NEWSLETTER

MedTechUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

AUSGABE 2024|05

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).

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1. NPPA revised ceiling prices of coronary stents

The National Pharmaceutical Pricing Authority (NPPA) has recalibrated the ceiling prices for coronary stents to mirror the Wholesale Price Index (WPI) fluctuation, which stood at 0.00551% in 2023 over the year 2022. This adjustment, as per the Drugs Prices Control Order (DPCO) 2013, mandates a revised price of EUR 117.20 per unit for Bare Metal Stents and EUR 426.72 for Drug Eluting Stents (DES), including metallic DES and bioresorbable vascular scaffold (BVS)/biodegradable stents. The revised prices are effective from April 1st, 2024. Consequently, the NPPA has instructed manufacturers and importers of coronary stents currently retailing below the revised ceiling price (including Goods and Services Tax, if applicable) to amend their Maximum Retail Prices (MRP) accordingly. The Ministry of Health and Family Welfare (MoHFW) included

coronary stents in the National List of Essential Medicines (NLEM) 2015 and 2022 due to the high prevalence of coronary artery disease (CAD) in India.

Relevance for German exporters and manufacturers: *The government oversees drug and medical device pricing through the Drug Price Control Order (DPCO), 2013, imposing maximum price limits known as ceiling prices. These limits may be adjusted according to the Wholesale Price Index (WPI) rate. The manufacturers and importers of coronary stents must comply with the ceiling prices, otherwise, they shall be liable to deposit the overcharged amount along with interest under the purview of the Drugs (Price Control) Order, 2013. Additionally, retailers are required to display the price list provided by manufacturers/importers, including any supplementary price lists.*

Link: http://www.nppaindia.nic.in/uploads/tender/13-S.O.1551-dt-26.03.2024-1.pdf

2. Draft guidance document on stability studies of medical devices issued by CDSCO

The Central Drugs Standard Control Organisation (CDSCO) has recently published a draft guidance document focusing on stability studies for In-Vitro Diagnostic Medical Devices (IVDMD). This document aims to aid IVDMD manufacturers in compiling the necessary premarket review documents essential for import or manufacturing license applications. These premarket review documents include scientific data required to substantiate the claimed shelf life, in-use stability, and shipping studies for the devices. Additionally, these documents are imperative not only for manufacturing/import licenses but also for Post Approval Change applications in accordance to the Medical Device Rules (MDR), 2017. The guidance document pertains to the stability assessment of IVDMDs, including calibrators, control materials, diluents, reagents, buffers, and reagent kits. However, it does not extend to IVD analysers, instruments, apparatus, equipment, software, and systems. Besides assisting with premarket review documents, the CDSCO has also recommended the latest standards for setting stability claims for IVDMDs.

Relevance for German exporters and manufacturers: *The guidance document from CDSCO also provides detailed insights into conducting various studies throughout different stages of a product cycle, including transportation and in-use conditions. The CDSCO strongly advocates that manufacturers of IVDMDs adhere to this guidance prior to submitting import or manufacturing license applications and Post Approval Change applications. This adherence is crucial as the stability of IVD reagents directly influences medical device performance, thereby impacting patient outcomes. Therefore, it is imperative for the manufacturers and importers of In-Vitro medical devices to comply with the guidance document to meet regulatory standards effectively.*

Link:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEwODA=

3. Recommendations to amend Medical Device Rules, 2017 provided by DTAB

The Drugs Technical Advisory Board (DTAB) recently issued recommendations proposing amendments to the Medical Device Rules (MDR), 2017. Among these recommendations is the proposal to revise the

definition and applicability clause of the MDR, 2017 to include disinfectants. Additionally, the DTAB suggests aligning Schedule V of the MDR with ISO 13485:2016. Schedule V of the MDR, 2017 pertains to the Quality Management System for medical devices and In-Vitro diagnostic medical devices. It is noteworthy that the DTAB has previously communicated similar recommendations to the relevant ministries, including the publication of draft rules. The Ministry of Health and Family Welfare conveyed to the Board that subsequent to the issuance of these recommendations, several significant notifications for amendments to rules under the Drugs and Cosmetics Act, 1940, have been released. Therefore, the Ministry has assured that the DTAB recommendations will be subject to critical review and may be revised accordingly.

Relevance for German exporters and manufacturers: *DTAB, constituted under the Drugs and Cosmetics Act, 1940, and a component of the Central Drugs Standard Control Organisation (CDSCO), has suggested various recommendations previously as well. One of the recommendations from the DTAB regarding the alteration of quality management regulations for medical devices aims to align them with the updated ISO standards. Upon consideration of the DTAB's proposed recommendations, amendments to the Medical Device Rules (MDR), 2017 may follow. German importers and manufacturers of relevant medical devices are expected to adhere to any forthcoming amendments to the MDR, 2017.*

Link: https://medicarepharmabusiness.com/dtab-recommends-various-amendments-in-medical-devices-rules-2017/

4. CDSCO seeks new registrations from private laboratories to join the MDTL network

The Central Drugs Standard Control Organisation (CDSCO) has issued a formal request to private medical testing facilities, urging them to submit applications for registration as Medical Device Testing Laboratories (MDTLs). This initiative aims to enhance the existing network of MDTLs and facilitate proficient testing of both imported and domestic medical devices. As of September 2023, CDSCO has accredited 39 laboratories nationwide, including nine MDTLs, to undertake the responsibility of testing and evaluating medical devices on behalf of manufacturers. To further bolster the network, the Drugs Controller General of India (DCGI) has invited private medical device testing facilities possessing the required capabilities to register under the Medical Device Rules (MDR), 2017. These private facilities are equipped to conduct various types of testing, including physical, mechanical, chemical, electrical, and microbiology testing. The expansion of MDTLs follows the industry-wide demand to increase the number of testing laboratories and expedite the regulatory compliance procedure.

Relevance for German exporters and manufacturers: *The CDSCO is responsible for ensuring the safety, efficacy, and quality of medical devices as outlined in the MDR, 2017. Through the introduction of new Medical Device Testing Laboratories (MDTL), the authority aims to streamline the approval process for medical devices. This expanded regulation emphasizes the necessity of a robust infrastructure to effectively test medical devices, thereby averting delays in market access for manufacturers. They will play a pivotal role in facilitating manufacturers, exporters, and importers by simplifying the registration and licensing procedures for the distribution of medical devices in both Indian and overseas markets.*

Link: DCGI calls for private MDTLs to join its network of labs (pharmabiz.com)

Das MedTechUpdate Indien – ein Angebot der Exportinitiative Gesundheitswirtschaft – gibt Ihnen einen umfassenden Überblick über die Gesetzesänderungen und -initiativen der letzten Monate. Die Exportinitiative Gesundheitswirtschaft will Deutschlands Stellung als eines der führenden Exportländer gesundheitswirtschaftlicher Produkte und Dienstleistungen stärken. Die Initiative wurde vom Bundesministerium für Wirtschaft und Klimaschutz (BMWK) ins Leben gerufen.

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