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 – February 2024

1. DoP extends the timeline for submission of applications for 5th round of the PLI scheme

The Department of Pharmaceuticals (DoP) has announced an extension of the timeline for the submission of applications by eligible Category B applicants (as per Annexure-1A) for the fifth round of applications under the Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices (PLI-MD). The new deadline is set for February 29, 2024. In December 2023, the DoP issued a corrigendum including modifications to the list of eligible medical devices falling under Categories A and B, allowing eligible companies to seek government support under the PLI scheme. Additions were made to Annexure-1A Category B medical devices list and a few devices were excluded from Annexure-1 Category A list. Subsequently, the DoP extended an invitation for the 5th round of applications from eligible candidates falling under Annexure-1A Category B list of medical devices covered by the PLI scheme to foster domestic manufacturing of the devices.

Relevance for German exporters and manufacturers: *The original deadline for applying to the 5th round of the PLI scheme was January 18, 2024, but it has been extended until the end of February. Manufacturers of*

medical devices eligible under Annexure-1A, Category B, can now submit applications for government support through an online platform until the updated deadline. A supplementary link provided in the government notification allows manufacturers to access detailed revised guidelines for the scheme. All other specifications of the notification remain consistent with the previous corrigendum.

Link:
https://pharmaceuticals.gov.in/sites/default/files/Notice%20for%20extension%20of%20timeline%20for%20submission%20of%20application.pdf

2. Mandatory licensing regime for medical devices facing challenges in implementation

The Surgical Manufacturers and Traders Association (SMTA) has emphasized the requirement for increased infrastructure and manpower to fully implement the mandatory licensing regime for all medical devices. According to the association, the private laboratories designated to conduct testing on medical devices lack sufficient capacity and impose excessively high costs. This situation is particularly burdensome for small and medium enterprises within the industry. The expenses associated with obtaining an import license are approximately 30 to 150 times higher than the fee for a local license. The association further highlighted that the new government laboratories, as outlined in the 2019 committee report, have not been constructed to date, causing a higher waiting time and cost for the medical device companies. Additionally, the association had approached the Supreme Court of India against the government's notification classifying all medical devices as "drugs", after the Delhi High Court refused to annul the government's notification.

Relevance for German exporters and manufacturers: *The Central Drugs Standard Control Organization (CDSCO) mandated that all Class A and B medical devices undergo a compulsory licensing regime starting from October 1, 2022. Additionally, Class C and D medical devices were required to transition to the licensing regime from October 1, 2023. According to SMTA, around 10% of the applications have been processed at present, and it takes approximately three to six months to obtain the license after completing the required documentation. German manufacturers and exporters of class C and D medical devices might also face delays in the timely issuance of their manufacturing and import licenses.*

Link: https://www.pharmabiz.com/ArticleDetails.aspx?aid=165903&sid=1

3. The medical devices industry advocating for a change in the customs duty structure

The interim Union Budget 2024 was introduced in Parliament and received favorable responses from the medical devices industry due to the announced measures for the healthcare sector. However, industry associations had anticipated changes in the custom duty structure for imported medical devices, which were not addressed in the budget. The Medical Technology Association of India (MTaI) has advocated for a reduction in high customs duty to 2.5% for medical devices, aiming to stimulate FDI growth in the sector. Additionally, they have called for the removal of the 5% health cess and simplification of tax provisions to alleviate the burden on both the industry and patients. Conversely, the Association of Indian Medical Devices Industry (AiMeD) has proposed an increase in customs duty on medical devices to 10-15%. They seek a predictable tariff policy and income tax benefits for project investments in medical device manufacturing to bolster domestic production in the sector.

Relevance for German exporters and manufacturers: *Between November 2022 and October 2023, the import of medical devices into India surged by over 21%, with key exporting nations including the USA, Germany, Netherlands, Singapore, and China. As per the data by AiMeD, imports from Germany grew by 27% during the same period. Consequently, industry associations representing domestic medical device manufacturers, such as AiMeD, are pushing for measures to lessen import reliance in the sector. Given the substantial impact potential, it is imperative for German exporters and manufacturers of medical devices to adhere to any forthcoming changes in the customs duty structure.*

Link: https://www.pharmabiz.com/ArticleDetails.aspx?aid=166132&sid=1

4. AiMeD signs an MOU with the GeM portal, facilitating a direct sales channel for firms

The Association of Indian Manufacturers of Medical Devices (AiMeD) has entered into a Memorandum of Understanding (MoU) with the Indian government's e-marketplace, the GeM portal. The GeM portal serves as a crucial platform for government institutions across India, streamlining public procurement processes by eliminating intermediaries. Through this collaboration, the partnership aims to establish a new sales avenue for AiMeD's 300+ members, who are medical device manufacturers. This initiative will enable them to directly sell through a government channel. Interested government buyers will establish direct market connections with manufacturers of various medical devices, such as disposables, consumables, electronics, instruments, equipment, diagnostics, and implants. The MoU also aims to concentrate on delivering workshops and training related to the GeM portal for all AiMeD stakeholders. This partnership signifies a step towards the government's objective of becoming a leading global manufacturer and capturing a 10-12% share in the global market.

Relevance for German exporters and manufacturers: *The GeM portal serves as a centralized platform for online procurement of commonly used goods and services needed by various government departments in India. It is designed to enhance speed, efficiency, and transparency in the public procurement process, offering tools such as e-bidding, reverse e-auction, and demand aggregation. These tools enable government users to obtain the best value for money. The government is said to be the largest buyer of medical devices in India. Introduction of a new sales channel will benefit the German manufacturers operating in India, facilitating their market expansion and growth opportunities.*

Link: https://thehealthmaster.com/2024/01/12/gem-portal-opens-direct-sales-channel-for-300-medical-device-manufacturers/

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