NEWSLETTER

MedTechUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

AUSGABE 2024|01

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 – January 2024

1. CDSCO launched the National Single Window System for medical devices

The Central Drugs Standard Control Organization (CDSCO) has launched a National Single Window System (NSWS) portal on 1st January 2024. The portal acts as an independent platform for conducting three major activities under the Medical Device Rules, 2017. These include the application for Registration Certificate of a notified body under Form MD-01, the application for manufacturing license of a medical device for the purpose of clinical investigations, evaluation, examination, test, demonstration or training under Form MD-12 and the application for license to import medical devices for the purpose of clinical investigations, evaluation, examination, test, demonstration or training under Form MD- 16. The portal has been developed by Invest India through Tata Consultancy Services (TCS) and will be independent from the

existing SUGAM portal and the cdscomdonline portal. The CDSCO has also released a user guide as a ready reference to help users navigate through the portal.

Relevance for German exporters and manufacturers: *The NSWS portal represents a pivotal initiative by the central government aimed at implementing a comprehensive Digital Drugs Regulatory System. This initiative strives to create a unified digital ecosystem that consolidates all regulatory activities under a single window. It is essential for the German exporters and manufacturers to note that the existing cdscomdonline portal for the above-mentioned three activities will be disabled with effect from 15th January 2024. Exporters and manufacturers are advised to exclusively submit applications for the activities via the NSWS portal only for seamless execution of the activities.*

Link:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTE=

2. DoP amends eligible medical devices list in the PLI scheme

The Department of Pharmaceuticals (DoP) has revised the guidelines to amend the list of medical devices under Categories A and B of the Production Linked Incentive (PLI) Scheme on which the industry stakeholders can apply for government support. Additions have been made to Category B medical devices list and a few devices have been excluded from Category A list under the PLI scheme. The DoP has further extended an invitation for the 5th round of applications from eligible candidates falling under category B of medical devices covered by the PLI scheme to foster domestic manufacturing of the devices. Three devices were removed from the radiology and imaging medical devices segment of Category A under the PLI scheme. Several new medical devices have been incorporated into segments of Category B such as cancer care and radiotherapy devices, radiology and imaging devices, anesthetic and cardiorespiratory devices, and implants including implantable electronic devices. The DoP, in its corrigendum, additionally specified that a key component, which constitutes a significant portion of the finished medical device (such as an MRI magnet, rotating anode tube, stationary anode tube, flat panel detector, and other similar components) and possesses a distinct HS code, will be deemed included in the corresponding target segment.

Relevance for German exporters and manufacturers: *The PLI scheme aims at promoting domestic manufacturing of medical devices. The manufacturers of eligible category A and B medical devices and their components may apply for government support. Invitations of applications and their requirements will be published on the Ministry`s website.*

Link:https://pharmaceuticals.gov.in/sites/default/files/Amendment%20in%20the%20Guidelines%20Annexure-1%20and%201A%20dated%2019.12.2023-1-5.pdf,

Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices. | Department of Pharmaceuticals

3. The new draft medical devices bill is witnessing a mixed response from the industry

While the Indian Drugs Manufacturers Association (IDMA) expressed its appreciation for the draft new Drugs, Medical Devices and Cosmetics Bill, 2023, other industry stakeholders such as the Association of Indian Medical Device Industry (AIMED), patient groups, and healthcare providers have again expressed their concerns over the draft new bill. The AIMED has conveyed the importance of addressing critical issues including regulatory complexities, potential impacts on innovation, and the need for a favorable business environment. It urged for these concerns to be sufficiently addressed in the proposed bill. The medical device industry has also been demanding a separate regulation and department for medical devices against the proposed bill. The government responded to the industry concerns stating that the comments from the stakeholders have been incorporated in the new bill. The proposed bill is anticipated to encompass medical devices, clinical trials, and other relevant areas within its scope, aligning with international legislative standards.

Relevance for German exporters and manufacturers: *The draft Drugs, Medical Devices and Cosmetic Bill, 2023 is expected to be presented in the ongoing parliament session soon. The industry experts have also urged the government to promptly pass the proposed new bill. The bill aims to regulate and oversee the import, production, distribution, and sale of drugs, medical devices, and cosmetics. German exporters and manufacturers of medical devices will benefit from the streamlined regulatory processes, structured frameworks for conducting clinical trials, provisions for accelerated approval of new drugs and investigational medical devices, and a conducive environment fostering research, development, and innovation incorporated in the new bill.*

Link: https://www.pharmabiz.com/ArticleDetails.aspx?aid=165278&sid=1

4. The Parliamentary Panel emphasized increasing fund allocations for medical device R&D

The parliamentary panel overseeing fund allocations for new initiatives of the Department of Pharmaceuticals (DoP) has emphasized the need for increased financial support from the government towards establishing the National Institute of Medical Devices Education and Research (NIMERs) and the Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR). The government had previously approved the scheme for the Promotion of Research and Innovation in Pharma-MedTech (PRIP) with a financial outlay of EUR 550 million, spread over five years from 2023-24 to 2027-28. The NIMERs and ICPMR are new initiatives under the PRIP scheme which are separate from other components of the PRIP scheme. The fund allocations for these new initiatives are relatively low and hence the parliamentary panel has recommended an increase in the fund allocations. The scheme was launched along with the National Policy on Research & Development and Innovation in the Pharma-MedTech sector.

Relevance for German exporters and manufacturers: *The government is actively promoting the development of the innovation ecosystem within the medical devices and pharmaceutical sectors. This strategic approach aims to generate opportunities for international collaborations in the field of research and development for medical devices. Through the introduction of new policies and schemes for research and development, the government is undertaking measures to enhance the ease of doing business, facilitate technological advancements, and streamline investment mechanisms. The German exporters and medical*

device manufacturers will benefit from the ongoing expansion of medical device infrastructure in the country.

Link: https://www.pharmabiz.com/ArticleDetails.aspx?aid=165471&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

VDDI Dental Solutions. German Manufacturers.

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.