NEWSLETTER

MedTechUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

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Market researchers are forecasting increased demand for medical technology in India. Economic expansion, a growing middle class, and political reforms are forces contributing to this development. At the same time, the Indian medical technology market is subject to relatively frequent and short-term regulatory interventions and new business are evolving. The export initiative for the German healthcare industry, HEALTH MADE IN GERMANY, set up MedtechUpdate India to ensure German companies are able to respond rapidly to changes in import, licensing, and marketing regulations. The English-language newsletter will appear regularly and provide the latest information on the most important new regulations for the medical technology market in India.

MedtechUpdate India is a service provided by HEALTH MADE IN GERMANY, the export initiative for the German healthcare industry, set up by the German Federal Ministry for Economic Affairs and Climate Action (BMWK).

MedTech – March 2024

1. Parliamentary Panel recommended DoP to add crucial medical devices in the NLEM

A Department-related Parliamentary Standing Committee on Chemicals and Fertilizers has recommended the Department of Pharmaceuticals (DoP) to include medium and high-end medical devices, crucial for critical care, in the National List of Essential Medicines (NLEM) in collaboration with the Ministry of Health and Family Welfare (MoHFW). The recommendation was presented in a report by the committee for the promotion of medical devices in the country. As per the report, currently, only four medical devices are a part of the NLEM—cardiac stents, drug-eluting stents, condoms, and intrauterine devices. These devices are covered under Schedule-I of the Drugs (Price Control) Order, 2013 and their ceiling prices are regulated by the National Pharmaceutical Pricing Authority (NPPA). Currently, the NPPA is overseeing the Maximum Retail Price (MRP) of non-scheduled medical devices, classified as drugs, to prevent any importer or manufacturer from raising prices by more than 10% of the MRP over the previous 12 months.

Relevance for German exporters and manufacturers: *The NPPA's mandate includes ensuring the availability of drugs and medical devices in the market while the MoHFW deals with the inclusion of drugs and medical devices in the NLEM. Hence, the parliamentary panel recommended a collaboration between the two entities to expand the price regulation on medical devices extensively used in government hospitals. The NPPA has previously fixed the ceiling price of certain medical devices under extraordinary circumstances. The German exporters and manufacturers of medium and high-end medical devices should remain vigilant regarding any forthcoming alterations in the pricing framework and adhere to the directives accordingly.*

Link: https://www.pharmabiz.com/NewsDetails.aspx?aid=166459&sid=1

2. Timeline for applying under AMD-CF scheme extended for the industry stakeholders

The Department of Pharmaceuticals (DoP) has extended the application deadline for the Assistance to Medical Device Clusters for Common Facilities (AMD-CF) scheme until March 15, 2024. The scheme invitations were initially issued in January 2024. Eligible candidates from the medical devices industry can apply online for the scheme via the Udyamimitra Portal. Guidelines for the scheme were previously released by the DoP in May 2023. The scheme is slated for a three-year period, spanning from FY2023-24 to FY2026-27, with a total financial allocation of approximately EUR 34 million. The scheme comprises two sub-schemes, with one focusing on enhancing the capabilities of medical device testing laboratories to support the licensing process of medical devices under the Medical Device Rules (MDR), 2017. The second sub-scheme aims to enhance domestic manufacturing of medical devices, elevate the quality of medical device clusters, and foster sustainable growth within the industry.

Relevance for German exporters and manufacturers: *The sub-schemes have been designed to establish 12 common facilities and 12 testing laboratories. The licensing regime for medical devices under the MDR, 2017 is ongoing. With the introduction of these schemes, the government is actively working to fortify testing facilities, aiming to streamline and accelerate the implementation of the licensing regulations. Previously the time taken for testing of medical devices and receiving approval was around 40 to 60 days. The capacity building would reduce the required days for completing the testing of medical devices from German manufacturers and exporters, expediting the licensing process while contributing to overall efficiency.*

Link: https://pharmaceuticals.gov.in/sites/default/files/Notice_11.pdf
https://www.pharmabiz.com/NewsDetails.aspx?aid=166348&sid=1

3. Parliamentary panel's recommendations to bolster the medical devices industry

The Parliamentary Standing Committee has provided significant recommendations aimed at strengthening India's medical devices industry and reducing its dependency on imports. The panel recommended the Goods and Services Tax (GST) on domestically produced goods to be reduced from the current tax rates, which range from over 12% to 18%. Additionally, the committee suggested implementing short-term import duty concessions on medical device components to ease the burden on manufacturers until the industry becomes self-reliant. The committee also highlighted the challenges faced by the sector, including inadequate investment in research and development, scarcity of skilled manpower, inverted duty structure, and a 70% import dependence on high-end medical devices. The Department of Pharmaceuticals (DoP) had previously introduced a Phased Manufacturing Programme (PMP) to address the issue of inverted duty structure, caused by an anomaly in the Basic Custom Duty rates. The parliamentary panel has recommended extending the PMP to more medical devices.

Relevance for German exporters and manufacturers: *India's dependency on imports in the medical devices sector surged by over 21% between 2022 and 2023, prompting the government and relevant authorities to fortify the domestic manufacturing ecosystem. In the recent budget announcement for fiscal year 2025, the government augmented the budget allocation for the healthcare industry. The measures recommended by the committee along with appropriate government support are poised to attract private investment in the sector. German exporters can capitalize on the burgeoning ecosystem by supplying critical components to Indian manufacturing units, forging collaborations with academic institutions for R&D, and establishing R&D centers in the country, among others.*

Link: https://thehealthmaster.com/2024/02/12/unlocking-the-potential-boosting-indias-medical-device-industry/

4. Government urged to expand the list of Notified Bodies for regulating medical devices

The Department of Pharmaceuticals (DoP) has reported that currently, 13 Notified Bodies are registered under the Medical Device Rules (MDR), 2017. These bodies are tasked with conducting audits and inspections of manufacturing sites for Class A and B medical devices to ensure compliance with quality standards. Furthermore, audits and inspections for Class C and D medical devices are conducted by Central Medical Device Officers. The Parliamentary Standing Committee has expressed concerns regarding the adequacy of the current Notified Bodies which could potentially delay the issuance of licenses to manufacturers of all medical devices within stipulated timeframes. The Committee has recommended the implementation of immediate measures to expand the number of notified bodies and allocate sufficient resources, including infrastructure and manpower. These steps are crucial to uphold the quality of medical devices, as well as to ensure the timely issuance of licenses to manufacturers across all classes of medical devices.

Relevance for German exporters and manufacturers*: The Department of Health and Family Welfare oversees regulations concerning the quality, labeling, and performance of medical devices. It has approved over 2,262 manufacturing license applications out of 3,413 total applications received. The Parliamentary Committee has also directed the DoP to expedite the hiring process of more Medical Device Officers tasked with regulating medical devices. Under India's medical device licensing regime, it is mandatory to obtain licenses from the respective regulators for manufacturing and marketing of all classes of medical devices. The expansion of regulatory provisions aims to facilitate timely issuance of manufacturing and import licenses, benefiting exporters and manufacturers.*

Link: https://www.pharmabiz.com/ArticleDetails.aspx?aid=166598&sid=1

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