AWWs and AWHs acted as the frontline workers during the pandemic and were responsible for spreading awareness about Covid-19 and safety protocols. They were also tasked with identifying as well as tracking COVID-19 positive cases and carrying out vaccination drives and

have played an important role in community surveillance as has also been applauded by WHO, however, these frontline workers remain unrewarded. **The Ministry of Health and Family Welfare and the Ministry of Women and Child Development should ensure timely payment of wages along with other social security benefits**. The Government should consider incentives and **financial protection for the workers under different financial packages**.

COMPLACENCY IN ADMINISTRATION OF BOOSTER DOSES : The administration of free booster doses has enhanced the booster dose uptake. However, the free precautionary dose window is only for 75 days. The Ministry should **extend the 75 days window and make the precautionary dose free** for all so that complete vaccination of all can be ensured.

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) : A total of 28 AEFI were reported across the country and total AEFI is reported to be 0.006% of the total cases. The Ministry must ensure that appropriate investigation must be done and the AEFI Committee must expedite its examination of each adverse and a clear framework of vaccine liability must be created for manufacturers in case of AEFI so that adequate compensation can be provided to the aggrieved individuals.

NEED OF AN ENHANCED ROLE OF AYUSH IN THE MITIGATION OF THE PANDEMIC COVID-19 : AYUSH must continue emphasis on evidence based scientific research and drug development process entailing pre clinical as well as clinical trials. The Ministry of Ayush must work towards building inter-ministerial linkages and collaborate with other Departments for undertaking clinical studies on newer drugs. In the wake of the global health crisis and the threat of emerging viruses, **Ayush system can be utilized as an effective means to tackle the challenges associated with the health sector.** The Government must continue making efforts in integrating Ayush in health.

CONCLUSION

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 and emphasizes to ensure that the set targets of complete vaccination are achieved and any existing disparity in vaccine distribution is addressed at the earliest. The Ministry must see Covid-19 as an opportunity to revamp the public healthcare infrastructure in the country and usher in new reforms and it is imperative that Government health expenditure and investments in research and development is enhanced. The Ministry must also work towards forging better public private partnerships for ensuring last mile delivery of healthcare services.