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R E S E A R C H A R T I C L E

Comparative Study between USFDA Medical Devices and CDSCO Medical Devices

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Abstract
Medical devices are an important aspect of healthcare as they help diagnose, monitor, and treat a wide range of medical conditions. These devices include everything from simple devices like tongue depressors and bandages to complex imaging machines and hi-tech surgical robots. The usage of medical device is on the rise due to the rise in incidence rate of chronic diseases, irregular health check-ups, and sedentary lifestyles and also rising cases of obesity, diabetes, neuro-based disorders, heart diseases, and chronic diseases relating to lifestyle disorders. Indian healthcare sector is a fast-growing industry which is expected to reach $280 billion by 2025. Medical devices market in India is one of the top 20 medical device markets in the world. It is currently valued at $5.2 billion and is expected to reach $50 billion by 2025. The usage of medical devices is on the rise due to medical device development is undergoing a huge technological advancement due to emergence 3D printing which allows development of devices designed specifically as per patient requirements. In India, there were no specific medical device regulations and devices were regulated under the Drugs and Cosmetics Act, 1940. To fulfil this gap, Central Drug Standard Control Organization released Indian Medical Device Rules, 2017, which are the new regulations for medical devices in India. Medical devices like freestyle liber system by Abbott laboratories eliminate need for routine finger pricking as it has sensor that measures and records glucose levels through clothing of the consumer. Quickie Q300 M mini Wheelchair fits even in tight doorways, navigates restaurants, that are crowded and also in difficult living spaces. Harmonization of medical devices registration across the markets is essential to pause way for their easy approval and also in dealing with the withdrawn issues related to quality, safety, and performance. This review involves a comparative study of medical device regulations in four regions (US, EU, India and China). The Medical Device Regulations are different in these countries, but PMA & Post market process is done for the marketing of Quality products. In US two third of the medical devices which are approved through the less rigorous 510 (k) process is recalled due to major harm/ death caused to the patient. I conclude that till, 2017 there was no such strict regulations for medical devices manufacturing, import and sale. From, 1stJanuary 2018, new regulations were implemented by Indian ministry of health and family welfare (MoHFW). The Indian government's recent decision to permit 100% FDI in the outsourcing of medical devices will greatly improve the prospects for the sector. High tax rates imposed on domestic manufacturers have made investment unappealing to some foreign companies, especially given the comparatively low amount of tax levied on imported medical goods. It is therefore hardly surprising that foreign firms often choose to access India's medical market without establishing a direct presence, many companies establish factories in neighbouring countries and export devices.

Keywords: Ministry of Health and family welfare (MoHFW), Centre for Devices and Radiological Health (CDRH), Central Drug Standard Control Organisation (CDSCO), Drug Controller General Of India (DCGI).

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C O N T E N T S

1. Introduction

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in . combination for a medical purpose.

FDA is liable for assuring the "safety and effectiveness" of all medical devices, the Food and Drug Administration (FDA) regulates device manufacturers ability to market devices within the US. Within the FDA, the Centre for Devices and Radiological Health (CDRH) has primary responsibility for the premarket assessment of the latest technology. The Central Drug Standard Control Organisation (CDSCO) headed by DCGI(Drug Controller General Of India) is mainly responsible for managing activities of the state drug licensing authorities, policies, and uniform implementation of the act throughout in India. The Indian Medical Device Regulations, as laid forth by the Central Drugs Standard Control Organisation, must be followed by any medical devices entering India (CDSCO).

Purpose:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

FDA is liable for assuring the "safety and effectiveness" of all medical devices, the Food and Drug Administration (FDA) regulates device manufacturers' ability to market devices within the US. Within the FDA, the Centre for Devices and Radiological Health (CDRH) has primary responsibility for the premarket assessment of the latest medical technology. The CDRH not only considers the risks of new devices but also monitors them via a nationwide post-market surveillance system.

The FDA was granted the authority to regulate devices in the 1976 Medical Device Amendments of the Food Drug and Cosmetic (FD&C) Act passed by Congress. Before the Medical Device Amendments, the FDA could bring charges of adulteration or misbranding, but it did not have the authority to request premarket testing, review, or approval. Subsequent laws, most recently the FDA Safety and Innovation Act of 2012, have modified FDA's medical device authority. One of the largest medical devices market in Asia is India, and growing at extensive rate. Till 2005, no regulations for medical devices existed in India. Medical devices form global industry which manufactures and develop healthcare equipment from simple devices like stethoscope and thermometers to form complex devices also like pacemakers, ultrasound and surgical robots.

The medical device sector is approximately 5.5 billion till 2016. Today, medical device sector is mainly regulated by multinational big companies which can be said as 75% sales are accomplished by imported medical devices. The importing of medical devices done by supervision of State government & Central government. The central drug standard control organization (CDSCO) headed by DCGI (Drug Controller General of India) is mainly responsible for managing activities of the state drug licensing authorities, policies, and uniform implementation of the act throughout in India. The state and central government sees the regulation of notified medical devices. The Indian Medical Device Regulations, as laid forth by the Central Drugs Standard Control Organization, must be followed by any medical devices entering India (CDSCO).The MDR was updated, and applied to all medical devices as of April 1, 2020 ("Newly Notified Medical Devices").

Medical Device Types:

- Active medical device - Any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.
- Active implantable medical device - Any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
- In vitro diagnostic medical device - Any medical device which is a reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens.

2. Methodology

Steps for Medical device approval pathway in US:

Step-1:

Determine the classification of your medical device by searching the FDA classification database using relevant search terms, or by identifying another (predicate) device with the same intended use and technology.

Step-2:

Some Class I devices are exempt from most QSR requirements, with exceptions. For Class II and III devices, implement Quality Management System (QMS) that meets the FDA Quality System Regulation (QSR) found in 21 CFR Part 820.

Step-3: Innovative Class II and all Class III devices will likely require clinical studies. Get "Pre Submission (Pre-Sub)" feedback from the FDA.

Step-4: If clinical studies will be required, apply for an Investigational Device Exemption (IDE). Develop clinical trial protocol and conduct study. Non-significant risk studies may be performed with IRB approval.

Step-5: For Class II devices, prepare and submit 510(k) Premarket Notification application and pay related fee. For Class III devices, prepare and submit Premarket Approval (PMA) application. Pay PMA submission fee.

Step-6:

For Class III devices, FDA conducts facility inspections of manufacturer and all major suppliers involved in the design and production of your device. All parties must be compliant with FDA QSR.

Step-7:

For Class II devices, the FDA issues 510(k) clearance letter and posts it online. For Class III devices, the FDA issues PMA approval letter and posts it online.

Step-8: At this time, you must be in full compliance with QSRs. The FDA will not inspect Class I or II.

Classification of Medical Device India

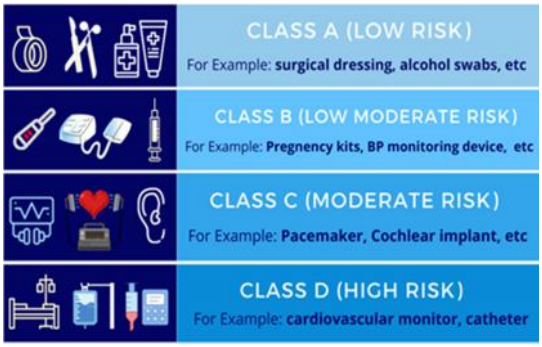
Agency

All medical devices are regulated by the Drug Controller General of India (DCGI) within the Central Drugs Standard Control Organization (CDSCO); part of the Ministry of Health and Family Welfare (MHFW).

Medical Devices Regulations in CDSCO and Classification: Between 2020-25, the diagnostic imaging market is likely to expand at a CAGR of 13.5%. Export of medical devices from India stood at US$ 2.53 billion in FY21, and are expected to rise to US$ 10 billion by 2025.

Table: 1 Classification of Medical Devices in India

S.NO	Class	Risk levels	Examples
1	Class A	Low	Thermometers, tongue depressors
2	Class B	Low-Moderate	Hypodermic needles, suction equipment
3	Class C	Moderate- High	Lung ventilator, bone fixation
4	Class D	High	Heart valves, implantable devices



Registration Process of Medical Device in CDSCO:

Steps for Medical device approval pathway in India:

Step 1

Medical devices and IVDs are regulated by the Drug Controller General of India (DCGI) within the Central Drugs Standard Control Organization (CDSCO), part of the Ministry of Health and Family Welfare. The regulatory framework for medical devices is based on the Medical Device Rules, 2017. Only a limited number of medical devices and IVDs require registration in India.

Step 2

Appoint an India Authorized Agent to interact with the CDSCO on your behalf. Your Agent must have a valid wholesale license (Forms 20B and 21B/21C), and be granted Power of Attorney to manage your registration and device importation in India.

Step 3

Class B, C, and D IVDs require in-country performance testing through the National Institute of Biologicals (NIB) or an accredited lab. Class D IVDs require performance testing through the National Institute of Biologicals (NIB). Class B and C IVDs require performance testing through an accredited Indian lab, though CDSCO may instead accept existing reports for such products with approval in a major regulatory market.

Step 4

Compile device application (Form MD-14), including manufacturing facility information, device technical information, ISO 13485 certificate, IFU, testing results (if applicable), clinical data (if applicable), proof of approval in the US, EU, Australia, Canada, or Japan, plus proof of approval in your home country (satisfied by CFS/CFG).

Step 5

File application for registration/Import License with the CDSCO and pay fees. All documents must be in English.

Step 6

The CDSCO reviews applications and may require a Technical Presentation. Approximately 25% of applications require a formal Technical Presentation. The Technical Presentation is an in-person meeting with the CDSCO to discuss the product in more detail.

Acceptability of the existing clinical data.

Step 7

The CDSCO issues an Import License in Form MD-15. Following the implementation of the Medical Device Rules, 2017, the processes for obtaining device registration and import licensing were combined in India. Accordingly, the CDSCO does not issue Registration Certificates under the

Medical Device Rules, instead issuing market authorization for foreign devices through the Import License (Form MD-15). The License does not expire; however, license retention fees are due every five years.

Step 8:

Once approved, only your India Authorized Agent may import products. However, you can obtain multiple registrations for the same device through different Authorized Agents. This is a simplified overview of the process. The CDSCO may choose to audit your submission and request more documents, which will add time to your approval.

3. Results and Discussion

USFDA

The USFDA (United States Food and Drug Administration) plays a pivotal role in regulating and overseeing the medical device market in the United States. This market is dynamic, complex, and vital to healthcare delivery. In this discussion, we'll explore various aspects of the USFDA's role, the evolution of the medical device market, regulatory frameworks, challenges, and future trends. The USFDA is responsible for safeguarding public health by ensuring the safety and effectiveness of medical devices. Its regulatory oversight covers a wide range of products, from simple tools to complex, cutting-edge technologies. The agency employs a risk-based approach, classifying devices into three categories (Class I, II, and III) based on their level of risk.

The medical device market has undergone significant evolution since the 2000s. Technological advancements, such as the rise of digital health, the Internet of Things (IoT), and artificial intelligence, have led to the development of innovative devices. The market has witnessed a shift from traditional, hardware-centric devices to software-driven solutions that enhance patient outcomes and healthcare delivery.

The 510(k) clearance and Premarket Approval (PMA) processes are key components of the regulatory framework for medical devices. The 510(k) pathway allows the approval of devices that are substantially equivalent to already legally marketed devices, while PMA is required for high-risk devices that pose potential threats to public health.

The regulatory landscape has adapted to technological advancements, incorporating guidelines for software as a medical device (SaMD) and other emerging technologies. Challenges in the medical device market include balancing innovation with safety, ensuring timely approvals, and addressing cybersecurity concerns. Striking the right balance is crucial to fostering innovation while maintaining a robust regulatory framework. Additionally, the globalization of the market poses challenges related to harmonizing international regulations and ensuring a consistent standard of safety and efficacy.

Post-market surveillance is a critical component of the USFDA's oversight. Manufacturers are required to monitor and report adverse events associated with their devices. The agency utilizes databases such as the Manufacturer and User Facility Device Experience (MAUDE) to track and analyze reported incidents, allowing for prompt intervention if safety concerns arise.

The future of the medical device market is likely to be shaped by advancements in personalized medicine, wearables, and the integration of data analytics. The USFDA is expected to continue adapting its regulatory processes to accommodate these innovations while maintaining a focus on patient safety. Collaboration between regulatory bodies, industry stakeholders, and healthcare providers will play a crucial role in shaping the regulatory landscape.

Given the global nature of the medical device industry, efforts toward international harmonization of regulatory standards are ongoing. Collaborative initiatives aim to streamline regulatory processes and enhance efficiency while ensuring a consistent level of safety across borders. These efforts are essential for facilitating the global exchange of medical technologies and fostering innovation.

The USFDA's role in regulating the medical device market is fundamental to ensuring the safety and efficacy of healthcare technologies. The industry's evolution, regulatory frameworks, challenges, and future trends all contribute to a dynamic landscape. Striking the right balance between innovation and safety will be crucial in shaping the future of the medical device market, with ongoing efforts to adapt to emerging technologies and globalize regulatory standards.

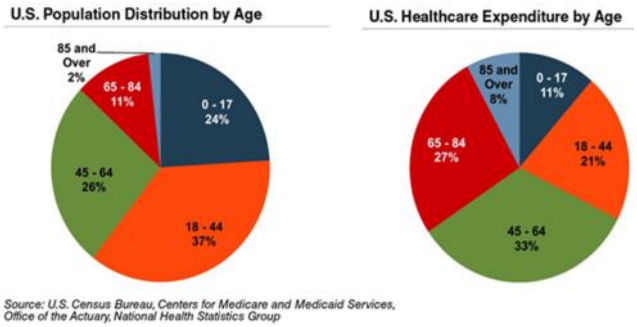


Fig.1

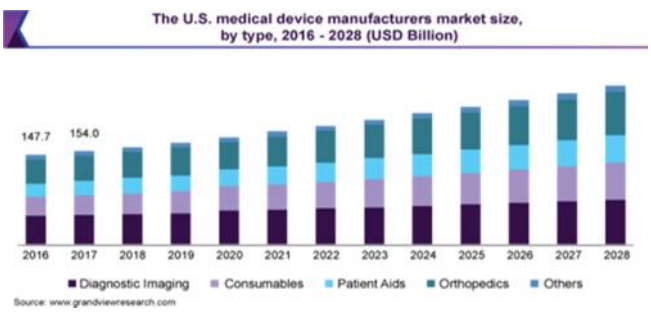


Fig.2

CDSCO

- The Drugs and Cosmetics Act, 1940 ("DCA") governs the quality and safety of medical devices in India. Only "Notified Medical devices" that are periodically notified by the government as "Drugs" are covered by the DCA.
- Under the DCA, the Medical Devices Regulations, 2017 ("MDR") were drafted.
- All producers, importers, and marketers of notified medical devices must adhere to these standards comprehensive quality criteria.
- The Indian Medical Device Regulations, as laid forth by the Central Drugs Standard Control Organization, must be followed by any medical devices entering India (CDSCO).
- The MDR was updated, and applied to all medical devices as of April 1, 2020 ("Newly Notified Medical Devices").
- Only 37 kinds of medical equipment were regulated prior to the change. To get the registration certificate, medical device Management Systems Requirements for Regulatory purposes.
- India is on course to introduce regulations governing all the medical devices in the country on October 1.
- Class A and B medical devices are at present being regulated. From October 1, regulations are in place for the remaining medical devices categorized under two more groups the Drugs Controller General of India Rajeev Singh Raghuvanshi said here on July 5.
- The DCGI, who was speaking at the 9th International Pharmaceutical Exhibition (iPhex 2023) in Hyderabad, said the regulations are aimed at quality control and to create a facilitating environment. An emerging sector, medical devices manufacturing is on the rise spurred by an upsurge in demand for many such products during the pandemic and the government's make in India emphasis.
- Earlier this year, the Central Drugs Standard organization had issued a circular setting the October 1 deadline for Class C and D non-notified medical devices to transition from the existing mandatory registration to a licensing regime. "It is suggested that the manufacturers/importers may apply for grant of manufacturing/import license with all the requisite documents," it had said Addressing the gathering and later responding to media queries, Mr. Raghuvanshi said amendments to the Drugs and Cosmetics Act are under discussions. Citing opportunities opening up in the backdrop of India aiming to grow the pharma industry, from existing $50 billion, to $100 billion by 2028 and more than $120 billion by 2030, he said quality of products will be essential to capitalize on them. "Everything will be knitted around quality," he asserted.

iPhex 2023

- iPhex 2023, a three-day event comprising meetings and exhibition, is being organized by the Pharmaceuticals Export Promotion Council of India (Pharmexcil), a body under the Union Commerce Ministry.
- Director General of Pharmexcil Ravi Uday Bhaskar said iPhex has grown in size over the years and the latest edition is special since it coincides with India's presidency of G-20 and seeks to serve as a platform to enhance collaboration between the country and members of the Group. India is aiming for $28 billion pharma exports this fiscal. The exports were nearly $25.39 billion in 2022-22.

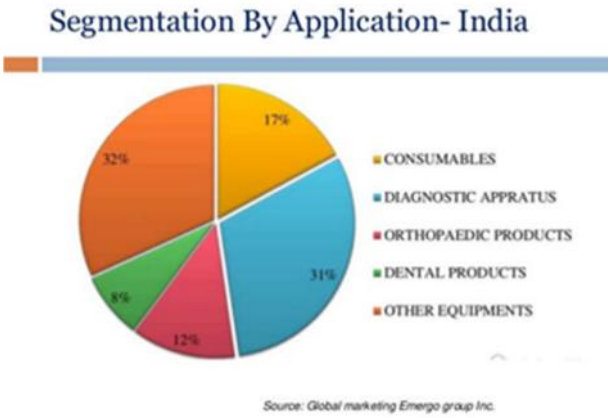


Fig.3

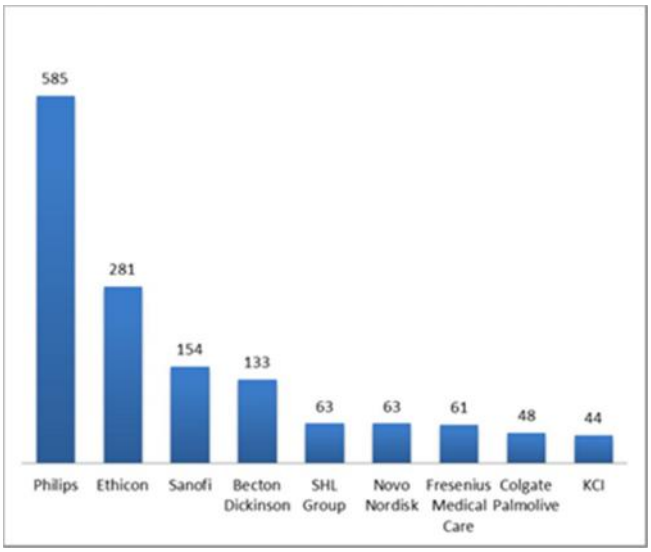


Fig.4

4. Conclusion

The Medical Device Regulations are different in these countries, but PMA & Post market process is done for the marketing of Quality products.

- In US two third of the medical devices which are approved through the less rigorous 510 (k) process is recalled due to major harm/ death caused to the patient.
- I conclude that till, 2017 there was no such strict regulations for medical devices manufacturing, import and sale. From,
- 1stJanuary 2018, new regulations were implemented by Indian MOHFW.

- The Indian government's recent decision to permit 100% FDI in the outsourcing of medical devices will greatly improve the prospects for the sector.
- High tax rates imposed on domestic manufacturers have made investment unappealing to some foreign companies, especially given the comparatively low amount of tax levied on imported medical goods.
- It is therefore hardly surprising that foreign firms often choose to access India's medical market without establishing a direct presence, many companies establish
- factories in neighbouring countries and export devices into India.
- Rising no of medical facilities will boost the demand for Medical devices in the market. The Medical devices sectors in India is projected to reach US 50 billion by 2025.
- In July 2022, the government tabled a draft for the new Drugs, Medical Devices and Cosmetics Bill 2022, to assure and offer thorough legal protections to ensure that the medical items sold in India are reliable, efficient, and up to required standards In July 2022, the government tabled a draft for the new Drugs, Medical Devices
- This sector has attracted significant investments over the years. FDI inflow in the medical and surgical appliances sector stood at US$ 2.41 billion between April 2000-March 2022.

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