

Standing Committee Report Summary

Availability of Medicines and Medicinal Devices

- The Standing Committee on Chemicals and Fertilizers (Chair: Ms Kanimozhi Karunanidhi) presented its report on 'Availability of Medicines and Medical Devices for COVID Management' on March 21, 2022. The Department of Pharmaceuticals (DoP) is responsible for industry promotion for pharmaceutical industry. It also works to augment the production and supply of essential drugs required for management of COVID-19. Key observations and recommendations of the Committee include:
 - **Availability of medicines:** The Committee noted that listing of drugs for COVID-19 management and prescribing them under the National Treatment Protocol is done by the Ministry of Health and Family Welfare (MoHFW). The DoP has no role in framing of the National Treatment Protocol. Currently, the Central Drugs Control Organisation (CDSCO) updates the MoHFW about the production capacity and availability of the drugs. Based on inputs from MoHFW from time to time, the DoP augments the production and supply of the essential drugs required for management of COVID-19. The Committee recommended that the DoP should be involved in determining the National Treatment Protocol, to initiate the coordination between DoP and MoHFW in the planning stage. Further, it recommended conducting a daily review of medicines and medical devices required by all states or union territories by DoP and MoHFW.
 - **Price control of medicines:** Currently, the National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified under the Drugs (Prices Control) Order, 2013 (DPCO). All manufacturers of scheduled medicines have to sell their products within the ceiling price fixed by the NPPA. However, manufacturers of non-scheduled formulations may be allowed to fix their own retail selling prices (provided that the price increase of such formulations is not more than 10% during the preceding 12 months). The Committee recommended DoP and NPPA to frame a new price regime for COVID-19 specific medicines and medical devices, where no annual increase in prices may be allowed till the pandemic is entirely over in the country. Further, the distinction between scheduled and non-scheduled drugs may be done away with.
 - **Prices of oxygen concentrator:** The Committee noted that the price range of oxygen concentrators is still on the higher side. It recommended DoP and NPPA to consider capping of the prices of various types of oxygen concentrators so as to make them affordable.
- Further, pharma PSUs under DoP may consider manufacturing the same. Further, the Committee recommended that medical devices such as ventilators and concentrators should be covered under National List of Essential Medicines for effective price control.
- **GST on medicines:** The Committee noted that GST on most COVID-19 essential medicines and medicinal devices was reduced to 5% in June 2021. It recommended that to further reduce the price, the DoP and MoHFW should submit a proposal to the GST Council to exempt all COVID-19 essential medicines and medical devices from the purview of GST. Further, basic customs duty exemptions on such medicines and medical devices should also be continued till the pandemic is over.
- **Import of medicines:** The Committee observed that import of certain raw materials (excipients) for drugs is a major constraint for availability of medicines. For instance, finished formulations of the drug Tocilizumab is not manufactured in India. The Committee recommended: (i) addressing the dependence on other countries for excipients by initiating necessary measures for manufacturing such raw materials in the country, (ii) reviewing the functioning of Indian missions abroad in the Drug Coordination Committee for providing necessary assistance to Indian manufacturers for production of drugs, and (iii) ramping up the import of medicines such as Tocilizumab and Liposomal Amphotericin B.
- **Remdesivir:** The Committee noted that Remdesivir has been included in the National Treatment Protocol of COVID-19 as an optional drug. It is a patented drug, which is manufactured by seven Indian manufacturing companies. However, none of the pharmaceutical PSUs under DoP have been granted voluntary license to manufacture Remdesivir and other COVID-19 essential drugs. The Committee recommended the DoP to initiate steps to explore the possibilities of manufacturing COVID-19 essential drugs by the PSUs under it. It also recommended conducting studies for effectiveness of medicines such as Remdesivir, which are optional under the National Treatment Protocol. Based on these studies, MoHFW should take steps to remove drugs from the protocol which are not necessary. Further, the Committee recommended organising nationwide online training programmes for all registered medical practitioners on the rational use of Remdesivir and other COVID-19 drugs included in the protocol.

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