

# India's Medical Devices Sector: A Window of Opportunity for South Korea

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## I. Introduction

The medical devices sector in India has been rapidly growing and evolving, driven by factors such as increasing healthcare expenditure, rising awareness of advanced medical technologies, government initiatives, and a growing population with a rising demand for healthcare services<sup>1</sup>. The Indian medical devices market was valued at approximately \$12 billion in 2021 and is expected to reach \$50 billion by 2025<sup>2</sup>, indicating significant growth potential. The sector covers a wide range of products, such as diagnostic imaging equipment, surgical instruments, patient monitoring devices, implants, consumables, and healthcare IT solutions. The market is primarily driven by imports, with domestic manufacturing accounting for a smaller share (Dang and Sharma

2019). However, the government has been promoting domestic manufacturing with an aim to reduce import dependency, the Medical Devices Policy-2023 of India should be seen in the same context.

The business segments of India's medical devices sector include diagnostics and imaging devices such as X-ray machines, ultrasound systems, CT scanners, MRI machines, and other diagnostic equipment; surgical instruments and consumables such as a wide range of instruments used in surgeries, including scalpels, forceps, sutures, and surgical meshes. There are patient monitoring devices for monitoring vital signs, such as blood pressure monitors, pulse oximeters, and ECG machines

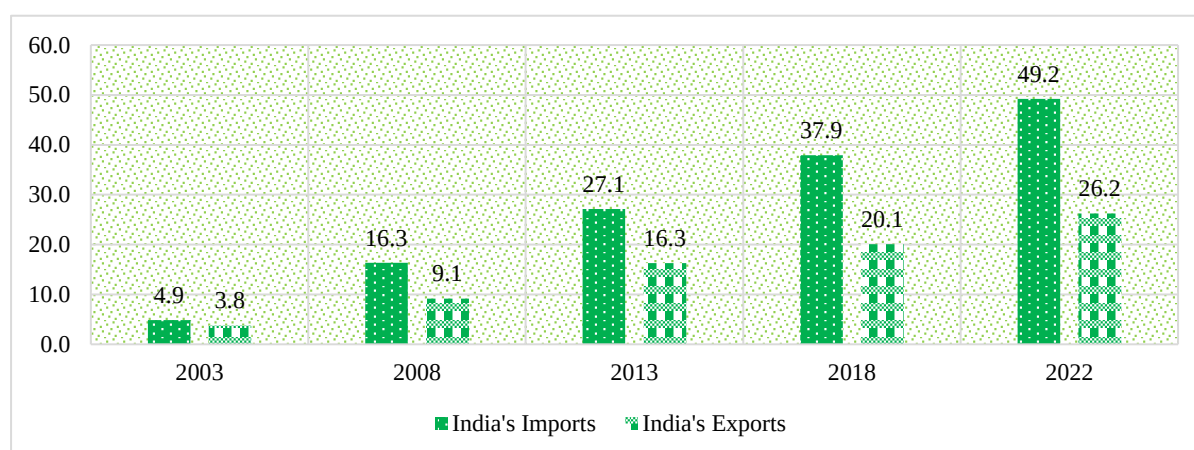
<sup>1</sup> Deloitte-NatHealth. 2016. "Medical Devices Making in India - A Leap for Indian Healthcare." <https://www2.deloitte.com/content/dam/Deloitte/in/Documents/life-sciences-health-care/in-lshc-medical-devices-making-in-india-noexp.pdf>

<sup>2</sup> <https://www.ibef.org/industry/medical-devices>

and implants and prosthetics which primarily includes orthopaedic implants, cardiac implants, dental implants, and various types of prosthetic devices (Chakravarthi 2013). Lastly, there is a range of healthcare IT solutions which includes both software and hardware solutions for managing electronic health records, hospital management systems, telemedicine, and health analytics. Considering the

huge size of the growing market with improving per capita income, India's Medical Devices Policy-2023 aims to strengthen domestic manufacturing capacities, capabilities and competencies and accordingly seeks capital and technology to meet the huge and growing requirements of the domestic market. Hence, Medical Devices Policy-2023 is an urgent need for India in the face of ever-expanding imports (Figure 1).

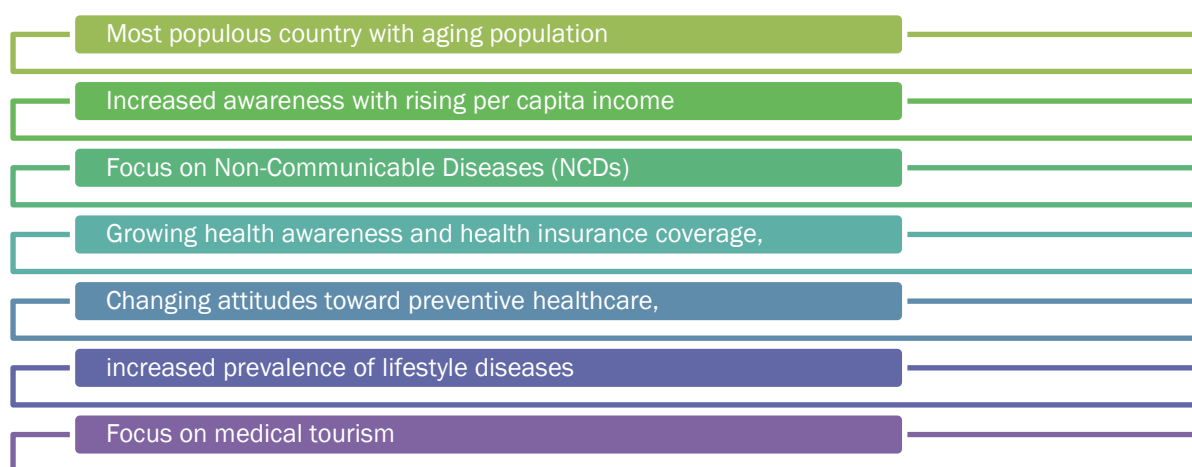
**Figure 1. India Imports and Exports (US\$ billion)**



Source: UN Comtrade, accessed at ITC-Trademap.

According to India Brand Equity Fund (2022), the Indian medical devices market was valued at approximately \$10-12 billion in 2020. It is projected to reach a value of \$50 billion by 2025, exhibiting significant growth. Unfortunately, India heavily relies on imports for medical devices to meet its domestic demand and given the low per capita income, sizable poor population and health-related ignorance, this is an area that requires immediate attention from policymakers to ensure the accessibility

of medical devices in India at reasonable prices (Bhat et al. 2019). India imports medical devices primarily from the United States, Germany, China, and Japan and in 2020, India's medical devices imports were valued at around \$6.3 billion. India also exports medical devices to international markets, valued at approximately \$2.7 billion with major export destinations being the United States, Europe, Africa, and Southeast Asia. India is fourth largest market in Asia and ranks among the

**Figure 2. Key Growth Drivers for India's Medical Devices Industry**

Source: Adapted from Invest India, <https://www.investindia.gov.in/sector/medical-devices> (accessed June 6, 2023)

top 20 global medical devices markets<sup>3</sup>. The country holds a relatively small global market share, accounting for less than 2% of the global medical devices market. The US dominates the global market with a 40% market share, followed by Europe and Japan at 25% and 15% respectively (KPMG 2020). Medical devices sector in India is mushrooming and the key growth drivers for medical devices in India are depicted in the Figure 2.

## II. Understanding Medical Devices Policy-2023

The Medical Devices Policy of India announces a window of business opportunities and growth drivers, paving the way for favourable regulatory environment. Accordingly, to simplify processes while ensuring patient safety and promoting innovation, it proposes

to establish a “Single Window Clearance System” involving collaboration among relevant departments and organizations of both human and animal health care, i.e., the Ministry of Electronics and Information Technology (MeitY) and Department of Animal Husbandry and Dairying (DAHD). Moreover, the policy places a strong emphasis on research and development (R&D) by complementing the proposed National Policy on R&D and Innovation in the Pharma-MedTech sector. It aims to establish Centres of Excellence, innovation hubs, and supportive ecosystems for start-ups, facilitating R&D and innovation in the medical devices field.

The policy aims to improve healthcare infrastructure, accordingly, the government's focus on strengthening healthcare infrastructure, including setting up new hospitals and healthcare centres, and creates opportunities

<sup>3</sup> <https://www.ibef.org/industry/medical-devices>

for medical devices manufacturers. Therefore, to create a conducive environment for the industry, large medical device parks with world-class infrastructure facilities will be set up near economic zones across the country (Sarwal et. al. 2021). Therefore, the government of India has taken initiatives to streamline regulations, promote domestic manufacturing, and encourage innovation in the medical devices sector. Figure 3 as under depicts the objectives of the Medical Devices Policy-2023.

The Medical Devices Policy factors in the growing awareness among the Indian population about advanced medical technologies and the importance of healthcare is driving the demand for medical devices. The policy aims to create an ecosystem for both private investments and Public-Private Partnerships (PPP) to actively encourage them for boosting the growth of the medical device industry. Given

the magnitude of R&D and innovation in the medical devices sector, the policy intends to engage the venture capitalists (VCs) to play a significant role in providing funding and support to develop the medical devices industry in India (Jarosławski and Saberwal 2013). The policy, inter-alia, synergizes the existing initiatives such as Make in India, Ayushman Bharat, Heal-in-India, and the Start-up mission and align them with the macro-objectives of this policy.

India has become a popular destination for medical tourism, attracting patients from around the world who require advanced treatments and procedures, leading to increased demand for medical devices (Vitthal et al. 2015). The policy is ambitious in terms of human resource development in the sector as it focuses on skilling, reskilling, and upskilling programs through the Ministry of Skill Development and Entrepreneurship. It proposes and plans

**Figure 3. Objectives of Medical Devices Policy–2023**



Source: Author's compilation based on Medical Devices Policy–2023.

for dedicated courses for medical devices manufacturing and uses in the existing institutions to produce skilled manpower for India's growing health care and related commercial needs. This includes promoting medical tourism at affordable prices at global level, anchoring exports for foreign exchange earnings and substituting imports with localized manufacturing. Overall, the policy seeks to regulate the manufacture, import, distribution, and use of medical devices in order to protect the interests of patients, healthcare providers, and the overall healthcare system.

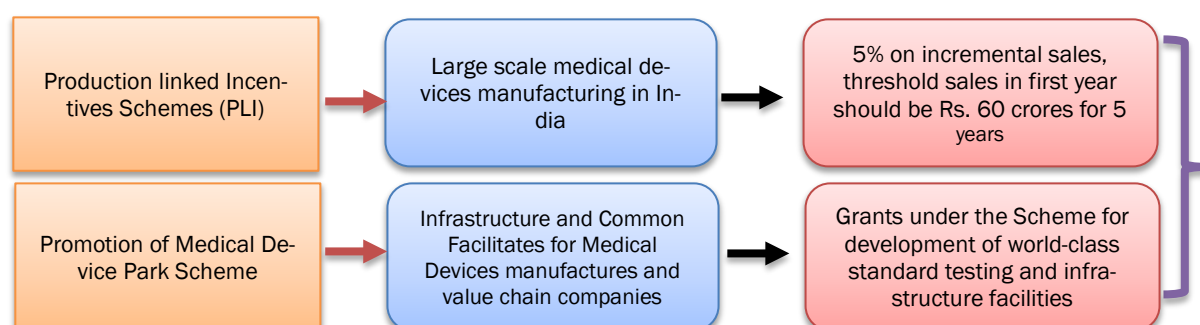
The rapid growth of digital health platforms and telemedicine services in India provides opportunities for medical devices companies to develop innovative solutions that integrate with these platforms. The policy aims to establish a robust telemedicine regulatory framework that provides clarity to healthcare providers, patients, and technology providers on the permissible scope of services and standards of care. Accordingly, the policy aims to enhance India's brand positioning and envisions to establish a dedicated Export Promotion Council for the sector, taking it away from Engineering Export Promotion Council (EEPC). This council will act as a facilitator and advocate for the industry, help create awareness conduct studies on market access issues, suggest policy interventions and seek improved market access in future trade agreements, thereby expanding its reach in international markets. All these policy measures will ensure the higher growth of telemedicine services.

### III. Medical Devices Manufacturing: A Window of Opportunity to RoK Companies

The medical devices manufacturers of South Korea can reap the business opportunities arising out of this huge and growing market of India and can become partners in India's 'Make in India'. The government of India is offering 'production-linked-incentives' program, which provides an opportunity for the ROK's medical devices industry to establish a strong presence and contribute to the growth of the sector in India. Notably, recent initiatives such as the Production Linked Incentive Scheme (PLI) and the Promotion of Medical Devices Parks Scheme exemplify this commitment (Figure 4). These well-designed schemes aim to incentivize and promote large-scale manufacturing while facilitating the development of the necessary infrastructure to promote manufacturing clusters in India.

The production Linked Incentives (PLI) Scheme for Medical Devices manufacturing aims to provide a financial boost to domestic manufacturing and attract significant investments in various segments of medical devices, including cancer care devices, radiology and imaging devices, anaesthesia devices, implants, and more (Vora et. al. 2021). Under this scheme, substantial production linked incentives amounting to \$456 million will be granted to eligible manufacturers. The objective of the scheme is to foster the emergence of global champions from India and further strengthen the "Make in India,

Figure 4. Policy Incentives of Medical Devices Sector



Source: Adapted from National Investment promotion and Facilitation Agency (Invest India), <https://www.investindia.gov.in/schemes-for-medical-devices-manufacturing>

"Make-for-the-World" initiative, promoting the country as a manufacturing hub for high-quality medical devices with global competitiveness. A total of 55 pharmaceutical companies have met the eligibility criteria for the 15,000 Crore PLI Scheme. This significant development provides a substantial impetus to enhance investment and manufacturing capacity in the pharmaceutical and medical devices sectors, further consolidating India's position as the "Pharmacy of the World." As part of the scheme, a 5% incentive will be granted on the increase in sales (compared to the base year of FY 2019-20) of medical devices manufactured

within India. These incentives will be available for a duration of 5 years, spanning from FY 2020-21 to FY 2025-26. To qualify for the incentives, applicant companies must meet certain investment and production thresholds, as well as fulfil the eligibility criteria set out in the scheme. Applicants fall into three groups (Figure 5).

Furthermore, Table 1 illustrates the target segments that can be targeted upon by ROK investors and business entities to reap the business dividend along with availing public subsidies as announced under PLI and Medical Devices Park Scheme.

Figure 5. Eligibility Criteria to Avail the PLI Incentives of Government of India

|                 |                                                                                                                                                                                  |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Group A:</b> | •Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices more than or equal to INR 5,000 Cr.              |
| <b>Group B:</b> | •Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices between INR 500 (inclusive) Cr and INR 5,000 Cr. |
| <b>Group C:</b> | •Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices less than INR 500 Cr.                            |

Source: Invest India, <https://www.investindia.gov.in/schemes-for-medical-devices-manufacturing>

**Table 1. Target Segments Eligible under PLI Scheme for Medical Devices**

| Medical Device Segment                                | Indicative Eligible Products                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Cancer care / Radiotherapy</b>                     | Brachytherapy Systems, Rotational Cobalt Machine, Radiotherapy Simulation Systems, Linear Accelerator (LINAC), Workstations- Radiotherapy Planning, Proton therapy system and other products in this target segment.                                                                                                                                                                                                                                    |
| <b>Radiology, Imaging and Nuclear Imaging Devices</b> | CT Scan, MRI, Ultrasonography, X-ray equipment, mammography, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single-photon emission tomography (SPECT), Cyclotrons and other products in this target segment.                                                                                                                                                                                                                              |
| <b>Anesthetics, Cardio-Respiratory and Renal Care</b> | Needles-Anaesthesia, Syringes-Anaesthesia, Anaesthesia workstation, Anaesthesia Unit Gas Scavengers, Anaesthesia Kits, Masks —Anaesthesia, Anaesthesia Unit Vaporizers, Anaesthesia Unit Ventilators, Automated external defibrillators (AEDs), Dialyzer, Dialysis Machine, Peritoneal dialysis kits, Biopsy Kits- Renal, Dialyser reprocessing   Lithotripters-Extracorporeal —Renal, Oxygen Concentrators, and other products in this target segment. |
| <b>All Implants</b>                                   | Cochlear Implants, Hip Implants, Knee Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses, heart valves, stents and other products in this target segment.                                                              |

Source: National Investment Promotion and Facilitation Agency (Invest India), <https://www.investindia.gov.in/schemes-for-medical-devices-manufacturing>

The Promotion of Medical Device Parks initiative aims to strengthen the infrastructure base and cultivate a strong manufacturing ecosystem for medical devices in the domestic market (Markan, et. al. 2020). Through the provision of grants, the scheme supports the development of state-of-the-art testing and infrastructure facilities, thus creating a favourable environment for domestic production and fostering the growth of the medical devices value chain in India. Moreover, these efforts are expected to substantially lower manufacturing costs, resulting in improved accessibility and affordability of medical devices across the country.

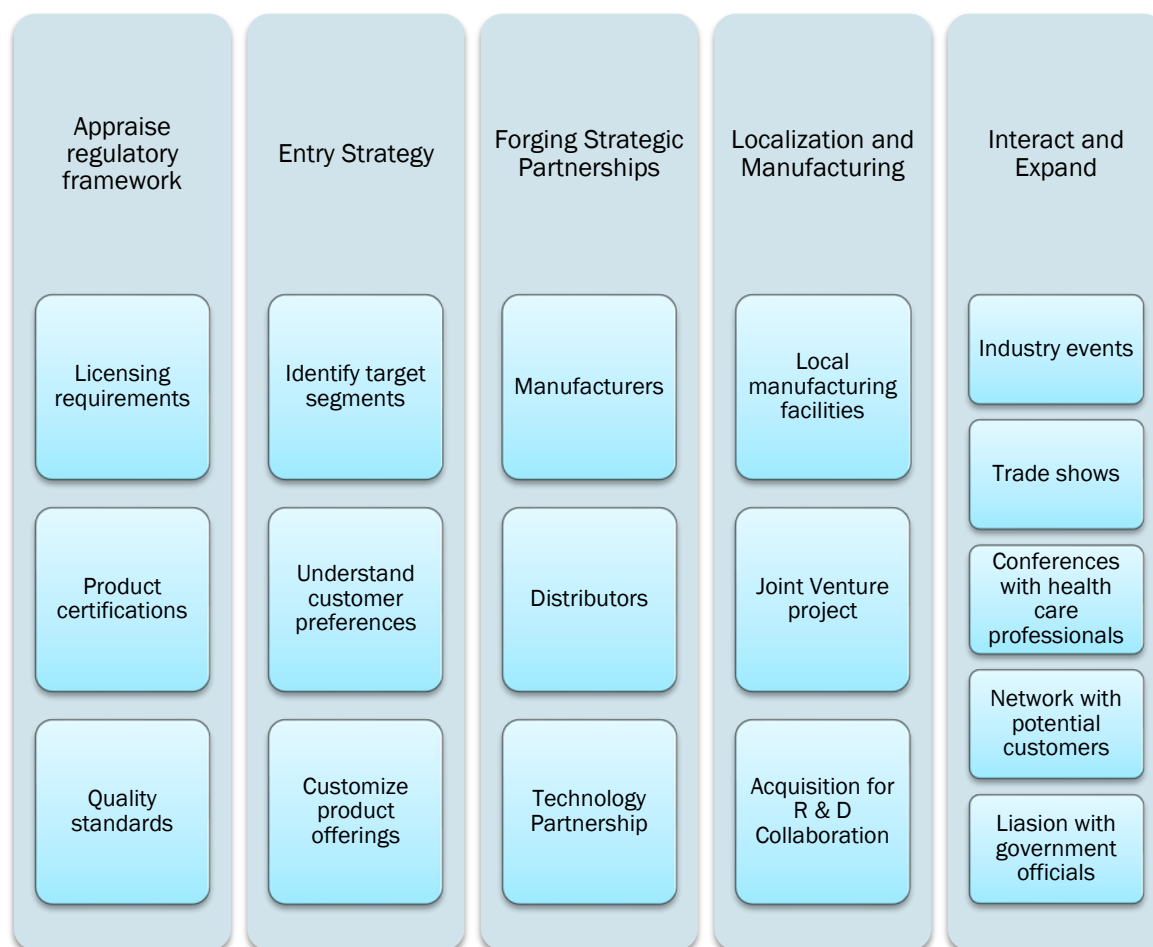
Given this huge business opportunity and associated policy stimulus both in the form of subsidies of 5% on the gross incremental production and infrastructure development, there is an economic logic for business firms of South Korea to explore the business prospects. This can be done through the following types of business initiatives.

### 1. Forging Strategic Partnerships

The business firms from South Korea can collaborate and partner with local Indian medical device manufacturers, distributors, or technology providers to leverage their market knowledge,



Figure 6. Business Success Roadmap for RoK's Medical Device manufactures in India



Source: Author's own Compilations.

distribution networks, and expertise in navigating the Indian business landscape. Alternatively, they can enter into joint ventures and technology transfer agreements with Indian companies to enhance local manufacturing capabilities and access to the Indian market.

## 2. Localization and Manufacturing

The medical devices manufacturers from RoK can establish their own local manufacturing facilities to produce medical devices locally, aligning with the Make in India objective

and take advantage of the subsidies and infrastructure support, as being offered. This can help reduce costs, improve supply chain efficiency, and comply with domestic manufacturing requirements. Further, the RoK's firms can allocate resources to local R&D initiatives to enhance product innovation and customization for the Indian market, addressing specific healthcare needs in this vast market. These firms can also train and develop a skilled workforce in India to support manufacturing operations, ensuring quality production and efficient processes.



While using either of the above two strategies, the firms from RoK need to familiarize themselves with the regulatory framework for medical devices in India, including licensing requirements, product certifications, and quality standards. They should also obtain the necessary certifications from mandated bodies such as the Central Drugs Standard Control Organization (CDSCO), the Ministry of Health and Family Welfare, and the Bureau of Indian Standards (BIS). Each of these bodies has its own regulations and processes for approval, which may result in different standards and requirements (Radhadevi et. al. 2012) to ensure that medical devices comply with Indian regulations.

Before entering the Indian market, it is recommended that they should develop a comprehensive market entry strategy to identify target segments, understand customer preferences, and tailor their product offerings accordingly. The Korean firms can partner with reputable distributors and healthcare providers to expand their market reach and ensure efficient product distribution throughout the country. Therefore, they should engage with key stakeholders in India's medical devices industry and actively participate in industry events, trade shows, and conferences to network with potential customers, healthcare professionals, and government officials.

Given the scale of business opportunity in India, the Korean firms can also establish local service and support infrastructure to provide timely maintenance, repair, and technical support for the medical devices sold. Hence, they need invest in training and education in the initial years and can plan training programs for healthcare professionals and technicians on the proper use, maintenance, and troubleshooting of medical devices. India now allows foreign universities and technical institutions to set up campuses under its the University Grants Commission (Setting up and Operation of Campuses of Foreign Higher Educational Institutions in India) Regulations, 2023<sup>4</sup>. Australia's Deakin and Wollongong are the two universities that have already set up their offshore campuses in India's Gujarat International Finance Tech (GIFT) City<sup>5</sup>. A total of 8 foreign universities are likely to set up their campuses in India.

Lastly, they need ensure to take advantage of government incentives under the PLI and the Medical Devices Parks scheme, as well as government incentives, subsidies, and tax benefits etc. which are being offered under the Make in India program to support the local manufacturing and business expansion plans. India's regulatory landscape is ambiguous; hence it is imperative to establish links with Indian government bodies responsible for

<sup>4</sup> [https://www.ugc.gov.in/pdfnews/9214094\\_Draft-Setting-up-and-Operation-of-Campuses-of-Foreign-Higher-Educational-Institutions-in-India-Regulations-2023.pdf](https://www.ugc.gov.in/pdfnews/9214094_Draft-Setting-up-and-Operation-of-Campuses-of-Foreign-Higher-Educational-Institutions-in-India-Regulations-2023.pdf)

<sup>5</sup> <https://economictimes.indiatimes.com/nri/study/for>

[eign-universities-to-enter-india-a-futuristic-move-for-the-countrys-education-system/articleshow/98599957.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](https://www.e-countrys-education-system/articleshow/98599957.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst).

healthcare and medical devices regulations to stay updated on policy changes, contribute to

policy discussions, and address any concerns or challenges faced by the industry. **KIEP**

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