NEWSLETTER

MedTechUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

AUSGABE 2024|04

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 – April 2024

1. CDSCO shifts submission of PSUR of medical devices to an online system

The Central Drugs Standard Control Organization (CDSCO) has implemented a notable transition in the process of submission of applications of the Periodic Safety Update Reports (PSURs) regarding the market authorization of medical devices and In-vitro devices, shifting from the offline mode to an online system. The previous offline method of submission of these applications has been discontinued from 1st April 2024. Henceforth, all the applicants submitting their PSURs are now required to apply through the Online System for Medical Devices portal. These efforts have been undertaken to streamline and digitize the regulatory submission procedures. Over recent years, the authorities have consistently endeavored to transition numerous application and approval procedures to online platforms, aiming to establish an e-governance framework within the industry. One of the most recent initiatives is the introduction of the National Single Window System (NSWS) portal in January 2024, aimed at fostering a conducive environment for conducting business.

Relevance for German exporters and manufacturers: *Previously, the CDSCO transitioned the application submission process for PSURs related to the marketing authorization of new drugs to an online platform in February. Additionally, the government commenced efforts to establish a Digital Drugs Regulatory System (DDRS) in November 2023, envisioning a unified digital interface for all regulatory functions. These initiatives by the Central Government signify a concerted effort towards fostering a comprehensive digital regulatory framework within the industry. German Exporters and manufacturers must take note of the alteration in application submission procedures to ensure smooth operational workflow.*

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

2. Committee formed by DoP to revamp the pricing structure for medical devices and drugs

The Department of Pharmaceuticals (DoP) has established a committee tasked with restructuring the pricing framework for medical devices and drugs, by drafting the Drugs and Medical Devices (Control) Order. Comprising members from various organizations, including the National Pharmaceutical Pricing Authority (NPPA) and DoP, the committee has been assigned to deliver a report within the forthcoming three months. A key focus area for the committee involves the development of a price moderation framework for medical devices, coupled with incentivization strategies for the industry aimed at facilitating sustainable growth and minimizing the level of imports. A Department-related Parliamentary Standing Committee had recently advised the DoP and NPPA to prioritize price control measures for medical devices. The recommendation included the incorporation of medium and high-end medical devices essential for critical care into the National List of Essential Medicines (NLEM). The DoP has taken proactive steps by forming the concerned committee for price reforms.

Relevance for German exporters and manufacturers: *The prevailing regulation governing drug and medical device pricing in the industry is the Drugs (Prices Control) Order, 2013. The newly formed committee is expected to release a draft Drugs and Medical Devices (Control) Order to fulfill a set of objectives. However, the Association of Medical Devices Industry (AiMeD) has reiterated that the medical devices industry needs a separate pricing mechanism and regulatory framework. The German exporters and manufacturers of medical devices must note that there can be changes in the pricing structure for certain medical devices in the future and they must comply with the directives accordingly.*

Link: https://www.pharmabiz.com/NewsDetails.aspx?aid=166927&sid=1

3. DoP issues a new UCPMP, 2024 for medical devices and pharmaceutical companies

The Department of Pharmaceuticals has introduced a new Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024. The provisions of this new Code will extend to medical devices and companies engaged in the manufacturing, sales, and distribution of medical devices, unless specifically exempted or modified by standing orders. Under the new code, companies are permitted to provide medical professionals with brand reminders such as informational and educational items, and free samples.

However, there are restrictions regarding the sample packs and the total value of the products. This updated version of the code comes nine years after its initial implementation. The Department of Pharmaceuticals has urged all industry associations to establish an Ethics Committee, create a UCPMP portal on their websites, and take any additional actions necessary for the implementation of the new code. The UCPMP 2024 elaborates upon multiple aspects of promoting ethical engagement between companies and healthcare professionals.

Relevance for German exporters and manufacturers: *The government has notified the new legal code to curb the unethical marketing of drugs and medical devices. The department has asked for strict compliance with the UCPMP 2024 by the industry. Members of industry associations are required to submit a self-declaration within two months after the end of a financial year confirming their compliance with the UCPMP. Additionally, any drug/ medical device must not be promoted until it receives marketing approval from the regulatory authority. Given that the code also encompasses medical devices, German exporters and manufacturers must ensure compliance with the new regulations.*

Link: https://pharmaceuticals.gov.in/sites/default/files/UCPMP%202024%20for%20website_0.pdf

4. Parliamentary panel recommends forming regulations for refurbished medical devices

The Department-related Parliamentary Standing Committee has raised concerns regarding the absence of a regulatory framework for pre-owned and refurbished medical devices. Emphasizing the need for government intervention, the committee underscores the importance of ensuring the safety, quality, and efficacy of imported second-hand medical devices. It advocates for the regulation of these devices under the Medical Device Rules (MDR), 2017, given the potential compromise on the standard of healthcare in the country. Presently, the MDR, 2017 does not include provisions for regulating refurbished medical devices. However, the Ministry of Environment, Forest and Climate Change (MoEF&CC) has been overseeing the import and utilization of refurbished medical devices under the Hazardous and Other Waste (Management and Transboundary Movement) (HOWM) Rules, 2016. Industry associations have also echoed the need for regulations concerning the importation and dumping of used medical devices. They emphasize that such regulations are necessary to ensure fair competition in the market.

Relevance for German exporters and manufacturers: *Importing refurbished and pre-owned medical devices is not a complex process in the country. In December 2022, the MoEF&CC amended the HOWM Rules, 2016 to allow the import of High-End and High-Value Used medical equipment. However, regulating the safe usage of such devices under the Medical Device Rules (MDR), 2017 is essential, especially in a price-sensitive nation like India where they are widely used to significantly reduce patient expenditure. German exporters of such medical devices would be expected to comply with any forthcoming regulatory frameworks implemented for such medical devices.*

Link: https://www.pharmabiz.com/NewsDetails.aspx?aid=167056&sid=1

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.

Ein Angebot der:

MITTELSTAND GLOBAL EXPORTINITIATIVE GESUNDHEITSWIRTSCHAFT

GTAI GERMANY TRADE & INVEST

Erstellt durch:

T&A CONSULTING
Business with India starts here...

Mit freundlicher Unterstützung:

BVMed Gesundheit gestalten.

GHA German Health Alliance

SPECTARIS Deutscher Industrieverband für Optik, Photonik, Analysen- und Medizintechnik

ZVEI: Die Elektroindustrie

Hinweise:

Alle Informationen im vorliegenden Newsletter wurden mit größtmöglicher Sorgfalt recherchiert. Wir bemühen uns, Ihnen diese Informationen möglichst aktuell, inhaltlich richtig und vollständig anzubieten. Dennoch ist das Auftreten von Fehlern nicht vollkommen auszuschließen. Soweit dies gesetzlich zulässig ist, können wir daher keine Haftung für die Richtigkeit und Vollständigkeit übernehmen, es sei denn, die Unrichtigkeit oder Unvollständigkeit beruht auf vorsätzlichem oder grobem Verschulden. Darüber hinaus enthält der Newsletter Kommentierungen und Handlungsempfehlungen allgemeiner Art, die auf persönlichen Erfahrungen beruhen. Diese Kommentierungen und Handlungsempfehlungen stellen keine Rechts- oder Unternehmensberatung dar und können diese im Einzelfall nicht ersetzen.

Gefördert durch:
Bundesministerium für Wirtschaft und Klimaschutz
aufgrund eines Beschlusses des Deutschen Bundestages