NEWSLETTER

MedTechUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

AUSGABE 2021|7

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 Energy (BMWi).

Legislative initiatives and regulatory procedures in India

1. NPPA caps trade margin on oxygen concentrators

The NPPA has stepped in to cap the trade margin on oxygen concentrators up to 70% at the distributor level. The Government noted that for the imported oxygen concentrators, the trade margins range for PTD-MRP was 7% -198%, and for domestic manufacturers, the range stood at 12%. Earlier, 89 manufacturers and importers of oxygen concentrators had submitted the MRP data after the NPPA demanded the pricing details to arrest the recent volatility in MRP because of the pandemic. The Government has directed State Drug Controllers (SDCs) to monitor the compliance to ensure that no manufacturer, distributor, or retailer sells oxygen concentrators to consumers at a price exceeding the revised MRP. Manufacturers/importers of oxygen concentrators have been asked to submit monthly stock details to monitor availability. After the order, 104 manufacturers/importers of oxygen concentrators have submitted the revised MRP for 252 products. The order is applicable up to 30th November 2021.

Link: www.deccanherald.com/business/business-news/nppa-justifies-70-trade-margin-on-oxygen-concentrators-994877.html

Relevance for German exporters and manufacturers: Indian manufacturers and importers must comply with the revised MRP range once the Government implements the trade margins mechanism. Companies found guilty of flouting the order will be liable to deposit the overcharged amount, along with 15% interest and penalty up to 100% under the Drugs Prices Control Order (DPCO) 2013, i.e., Essential Commodities Act, 1955.

2. NPPA directs manufacturers/importers to revise MRP of medical devices in line with new GST rates

The NPPA has directed manufacturers and marketing firms to revise the Maximum Retail Price (MRP) of medical devices on which the regulator has reduced the GST. Last month, the Government decreased the tax rates on various medical devices, including testing kits, to 5% till 30th September 2021, amid the rising number of COVID-19 patients. The Goods and Services Tax (GST) Council had slashed the tax rate from 12% to 5% on ventilators, medical-grade oxygen, oxygen concentrators, high-flow nasal cannula (HFNC) devices, and BiPAP machines. The manufacturers or marketers do not need to recall, re-label or re-stick on the containers or packs of released products in the market before the date of notification if they can ensure price compliance at the retailer level through a revised price list. The Government's response came following the industry-wise deliberations to reduce the GST on the prices of essential medical devices required for covid treatment.

Link: www.nppaindia.nic.in/wp-content/uploads/2021/06/OM-15.6.2021.pdf

Relevance for German exporters and manufacturers: The Government controls prices of medical devices through various pricing mechanisms, including seeking the MRP and supplementary price lists from manufacturers/importers and ensuring that they do not increase the MRP by over 10% in the last 12 months. The industry had also sought price reduction on medical devices as a higher GST rate was passed on to the patients as a burden. Both Indian manufacturers and importers will benefit from the decision, which serves the twin purpose of regulating prices and ensuring adequate availability of devices in the Indian market at a reduced cost.

3. QCI extends scope of Indian Certification of Medical Devices scheme

The Quality Council of India (QCI) has expanded the scope of the Indian Certification of Medical Devices scheme to assist procurement agencies in tackling counterfeit products and fake certification. The scheme – Indian Certification for Medical Devices (ICMED) 13485 PLUS – will integrate product-related quality validation processes and quality management system components through witness testing of products with defined product standards and specifications. The new scheme will undertake verification of the quality, efficacy, and safety of medical devices. The mechanism will help eliminate the circulation and installment of sub-standard medical products or devices, which could be severe health hazards. The Association of Indian Manufacturers of Medical Devices (AiMeD) and QCI have added additional features to the ICMED, launched in 2016.

Link: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1728368

Relevance for German exporters and manufacturers: The Indian medical equipment industry faces challenges because of the pandemic and its resultant influx and prevalence of sub-standard products. The

ICMED 13485 PLUS is among the first regulatory mechanisms worldwide that integrate quality management systems with product certification standards to ensure quality and efficacy in the Indian medical devices sector. The instrument will reduce the prevalence of counterfeit medical devices and enhance industry value in line with global best practices and standards. German exporters of medical devices to India will benefit from a transparent, fair, and risk-free market.

4. Government plans to create national stockpile of medical equipment to tackle COVID-19 third wave

In light of the national shortage of critical medical equipment, the Government plans to create a "national stockpile" to prepare for the potential third wave of the pandemic. Under the Department of Pharmaceuticals, a task force is engaged in discussions with the medical devices and pharma sectors to shortlist critical items and create inventory. During the first and second COVID waves, India had faced an acute shortage of essential medical devices. Experts predict that a third wave may hit the country starting mid-August. Currently, the Government is undertaking a weekly review on the availability of critical medical devices and drugs. Both Central and State Governments note that strategic stockpiling of essential medical devices such as nasal cannulas, oxygen regulators and humidifiers, ICU beds, and multi-parameter patient monitors is crucial to tackling the Covid 3.0. Meanwhile, some state governments are already creating an inventory of 25-30% of the annual national demand.

Link:
www.timesofindia.indiatimes.com/articleshow/83940369.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Relevance for German exporters and manufacturers: Led by the Government's push and strategic planning, medical device manufacturing firms are already working on their production cycle, inventory management, and supply chain to ensure a faster turnaround of critical medical devices in case of an emergency. As domestic manufacturing of several of these products, including pulse oximeters and oxygen concentrators, is limited, German exporters of critical medical devices can firm up their manufacturing and partner with Indian firms on devices or components exports and focus on selected products to cater to the emerging demand.

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 Energie (BMWi) 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.