Standing Committee Report Summary

Medical Devices: Regulation and Control

- The Standing Committee on Health and Family Welfare (Chair: Mr. Ram Gopal Yadav) presented its report on 'Medical Devices: Regulation and Control' on September 12, 2022. Key observations and recommendations of the Committee are:
- **Domestic manufacturing:** 80% of the requirement for medical devices is met by imports. The Committee observed that the Indian medical device industry is facing several challenges: (i) inadequacy of indigenous research and development (R&D), (ii) lack of qualified manpower, (iii) non availability of finances, and (iv) high manufacturing costs. It recommended: (i) providing incentives for domestically manufactured products in government procurement, (ii) that the Department of Pharmaceuticals establish a dedicated corpus for start-ups undertaking R&D in medical devices, and (iii) starting research linked incentive scheme for academic institutions to promote R&D.
- The Committee observed that India has a huge growth potential in manufacturing of medical devices. It recommended several measures for medical device parks to increase their efficiency. These include: (i) dedicated offices for skilled and unskilled labour forces, (ii) effluent treatment plants, and (iii) subsidised power and water. Some of these parks should focus on manufacturing medical device components to make India a hotspot for medical devices spare parts and repairing and service centres for other countries.
- **Medical devices are primarily imported:** This is due to (i) a lack of high-end technology, and (ii) poor availability of raw materials. Segments which include high-end technology such as CT scanners, MRI, ultrasound, and X-Ray machines are imported. Importing is cheaper than manufacturing domestically because of a low import duty, and a 12% GST on manufactured goods. The Committee recommended reducing the excise duty on importing machinery used for setting up manufacturing plants.
- **Insufficient testing infrastructure:** The Committee noted that the country has only 18 certified Medical Device Testing Labs approved by the Central Drugs Standards Control Organisation (CDSCO). It recommended setting up accredited laboratories in different regions of the country for local manufacturers to get their products tested for standards.
- **Role of the Quality Council of India:** The Indian medical devices industry lacks the facilities to produce devices comparable to international standards. The Committee noted that the Quality Council of India can play a role in establishing quality norms and ensuring that Indian manufactured products have a competitive advantage as compared to international standards. It recommended that the Ministry of Health and Family Welfare introduce standards and certification processes comparable to international standards. Until the time such standards are in place, the Ministry should extend financial support to local manufacturers to build capacity for complying with international regulations as certification processes are costly. Further, the Bureau of Indian Standards harmonise Indian standards with globally accepted quality standards for medical devices.
- **Regulatory framework of the industry:** Presently medical devices are regulated as drugs under the Drugs and Cosmetics Act, 1940. The Medical Devices Rules, 2017 contain provisions regulating medical devices. The scope of these Rules is restricted to only those medical devices which are notified by the government as 'drugs'. The Committee recommended: (i) formulating a separate legislation for medical devices, and (ii) coming up with a National Commission on Medical Devices to examine all aspects of the industry.
- CDSCO is the national regulating authority for medical devices and pharmaceuticals. It was originally set up to regulate pharmaceuticals, and its mandate was extended to medical devices in 2017. The Committee noted that CDSCO in its current form is incapable of effectively regulating the medical industry, and recommended having regulators technically skilled for regulating medical devices.
- **Price regulation:** The National Pharmaceutical Pricing Authority monitors the price of non-essential medical devices and allows an annual increase of 10% in prices. The Committee recommended that medical devices that are required for critical care be scheduled, and listed under the National List of Essential Medicines. It also recommended that: (i) pricing be based on the cost and quality considerations, and that (ii) Ministry continue with price exemptions, value-based procurement, and subsidies for domestic manufacturers until an ecosystem for innovation and R&D is built.
- The Committee also noted unfair pricing by certain entities and recommended the Department to implement the Trade Margin Rationalisation Policy. This is expected to address arbitrary pricing by importers, and reduce the out-of-pocket expenditure of households.

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