

Standing Committee Report Summary Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19

- The Standing Committee on Health and Family Welfare (Chair: Mr. Ram Gopal Yadav) submitted its report on 'Vaccine Development, Distribution Management and Mitigation of Pandemic Covid-19' on September 12, 2022. Key observations and recommendations of the Committee include:
- Response to COVID-19: The Committee observed several shortcomings in India's response to COVID-19. These include: (i) fragile health infrastructure and shortage of healthcare workers, (ii) poor vaccination rate in rural areas in the beginning, and (iii) mismanagement of oxygen supply during second wave. Further, the Committee observed that there was ease in restrictions and decline in testing after the first wave. Both these factors could be attributed to the high number of cases followed by enormous fatalities during the second wave. Large scale social, political, and religious gatherings with no social distancing were also a major factor for the second wave.
- The Committee recommended the Ministry of Health and Family Welfare to see COVID-19 as an opportunity to bring reforms in public health infrastructure in the country. These reforms include: (i) increasing public expenditure on health and investments in research and development, (ii) promoting public-private partnerships for ensuring last mile delivery of health services, and (iii) expanding capacity of health services.
- **Emergency Use Authorisation (EUA):** The Committee observed that vaccines in India were given EUA without any specific provisions in the Indian drug rules and regulations. Provisions for EUA are absent in New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940. Laws in other countries are clearly defined for EUA which ensured transparency in the granting of approvals to vaccines and drugs during the pandemic. However, there was lack of transparency in information regarding the protocol followed and clinical trial data of vaccines in India. There is also lack of clarity in the procedure followed for granting approval for booster doses. The Committee recommended: (i) making specific provisions for EUA, (ii) conducting rigorous assessments of clinical trial data before granting

- any future EUA, and (iii) using scientific findings for making changes in vaccine policy.
- Booster doses: Booster/precautionary doses commenced for all adults at private vaccination centres from April 2022. The Committee asked the Ministry to submit: (i) evidence-based research that necessitated the administering of booster doses, and (ii) reasons behind providing booster doses of the same vaccine. The Committee observed that some reports suggest that a booster dose of a different vaccine is better. It noted the that implementation of such propositions requires scientific research and clinical trials. The Ministry should also encourage studies on potency and efficacy of different combinations of vaccines.
- Vaccine procurement: The Committee noted that India did not make any upfront payments or signed any pre-purchase agreement with vaccine manufacturers during development phase of vaccines. The need of such agreements was felt when vaccine supply could not match the demand from states. A better assessment of vaccine requirement could have accelerated the vaccination drive. The Committee recommended the Ministry to seek technical and financial assistance to strengthen procurement planning strategy for future emergencies.
- Public sector vaccine manufacturing: Ensuring a constant supply of vaccines during COVID-19 was a major challenge. The Committee observed that the contribution of public sector vaccine units to COVID-19 vaccine production was negligible. Currently there are seven public sector vaccine manufacturing units which includes Central Research Institute (CRI), and Pasteur Institute of India (PII). The Committee observed that these units are underutilised. It recommended the Ministry to revive these public sector units.
- India has been advocating the waiver of Intellectual Property Rights (IPR) of COVID-19 vaccines at the global level. However, the Committee observed that the central government has not waived the IPR for indigenous vaccine Covaxin. It recommended examining the possibility of technology transfer of Covaxin to public sector vaccine manufacturing units and start its production in these units.

DISCLAIMER: This document is being furnished to you for your information. You may choose to reproduce or redistribute this report for non-commercial purposes in part or in full to any other person with due acknowledgement of PRS Legislative Research ("PRS"). The opinions expressed herein are entirely those of the author(s). PRS makes every effort to use reliable and comprehensive information, but PRS does not represent that the contents of the report are accurate or complete. PRS is an independent, not-for-profit group. This document has been prepared without regard to the objectives or opinions of those who may receive it.

Omir Kumar omir@prsindia.org

September 28, 2022