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Review Article

Emerging Dynamics of the Medical Devices Sector in India

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ABSTRACT

With a current compounded annual growth rate of more than 16% and a projected market value of 12 billion US$, the medical device industry in the Indian subcontinent alone is projected to reach a market size of over 50 billion US$ by 2030. Despite being a vast market, emerging markets like India rely heavily on imports to meet most of their medical device needs. To bridge this gap, the government has envisioned developing innovative policies, indigenous facilities, practices, rules, and regulations to foster the production of medical devices. Keeping this in view, a series of initiatives have been rolled out, concealing the aspects related to classification, registration, manufacturing, pricing, sales, and market supplies. This review provides a comprehensive 360-degree understanding of the Dynamics of the medical device perspective, using a case study of an emerging market like India. The primary objective is to outline the ongoing regulatory amendments, new policy enforcement, adopted quality management tools, and quality standards required for medical device products. This review will also assist as a guide for stakeholders in subjects related to this sector, providing insight into the federal government's efforts to strengthen the country's medical device production capabilities, thereby improving access and affordability. It is anticipated that continued debate and effective action will benefit diverse sectors and ultimately enhance the worldwide development of medical device industries.

Keywords: Medical Devices, Medical Device Regulations, Government Initiatives, Federal Policies.

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INTRODUCTION

Medical device refers to an instrument, appliance, apparatus, material, implant, or other article, that is employed as such or in association with other modalities and proposed to be used in humans or animals for some specific applications.[1-3] These applications may serve various purposes, including diagnostics, preventive measures, monitoring, treatment, and the mitigation of specific diseases or ailments. It can be applied for diagnostic, monitoring, therapeutic, or mitigation purposes in the context of an injury or disability. It also denotes to an instrument, appliance, apparatus, material, implant, or other article for examination, modification, replacement, or support of anatomical/physiological processes. These also involve their application as life support or for life sustenance, disinfection, or as the controller of conception.[4]

Notably, it should not achieve the primary activity in humans or animals through pharmacological, immunological, or metabolic approaches; however, the activity of such instruments, apparatuses, appliances, implants, materials, or other articles may be assisted by such means in mediating their intended purpose. The term "medical device" often refers to instruments, appliances, apparatuses, materials, implants, or other articles used for diagnostic purposes, including reagents, calibrating machines, standards, assessment kits, or equipment. These can be employed alone or in combined form with each other for inspection and providing medical or diagnostic information by examining specimens derived from humans or animals.[5]

Recently, medical devices have emerged as a crucial component of the healthcare sector, addressing a wide range of healthcare needs. With a growing population and an ever-increasing demand for affordable and high-quality healthcare, these sectors have demonstrated significant potential. The medical device industry requires substantial capital investment and has a lengthy development process, often necessitating the introduction of new

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technologies.[6] Over the past decade, the global medical devices sector has experienced substantial growth. The medical devices sector is projected to grow at a Compound Annual Growth Rate (CAGR) of 7% between 2025 and 2030, driven by robust technological advancements. Furthermore, the rapid growth in the global aging population, as well as the increasing prevalence of chronic diseases, further enhances the potential of the medical device industry. Notably, the medical device sector is primarily occupied by the USA, accounting for a 40% share, followed by the European market and Japan, with shares of 25% and 15%, respectively.[7] With a current compounded annual growth rate of more than 16% and an estimated market value of US$12 billion, the medical device industry in the Indian subcontinent alone is projected to reach a market size of over US$50 billion by 2030.[8]

INDIA AS AN EMERGING MEDICAL DEVICE MARKET

The Indian medical device sector is one of the top twenty global medical device markets.[9,10] The rising global market for medical devices opens opportunities for the Indian medical device sector to achieve new heights of growth.[9] India is positioned as one of the rapidly rising medical device industry markets globally, with an anticipated CAGR of 15%. In India, the factors driving this growth include the increasing prevalence of chronic diseases, technological advancements, and improvements in healthcare infrastructure. Medical device manufacturers are increasingly attracted to establishing manufacturing facilities in India, primarily due to its sizable population and favorable regulatory environment.[11]

The medical device sector in India encompasses a diverse range of products, spanning from consumables to implantable devices. These medical device products fall under various segments that differ in terms of their share in the Indian market. The most significant segment is medical instruments and appliances, which account for approximately 35%. This is followed by investigative imaging and diagnostic devices (30%), implants and consumables (20%), patient aids (15%), and other categories. The country focuses its manufacturing endeavours on disposable items such as syringes, needles, catheters, extensions, cannula, feeding tubes, and perfusion sets. Moreover, India plays an active role in the production of implants, including orthopaedic implants, cardiac stents, drug-eluting stent devices, and ocular lenses.

Based on the projected application of the medical device, its underlying risks, and the prominent parameters listed in the Indian Medical Device Rules (IMDR), the Indian Central Licensing Authority categorizes Medical Devices and *in vitro* Diagnostic Medical Devices (IVDMDs) into four major risk classes. Namely, (i) low risk-Class A Low; (ii) moderate risk-Class B; (iii) Moderate to high risk-Class C, and (iv) High risk-Class D. Figure 1 demonstrates the principle on which the classification of Medical Devices or IVDMDs is based. It is worth noting that

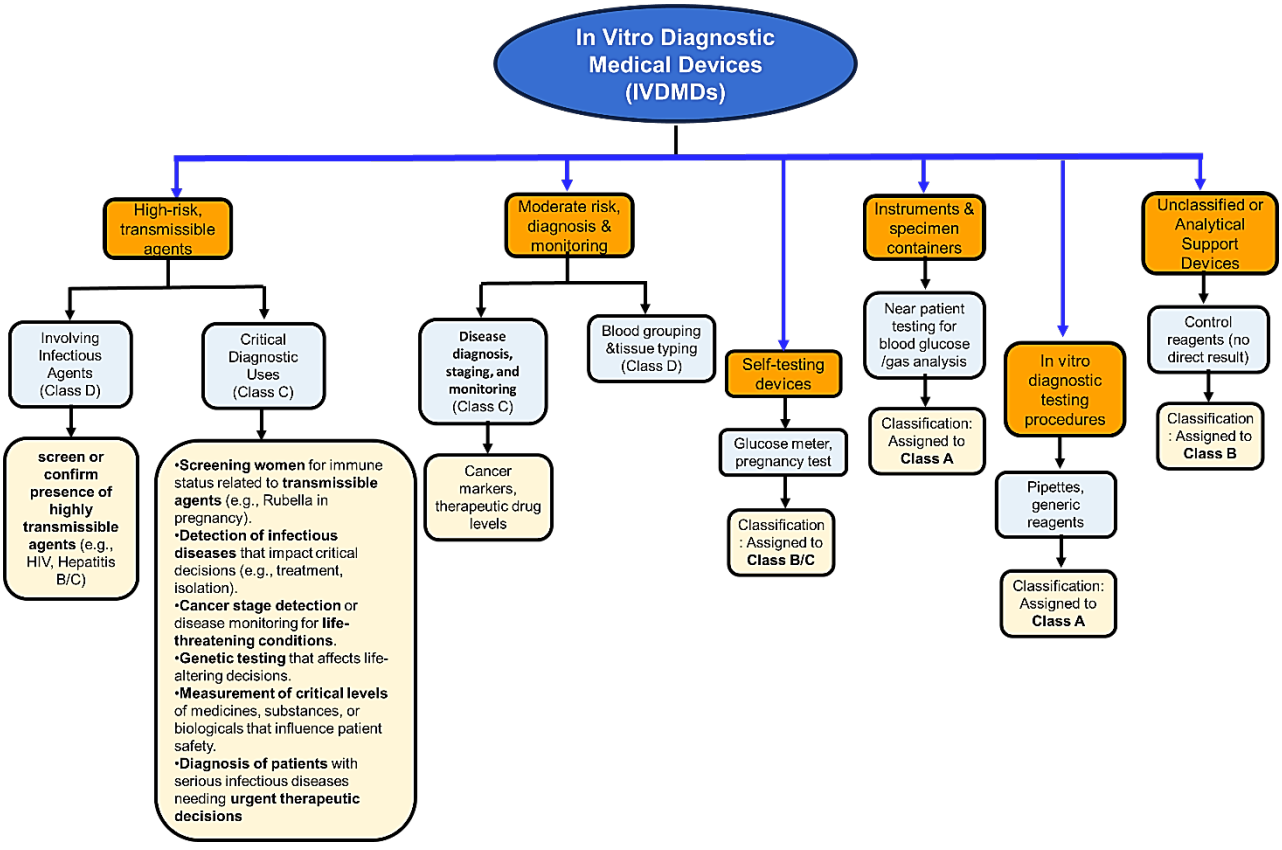

Figure 1: Distinct parameters involved in the classification of *in vitro* diagnostic medical devices.

combination hybrid devices must be classified distinctly. The software must be classified in the same class as its associated devices. Furthermore, the calibrators used in conjunction with the reagent must have the same class as the IVDMD reagents. The device with multiple specified applications must be classified according to its most critical application. If multiple guidelines apply to a specific class, the most stringent rule that results in an advanced classification of the medical devices must be adopted.

It is evident from the above discussion that today, India is one of the leading global medical device markets.[3,10] However, despite being such a vast market, India relies heavily on imports to meet most of its medical device needs. The existing gap between medical device import and manufacturing presents a significant opportunity for medical device manufacturers to bridge it through indigenous manufacture and sales.[12,13] To bridge this gap, the Indian government and manufacturers have long envisioned developing India-centric policies, indigenous facilities, practices, rules, and regulations to foster the production of medical devices in India. Keeping this in mind, a series of policies have been recently rolled out, concealing aspects related to classification, registration, manufacturing, pricing, sales, and market supplies, among others. It must be noted that the process of innovating and developing a new medical device is an intricate, as well as a lengthy, laborious, and time-consuming operation.

Notably, its approval is one of the most precise and exceedingly regulation-driven processes, governed by the IMDR and the Medical Devices Amendment Rules released in 2020. These rules encompass various aspects of medical device-related regulations, including the designated classification system, registration protocol, manufacturing leads, importation, labeling requirements, sales prerequisites, and post-market obligations.

Lately, the Indian government has taken giant initiatives to promote the domestic manufacturing of medical devices through campaigns like "Make in India." This increased investments in the medical device sector and created opportunities for domestic and international companies. Moreover, implementing policies such as the National Health Protection Scheme, which aims to provide health insurance coverage to millions of Indian citizens, is expected to further boost the prospects of medical devices in India. Although the statistical data on India's import and export of medical devices suggests a rising importance in the medical devices sector, achieving a balance between domestic and global demand and supply remains a concerning challenge. However, the timely government initiatives being undertaken to foster the growth of medical devices will undoubtedly be fruitful in their purpose. The enduring dynamics of demand and supply provide a significant opportunity and rationale for manufacturing medical devices in India.

This manuscript aims to provide a comprehensive 360° understanding of the dynamics from a medical device perspective, using a case study of an emerging market like India. The primary objective is to expound on the ongoing regulatory amendments, new policy enforcements, adopted quality management systems, and quality standards required for medical device products. It is also anticipated that this manuscript will serve as a comprehensive guide for stakeholders in cases related to medical devices, providing insight into the federal government's efforts to enhance medical device production capabilities and improve access and affordability within the country. It is anticipated that continued debate and effective action will improve the medical device industry, benefiting the medical device sectors worldwide.

REGISTRATION OF MEDICAL DEVICES IN INDIA

In India, the Central Drugs Standard Control Organization (CDSCO) is the regulatory body responsible for regulating pharmaceuticals, medical devices, and cosmetics. Recently, the CDSCO has organized its norms for regulating the medical device sector in the nation, aiming at ensuring the identity, purity, safety, efficacy, and quality norms. Previously, manufacturers were allowed to sell medical devices in the country without any regulations.[13,14] It was later made compulsory that the medical devices entering India must comply with the Medical Device India 2017 Regulations set forth by the CDSCO. There are two ways to register medical devices in India, which are as follows:

Notified Medical Device Registration

There are thirty-seven device categories listed as notified medical devices by the CDSCO department. In this category, medical devices are classified according to the Medical Devices Rules 2017. Medical Devices are classified in a process.[15,16] as per the Global Harmonised Task Force (GHTF) risk-based assessment.

Non-Notified Medical Device Registration

In this legislation, the CDSCO has amended the new rules 2020 by introducing a new set of rules for the rest of the devices which is not included in the above 37 notified devices, which include apparatus, instruments, appliances, and implants for different applications like analysis, treatment, prevention, replacement, and investigation. This set of rules is known as the Medical Device (Amendment) Rules, 2020. The previous medical device Rule 2017 incorporated Chapter IIIA in Medical Device (Amendment) Rules, 2020, which was imposed on 1st April 2020.[16,17]

As of October 2023, it is compulsory for all medical devices classified as Class A, B, C, and D to hold an MD-14/15 Import License for import purposes. The formal procedure for the MD-14 application mandates submitting a detailed Device Master File (DMF) for each device. It is worth noting that the regulatory body also requires the submission of a DMF, along with an explicitly detailed Plant Master File (PMF). The authority grants an MD-15 Import License after a rigorous approval process to a local license holder for the manufacturing site, with an inclusive

list of all approved devices. The circular released by the Indian Ministry of Health and Family Welfare in October 2023 [(G.S.R. 777(E)] exempts Class A non-measuring and non-sterile medical devices from the MD-15 import licensing.

On the contrary, Class A devices (non-measuring and non-sterile) do not require an importation license; however, they must obtain registration and provide self-certification to the applicable standards. Additionally, in the case of medical devices imported into India, the registration process primarily involves a re-examination of the existing documents filed in the country of origin. For the same, the CDSCO critically scrutinizes the established (Predicate) device section of the application to compare the product under consideration. Therefore, it is recommended that manufacturers carefully identify the predicate device for comparison and provide necessary proof to establish equivalency.

Appropriate certification (e.g., ISO 13485) is mandatory to confirm the quality management system of both the legal and actual manufacturing facilities.[18] To demonstrate compliance, the applicant must provide a detailed Plant Master File (PMF) for the manufacturing site. After approval of the PMF and other formalities, the medical device is added to the license list, and an Importation License is allotted. It may be noted that the medical device product manufactured at two separate sites will need to have two separate PMFs as well as be separately listed on the Import License once approved.

In the context of medical devices that are new to the Indian medical device sector, the material of construction, mechanism of action, or application of these devices are regarded as 'investigational devices'. Such products must undergo additional clinical studies to demonstrate their safety and efficacy in India. The list of clinical investigation studies is usually determined by a Subject Expert Committee (SEC) of CDSCO.

MEDICAL DEVICE REGULATIONS IN INDIA AND THEIR CURRENT STATUS

Medical devices have a direct connection to the health and safety of the subject; therefore, their production must be carried out in a strictly controlled environment that meets regulatory requirements and established guidelines. Medical devices fall under Schedule M-III under the Drug and Cosmetic Act of 1940, but there are no specific rules and regulations for the manufacturing and monitoring of medical devices under the Drug and Cosmetic Act of 1940.[19] In India, the guidelines and intriguing laws for drug manufacturing have been in place for decades, but a clear regulation for medical devices has been lacking for a prolonged period.

Nonetheless, the regulatory landscape of medical devices in India has recently transformed into a very dynamic and continually evolving.[14,20,21] Therefore, to overcome this barrier, the CDSCO has framed the IMDR 2017 and Medical Devices (Amendment) Rules 2020 for the effective regulation of Medical Devices.[1,2] These rules cover various perspectives of medical devices, like registration, classification, import, manufacturing, sales, labelling, and post-market surveillance.[22,23]

The CDSCO department under the Directorate General of Health Services in the Ministry of Health and Family Welfare is the National Regulatory Authority that accounts for the regulation of import, manufacturing, licensing, sales, clinical trials, and distribution of medical devices via the imposition of Medical Devices Rules, 2017.[24,25]

The medical devices and diagnostics division of CDSCO has framed guidelines for medical devices, in the form of IMDR, which were released in 2017 and came into full enforcement from 2018. Later, IMDR was also amended in 2020 as "Medical Devices (Amendment) Rules, 2020" which came into enforcement in 2020. It is worth noting that the 2020 IMDR amendment was introduced by adding "registration of certain medical devices". Interestingly, many medical devices are still considered controlled substances and are therefore regulated under the D&C Act of 1940.[14] The drafting of the IMDR and other auxiliary guiding principles has facilitated the Indian medical device market to take patient safety-centric steps concerning medical devices. In the years to come, amendments to the IMDR are anticipated to focus on aligning the regulations of the MDR and IVDR, the most recent European Union (EU) international regulations establishing the safety and intended performance of medical devices.[26] A schematic representation of the evolution of the regulatory landscape of medical devices in India is shown in Figure 2.

According to IMDR, guidelines are valid for both medical devices and IVDMDs, which can be licensed for production, distribution, import, sale, as well as for stock, exhibition, or offer for sale. This also applies to medical devices and IVDMDs, which can be manufactured for clinical investigations, assessment, training, or for specific demonstration purposes. The IMDR primarily discusses the regulatory features of the medical devices, including classification, classification parameters; their sub-grouping, underlying critical principles, applied standards; applicable governing subsidiaries; registration protocols; manufacturing standards; import framework; labelling requirements; clinical investigation; obligations of governing bodies; registration of laboratories; medical device sales; underlying fees; licensing; QMS-quality management system; PMS-post-approval changes. A depiction of these guiding principles is illustrated in Figure 3.

MEDICAL DEVICES AMENDMENT RULE 2020

The CDSCO enrolled Medical Devices Rules, 2017, have been amended as Medical Device (Amendment) Rules, 2020,[27] which consists of the chapters as presented in Table 1. Moreover, the Government of India established the National Medical Device

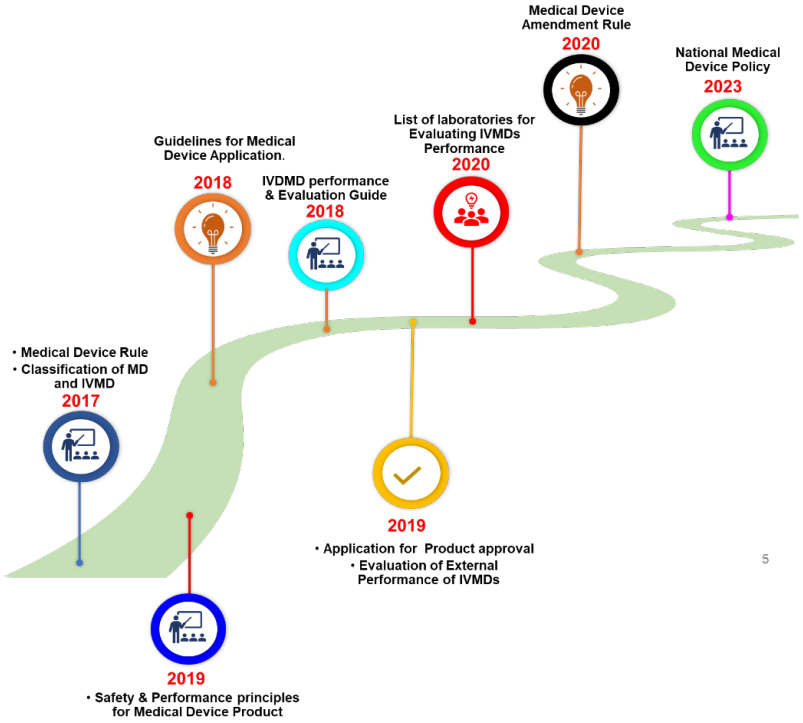

Figure 2: India's Roadmap for Medical Device Legislation. MD: Medical Device; IVDMD: *In vitro* Diagnostic Medical Device; IVDs: *In vitro* Diagnostics.

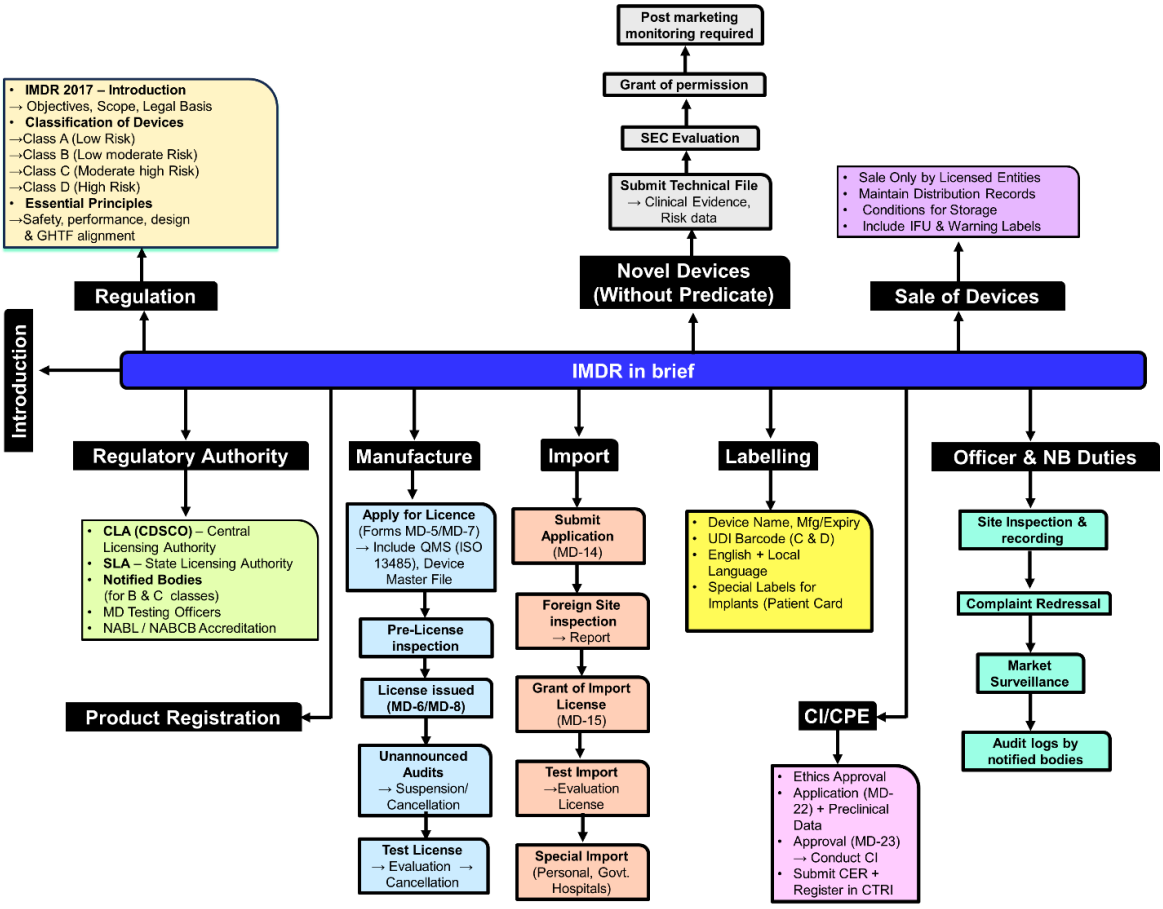

Figure 3: Summary of IMDF. CLA: Central Licensing Authority; MD: Medical Devices; NABL: National Accreditation Board for Testing and Calibration Laboratories; CER: Clinical Evaluation Report; NABCB: National Accreditation Board for Certification Bodies; SLA: State Licensing Authority.

Table 1: Medical Devices Amendment Rule 2020.

Chapter	Chapter Title	Role
I	Preliminary	Introduction
II	Medical Devices Regulation	Classes of Medical Devices and *in vitro* Diagnostic Medical Devices.
II	Authorities, Officers, and Regulatory Bodies	Central Licensing Authority Controlling Officer National Accreditation Body Notified Body Medical Device Testing Officers Central Medical Device Testing Labs.
III A	Registration of Certain Medical Devices	This chapter applies to all non-notified medical device registrations that are exempted by 37 categories of already existing medical devices.
IV	Import of Medical Devices	Application for the Import Licence grant .
V	Labelling of Medical Devices	All the essential information shall be printed with indelible ink on the packed cover of the medical device.
VI	Clinical Assessment and Performance Valuation of an *in vitro* Diagnostic Medical Device	Application to grant permission to conduct a Clinical Trial.
VII	Import/ Production of Medical Devices that do not have a Predicate device	Permission to import/ manufacture a medical device that do not have a predicate device.
VIII	Registration of a Laboratory to perform Testing	Application for Medical Device Testing Laboratory Registration with Central Licensing Authority (CLA).
IX	Sale of Medical Devices	Provisions for the license of sale of medical devices from the State Licensing Authority of Medical Devices.
X	Miscellaneous	Exemptions from provisions related to medical devices.

Promotion Council in January 2020 to promote the manufacture of indigenous medical devices. It has been regulated by the Department for Promotion of Industry and Internal Trade (DPIIT). The National Medical Device Promotion Council was reconstituted by the Department of Pharmaceuticals in August 2022.

As a result, the Union Cabinet approved the new National Medical Devices Policy, 2023, on April 26, 2023, to accelerate the growth of the medical devices sector from its current US$11 billion to US$50 billion by 2030. This policy aims to improve the public health sector by escalating the affordability, innovation, accessibility, and quality of medical devices.[28]

REGULATORY AUTHORITIES FOR MEDICAL DEVICES

For the controlled regulation of medical devices, CDSCO has assigned two regulatory authorities, which are as follows:[27]

Central Licensing Approval Authority

Central Licensing Approval Authority (CLAA) is a sub-division of CDSCO that serves as the main regulatory body for medical devices, as well as the competent authority which is responsible for the enforcement of medical device rules, like:

- Import all medical device classes,
- Manufacturing of Class C and Class D devices,
- Clinical testing and licensing of experimental medical devices,
- Assessing clinical performance and approving newly developed *in vitro* diagnostic medical devices,
- Collaborating with state licensing authorities.[17]

State Licensing Approval Authority

The State Licensing Authority is the governing body responsible for regulating medical devices within the state. The State Controller is the competent authority for the imposition of certain rules applied to (i) manufacturing for the sale of Class A and B Medical Devices, and (ii) stock, sale, or exhibit for sale of medical devices. Therefore, both authorities work simultaneously, i.e., the Central Licensing Authorities delegation of licensing powers has been given to the Drug Controller General of India (DCGI). Likewise, the State Licensing Authority has to get prior approvals from the State Government, and power has been given to Drug Controllers under its name and seal.[17,29]

Over the past decade, India has made enormous strides in the fields of medical equipment and healthcare. Notably, India has set a new standard in medical equipment with the implementation of Medical Device Rules in 2017. Nowadays, governments are incentivizing manufacturers to prioritize the indigenous

production of medical devices over imports. However, India has ample opportunities to capitalize on unexplored sectors of federal, transparency, policy accessibility, and ease of doing business. Therefore, India has revised the Medical Device Rules 2020, as well as the National Medical Device Policy 2023, and introduced Unique Device Identification (UDI) to navigate the regulatory landscape more effectively, facilitating traceability, harmonizing practices, safeguarding safety, effectiveness, and approachability of medical devices.

INVESTMENT CLIMATE FOR MEDICAL DEVICES IN INDIA

Foreign Direct Investment (FDI) refers to the ownership stake in a foreign establishment or venture undertaken by a stakeholder, investor, company, or even the government of another country. It typically describes a business's aspiration to acquire a substantial stake in a foreign company or to expand its operations into a new market. In this regard, FDI has now been permitted in almost all sectors in India, without the need for prior regulatory approvals, except in exceptional cases such as defence, housing, and media. If the FDI is not in compliance with the stated guidelines, approval from the competent government authority must be obtained.

Recognizing the need to cut dependency on imports, the Indian Government has taken several decisive steps to make the investment environment more favorable, particularly for foreign investors. A detailed account of this can be traced back to the Press release note issued by the Department for Promotion of Industry and Internal Trade (DPIIT), which became operative from the first quarter of 2015. It may be noted that, as per this modification, the FDI in the manufacturing of medical devices is permitted to the extent of one hundred percent.

This signifies that foreign companies may invest in or establish a new manufacturing facility in India without obtaining formal prior approval from the government. This move was made to substantially create a business-friendly environment by attracting global players to the Indian market. Notably, the norms in the medical device division were explicitly defined from the pharma sector to enable funding and investment. Moreover, these FDI policies apply to both greenfield and brownfield projects, without any limitations specific to the pharmaceutical industry, such as the non-competitiveness section or former agreements for acquiring any existing company.

Notably, greenfield projects refer to initiatives undertaken from scratch on undeveloped property without any existing building structure. Such projects offer absolute autonomy in designing and construction efforts, such as a new factory, building, power plant, or housing society on designated agricultural or unoccupied land. On the other hand, the brownfield projects refer to the renovation or extension of a preexisting facility with a likelihood of contamination or outdated infrastructure. Such projects comprise refurbishing old plants, upgrading facilities for API synthesis, and upgrading buildings for new purposes. The Production Linked Incentive Scheme (PLI) Scheme of the government of India under the medical device sector offers ground for financial incentives on the basis of incremental market and sale of medical devices internally manufactured in Indian settings to generate robust in-house manufacturing base for high-end medical devices (dialysis machine, diagnostic and imaging tool, etc., to name the few).

The Indian Government has also initiated the notion of dedicated Medical Device Parks across the country. Today, the concept of such parks has been implemented in states such as Tamil Nadu, Gujarat, Himachal Pradesh, Andhra Pradesh, Telangana, and Madhya Pradesh. Such parks are equipped with top-notch facilities, high-end testing equipment, and accreditation services. These facilities are designed to enable cost-effective manufacturing processes, support basic research, and reduce product development time to market, thereby contributing to India's development as an internationally competitive destination for the production of medical devices.

Ayushman Bharat is one of the world's most significant federally funded healthcare insurance initiatives, expanding access to healthcare nationwide. In line with this vision, the Indian government is continually seeking potential trade partners to ensure that Indian-originated medical devices gain wider global acceptance and deeper market access. To achieve this goal, the Indian federal agency, the Indian Brand Equity Foundation (IBEF), is making exceptional efforts to streamline the regulatory approval process and location valuation, as well as provide hand-holding support for easy market entry and operation thereafter. India's emphasis on self-sufficiency, as marked by initiatives such as "Make in India" and "Atmanirbhar Bharat", has further strengthened the country's investment climate.

The globally harmonized regulatory policies also play a prominent role in creating a transparent and progressive investment environment. In this regard, as discussed, the Medical Devices Rules of 2017 have helped establish a required regulatory framework for the previously under-regulated medical device market. It assigns governing responsibilities in terms of regulation to the CDSCO, describes the licensing protocol for domestic medical device manufacturers, and outlines the medical device import policies. These policies outline the practices, as per the International Medical Device Regulators Forum (IMDRF), for making Indian medical device products more acceptable in global markets.

Furthermore, the CDSCO has also launched platforms like SUGAM to assist with registration, licensing, and post-marketing observations, aiming to generate transparency and reduce delays due to administrative processes. This platform has also facilitated smooth and well-organized interaction between national and

international partners. Due to these coordinated efforts, India has today emerged as a dynamic ecosystem with ease of doing business and an investment-friendly sector in the medical devices industry.

DRIVERS OF THE MEDICAL DEVICES INDUSTRY IN INDIA

The amended FDI policy by the Government of India, backed by major regulatory reformations and lucrative incentive schemes, has played a vital role in transforming India into a key hub. Furthermore, the existence of a vast consumer base, skilled manpower, and technical knowledge is anticipated to further enhance medical device innovation and manufacturing in the country over the upcoming decade.[3,23] This section explicitly expounds the key drivers of the medical devices industry in India.

Government initiatives for the promotion of medical devices

Over the years, the medical device industry has become a vital component of India's healthcare system. However, producing medical devices with international quality standards at an affordable cost has been an area of concern for the industry. Given this fact, the Government of India has designated the medical device industry as an essential focus area for its signature "Make in India" initiative to bolster manufacturing facilities.

Regarding market share, India ranks fourth in Asia in terms of medical equipment. Though exports have increased recently, the Indian market still depends heavily on imports. India is gaining momentum toward its goal of developing into a global centre for medical device manufacture, thanks to the Atma Nirbhar Bharat initiative. This is demonstrated by recent programs, such as the Encouragement of Medical Device Parks Scheme and the Production Linked Incentive Scheme (PLI). These programs have been thoughtfully designed to encourage massive production and provide the necessary facilities for establishing industrial hubs in India. Extending these actions requires a comprehensive policy framework to facilitate this expansion and realize the sector's full potential.

The present strategy aims to establish a comprehensive set of priorities for the industry to develop organizationally, despite multiple government agencies having implemented proactive measures to support the industry. Furthermore, because the field of medical devices is diverse and multifaceted, legislation, talent development programs, and promotional efforts are dispersed across multiple ministries at the state and federal levels. It is necessary to organize the variety of actions logically so that the corresponding agencies may provide targeted, practical assistance as well as encouragement for the industry.[30]

The National Medical Devices Policy of 2023 is projected to support the logical expansion of the medical device industries, to foster the attainment of the public health goals, viz accessibility, affordability, excellence, and research-centric innovations. With the tactics that follow, this industry is expected to reach its full potential: establishing a strong and efficient legal structure, supporting development and training programs, encouraging higher learning to develop skills and proficient assets tailored to the sector's needs, and establishing a structure that fosters innovation.

National Medical Device Policy 2023 and Its Key Elements

The vision of this policy is a patient-centred, expedited expansion strategy to become a world pioneer in medical device invention and manufacture, securing a 10-12% revenue share in the growing worldwide marketplace over the next twenty-five years. By 2030, the strategy is projected to assist the expansion of the medical device sector from its current eleven billion USD to fifty billion USD. To accomplish these goals, the strategy puts out a mission for the quick expansion of the medical device industry: accessibility and inclusivity; economy; excellence; patient-centred and high-quality care; proactive and promotional healthcare; safety; investigation and innovations; and qualified workers.[3,23,31,32] The medical device sector is assisted and directed by various plans encompassing six primary categories of government measures. These measures can be visualized primarily under the following heads:

- **Facilitating infrastructure:** To improve progress and retrogression with the medical device industry, the State Governments, industry, and the National Logistics Policy 2021 under the horizon of Gati Shakti program will work together to build and fortify massive medical device parks, as well as medical device clusters outfitted with worldclass infrastructure/ amenities that are lying in a closer proximity to commercial areas with adequate transport access.
- **Encouraging Research and Development:** The strategy aims to support Research and Development (R&D) in India and supplement the Department's National Policy on R&D and Innovation in the pharmaceutical and medical technology (Pharma-MedTech) Sector of India. In addition, it seeks to create innovative centres, "plug and play" infrastructures, Centres of Excellence (CoE) established in association with institutions of higher learning and research, and business assistance.
- **Human Resources Development:** The policy envisions the following as a means to maintain a consistent supply of competent workers throughout the entire value chain, including scientists, regulators, health experts, managers, technicians, and others. Investors can utilize the assets offered by the Ministry of Skill Development

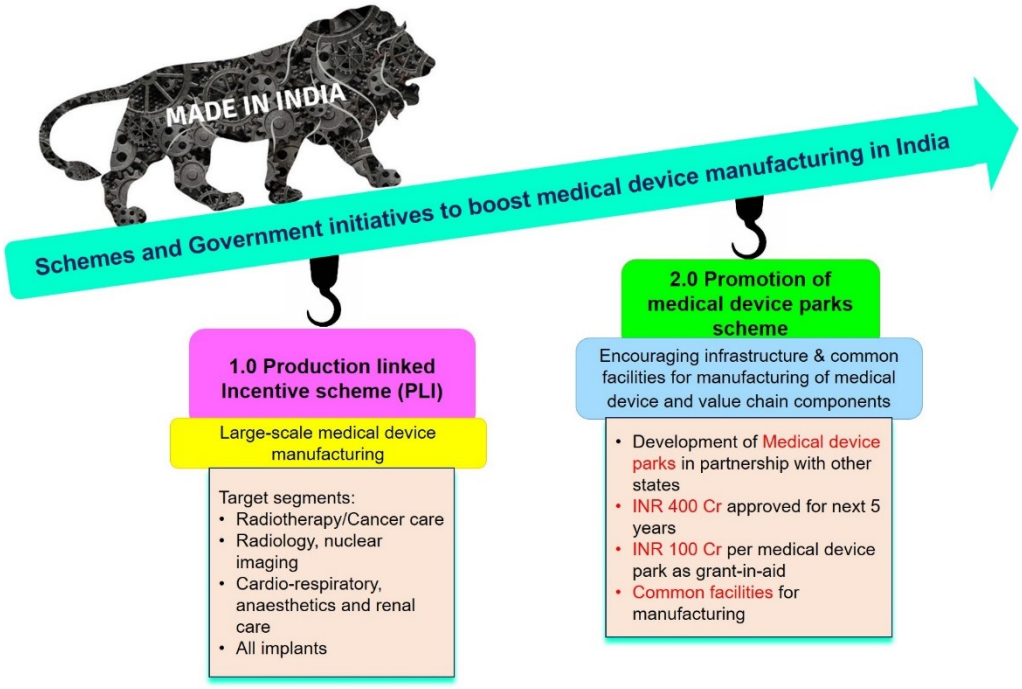

Figure 4: Government initiatives for the production and promotion of medical devices.

and Entrepreneurship to provide expertise, retrain, and upgrade medical device industry professionals.

To guarantee a steady supply of qualified workers for contemporary medical and healthcare technologies, high-end equipment manufacturing, and cutting-edge research, and to create future-ready MedTech human resources, the policy will promote specialized, multifaceted training in medical devices within existing institutions. Forming alliances with overseas academic and business institutions to create medical technology and meet global demand jointly.

- **Bringing in Investments:** In addition to current programs and initiatives, the Indian government has implemented several measures to develop further initiatives, including Ayushman Bharat, Make in India, Startup India, and Heal-in-India. The policy also promotes venture capitalist funding, private investments, and Public-Private Partnerships (PPP).
- **Positioning the brand and raising awareness:** The strategy calls for the department to establish a special Export Promotion Council for the industry, which will facilitate the resolution of several accessibility concerns in markets.
- **Regulatory streamlining:** Strategies like "Single Window Clearance System" to license medical devices, which includes participation from every relevant agency and organization, including MeitY (Ministry of Electronics and Information Technology), AERB (Atomic Energy Regulatory Board), etc., taken to enhance the ease of conducting studies and business, regulate patient security with new product development, and strengthen the function of Standards of India like Bureau of Indian Standards (BIS).

The PLI and the Promotion of Medical Devices Parks are the two crucial and skillfully designed schemes laid out by the Indian Government to encourage industrial production as well as provide the necessary infrastructure for the growth of manufacturing hubs, as shown in Figure 4.

Production-Linked Incentive (PLI) scheme to promote domestic manufacturing of medical devices

To encourage substantial investments in medical device segments, such as implants, radiation therapy, imaging, cancer treatment, analgesics, and others, the PLI Scheme for Medical device manufacturing facilities offers a monetary reward. This PLI scheme shall offer a 5% incentive on the incremental sales of goods manufactured in India. The program's assistance will be provided to authorized businesses that produce target categories in India and have a total asset value of at least Rs. 18 crores (net cost of the candidate business plus the net cost of member firms included).

Promotion of medical device parks

Marketing of health-related products parks aims to establish a robust infrastructure and foster a thriving local medical device manufacturing ecosystem. Creating outstanding standard

testing and infrastructure assets through grants under the Scheme will accelerate local manufacturing and expand India's medical device value chain. These are also expected to drastically lower production costs, thereby improving the availability and affordability of medical devices nationwide. To create Common Infrastructure Facilities (CIF), which would lower the production costs of medical devices made in the country, the Scheme for Promotion of Medical Device Parks has been notified. The budget of the entire scheme is approximately 400 crores of Indian rupees. The tenure for this scheme is the financial year 2020-2021 to 2024-2025. This scheme shall cover products from three categories: Category 1 includes orphan drugs, biopharmaceuticals, phytopharmaceuticals, and other similar products. Category 2 contains APIs and drug intermediates. Category 3 includes *in vitro* diagnostic devices, repurposed drugs, anti-cancer drugs, and other related products.[33]

Foreign Direct Investment (FDI) for medical devices

India now holds the top spot in the global pharmaceutical industry. Nevertheless, the medical device industry could not replicate this success. The nation boasts a significant number of researchers and engineers who can propel the medical device industry to unprecedented heights. The local financial system fails to supply the industry with vital investment. By press note no. 2 of 2015, the Government of India has examined the FDI policy for pharmaceutical companies and determined that a particular breakout would be for medical devices. Up to 100% FDI is allowed to produce medical devices in the automated route. Both brownfield and greenfield developments are exempt from the following requirements:[34]

- Non-compete provisions would only be permitted under certain conditions and with the Foreign Investment Promotion Board's permission.
- The document must be submitted with the FIPB petition by both the potential investee and the investor.
- The federal government can include suitable FDI requirements when approving a brownfield project.

Export opportunity for medical devices

India has become a hub for affordable and high-quality healthcare products, resulting in an increased export of medical devices that offer a diverse range of products, from diagnostic equipment to hospital furniture. However, exporting material from India requires proper arrangements and adherence to the rules. Notably, CDSCO is responsible for issuing the NOC for the exportation of medical devices from India.[30,35]

Requirements for medical device export in India compliance by licensees

The Medical Devices Rules, 2017, govern the export conditions for medical devices in India. Some general conditions that apply include: (i) *Registration:* Medical device exporters must have a valid license for CDSCO-registered devices; (ii) *Quality Management System:* Ensuring compliance manufacturing and export procedures requires an efficient CDSCO import quality control system, frequently in line with ISO 13485; (iii) *Product Classification:* Due to varying laws and regulations, an exporter is required to appropriately categorize the medical supplies according to its expected application and safety grade; (iv) *Standards Compliance:* Indian Pharmacopoeia, IEC standards, and device-specific standards are only a few examples of the pertinent national and international standards that the medical device must meet.

Furthermore, it may be noted that other conditions also play pivotal roles, including (v) *Labelling and Packaging Requirements:* The exporter must ensure proper labeling and packaging of the medical device, with essential information included; (vi) *Clinical Data:* For legal compliance, scientific information or security and efficacy proof may be needed, based on the risk category and purpose of the device; (vii) *Export Documentation:* For exporting reasons, the correct documentation, such as bills, packaging lists, details about shipping, as well as other required records, must be kept; and (viii) *Adverse Event Reporting:* It is crucial to set up a system for gathering, evaluating, and reporting adverse events or accidents involving the medical equipment.[36,37]

Essential documents for exporting medical devices from India

In India, the documents required for exporting medical devices may differ depending on the specific device. A significant set of essential documents must include (i) *Free Sale Certificate:* This certificate is issued by the regulatory authority to authorize that the medical device is freely sold or marketed in India; (ii) *Manufacturing License:* A duplicate copy of the production license that was acquired from the concerned Indian authorities; and (iii) *Registration Certificate:* If the medical device is registered with the CDSCO, a copy of the registration certificate must be provided.

Furthermore, documentation on product specification and appraisal must include documents ranging from (iv) *Technical Specifications:* Comprehensive practical specifications of the

Table 2: Classification of medical devices in India.

Class	Risk	Examples
A	Low-risk medical devices	Bandages, syringes
B	Low-to-moderate risk medical devices	Non-invasive devices like stethoscopes
C	Moderate-to-high risk medical devices	Orthopaedic implants, X-ray machine
D	High-risk medical devices	Cardiac implants, implantable defibrillators

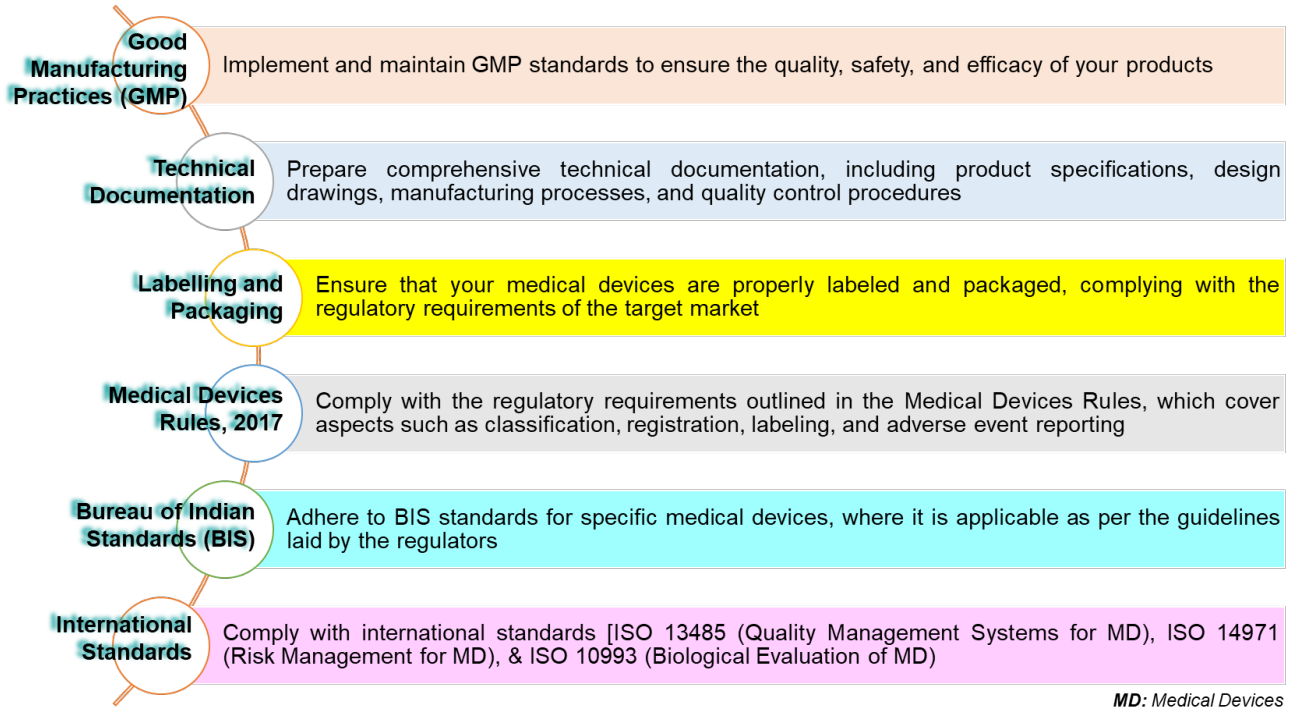

Figure 5: Various quality standards and regulations must be met by medical devices.

medical device, including plan, parts, and industrial procedure; (v) *Product Information:* Product leaflets, labeling, and directions for use; (vi) *Quality Certifications:* Any quality certifications obtained for the medical device, such as ISO 13485 (Quality Management System for Medical Devices); (vii) *Clinical Data:* Clinical trial information or other relevant clinical proofs giving safety confirmation and efficacy of the medical device; (viii) *Regulatory Approvals:* Documents of regulatory approvals obtained from international regulatory authorities, if applicable;[3,11,23] and (ix) *Importer/Exporter License:* A proof of the exporter or importer license obtained from a suitable consultant.

Process for exporting medical devices

It is imperative to understand the process and protocols needed to be followed for exporting medical devices in India, which essentially can be subdivided into the following significant steps:

Step 1: It is necessary to understand India's regulatory framework for exporting medical devices to India. The CDSCO regulates medical devices in India and has established rules to ensure safety, quality, and efficacy. After this, market Research and product selection will be initiated. Research potential export markets for your medical devices, considering demand, competition, pricing, and regulatory requirements. Assess compliance with international standards and regulations for your specific devices.

Step 2: The medical devices in India are categorized into four levels based on the level of risk associated with their intended use. This classification determines the documentation and other regulatory requirements needed for exporting. The classification is shown in Table 2.

Step 3: Obtaining the licenses and registrations to export medical devices from India legally.

The following are some essential requirements:

- **Medical Device Manufacturing License:** The CDSCO license or the State licensing authority ensures compliance with quality standards and is mandatory for manufacturing or selling medical devices.
- **Import-Export Code (IEC):** To obtain an IEC, the applicant needs to register with the DGFT or the Director General of Foreign Trade. This code is essential for export transactions and can be obtained online by submitting the required documents.
- **Free Sale Certificate (FSC):** The application is made to the CDSCO to get an FSC, which certifies that the medical devices are freely sold in India. This certificate is often required by foreign authorities for the clearance of imports.
- **ISO Certification:** Obtain ISO 13485 certification, which demonstrates compliance with international quality standards for medical devices.
- **Goods and Services Tax (GST) Registration:** Register for GST with the appropriate tax authority if your turnover exceeds the prescribed threshold.

Figure 6: Documentation and logistics requirements for exporting medical devices.

Step 4: Ensure your medical devices meet quality standards and regulations Figure 5.[11,21,36]

Step 5: Conduct market research to identify potential export markets for your medical devices. Consider factors like demand, competition, regulations, and reimbursement policies. Identify partners who can assist with market entry and distribution in target countries. Documentation and logistics requirements for exporting medical devices are listed in Figure 6.

Step 6: Customs Clearance: Ensure compliance with customs rules and procedures. Submit the obligatory papers to the customs authorities, including the shipping documents, invoice, packing list, and other relevant certificates. Pay any applicable customs duties and taxes. If necessary, engage a licensed customs broker to facilitate a smooth customs clearance process. Then, one needs to evaluate the post-export responsibilities. The shipment is to be tracked until it reaches its destination. Maintain communication with the importer to address any concerns or inquiries.

Role of the Department of Pharmaceuticals (DoP) in Medical Device Policy

To improve and move forward with the implementation of the National Medical Devices Policy, 2023, the DoP has released an expanded approach document that focuses on privacy and security policies, the implementation of national designation for medical devices, a plan to manage e-waste of obsolete medical devices, and the enhancement of technology transfer capabilities within the medical device sector.

According to the strategy document, consistent with the approach paper on the NMDP, which was published for stakeholder consultation, and the NMDP, 2023, which was notified on May 2, 2023, the government would consider aligning medical device regulations with national laws for personal health data security. It stated that appropriate data security and data annotation procedures will be attempted. It should be emphasized that, with the rapidly increasing impact and the use of digital technology platforms in the medical and healthcare sector, there is a rising need for sufficient security protocols to safeguard the confidential data of patients.

Furthermore, the DoP also stated that it will work closely with the CDSCO and the Department of Health and Family Welfare to develop a National Nomenclature for Medical Devices. As part of its regulatory restructuring efforts, the policy also encourages the implementation of Global Medical Devices Nomenclature (GMDN) or Universal Medical Device Nomenclature System (UMDNS) and establishes guiding rules under Standard Setting Organizations, such as the BIS, to guide innovators and entrepreneurs throughout the developmental stages of a medical

device product. It also aspires to prepare researchers, innovators, and entrepreneurs during the testing phase.

These guidelines aim to encourage the research and innovation fraternity to consider regulatory compliance prerequisites from the outset of product development, employing programs such as course content, skill development, routine training, and seminars. The NMDP-2023 encompasses six broad areas aimed at promoting the medical devices industry for general awareness, investment climate, infrastructure development, facilitating R&D, motivating need-oriented innovation, trained manpower generation, regulatory streamlining, and brand management.

The strategy paper specifies that, as part of infrastructure development, mechanisms for e-waste management of old medical devices would be created in close collaboration with the Ministry of Environment, Forest, and Climate Change. It emphasizes that fostering the tech-transfer competences would create additional chances to translate R&D set-up grown ideas and knowledge into goods and technologies to support innovation. Technology transfer agencies established by the Indian Council of Medical Research (ICMR), Patent-Mitra, DBT-PACE, DBT-BIRAC, and AGNIi would be engaged to facilitate technology transfers. The program aims to build and foster an R&D-centric environment to mediate Innovation as part of the policy of these departments to catalyze research and innovation in the medical device segment of the country. It aspires to create a framework that can support inventors and IP holders in commercializing their inventions. It looks at incubation support for startups in R&D and innovation, mentorship for entrepreneurs along with skill development, such as business management, market access, and commercialization efforts for the innovation solutions development, technology transfer mechanism for innovative solutions, and relations for startups in compliance and regulatory regime as financial and non-financial measures to invite and motivate investments in this sector. As human resources in the field of design are scarce, the National Institute of Design (NID) and private design schools are motivated and encouraged to provide design-centric curricula and courses to fill the gap, according to the human resources development strategy.

One noteworthy intellectual property development plan is to collaborate with DPIIT on medical devices, stimulating innovation by incentivizing both institutions and inventors, and building a strong technology transfer ecosystem within the country to capitalize on the utilization of government-funded discoveries. Basically, the focus is towards developing creative products that create new IPR and enter the market. This will necessitate improved support for startups looking to expand globally.

ESTABLISHING THE CLINICAL PERFORMANCE OF MEDICAL DEVICES

A clinical trial of an investigational medical device must be conducted on human volunteers to establish its biosafety and effectiveness. This applies to novel IVDMD, where clinical trials must be performed on samples from volunteers to assess its performance. Such clinical evaluation is performed based on protocols as detailed in the clinical investigation plan, which governs their conduct. During this time, the constitutional rights and safety of human volunteers must be protected as per the ethical protocols mentioned in the Declaration of Helsinki.[38]

Medical device products considered under IMDR are required to undertake (i) a pilot investigation and (ii) a critical clinical study. For all completed clinical trials, the sponsor needs to provide the clinical trial report and clinical performance evaluation report to the human ethics committee, volunteers, and the central licensing authority of the country.[39]

In India, clinical investigation data is mandatory for all class B, C, and D categories of medical devices that do not have a predicate product or if the medical device product falls under the new IVDMD category. On the other hand, if the medical device has been successfully available in the market of the countries such as the USA, Australia, Japan, Canada, or in Europe for more than two years, and the regulatory bodies of the respective Central Licensing Authorities in that country are contented with the available clinical investigation evidence, then a separate set of Clinical report is not warranted to issue the import license. However, in these cases, the Central Licensing Authority requires the post-marketing investigation report, review report of the concerned subject expert committee, and their recommendation.

To obtain an import license for medical device products from other countries, a detailed clinical investigation must be conducted in India for class C and D medical devices to establish their safety and effectiveness. For Class A and Class B medical devices, an import license can be approved if the safety and performance have been proven via a clinical investigation in the country of origin. Furthermore, the Free Sale Certificate is a mandatory export document required by law for exporting products to a specific country. This Free Sale Certificate must also be provided by the country of origin, along with documents that support the claim of a clinical investigation conducted in the country of origin for the issuance of an import license, in cases of Class A and Class B medical devices.

PROTOCOLS FOR REPORTING POST-MARKETING SURVEILLANCE OF MEDICAL DEVICES

A post-market surveillance report is required from the manufacturer for all medical devices introduced into the market. This report must comprise the details of the reporting protocol,

complaints, and the corrective and preventive measures taken to address the complaints.[40] For medical devices that do not have a predicate, manufacturers must also conduct a post-marketing clinical investigation to ensure ion safety and performance, with special emphasis on drug-device interactions, safety studies, mortality and morbidity studies, among other aspects.

A periodic safety update report is a pharmacovigilance document that provides a comprehensive and critical assessment of the risk-benefit ratio of a product at a given time after its authorization.[41] The periodic safety update report considers all newly established safety norms to provide cumulative evidence on associated risks and benefits. For clinical safety monitoring, a Periodic Safety Update Report for each medical device product is mandatory to report relevant data collected by all stakeholders and correlate this information with patient exposure.

The periodic safety update report must also provide a summary of remarks on the existing market authorization status of the product in other countries, highlighting notable discrepancies related to safety. The report should also highlight whether any deviations will be applied to the product information to adjust its usage. Any substantial variations in the reference safety information relating to contraindications, adverse reactions, precautions, warnings, or any significant observations from ongoing/completed clinical investigations or substantial nonclinical findings observed within the reporting period must also be recorded in the report.

Continuous monitoring facilitates the timely detection and assessment of adverse effects of medical devices, malfunctions, and other issues.[42,43] In this regard, to foster medical device monitoring, minimize risk, and ensure a tolerable risk-benefit ratio, the Indian Pharmacopoeia Commission has introduced the Materio-vigilance Program of India (MvPI). Since its launch, this program has been vital in screening as well as the recall of several non-compliant medical device products from the Indian market.[44]

INDIAN PERSPECTIVES OF INDUSTRIAL-ACADEMIA COLLABORATIONS FOR DEVELOPING MEDICAL DEVICES

Recently, in India, the collaborative efforts between industry and academia for the development of medical device products have been increasing. Such collaborations play a crucial role in fostering innovations and bridging the gap between academic research and its industrial application to address healthcare concerns. Such collaborations are expected to leverage resources, facilities, and expertise from both industry and academia, thereby enhancing innovations and research capabilities in the development of medical devices. Industrial experts can thus work closely in collaboration with academia and contribute to curriculum development, ensuring that learners are equipped with the relevant skills and knowledge to make a better contribution to the progress of the medical devices sector within the country.

In one such instance, Boston Scientific teamed up with the Indian Institute of Technology (IIT)-Ropar and launched a customized course for engineers at Boston Scientific.[45] This initiative was first conceived in 2021 and has continued since then. Boston Scientific intends to scale up these efforts and develop customized, multidisciplinary courses that cover various domains of medical device design and development. Such efforts to upskill the workforce help industries achieve accelerated employee learning and promote academic institutions to produce industry-ready

Table 3: Some industry-academia collaborations in the domain of medical devices.

Collaborating Bodies	Product developed	Description of product	References
Boston Scientific, India, and IIT-Ropar	Customized course	A customized course for the engineers at Boston Scientific India covering various domains of medical device design and development.	45
Tata Medical Center, Kolkata, and IIT, Kharagpur	CHAVI	India's first imaging bank for oncological imaging data, with access to researchers all over the globe for research purposes.	46
ICMR, DHR, and IIT-Delhi	Pragati	medical device manufacturing and testing facility at IIT, Delhi, to provide support for the translation of technologies and products from the proof-of-concept stage to the clinical evaluation stage.	47
IIT Bombay and Effecmed Pvt. Ltd.,	Bone Screws	low-cost, bioresorbable bone screws for soft tissue and bone fixation applications especially in bone fracture surgeries.	48

talent. Such collaborations are necessary to align research and development activities with international standards and trends, ultimately ensuring the global acceptance of Indian medical devices. Table 3 provides a few examples of industry-academia collaborations in the medical device sector.

Tata Medical Centre, Kolkata, and the Indian Institute of Technology (IIT), Kharagpur, have collaboratively developed India's first cancer imaging bank- CHAVI.[46] CHAVI was created as part of the National Digital Library of India (NDLI). CHAVI is a comprehensive archive database of imaging that enables researchers worldwide to freely access patient images and relevant medical data for investigation purposes. The image bank permits researchers to evaluate the effectiveness of existing treatment regimens and promote the evolution of novel protocols to improve therapeutic effects. Although CHAVI is a database specifically for oncological imaging data about India, such collaborations at the international level would contribute immensely to global cancer care.

Department of Health Research (DHR), ICMR, and IIT-Delhi jointly established the MedTech Product Development Acceleration Gateway of India (mPRAGATI), which is a medical device manufacturing and testing facility to provide support for the translation of technologies and products from the ideation, proof-of-concept, to the clinical evaluation stage.[47] The mPRAGATI offers services, including product conceptualization, design, prototyping, testing, and regulatory compliance, all under one roof. This enables the rapid conception, execution, and application of innovative ideas and medical device technologies. These initiatives created fertile ground to flourish the medical devices sector in terms of research and development, as well as the commercialization of products.

The researchers at IIT Bombay, in collaboration with Effecmed Pvt. Ltd., a startup registered at Society for Innovation and Entrepreneurship (SINE), IIT Bombay, have developed low-cost, bioresorbable bone screws for soft tissue and bone fixation applications.[48] This opens the gateway to immense opportunities in orthopedic applications owing to the product's superiority over the existing ones in terms of biodegradability and patient compliance. This technology has been patented, and collaborators are planning to file another patent for the improved design of bone screws, aiming to enhance function in human physiological settings.

The Memorandums of Understanding (MoUs) between industry and academia ensure close cooperation between the two institutions to enhance the mutual skills and knowledge of the domain of medical devices. Given this, IIT Bombay has signed an MOU with Max Healthcare to foster joint research endeavors, skill development and training, technology transfer, and commercialization.[49] Similarly, IIT Madras has signed an MoU with MGM Healthcare.[50]

Considering the recent launch of the medical science and technology department at IIT Madras, this MoU holds immense importance. The MoU will facilitate a platform for student-employee exchange between the two parties. IIT Jodhpur has signed a MoU with Johari MedTech to establish the Johari Incubation Centre at IIT Jodhpur.[51] This incubation centre will serve as a bridge between these two bodies, facilitating the development of innovative products and technologies related to medical devices. It will also serve as a funding source for aspiring startups in the medical device sector. Similarly, IIT Goa has signed an MoU with Sciverse Solution for the design, development, and fabrication of lab-on-chip and microfluidics-based technologies for rapid, cost-effective, and sensitive detection of infectious diseases and pathogens such as Human Immunodeficiency Virus (HIV) and tuberculosis.[51]

The National Institute of Pharmaceutical Education and Research, Ahmedabad (NIPER-A) has signed multiple MoUs with Johnson and Johnson and Sahajanand Laser Technologies to develop industry-oriented skilled human resources in the medical device sector.[52] Such MoUs, being signed between academic institutes and industries, facilitate personnel exchange programs and the development of a skilled workforce.

The Tekade lab at NIPER-A is actively developing nanotechnology-assisted platforms for the diagnosis and treatment of various ailments, including cancer, arthritis, diabetes, and topical conditions, among others.[53-57] Recently, NIPER-A and Madhya Pradesh Industrial Development Corporation (MPIDC) have entered into an MoU under which NIPER-A will provide technical and academic support to the Ujjain Medical Device Park. NIPER-A has also offered testing and certification services to the Government of Madhya Pradesh for the MD Park. The MoU was signed during the Spiritual and Wellness Summit in Ujjain by Dr. Shailendra Saraf, Director of NIPER Ahmedabad, in the eminent presence of the Chief Minister of Madhya Pradesh, Dr. Mohan Yadav.

Although collaborations between academia and industry are crucial to achieving India's goal of a higher contribution to the global medical devices market and improved patient care, it is the responsibility of policymakers to frame and implement policies and regulations that are conducive to these goals. The union cabinet of the government of India, given the expanding medical devices sector, has come up with the National Medical Devices Policy (NMDP) 2023, with the idea to lead the medical devices sector on a path of fast-tracked growth with a patient-centric approach to serve the growing healthcare needs by building an innovative and globally competitive industry in India. NMDP 2023 serves as a stepping stone in establishing India as a leading player in the global medical devices market.

INNOVATION TRENDS IN MEDICAL DEVICES: "CASE STUDIES"

India has witnessed several innovative trends in the medical device industry, with a particular emphasis on addressing healthcare issues, enhancing accessibility, and improving patient care. In India, a few innovative trends in medical equipment are as follows:

TTK Chitra heart valve

The TTK Chitra heart valve is among the most reasonably priced heart valves available worldwide and the first heart valve to be manufactured in India. The Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), a nationally significant institution housed within the Department of Science and Technology (DST) of the Government of India, is responsible for its design and development. Since 1990, it has been implanted in approximately 300 cardiac clinics throughout India. The production plant is situated in Trivandrum's KINFRA International Apparel Park. The three parts that make up the heart valve are the sewing ring, the frame, and the disc. Its design incorporates excellent hemodynamics, structural integrity, a low profile, and smooth operation. The special plano-conical disc is positioned to maximize flow through the small aperture. The disc has thromboresistance due to its highly polished, slick surface that resembles wax.[58]

Altius™ (Cemented Hip Replacement System)

RCH Orthopaedics, one of India's leading manufacturers and international suppliers of hip replacement implants, is the developer of the Altius Cemented Hip Replacement System. Altius is a High-nitrogen Stainless Steel (HNS) double-tapered stem that has been cemented and fitted with a PMMA/UHMWPE distal centralizer to assist with stem placement and equal distribution of cement mantle. Hip replacement has been successfully using a collarless, highly polished, double-tapered design that served as the model for the cemented stem for over 45 years. Because ALTIUS is a collarless stem, it makes it easier for surgeons to deal with a wide range of patient anatomy and indications, including primary cases and fractures. In a surgeon's practice, it can be selected as a whole or partial hip replacement method.[59]

SanketLife Pro+

A unique Electrocardiogram (ECG) gadget, the SanketLife Pro+, can be employed for wired and touch-based ECG and stress and HRV level monitoring. To use the gadget for wire-based 12-lead ECG, attach a cable and converter. Both on-site and remote ECG testing can be performed with this portable ECG gadget. SanketLife Pro+ is a simple device for immediate cardiac monitoring at home or in an ambulance. The highest quality requirements were taken into consideration when creating this ECG monitor. This gadget works with both iOS and Android smartphones. It also provides the opportunity to have your ECG professionally reviewed, and may also immediately communicate with a cardiologist to have your report evaluated.[60]

SSi Mantra

SS Innovations, an Indian medical technology firm, is the creator of the "SSi Mantra," an affordable and adaptable surgical robotic device. SSi Mantra represents the first surgical device manufactured in India. It is among the few systems worldwide created for broad surgical usage and was notably cost-effective in design and construction. The CDSCO in India has granted regulatory approval to the technique, which has also undergone hundreds of clinical validations in the country through its use in over 40 distinct surgical operations, including cancer, spinal, head, and heart surgeries. The SSi Mantra Surgical Robotic device, the flagship innovation of the SSi Team, is designed with numerous advanced and intuitive features for the entire surgical team. The company thinks that many more hospitals, doctors, and patients will be able to take advantage of this cutting-edge non-invasive approach because it additionally offers multi-specialty usage, including cardiac surgery, but also costs less than half of the world's best-selling surgical robot.[61]

US 111

The US 111 Medical Ultrasound Therapy equipment is a well-known medical breakthrough that offers a natural, non-invasive solution for treating chronic muscle pain. With the help of crystals vibrating within the probe's head, this handheld ultrasound treatment device, featuring advanced technology, produces both pulsed and continuous sound waves at a frequency of 1 MHz. These waves subsequently penetrate through the skin to a depth of 1.6 inches (4 cm) into the body tissues and muscles, leading to deep heating that the patient typically does not feel. When used promptly and consistently, US 111 can help accelerate the recovery of muscle pain and reduce swelling and inflammation.

Using the settings on the gadget, one can adjust the duration, intensity, and mode of treatment according to the patient's pain level. US 111 has been scientifically shown to be a highly effective pain reliever. Pain management specialists, including doctors, chiropractors, and physical therapists, have tested, authorized, and even utilized US 111. Due to its fundamental functionality, the device's operation requires no specialized knowledge or assistance. A Naturecure ultrasonic gel, a power adapter, an ultracool pack, an instruction booklet, and a stylish carrying pouch are included with the US 111 set.[62]

AyuLynk

The AyuLynk Wired Digital Stethoscope is a specially designed medical device for caregivers working in demanding situations, such as emergency rooms. In addition to supporting noise reduction, the denoise feature and the in-app heart and lung filters

can detect minute sounds that confirm the diagnosis. With the help of an amplifier, this cardiac stethoscope can improve audio quality by up to 40 times, which can help prevent late diagnoses by conducting more accurate auscultation examinations. The visually impaired digital stethoscope on the Ayu device may be used to record and share auscultated sounds when linked to a smartphone or tablet via an OTG connection with the AyuShare app. In addition, the app displays the phonocardiogram of the auscultated sounds, which aids in objectively assessing the sounds of the heart and lungs. AyuSynk is the most cost-effective diagnostic instrument for normal practice and telemedicine to improve diagnosis and prompt detection.[63]

DRISTi

Diabetic Retinopathy Screening (DRISTi) is an artificial intelligence tool designed to instantly identify patients with Diabetic Retinopathy (DR) at an early stage during the eye examination procedure. They have brought DR screeching to the most remote corners of the world by breaking the cord and developing the first AI on a chip. Their goal is to reach out to communities without access to DR specialists by offering early screening at no cost. This application is simple to use, and integration with retinal cameras on smartphones and skilled technicians for prompt and early assessment is also offered.[64]

MARKET SIZE AND GROWTH RATE OF MEDICAL DEVICES

The Indian medical device market is projected to approach US$50 billion by 2030 at a CAGR of 16.4% from its estimated value of ₹90,000 crores (approximately US$11 billion) in 2022. India is projected to account for 1.65% of the global medical device market. India ranks among the foremost 20 medical device markets worldwide and the fourth-largest Asian market for medical devices, behind China, South Korea, and Japan. In general, India relies on imports to meet 75-80% of its medical device needs. India is a major importer of medical devices to the US, China, Germany, Iran, Brazil, and other nations.

The Indian states that produce the majority of medical devices are Gujarat, Andhra Pradesh, Maharashtra, Tamil Nadu, Haryana, Karnataka, and Telangana. During a medical device panel discussion at BioAsia 2021, major stakeholders projected that India would achieve self-sufficiency in medical device production by 2025-2026. The panel noted that to support the overall development of India's domestic medical device market, the government is implementing supportive measures, such as encouraging the manufacture of high-tech medical devices domestically, offering Production-Linked Incentive Schemes (PLIs) on medical equipment, and enhancing novel medical device parks.[65] Under the Medical Device and *in vitro* Diagnostic (IVD) laws, the Health Ministry of India has classified the Indian medical device market into four distinct groups.[66]

While addressing the India MedTech Expo 2023 gathering in August 2023, Dr. Mansukh Mandaviya, Union Health Minister of India, declared that the country is set to emerge as an international hub for medical device technologies. Medtronic announced in May 2023 that the company would invest over US$350 million, or approximately ₹3,000 crore, to develop the Medtronic Engineering and Innovation Centre (MEIC) in Hyderabad. MEIC is Medtronic's biggest R&D facility outside of the United States. Omron Healthcare, a Japanese distributor and manufacturer of personal healthcare goods, announced in May 2023 that it will establish a medical device production facility in Tamil Nadu for US$15.5 million (₹128 crores).

Siemens Healthineers, a medical technology company focused on digitalizing healthcare, developing care delivery, enhancing patient experience, and precision medicine, announced in March 2023 that it would invest ₹1,300 crore (US$157.2 million) at Bommasandra, Bengaluru, to establish a campus. Wipro GE Healthcare announced in August 2022 that it has partnered with Boston Scientific, a leading manufacturer of medical devices, to deliver comprehensive, state-of-the-art cardiac interventional care solutions to India. Northern India's first medical instrument and system manufacturing park is anticipated to open in Gautam Budh Nagar, Noida, by 2022. A mission scheme of around ₹5,000 crore (US$685.35 million) is expected to be introduced by the Yamuna Expressway Industrial Development Authority (YEIDA) in March 2021. The central government is expected to contribute approximately ₹100 crore (US$13.71 million) of this amount.[67]

SOME PLAYERS IN THE MEDICAL DEVICES MARKET IN INDIA

There are several National and International critical players in the Indian medical device market. The national vital players are the med-tech companies, usually startups or developing. In contrast, international vital players are the internationally based med-tech companies that have established their headquarters in India. Both key players are discussed in this section as follows:

Monitra Healthcare Private Limited

The Hyderabad-based medical technology company Monitra Healthcare is creating tools to record cardiac occurrences anywhere. These devices identify cardiovascular disease and cardiac arrhythmias in real-time to provide preventive care. The diagnosis of heart illness, the assessment of therapeutic medications' effects on cardiac activity, and the monitoring of cardiac activity before and during surgery, as well as other cardiac operations, are all common uses for cardiac monitoring. The company's goal is to significantly lessen the impact of cardiovascular disease by integrating preventive cardiac care and monitoring into daily living.[68]

Robo Bionics

Robo Bionics is a medical technology firm established in 2016 in Mumbai, with the tagline "to give a hand to those who are missing a hand. They developed Grippy, a Functional Upper Limb Prosthetic Hand. Grippy is India's first 3D-printed prosthetic hand with multi-grip control and a tactile sensation, approved by the NABL Lab for safety testing. It is created, developed, and manufactured with pride in India. Grippy is a lightweight, reasonably priced, battery-operated prosthesis currently accessible in the Indian market for patients with below-elbow amputations who are at least 15 years old.[69]

Brainiac Healthcare

Brainiac Healthcare, a medical technology firm based in Ahmedabad, specializes in developing cutting-edge, innovative medical equipment for healthcare professionals. They have developed the world's first smart capnometer gadget. The Internet of Things powers this respiratory CO_2 gas monitoring equipment (capnometer) for anesthesiologists and can be operated via a mobile app. They have created a little hardware piece that is attached to the patient in the operating room during the operation. The patient's data will be wirelessly transmitted via the hardware to the mobile application, where it will be processed and shown in both numerical and graphical form.[70]

Team Spectral Insights

Team Spectral Insights is a 2016-founded medical technology firm in Bangalore, specializing in digital pathology and analytics to serve the pharmaceutical, hospital, and laboratory industries. They provide the pathology area with a completely vertically linked digital solution. One standard hardware unit and multiple software modules are required to handle the range of tests carried out under a microscope in a pathological lab-biopsies, pap smears, blood smears, bone marrow smears, TB sputum smears, etc. They have developed an extremely inexpensive, completely automated digital tool that creates stitched panoramas, photos from glass slides, and tools for objectively classifying objects and producing results for users. Machine learning and Artificial Intelligence (AI) algorithms have been developed to assist with a rapid assessment of pap smear slides to identify questionable cells, count morphologies of Red blood cells and White blood cells on blood smears, and identify cancer spots on tissue biopsies.[71]

Designocare Innovative Devices Pvt. Ltd.,

Designocare Innovative Devices is a Gurgaon-based medical technology startup firm focused on the research and development of medical devices. The Unique Hospital Bed is the company's debut product, and creativity in the healthcare industry is its foundation. Moving a patient from a stretcher or bed is typically done manually or with the assistance of complex transfer technologies that have limited application and unique challenges. The bed, which incorporates the stretcher into its design, is their solution. Therefore, the patient will not be manually moved from their bed to a stretcher.[72]

Transasia®

Transasia is India's leading diagnostic company, established in 1979, and a member of the Erba Mannheim GmbH Group, a leading IVD solution supplier in Germany. Transasia Bio-Medicals Ltd., announced in December 2022 that it would be collaborating with the Andhra Pradesh Medical Services and Infrastructure Development Corporation (APMSIDC) to enable the distribution of the Erba range of fully and semi-automated biochemistry analyzers, urine chemistry analyzers, and coagulation analyzers. In August 2022, Transasia introduced the first domestically manufactured Reverse Transcription-Polymerase Chain Reaction (RT-PCR) kit for monkeypox testing at the Andhra Pradesh Medtech Zone (AMTZ). The Mumbai-based IVD company Transasia Bio-Medical Ltd. announced in March 2021 that it would invest ₹150 crore (approximately US$21 million) to establish its manufacturing facility at Telangana's Medical Devices Park in Sultanpur. The company intends to produce cutting-edge, high-tech analysis equipment in the facility for biochemistry, hematology, immunology, and molecular testing, as well as for COVID-19, dengue, HIV, and tuberculosis testing, serving both local and international markets.[73]

Medtronic

In 1979, Medtronic India Pvt. Ltd. started conducting business in India, and it is an entirely operated subsidiary of the Irish-American medical device manufacturer Medtronic Plc. Across India, the organization is present in cities like Gurgaon, Vadodara, Hyderabad, Pune, Ahmedabad, New Delhi, Bangalore, Chennai, Kolkata, Cochin, Dhaka, and Mumbai. The Cardiac and Vascular Group (CVG), the Diabetes Group, the Restorative Therapies Group (RTG), and the Minimally Invasive Therapies Group (MITG) are the four business areas that make up this organization. Medtronic India and Qure.ai announced their partnership in April 2023 to incorporate AI for improved stroke treatment in India. The MiniMed 780G, a future-oriented closed-loop insulin pump structure, was introduced by Medtronic India in March 2022 to treat type 1 diabetes in patients aged 7 to 80. Medtronic India Pvt. Ltd. opened a robotic surgery experience hub in Gurugram in September 2021, to aid physicians with surgery performed with robotic technology.[74]

Johnson and Johnson

Johnson and Johnson is one of the world's leading manufacturers in the healthcare industry, having been founded in 1886. The company is the largest provider of medical devices in India, offering products that target unmet demands in the areas of diabetes management, metabolic and bariatric surgery, hernia surgery, cancer surgery, general surgery, vision care, urologic surgery, cardiovascular disease, peripheral vascular and

obstructive disease, coronary artery disease, neurovascular disease, orthopedics, arrhythmias, and infection prevention. According to information released in March 2022, Stayfree and United Nations International Children's Emergency Fund (UNICEF) have taught over 1.7 million girls about Menstrual Hygiene Management (MHM) during the previous seven years. The firm stated in June 2021 that it is in discussions with the Indian government to introduce the COVID-19 vaccine as a single dose. India approved Johnson and Johnson's COVID-19 single-dose vaccine for emergencies in August 2021. They established a public-private collaboration in 2015 with the National Institute of Pharmaceutical Education and Research (NIPER) in Ahmedabad, India, for a postgraduate training curriculum for future regulators of the medical device industry.[75]

Siemens Healthineers

Siemens Healthineers, a German enterprise, offers services and solutions for the healthcare industry. Their production plants are located in Bangalore and Vadodara, India, for the medical imaging and diagnostic products. Siemens Healthineers and the Manipal Academy of Higher Education (MAHE) signed a Master Research Collaboration (MRC) in August 2023 to further enhance their future collaboration and achieve shared objectives for stakeholders. Siemens Healthineers stated in September 2021 that it's Vadodara, Gujarat, facility will produce molecular diagnostic kits. Siemens Healthineers and SyntheticMR expanded their partnership in September 2021 with the signing of a new license agreement for product distribution. In 2020, Siemens Healthineers, a multinational med-tech firm, committed an investment of ₹1,300 crore (US$177 million) in Bangalore, Karnataka, over the following five years, aiming to establish India as one of its four primary global hubs for digital innovation.[67]

MAJOR CHALLENGES FOR THE MEDICAL DEVICE INDUSTRY

Medical device manufacturing can be a highly intricate and complicated business. The medical devices sector in India is a vital and essential component of the Indian healthcare sector. As per the Government's medical devices draft policy, the share of India in the total market is approximately two percent, while the sector is still in its infancy phase in the country.[76,77] The country is heavily dependent (approximately 80%) on imports from other countries supply of sophisticated equipment (viz: diagnostic devices, imaging modalities, etc.,). Local companies are mostly restricted from manufacturing low-end products for domestic and international consumption.[78]

Recently, the government launched a PLI scheme to motivate investments, boost indigenous manufacturing towards reducing dependency on medical device imports. Nevertheless, the "Make in India" and "Atmanirbhar Bharat" programs are admirable, domestic production of medical devices is still distant from achieving self-reliance in producing world-class medical devices.[79] While the government is attempting to simplify regulations and paperwork, the landscape remains complex, characterized by the presence of numerous high-level government bodies at both the state and central levels. Also, India's per capita expenditure on health is among the lowest in the world. The government's focus on self-reliance is appreciated, but the changes need sustained financial and policy support from the government.

Notwithstanding the strong growth of the medical device industry, it is facing abundant challenges.[80] There is a continually rising demand for technology, which paints a positive outlook for future income, but many obstacles stand in the way. The following are the challenges of medical device invention in India.

Slow, Expensive R&D

More than any other industry, medical device manufacturing relies heavily on thorough research and development. Conducting the necessary clinical trials is often a slow and expensive process, which can delay time to market and hinder profitability. Our government spending on healthcare is only 3% of Gross Domestic Product (GDP), compared to the world average of 11%.[81] This suggests that India has a significant shortage of hospitals and medical devices. One of the primary challenges encountered by the Indian medical device manufacturing industry is the deficiency of a robust research and development ecosystem. However, research and development efforts in the medical devices industry are limited, which hampers the development of advanced technologies and new products.[79] Many Indian medical device manufacturing companies give emphasis on producing cheaper, low-tech devices rather than investing in more advanced research and development.

Lack of supply chain visibility and product traceability

The recent COVID-19 pandemic faced by humankind emphasized the necessity for vigorous supply chain systems and has impacted medical equipment manufacturers. The existing size of the medical industry in India is approximately US$12 billion, compared to a global market size of around US$500 billion. Therefore, India accounts for just 2.5% of the global total available market.[76] Operating at this size makes the supply chain expensive and non-competitive. Indian manufacturers are often overlooked by global suppliers. As most components are imported into our country, we also suffer geopolitical risks. This resulted in delayed delivery and rising prices. Several firms were affected by the ambiguous supply chain, as well as the rising prices of raw/ starting materials, labor, and the end product, reaching sky-high levels. The end-user market, specifically hospitals, in India is highly fragmented, with numerous small hospitals spread across various geographies, resulting in an expensive downstream supply chain. Some companies ramped up operations to meet

the requirements of demand and supply, to safeguard the timely Medicare to the patients.[82]

Duplication, Imitation, and Counterfeit Devices

We live in an age of IP theft and iteration. Too often, new and innovative products are only seen by counterfeiters and imitators before they are released. This is a devastating blow to the medical device market, and these 'copies' are responsible for providing inferior medical care. These lookalike devices deceive patients and exacerbate the challenges of inadequate healthcare facilities, leading to further illness or injury. India has been criticized on global forums for its deficiencies in protecting intellectual property rights. This needs the immediate attention of the government to encourage global houses to bring innovation to India. Responsible manufacturers create the device with utmost care and compliance.[79,83]

Regulatory challenges

Some life science segments are profoundly regulated, while others have very light regulatory oversight. One of the most pervasive challenges in medical device manufacturing is navigating the industry's challenging regulatory environment.[11] Manufacturers often face uneven regulations with inconsistent language and standards. The Indian government has recently introduced new regulations for medical devices; however, some confusion and uncertainty remain regarding the approval process and compliance requirements.

In India, the inconsistent structure and lack of global harmonization make it difficult for manufacturers to determine the correct regulatory pathway. This inconsistency also challenges patients and clinicians as they cannot determine what device is optimal for their healthcare. This gap further widens due to the costs associated with regulatory requirements. Exponential increases in time, cost, and effort are required to manage regulatory compliance, affecting the timely launch of medical devices.[82]

Import-centric

Kits designed in other countries may fail to perform effectively due to India's unique climate and environment. Additionally, the kits are manufactured for well-equipped laboratories, but proper maintenance is often not performed in Indian laboratories. The regulator is challenged to tackle both the flood of substandard imports and the production of poor-quality medical devices in the country.[81,82]

Proper training and education

A deficiency in training and education is another challenge for medical device invention. Developing and maintaining a skilled workforce is vital for the growth of a robust medical devices industry. However, India faces a shortage of specialized engineers, technicians, and healthcare professionals with expertise in medical device technology, which increases the risk of damage to the kits. This scarcity limits the industry's capacity to undertake and drive meaningful research projects. Bridging this skill gap through training and educational initiatives is essential.

Weak technology transfer process

Technology has spun out MedTech innovations. The integration of AI, ML, and other technological advancements in the medical industry is lucrative, but it also has an unexplored grey area. These advancements are designed to improve the patient experience; however, several factors should be considered. There is a huge gap between industry and academia. A World Intellectual Property Organization (WIPO) document stated that most Indian universities have not encouraged in-house projects.

Complex pricing and distribution

High costs are another significant challenge in the healthcare industry. Different states in India often have distinct pricing policies, resulting in a fragmented market. This non-uniformity complicates the pricing strategies for medical device companies nationwide. This fragmented distribution network can lead to higher mark-ups, inefficiencies, and complexities in reaching end-users. Medical device manufacturers face increasing pressure to lower product costs, but that can be a challenge with high production expenses.[81]

Lack of infrastructure and resources

India has a large population, and the demand for healthcare services is consistently increasing. However, the country's healthcare infrastructure is inadequate to meet the needs of its population. The Indian medical devices manufacturing industry lacks the necessary infrastructure to produce high-end medical devices. The country needs modernized testing facilities, proper storage facilities, and skilled workspace, which are currently insufficient.[79]

Lack of awareness

Some medical devices are complex and may require specialized knowledge for their proper use. The lack of awareness about these devices can stem from their technical intricacies. The Indian population lacks awareness about the importance of medical devices, which results in a low demand for these products. This low demand makes it difficult for companies to invest in research and development, which ultimately affects the growth of the industry.[79]

Lack of ecosystem

Healthcare costs are trending upwards because managing chronic diseases requires heavy deployment of medical devices. Many factors, from the planning phase to the use of medical devices, contribute to this upward trend in costs. However, the Indian

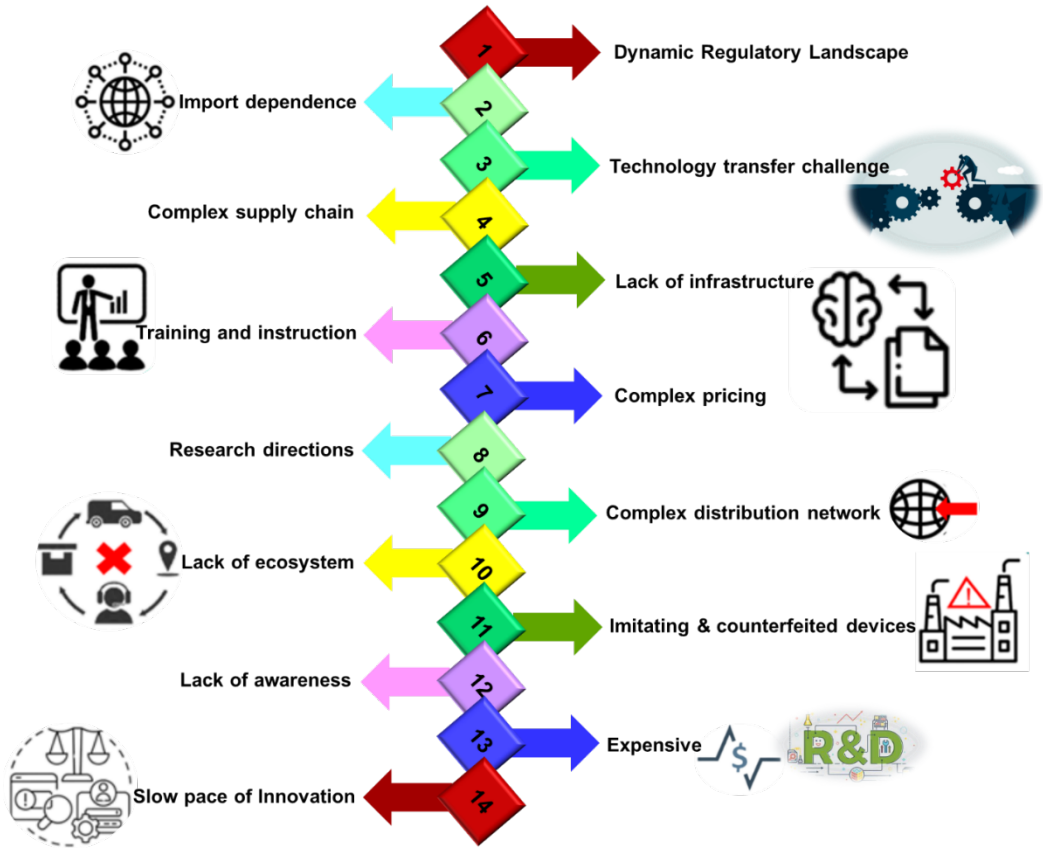

Figure 7: Challenges of the medical device industry.

medical devices industry struggles to attract investments due to the lack of a robust ecosystem for venture capital and angel investors (Figure 7). Due to a lack of ecosystem, Limited profit margins, decreased visibility across assets, and inability to optimize utilization and operational performance, medical device companies face some daunting challenges.[84] Manufacturers are vulnerable to the increasing costs of raw materials, innovation, and logistics, while patients are vulnerable to rising insurance, device, and healthcare costs. These costs must be adjusted to ensure economic stability in demand and supply.[79]

GLOBAL HARMONIZATION INITIATIVES AND THEIR IMPACT

Establishing a reliable and consistent quality practice with minimum variation in safety assessment protocol significantly improves the patient safety record and diminishes the chances of associated risks.[85] Global harmonization initiatives play a crucial role in ensuring the availability of safe and efficacious products that meet the required quality standards, which are in line with global regulatory standards. The product manufactured with this thought process enhances patient acceptance and ensures the availability of a compliant product, while providing significant impetus for global trade.[86] The adoption of globally harmonized practices significantly nurtures innovation, owing to the simplification of the regulatory trail and the easy translation of newly developed products into the market. Eventually, this leads to development as well as compliance-enhanced access to novel and advanced technologies in the market.[87]

It plays a vital role in reducing manufacturing cost, time-to-market cost, and promoting cost efficiency. A well-informed and integrated reporting system improved the post-market surveillance by rationalizing the follow-up procedure for reporting adverse events. This significantly safeguards the operation of the medical device monitoring throughout its lifespan. The following section provides an overview of various global harmonizing regulatory forums for medical devices.

Global Harmonization Task Force (GHTF)

Medical devices are an intricate and industrially advanced sector. Hence, the regulators and the governing bodies overseeing this sector must be the first to adapt to the review and regulation of these devices to confirm safety and efficacy. The quality management system is becoming increasingly complex and stringent, particularly in manufacturing, clinical investigation protocols, and post-marketing surveillance.[14] This makes the review and harmonization of the regulatory progression process a mandatory formula to ensure a balance.

The Global Harmonization Task Force (GHTF) is a globally recognized forum established in 1993 by representatives from federal governments and industry nominees from the United States. Canada, Japan, Australia, and the European Union. The

GHTF provides for both regulatory bodies and representatives from the medical device industry to address complex issues. The primary objective of GHTF is to promote the harmonization of standards and regulatory practices concerning the performance, safety, and quality control of medical devices. The GHTF also works to foster high-tech innovation and facilitate international trade. To achieve this goal, it circulates harmonized documents for regulatory rules, regulations, and practices.

It promotes the alignment among affiliate countries, inducing regulatory frameworks and structuring the medical device regulation worldwide.[88] Initially, the forum comprises intriguing members from Canada, Japan, the USA, the European Union, and Australia. Over time, the membership expanded to include other governments from various countries, thereby enhancing its role and influence in global regulatory practices.[89] The GHTF played a vital role in laying the foundation for the IMDRF and continues to lead the international regulatory union, thereby enhancing the trade of medical devices.[13]

International Medical Device Regulators Forum (IMDRF)

The IMDRF was established in 2011 and has since played a key role as a global harmonizing regulatory body for medical devices. Its primary objective is to accelerate international regulatory convergence and promote consistent standards for medical devices that enhance user safety and efficacy.[21,90]

In the evolving landscape of the medical device sector, IMDRF facilitates collective knowledge sharing for the development of effective global regulatory policies by fostering discussions among regulators from key markets. IMDRF clarifies the expectations of regulatory agencies, facilitating the easy alignment of regulatory requirements and promoting market access for medical device companies.[91] It primarily focuses on aspects related to developing guidance documents that serve as internationally recognized references for regulatory agencies. IMDRF also emphasizes initiatives aimed at regulatory capacity-building and supporting emerging medical device markets in firming up their regulatory frameworks.[13,92] Its collaborative approach helps address evolving challenges and discrepancies that arise during the innovation and commercialization cycle of a new medical device product, with due regard for public health.

The Medical Device Single Audit Program (MDSAP) is a notable initiative of the IMDRF that enables a single audit for medical device manufacturers to meet the regulatory requirements of multiple countries. This initiative significantly helped in avoiding redundant audits, thereby reducing the time and costs associated with launching a new medical device to market. The development of a universally harmonized UDI system is another key accomplishment of MDSAP. This led to an enhancement of the informed traceability of medical devices, ensuring reliable communication of critical information on medical device products across global markets.[93,94]

The IMDRF guidelines have also aided global regulators in developing a classification system for medical devices based on associated risk concerns, enabling them to conduct thorough inspections to ensure patient safety through a regulated regulatory procedure. The ongoing efforts of IMDRF in harmonizing international medical device regulations are significantly enhancing patient safety and facilitating the regulated distribution of medical devices worldwide. Companies like Medtronic have effectively utilized MDSAP to streamline their regulatory procedures. It is anticipated that through unified initiatives like IMDRF, MDSAP, and UDI, the regulatory landscape will continue to evolve, ensuring it remains compliant to ongoing technological advancements and public health requirements.

AI IMPLEMENTATION AND FUTURE OUTLOOK IN MEDICAL DEVICES

The potential of a machine to replicate human intelligence and behavior, including decision-making and task execution, is known as Artificial Intelligence (AI). The fundamental algorithm serves as the basis for the strategies employed to integrate AI technologies into medical equipment. Neural network-based advanced machine learning methodologies are gaining popularity in the medical device industry. A collection of algorithms known as neural networks is created to recognize connections and is based on a loose approximation of the human cognitive system.

Machines' deep learning approaches can replicate how humans learn and adapt without programming when they receive access to information via neural networks. With deep learning processes and neural networks, AI is utilized in medical devices to augment or replace human tasks. These functions involve, but are not limited to, disease forecasting and identification, evidence grouping and interpretation for disease epidemics, and healthcare optimization. According to studies, these applications include the processing of natural language, customized medicine, pharmaceutical research and development, surgical support, diagnostic assistance, clinical trial optimization, and cybersecurity and compatibility.[95-97]

India stands to gain significantly from the application of AI in medical devices, which will enhance patient outcomes, improve diagnosis, and enhance the provision of healthcare. Numerous elements demonstrate AI's potential and possibilities in India's medical gadgets. AI can potentially enhance the speed and precision of medical imaging, enabling the prompt diagnosis of health problems, including cancer, cardiovascular issues, and neurological abnormalities. Radiological services provided by AI systems can help radiologists evaluate patients more quickly and accurately by assisting them in analyzing and interpreting medical images.[98,99] AI-powered gadgets can continuously screen patients, enable immediate intervention, and reduce the need for

hospital visits. By offering symptomatic investigation, therapeutic suggestions, and tools to support decision-making, AI can enhance telemedicine consultations.[100,101]

AI machines can analyze vast datasets to create personalized treatment programs tailored to an individual's genetic composition, lifestyle, and medical history. AI can expedite the process of drug discovery and development by analyzing massive datasets to identify prospective potential treatments.[102,103] Machine learning algorithms can save time and money compared to more labor-intensive approaches by predicting the safety and efficacy of novel medications. AI can enhance overall effectiveness, streamline hospital operations, and allocate resources more efficiently. AI has the potential to enhance inventory control, ensure an adequate supply of essential healthcare products, and reduce waste.[104,97].

AI-powered healthcare information analyses can forecast and track illness outbreaks, enabling the implementation of preventive public health strategies. According to,[105] AI can help with epidemiological research and population health trend analysis. AI in medical devices has the potential to reduce healthcare costs by increasing productivity, decreasing the need for manual labor, and optimizing resource utilization. Utilizing telecommunication and AI-driven diagnostics, AI can play a crucial role in providing healthcare facilities to underprivileged and remote areas.[106,107] Strong rules and regulations must be established before AI may be used in healthcare to guarantee patient safety, confidentiality of information, and address ethical issues.

Advancements in AI for medical devices can be promoted by fostering partnerships among the public, commercial, and academic sectors. To fully benefit from new technologies, healthcare workers must be educated and trained in the use of AI.[108] Conclusively, India and the rest of the world have great prospects for AI in medical equipment. This may lead to increased accessibility, improved health outcomes, and breakthroughs in medicine and therapy. Governmental authorities, healthcare facilities, technology developers, and regulatory organizations must collaborate to create an environment that supports the moral and practical application of AI in the medical field.

CONCLUSION

Recently, India has witnessed significant progress in its capabilities as both a producer and consumer of healthcare and medical devices. With thriving support from the development and implementation of medical device policies, India has made constructive progress in developing quality, affordable, and regulated medical devices. Government policies are exceedingly supportive, goal-oriented, and business-friendly, encouraging the shift towards indigenous manufacturing rather than importing. The objective is to reduce import dependency by fostering indigenous production capability. It is primarily advocated that there is a big room for countries like India to tap the untouched areas relating to government policies, business, and collaboration protocol, ways to foster ease of business, and increase reach and compliance with the regulatory guidelines. Still, grounds for improvement exist in the areas of evaluating clinical performance, certification, safety, reporting, and planning; efforts in this area are indeed in progress at the national level to bring them into line with global policies.

Today, many of the devices in India are still defined as drugs as per the Drugs and Cosmetics Act 1940, while others are defined under the IMDR as devices. In subsequent revisions of the guidelines, the CDSCO may also realign these definitions and consolidate all medical devices under a single umbrella, making the rules and norms for all these devices uniform. This will enhance the ease of doing business in the medical device industry in India and attract more manufacturers to invest in this segment. Furthermore, India's new medical device regulatory guidelines certify the introduction of novel and innovative medical devices. It is anticipated that in the years to come, India will develop itself as a major player in manufacturing and emerge as one of the primary consumers of indigenous healthcare medical devices.

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ABBREVIATIONS

AERB: Atomic Energy Regulatory Board); **AI:** Artificial intelligence; **AMTZ:** Andhra Pradesh Medtech Zone; **APMSIDC:** Andhra Pradesh Medical Services and Infrastructure Development Corporation; **BIS:** Bureau of Indian Standards; **CAGR:** Compound annual growth rate; **CDSCO:** Central Drugs Standard Control Organization; **CER:** Clinical Evaluation Report; **CIF:** Common infrastructure facilities; **CLA:** Central Licensing Authority; **CLAA:** Central Licensing Approval Authority; **CVG:** Cardiac and Vascular Group; **DCGI:** Drug Controller General of India; **DHR:** Department of Health Research; **DMF:** Device Master File; **DoP:** Department of Pharmaceuticals; **DPIIT:** Department for Promotion of Industry and Internal Trade; **DPIIT:** Department for Promotion of Industry and Internal Trade; **DRISTi:** Diabetic Retinopathy Screening; **DST:** Department of Science and Technology; **ECG:** Electrocardiogram; **EU:** European Union; **FDI:** Foreign direct investment; **FSC:** Free Sale Certificate; **GHTF:** Global Harmonised Task Force; **GMDN:** Global Medical Devices Nomenclature; **GoI:** Government of India; **GST:** Goods and Services Tax; **HIV:** Human immunodeficiency virus; **HNS:** High-nitrogen Stainless Steel; **IBEF:** Indian Brand Equity

Foundation; **ICMR:** Indian Council of Medical Research; **IEC:** Import-Export Code; **IIT:** Indian Institute of Technology; **IMDR:** Indian Medical Device Rules; **IMDRF:** International Medical Device Regulators Forum; **IVDMDs:** *In vitro* Diagnostic Medical Device; **IVDs:** *In vitro* Diagnostics; **MAHE:** Manipal Academy of Higher Education; **MD:** Medical Device; **MPIDC:** Madhya Pradesh Industrial Development Corporation; **MDSAP:** Medical Device Single Audit Program; **MEIC:** Medtronic Engineering and Innovation Centre; **MeitY:** Ministry of Electronics and Information Technology; **MHM:** Menstrual hygiene management; **MITG:** Minimally Invasive Therapies Group; **MoHFW:** Ministry of Health and Family Welfare; **MoUs :** Memorandums of understanding; **mPRAGATI:** MedTech Product Development Acceleration Gateway of India; **MRC:** Master Research Collaboration; **GDP:** Gross Domestic Product; **NABCB:** National Accreditation Board for Certification Bodies; **SLA:** State Licensing Authority; **NABL:** National Accreditation Board for Testing and Calibration Laboratories; **NDLI:** National Digital Library of India; **NID:** National Institute of Design; **NIPER-A:** National Institute of Pharmaceutical Education and Research, Ahmedabad; **PLI:** Production Linked Incentive Scheme; **PMF:** Plant Master File; **PMS:** Post-approval changes; **PPP:** Public-private partnerships; **QMS:** Quality management system; **R&D:** Research and development; **RTG:** Restorative Therapies Group; **RT-PCR:** Reverse transcription-polymerase chain reaction; **SCTIMST:** Sree Chitra Tirunal Institute for Medical Sciences and Technology; **SEC:** Subject Expert Committee; **SINE:** Society for Innovation and Entrepreneurship; **UDI:** Unique Device Identification; **UMDNS:** Universal Medical Device Nomenclature System; **UNICEF:** United Nations International Children's Emergency Fund; **WIPO:** World Intellectual Property Organization; **YEID:** Yamuna Expressway Industrial Development Authority.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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SUMMARY

The Indian medical device industry is an emerging and rapidly growing healthcare sector. However, to meet the rising demands of this sector, India relies primarily on imports. Considering this situation, the Indian Government has initiated several measures and policies to boost the production of indigenous medical devices. This manuscript offers an all-inclusive crosstalk on the emerging dynamics of medical devices in India with the help of thoughtfully presented case studies. It is anticipated that this manuscript will also serve as a ready reference source for all shareholders of the medical devices sector in India.

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