Medical Technology Market in India – Engagement pays off

Authors: Maria Klaas, Klaas consulting and Harshita Gupta, Morulaa Healthtech PVT. Ltd.

May 2023 - India, the seventh largest country in the world with a population of almost 1.4 billion, offers medical device manufacturers a market with great opportunities, but also with many challenges.

According to GTAI, the market is growing at an average rate of 22% per year. The current market size is estimated at 11 billion USD. Ernest & Young consider a growth of up to 50 billion USD possible in 2050.
70% of all medical devices alone are imported. After China, Germany is the most important trading partner, because: *Medical technology from Germany is highly valued*.

The medical technology sector has become the largest and most important for India. In its draft "National Medical Device Policy", the Indian government underlines this importance. On the one hand, it has already initiated stronger regulation of the market approval of medical products. On the other hand, it wants to promote the domestic medical technology industry in the future.

What does this mean for German medical device manufacturers? Our Indian partner Morulaa has summarised this:

Registration of Medical Devices

In order for a German company to export medical devices to India, an import licence must be obtained. Manufacturers must apply to the Central Drug Control Organization (CDSCO) through a local agency. This local body is the manufacturer's Authorised Indian Agent (AIA).
The AIA can be a distributor of the manufacturer, a subsidiary or an independent company.

The required documents are similar to those of a European application for CE certification. The most important documents are the Free Sale Certifi-cate (FSC), ISO 13485, the quality manual and the technical dossier.

For the approval of medical products in India, a distinction is made between:

- Registration of a Notified Medical Device
- Registration of a "Non-Notified Medical Device

Registration of a Notified Medical Device

In India, 37 product categories have been listed as "Notified Medical Devices" by the CDSCO. These are subject to extensive review by the CDSCO. These include, for example, hypodermic syringes for single use, stents, catheters, IV cannulae, heart valves, intrauterine devices, blood glucose meters, etc.

All medical devices are classified under the new rules, the Medical Devices Rules, 2017, according to the Global Harmonization Task Force (GHTF) based on the risks associated with them,
- Class A (low risk)
- Class B (low to moderate risk)
- Class C (moderately high risk)
- Class D (high risk)

The registration process is as follows:

Step 1: Determination of the classification of the medicinal product
To take a final decision on the regulatory status of a product and its classification, the manufacturer should check the official notices issued by CDSCO. Only then can he register his product in India.

Step 2: Appointment of an Indian representative
The manufacturer must appoint an authorised Indian agent who holds a wholesale licence. The Indian representative will receive a manufacturer's authorisation to register the

product and to regulate the import.

Step 3: Compiling the documents
The manufacturer must compile the following documents:

- authorisation
- 2. free trade certificate (FSC) of the country of origin
- free trade certificate (FSC) of the USA, EU, Canada, Japan or Australia
- ISO certificate
- full quality assurance certificate
- CE certificate
- declaration of conformity
- device information
- labels
- instructions for use (IFU)
- batch release certificates for at least 3 batches
- audit report
- domestic price list of the country of origin
- product recall details
- details of CAPA (Corrective and Preventive Action)
- post market surveillance report
- if available, the old certificate of registration from CDSCO
- letter with details of any adverse and/or serious incidents/deaths or complaints worldwide
- letter with details of any adverse and/or serious incidents/deaths or complaints in India in the last 3 years and CAPA taken by the manufacturer (if applicable).
- manufacturer's undertaking that no changes will be made to product/device master data and production master data.
- quality manual
- schedule DII
- MD-14 application

Step 4: Procedure and deadlines
The next step is to submit the application for registration and import licence to the CDSCO (CDSCO fees are based on current prices). All documents submitted must be in English. Once all documents have been submitted completely and correctly and the fee has been paid, it usually takes 6-9 months for the medicine product to be approved. As soon as an application is submitted, the time stops and does not start again until it has been answered. If there is no strong predicate in India for new products, registration may take longer and/or the CDSCO will request an MDAC review.
Important for the manufacturer: Once an approval has been granted by the CDSCO, it is unlimited in time. It does not have to be renewed. However, fees for the continuation of the licence have to be paid every 5 years.

Step 5: Import:
Only the authorised domestic representative is allowed to import medical devices into India.

Registration of a "Non-Notified Medical Device“

Medical Devices (Amendment) Rules, 2020
On 11 February 2020, the CDSCO adopted a new amendment to the Medical Devices Registration Rules. All other medical devices that do not fall under the aforementioned 37 product categories are now also covered by the legislation. These include instruments, devices, appliances and implants, whether used alone or in combination for various purposes such as analysis, prevention, treatment, alleviation of disease, examination, replacement, or modification or support of anatomy.

In the past, these "non-notified" medical devices had to undergo voluntary registration, for which no government fees were charged.
Only two documents had to be submitted - the certificate for ISO 13485 and the free trade certificate.
In this procedure, a file number was assigned on the same day as the application. This has changed with the Medical Device Rules, 2020.

The voluntary registration of medical devices of classes A, B, C and D was maintained for a period of 18 months - until 30 September 2021 (until the "Medical Device Rules, 2020" come into force). The registration of class A and B devices could be continued until 1 October 2022. For high-risk medical devices of classes C and D, a little more time remains. A corresponding registration does not have to take place until 1 October 2023.
This applies to all non-notified medical devices

that are not manufactured in India - regardless of whether they are already sold in India or not. The procedure for these products will be similar to the "notified" registration. However, only the portal for Class C and D non-notified medical devices is currently open to obtain a non-notified registration number.

Market launch after registration

Due to its vast size, the Indian subcontinent is divided into North, South, East, West and the Centre for planning business activities. To ensure good market penetration, it is recommended to launch medical products in phases. This is more likely to guarantee that the different regions are covered. Suitable distribution partners should be selected according to region. In addition, they should have local expertise and market knowledge.
The most suitable business partners are those who have medical products of a similar type and price range and who work with a sales team with the appropriate expertise.

In summary, it can be said that entering the Indian market is definitely worthwhile. What you need is a competent partner for regulations and one or more local business partners.

The AUTHORS

Maria Klaas (MBA) is the owner of Klaas consulting. Klaas consulting specialises in marketing, sales consulting and business development of medical devices in Europe.

Harshita Gupta (MBS) is CEO and co-founder of Morulaa HealthTech Pvt. Ltd. Morulaa focuses on regulations, import and distribution for medical devices in India.

Contact: contact@klaasconsulting.com