

Standing Committee Report Summary

Promotion of Medical Device Industry

- The Standing Committee on Chemicals and Fertilisers (Chair: Dr. Shashi Tharoor) presented its report on ‘Promotion of Medical Device Industry’ on February 8, 2024. Key observations and recommendations of the Committee include:
 - **Impediments to growth of medical device industry:** Domestic manufacturing of medical devices is currently limited to low-end to moderate-end medical devices such as consumables, disposables, and implants. 70% of high-end devices such as electronic equipment, advance surgical instruments, and diagnostic products are imported. Issues that impede growth of the sector include: (i) low investment in research and development, (ii) fewer tax concessions and inverted duty structure (higher tax on the raw material than on the finished good) for domestic manufacturers, (iii) low capital investment, (iv) lack of skilled manpower, (v) limited price and quality regulation, and (vi) fewer trained healthcare professionals. The Committee noted that initiatives taken by the Department of Pharmaceuticals since 2015 are yet to materialise.
 - **Import dependence:** The domestic medical devices sector is expected to be worth USD 50 billion by 2030. However, currently 80% of our domestic sales constitute imported medical devices. Import of high-end devices has risen between 2019-20 and 2022-23, despite production linked incentives being in place. The Committee recommended an inter-ministerial and inter-governmental strategy to offer domestic manufacturers competitive advantage.
 - **Medical devices parks:** Under the Promotion of Medical Devices Parks Scheme, four medical device parks are to be established in four states. These parks will have common testing facilities and labs. Of the Rs 120 crore allocated in the first phase (2022-23), only Rs 89 lakh has been spent so far. It suggested that there needs to be regular progress monitoring with state agencies. It also recommended expanding the scheme to other states.
 - **Production linked incentive (PLI) schemes:** Under the PLI scheme for medical devices, the government will provide an incentive of Rs 3,420 crore to new projects between 2022-23 to 2026-27. As of June 2023, 26 applicants have invested Rs 852 crore out of committed investment of Rs 1,330 crore (64%). 14 projects have been commissioned covering 36 medical devices related to cancer care, radiology and imaging, anaesthetics, and pacemakers. The Committee recommended increasing the number of beneficiaries under the PLI scheme. Under the pharmaceutical PLI, incentives worth Rs 250 crore on incremental sales of certain medical devices are to be provided between 2020-21 and 2028-29. However, only Rs 4.8 crore has been released so far. The Committee recommended the Department to take serious efforts to implement the Scheme.
 - **GST and custom duty:** The Committee noted that GST on medical devices (12-18%) is high. At the same time, the import duty on finished medical devices is lower than the import duty on raw materials or manufacturing components. The Department of Pharmaceuticals has requested the Department of Revenue to increase the custom duty for 40 finished products. The Committee noted that since the industry is at a nascent stage, government support in the form of lower taxes rates is necessary. It suggested that custom duty concessions on import of components must be provided until the industry can become self-sufficient. The Department of Revenue stated that reducing the GST rates would create an inverted duty structure.
 - **Price regulation:** Currently, few medical devices are listed as essential medicines for price regulation. The Committee recommended that the Department must list medium and high-end medical devices used for critical patient care as essential medicines.
 - **Testing labs:** Currently there are only six central medical device testing labs, and 39 private labs registered with the Central Drugs Standard Control Organisation (CDSCO). The Committee noted that the number of central labs is inadequate, and recommended that at least one lab be set up in proximity of each industry cluster.
 - **Regulation of refurbished devices:** Presently, Medical Device Rules, 2017 do not regulate second-hand medical devices. These are regulated under environment rules. The CDSCO does not maintain safety standards for such devices, or evaluate their ill effects on public health. The Committee suggested that the safety, quality and efficacy of imported second-hand medical devices must be ensured through regulation. It also suggested restricting such imports to protect domestic manufacturers.

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