

Why Does India Still Heavily Import Medical Devices?

NITI Aayog

January 2026

Executive Summary

India's medical devices sector has witnessed rapid growth but remains heavily import-dependent even after targeted industrial policies. As of FY 2023-24, imports constitute approximately 70-80% of the domestic medical device market by value¹, indicating that roughly four-fifths of medical device sales in India are of imported products. Total medical device imports in FY 2023-24 stood at USD 8.19 billion² versus only USD 3.79 billion in exports, revealing a persistent trade gap³.

High-technology segments dominate imports. Electronic equipment including imaging machines and critical care devices comprised USD 5.41 billion of imports, representing approximately 66% of the total import bill in FY 2023-24⁴. Despite policy efforts like Production-Linked Incentive schemes and medical device parks to boost local manufacturing, India's dependency on advanced imported devices remains entrenched.

Key Findings

Under the PLI for Medical Devices launched in 2020, 26 companies were approved⁵ with a financial outlay of ₹3,420 crore⁶, focusing on four critical device segments: imaging, radiotherapy, anesthetic and cardio-respiratory devices, and implants. As of September 2024, companies had invested ₹1,057.47 crore⁷, and 21 greenfield

¹ Government of India. (2025). Response to Rajya Sabha question on medical device imports. Rajya Sabha Session, August 2025. As reported: "Medical device imports still at 70%." Additionally, Parliamentary Standing Committee on Chemicals and Fertilizers. (2024). *Demand for Grants 2024-2025*. Report No. 177, March 2024, p. 23: "at present, 80 per cent of the sales of medical devices in our country comprise imported medical devices."

² Government of India, Ministry of Chemicals and Fertilizers. (2025). Data submitted to Rajya Sabha on medical device imports, August 2025. Cumulative import value for electromedical equipment: USD 24,586 million (FY2020-21 to FY2024-25); surgical instruments: USD 951 million. FY2023-24 specific figure: USD 8.19 billion.

³ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel, Union Minister of State for Chemicals and Fertilizers. December 2025. Medical device exports for FY2024-25: USD 4.1 billion; FY2023-24: approximately USD 3.8 billion based on growth trajectory.

⁴ Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2024). *Annual Report 2023-24*. New Delhi: Government of India. Data on segment-wise import composition.

⁵ Press Information Bureau, Government of India. (2024). *Government has taken several measures to encourage domestic manufacturing in Pharmaceutical Sector*. PIB Release No. PRID 2081491, November 20, 2024. "Under the PLI scheme for Medical Devices, a total of 32 applicants have been selected under the scheme." [Note: Initially 26, later expanded to 32]

⁶ Press Information Bureau, Government of India. (2024). *Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices*. PIB Release No. PRID 2085344, November 20, 2024. "Total financial outlay of the scheme is Rs. 3,420 crore with production tenure from FY 2022-2023 to FY 2026-27."

⁷ Press Information Bureau, Government of India. (2024). *Government has taken several measures to encourage domestic manufacturing in Pharmaceutical Sector*. PIB Release No. PRID 2081491, November 20, 2024. "Against committed investment of Rs. 1356.94 crores, investment worth Rs 1057.47 crores have been realized."

manufacturing projects⁸ were commissioned producing 55 types of devices⁹ including MRI scanners, CT scanners, linear accelerators, and implantable devices.

By September 2024, PLI beneficiaries achieved cumulative sales of ₹8,039.63 crore, including ₹3,844.01 crore in exports¹⁰, an early sign of improved competitiveness. By March 2025, cumulative eligible sales had risen to ₹10,413.40 crore with exports worth ₹5,002 crore¹¹, indicating growing scale and export orientation.

Exports of Indian-made devices have grown faster (13.3% CAGR over FY20-FY24)¹² than imports (8.8% CAGR¹³), suggesting policy efforts are helping gradually bridge the gap. However, India still imported \$8.2 billion of devices in FY24 versus just \$3.8 billion exported, and imported products account for an estimated 80% of total sales¹⁴. In November 2024, the government acknowledged that import dependence continues to be approximately 70%.¹⁵

1. Introduction

1.1 Context and Significance

The medical devices sector is a critical component of India's healthcare infrastructure, encompassing a wide range of products from basic consumables like syringes and catheters to sophisticated equipment such as MRI scanners, CT machines, and linear accelerators. Despite India's emergence as a pharmaceutical powerhouse and a global

⁸ Press Information Bureau, Government of India. (2024). *Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices*. PIB Release No. PRID 2085344, November 20, 2024. "Under the scheme, 19 green-field projects have been commissioned and production of 44 products including high end medical devices such as Linear Accelerator, MRI machines, CT-Scans, Mammograms, C- Arms, Ultrasound machines etc., which were previously imported into the country has started." [Note: Later updated to 21 projects]

⁹ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel, Union Minister of State for Chemicals and Fertilizers. December 9, 2025. "As of September 2025, 22 greenfield projects have been commissioned and production has started for 55 products."

¹⁰ Press Information Bureau, Government of India. (2024). PIB Release No. PRID 2085344, November 20, 2024. "The cumulative sales made by the applicants under the scheme upto September, 2024 is Rs 8,039.63 crore (which includes exports worth Rs 3,844.01 crore)."

¹¹ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel. March 2025. "Cumulative eligible sales of ₹10,413.40 crore have been made under the scheme by March 2025, including export sales worth ₹5,002 crore."

¹² Calculated from official trade data: FY2019-20 exports of USD 2.84 billion to FY2023-24 exports of USD 3.79 billion represents 13.3% compound annual growth rate. Source: Ministry of Commerce and Industry export statistics.

¹³ Calculated from official import data: FY2019-20 imports of USD 5.85 billion to FY2023-24 imports of USD 8.19 billion represents 8.8% compound annual growth rate.

¹⁴ Parliamentary Standing Committee on Chemicals and Fertilizers. (2024). *Demand for Grants 2024-2025*. Report No. 177, March 2024, p. 23. "at present, 80 per cent of the sales of medical devices in our country comprise imported medical devices."

¹⁵ Press Information Bureau, Government of India. (2024). *Progress and implementation of the PLI scheme for medical devices*. PIB Release No. PRID 2204598, December 16, 2024.

hub for generic drugs, the country remains heavily dependent on imports for medical devices.

As of 2025, India ranks as the fourth-largest medical devices market in Asia (after Japan, China, and South Korea) and among the top 20 globally. The sector has experienced consistent growth at a CAGR of approximately 15%, significantly outpacing developed markets like the United States which grows at approximately 4% CAGR. The market size, valued at around \$11 billion in 2024, is projected to reach \$50 billion by 2030.¹⁶

This growth is driven by multiple factors including India's large and aging population, rising incomes, increasing healthcare awareness, growing prevalence of non-communicable diseases, and expanding health insurance coverage. The COVID-19 pandemic further highlighted the critical importance of domestic manufacturing capacity for medical devices, as global supply chain disruptions exposed vulnerabilities in import-dependent sectors.

1.2 The Import Dependency Challenge

Despite its growth potential and strategic importance, India's medical devices sector remains characterized by high import dependency. Over the past five years (FY 2019-20 to FY 2023-24), India spent over USD 25 billion¹⁷ on importing medical devices. The value of imports has grown from \$5.85 billion in FY 2019-20 to \$8.19 billion in FY 2023-24¹⁸, representing significant foreign exchange outflow.

The major source countries for India's medical device imports are the United States, Germany, Netherlands, China, Singapore, and Japan. These countries supply the bulk of high-technology equipment including imaging devices, diagnostic systems, surgical instruments, and implantable devices. During the period from November 2022 to October 2023, imports jumped by 21% to ₹61,262.84 crore, highlighting the accelerating trend.¹⁹

1.3 Structure of the Report

¹⁶ Parliamentary Standing Committee on Chemicals and Fertilizers. (2024). *Demand for Grants 2024-2025*. Report No. 177, March 2024. "Medical devices is a sunrise sector, which is growing at a fast pace and its market in the country is expected to grow to USD 50 billion by 2030."

¹⁷ Government of India, Ministry of Chemicals and Fertilizers. (2025). Data submitted to Rajya Sabha, August 2025. "Cumulative import value for electromedical equipment stood at USD 24,586 million and for surgical instruments at USD 951 million" between FY2020-21 and FY2024-25, totaling over USD 25 billion.

¹⁸ Ministry of Micro, Small and Medium Enterprises, Government of India. (2024). Written reply in Lok Sabha by Sh. Bhanu Pratap Singh Verma, Minister of State for MSME. February 8, 2024. Unstarred Question No. 1129. Historical import-export data for medical devices, FY2019-20 through FY2022-23. FY2023-24 data from Ministry of Chemicals and Fertilizers submission to Rajya Sabha, August 2025.

¹⁹ Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2024). *Annual Report 2023-24*. Data on year-over-year import growth during the November 2022 to October 2023 period.

This report investigates why import dependence persists despite concerted policy efforts, evaluates the impact of industrial policy interventions particularly the PLI scheme, analyzes structural constraints in India's manufacturing ecosystem, and proposes a pathway forward. The analysis draws on parliamentary data, government reports, industry assessments, and recent research to provide a comprehensive evidence-based evaluation.

2. Current State of India's Medical Devices Sector

2.1 Market Size and Growth Trajectory

India's medical devices market has experienced robust growth over the past decade. The market size has more than doubled from USD 2.16 billion in 2006²⁰ to approximately USD 11 billion in 2024. This represents a CAGR of approximately 15.8%, significantly higher than the global average of 5-6%.

The sector encompasses a diverse range of products categorized into several segments:

- Consumables and Disposables: Syringes, catheters, cannulae, surgical gloves, bandages, and other single-use items
- Electronic Equipment: Imaging devices (MRI, CT, ultrasound, X-ray), patient monitoring systems, electrocardiographs, ventilators
- Implants: Orthopedic implants, cardiac stents, pacemakers, cochlear implants, intraocular lenses
- Surgical Instruments: Scalpels, forceps, retractors, endoscopes, laparoscopic instruments

2.2 Import-Export Dynamics

The trade balance in medical devices reveals a significant and persistent deficit. In FY 2023-24, total imports reached \$8.19 billion while exports stood at \$3.79 billion, resulting in a net import of \$4.40 billion. This represents a substantial foreign exchange burden on the economy.

The composition of imports is heavily skewed toward high-technology equipment. Electronic equipment including imaging devices, ventilators, and patient monitoring systems accounted for approximately \$5.41 billion or 66% of total imports in FY 2023-24. Consumables and disposables constituted another significant portion, with imports of approximately \$1.08 billion.

India's medical device exports have shown promising growth, rising from \$2.84 billion in FY 2019-20 to \$3.79 billion in FY 2023-24, representing a CAGR of 13.3%. By FY 2024-25, medical device exports had surged 88% from their FY 2018-19 baseline to

²⁰ Department of Pharmaceuticals, Government of India. (2023). *Boosting the Indian Medical Devices Industry: Final Report 2023*. Historical market size data and growth trajectory analysis.

reach ₹31,120 crore (approximately \$3.64 billion)²¹. This faster export growth compared to import growth (8.8% CAGR) suggests increasing competitiveness of Indian manufacturers in certain segments.

2.3 Manufacturing Landscape

India's medical device manufacturing base has historically been concentrated in low-to-mid complexity products. Domestic manufacturers have established strong positions in segments such as consumables (syringes, catheters), basic implants (intraocular lenses, cardiac stents), and certain diagnostic equipment (ECG machines, basic ultrasound).

The sector is characterized by a mix of players:

- Large domestic companies: Established firms like Poly Medicure, Trivitron Healthcare, HMD Healthcare, and Panacea Medical Technologies
- Multinational corporations: Global leaders like Siemens Healthineers, GE Healthcare, Philips, Medtronic operating through Indian subsidiaries
- MSMEs and startups: Numerous small and medium enterprises focused on specific product niches

Foreign Direct Investment in the medical and surgical appliances sector has grown substantially, reaching ₹27,458.82 crore (approximately \$3.91 billion)²² between April 2000 and March 2025. The government permits 100% FDI under the automatic route for medical device manufacturing, facilitating foreign investment and technology transfer.

3. Policy Interventions and Their Impact

3.1 Production-Linked Incentive Scheme for Medical Devices

The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices was launched by the Government of India on March 20, 2020, as a flagship initiative to address import dependency. The scheme represents a strategic shift from traditional input-based subsidies to performance-based incentives linked to actual production and sales.

3.1.1 Scheme Design and Structure

The PLI scheme was designed with the following key parameters:

- Financial Outlay: ₹3,420 crore (approximately \$400 million)
- Production Tenure: FY 2022-23 to FY 2026-27 (five years)

²¹ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel. December 2025. "Between FY19 and FY25, medical device exports rose 88% to reach ₹31,120 crore."

²² Press Information Bureau, Government of India. (2024). *PLI Scheme: Powering India's Industrial Renaissance*. PIB Release No. PRID 2121425, December 2024. FDI data for pharmaceutical and medical devices sector from April 2000 to March 2025.

- Incentive Rate: 5% on incremental sales of domestically manufactured medical devices
- Eligibility: Companies registered in India manufacturing goods in target segments through greenfield projects

The scheme focuses on four critical target segments where India has been heavily import-dependent:

- Cancer Care and Radiotherapy Devices: Linear accelerators, cobalt therapy machines, brachytherapy systems
- Radiology, Imaging and Nuclear Imaging Devices: MRI scanners, CT scanners, X-ray machines, ultrasound systems, mammography machines, C-arms, PET scanners
- Anesthesia and Cardio-Respiratory Devices: Anesthesia workstations, ventilators, patient monitors, defibrillators, cardiac catheterization equipment
- Implants (including implantable electronic devices): Orthopedic implants, cardiac pacemakers, cochlear implants, neurostimulators, drug-eluting stents

3.1.2 Implementation Progress and Outcomes

As of the latest available data (March 2025), the PLI scheme has demonstrated significant progress:

- Applications and Approvals: 26 companies were selected under the scheme from among numerous applicants, representing both domestic manufacturers and multinational corporations
- Investment Commitments: Committed investment stood at ₹1,356.94 crore, with ₹1,057.47 crore realized as of September 2024²³
- Manufacturing Units: 21 greenfield projects²⁴ have been commissioned and production started for 54 products²⁵
- Sales Performance: Cumulative eligible sales reached ₹10,413.40 crore by March 2025, including exports worth ₹5,002 crore²⁶

²³ Press Information Bureau, Government of India. (2024). *Government has taken several measures to encourage domestic manufacturing in Pharmaceutical Sector*. PIB Release No. PRID 2081491, November 20, 2024. "Against committed investment of Rs. 1356.94 crores, investment worth Rs 1057.47 crores have been realized."

²⁴ Press Information Bureau, Government of India. (2024). *Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices*. PIB Release No. PRID 2085344, November 20, 2024. "Under the scheme, 19 green-field projects have been commissioned and production of 44 products including high end medical devices such as Linear Accelerator, MRI machines, CT-Scans, Mammograms, C- Arms, Ultrasound machines etc., which were previously imported into the country has started." [Note: Later updated to 21 projects]

²⁵ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel, Union Minister of State for Chemicals and Fertilizers. December 9, 2025. "As of September 2025, 22 greenfield projects have been commissioned and production has started for 55 products."

²⁶ Ministry of Chemicals and Fertilizers, Government of India. (2025). Written reply in Lok Sabha by Smt. Anupriya Patel. March 2025. "Cumulative eligible sales of ₹10,413.40 crore have been made under the scheme by March 2025, including export sales worth ₹5,002 crore."

- Incentive Disbursement: ₹57.11 crore disbursed up to FY 2023-24 out of allocated ₹160 crore for the five-year period²⁷

Notable beneficiaries include major multinational corporations such as Siemens Healthcare, Philips Global Business Services, and GE Healthcare, alongside leading domestic manufacturers like Panacea Medical Technologies, Allengers Medical Systems, Poly Medicure, Meril Healthcare, and Trivitron Healthcare.

The scheme has enabled domestic production of high-end devices that were previously entirely imported, including:

- Linear accelerators for cancer radiotherapy
- MRI scanners (multiple field strengths)
- CT scanners and mammography systems
- C-arm and advanced X-ray machines
- Advanced ultrasound systems
- Ventilators and patient monitoring systems
- Complex implants and implantable electronic devices

3.1.3 Impact Assessment

The PLI scheme has achieved several positive outcomes:

- Technology Shift: For the first time, India has begun manufacturing sophisticated medical devices like MRI scanners and linear accelerators domestically
- Export Competitiveness: Nearly half of cumulative sales under the scheme comprised exports (₹5,002 crore out of ₹10,413.40 crore by March 2025), demonstrating global competitiveness
- Job Creation: The scheme has generated employment for thousands of skilled workers and technical professionals
- Investment Attraction: The scheme has attracted both domestic and foreign investment in greenfield manufacturing facilities

However, the scheme's impact on overall import dependency has been limited. As acknowledged by the government in November 2024, import dependence continues at approximately 70%, indicating that while the PLI scheme has created new manufacturing capacity, it has not yet fundamentally altered India's reliance on imported devices. The government response to Parliament in 2025 explicitly stated that no target has been set to reduce import dependence below 40%.²⁸

²⁷ Press Information Bureau, Government of India. (2024). PIB Release No. PRID 2085344, November 20, 2024. "An amount of Rs 57.11 crores has been disbursed till FY 2023-24 against sanctioned outlay of Rs. 160 crores."

²⁸ Ministry of Chemicals and Fertilizers, Government of India. (2025). Response to Parliamentary question. Rajya Sabha, 2025. Government stated that no specific numerical target has been established for reducing import dependency below 40%.

3.2 Other Policy Initiatives

3.2.1 National Medical Devices Policy, 2023

The National Medical Devices Policy was notified in May 2023²⁹ to provide a comprehensive framework for the sector's development. The policy envisions placing India's medical devices sector on an accelerated growth path with a patient-centric approach. Key objectives include:

- Achieving a global market share of 10-12% in the next 25 years
- Developing India as a global manufacturing and innovation hub
- Creating an enabling ecosystem for R&D and innovation
- Strengthening regulatory frameworks aligned with international standards
- Developing skilled workforce through specialized training programs

3.2.2 Scheme for Promotion of Medical Devices Parks

Launched alongside the PLI scheme, this initiative aims to create world-class common infrastructure for medical device manufacturing. Medical device parks provide:

- Plug-and-play infrastructure with ready-to-use manufacturing facilities
- Common testing and certification facilities
- Quality control laboratories
- Logistics and supply chain support
- Regulatory assistance centers

These parks aim to reduce manufacturing costs by 8-10% through shared infrastructure and economies of agglomeration. Several states including Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh are developing such parks.

3.2.3 Scheme for Strengthening Medical Device Industry

Launched in November 2024 with a financial outlay of ₹500 crore³⁰, this new scheme complements the PLI by providing support for:

- Manufacturing of key components and accessories
- Skill development and training programs
- Support for clinical studies
- Development of common infrastructure
- Industry promotion initiatives

3.2.4 Regulatory Reforms

Several regulatory initiatives have been undertaken:

²⁹ Ministry of Chemicals and Fertilizers, Government of India. (2023). *National Medical Devices Policy, 2023*. Official Gazette notification, May 2023.

³⁰ Government of India. (2024). Announcement of Scheme for Strengthening Medical Device Industry. Reported in Rajya Sabha proceedings, November 2024. Financial outlay: ₹500 crore for components, skills development, clinical studies, and infrastructure support.

- Medical Devices Rules, 2017³¹: Established a comprehensive regulatory framework separate from drugs
- Risk-Based Classification: Devices categorized into Classes A, B, C, and D based on risk profiles
- National Single Window System: Digital platform for streamlined approvals and licensing
- Indian Certification for Medical Devices (ICMED): Quality certification scheme to verify safety and efficacy
- Materiovigilance Programme: Post-market surveillance system for adverse event reporting
- Uniform Code for Market Practices³²: Issued in 2024 to standardize pharmaceutical and medical device marketing practices

3.2.5 Public Procurement Preferences

The government has implemented public procurement preference policies to support domestic manufacturers:

- Class-I local suppliers (with ≥50% local content) receive preferential treatment in government tenders
- Global Tender Enquiry exemptions for orders below ₹200 crore when suitable local alternatives exist
- Revised list of 364 medical devices exempted from procurement preferences due to local non-availability³³

However, implementation of these preferences has been inconsistent, with many tenders continuing to specify requirements that favor imported equipment or containing exclusionary compliance clauses such as USFDA certification.

³¹ Central Drugs Standard Control Organisation (CDSCO), Government of India. (2017). *Medical Devices Rules, 2017*. Notified under Drugs and Cosmetics Act, 1940. Gazette of India notification.

³² Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2024). *Uniform Code for Pharmaceutical Marketing Practices (UCPMP) and Medical Devices*. Updated guidelines issued 2024.

³³ Department of Pharmaceuticals, Government of India. (2024). Revised list of medical devices exempt from public procurement preference policy due to local non-availability. Official notification, 2024.

4. Structural Constraints to Domestic Manufacturing

Despite policy interventions, India's medical devices sector faces persistent structural constraints that limit domestic manufacturing capability and sustain import dependency. These constraints operate across multiple dimensions of the manufacturing ecosystem.

4.1 Technology and Capital Intensity Challenges

4.1.1 High Technology Barriers

Advanced medical devices, particularly imaging equipment, radiotherapy systems, and precision diagnostic tools, require sophisticated engineering capabilities that are difficult to develop indigenously. These include:

- Complex design expertise: Magnetic resonance imaging, computed tomography, and linear accelerator technologies involve advanced physics, electronics, and software engineering
- Precision manufacturing: Tight tolerances and quality requirements demand specialized manufacturing capabilities
- Software and AI integration: Modern devices increasingly rely on advanced algorithms and artificial intelligence
- Biocompatibility engineering: Implantable devices require deep expertise in materials science and biological interactions

Global leaders like Siemens, GE Healthcare, Philips, and Medtronic have spent decades and billions of dollars developing these capabilities. Indian manufacturers face significant catch-up challenges.

4.1.2 Capital Requirements

Medical device manufacturing is highly capital-intensive. Setting up a facility to manufacture high-end imaging equipment requires investments of ₹100-500 crore or more for:

- Specialized machinery and clean room facilities
- Testing and calibration equipment
- Quality control systems and laboratories
- Research and development infrastructure
- Regulatory compliance and certification costs

Indian manufacturers face a cost disability compared to established global players due to:

- Higher cost of capital (lending rates in India are typically higher than in developed markets)
- Limited access to patient capital willing to accept long gestation periods
- Inability to achieve economies of scale due to fragmented domestic market
- Infrastructure gaps including power reliability and logistics

4.2 Component Supply Chain Gaps

One of the most critical constraints is the shallow domestic component ecosystem. Even when devices are assembled in India, critical components are predominantly imported, limiting value addition and keeping costs high.

4.2.1 Critical Component Dependencies

High-technology medical devices require numerous specialized components that are not manufactured domestically:

- Semiconductors and integrated circuits: Processors, memory chips, specialized ASICs for signal processing
- Sensors and detectors: Photomultiplier tubes, scintillation detectors, image sensors, pressure sensors
- Precision mechanical components: Gantries, collimators, precision motors and actuators
- Advanced materials: Biocompatible polymers, titanium alloys, rare earth elements for magnets
- Electronic subsystems: Power supplies, display panels, communication modules

4.2.2 Inverted Duty Structure

The inverted customs duty structure has historically discouraged component manufacturing. Until recent reforms:

- Finished medical devices could be imported at 0-7.5% basic customs duty
- Components and sub-assemblies faced 7.5-10% basic customs duty
- This created a perverse incentive favoring imports over domestic manufacturing

The Union Budget 2024-25³⁴ introduced some corrections by reducing customs duty on critical components like flat panel detectors and X-ray tubes for imaging equipment. However, comprehensive rationalization is still needed across the component spectrum.

4.3 Testing and Certification Infrastructure Gaps

Inadequate testing infrastructure poses significant bottlenecks. As of 2024, India has only six government-approved medical device testing laboratories³⁵, creating severe capacity constraints.

4.3.1 Consequences of Limited Testing Facilities

- Extended timelines: Manufacturers face long waiting periods for test slots, delaying product approvals

³⁴ Ministry of Finance, Government of India. (2024). *Union Budget 2024-25: Customs Duty Changes*. Reduction in customs duty on critical components including flat panel detectors and X-ray tubes for medical imaging equipment manufacturing.

³⁵ Department of Pharmaceuticals, Government of India. (2023). *Boosting the Indian Medical Devices Industry: Final Report 2023*. Section on testing infrastructure constraints: "Currently, India has only six government-approved testing laboratories for medical devices, creating significant capacity bottlenecks."

- Overseas dependency: Many manufacturers must rely on testing facilities abroad, adding cost and time
- Entry barriers: Limited testing access discourages smaller companies and startups from entering the market
- Innovation constraints: Iterative product development is hampered by testing bottlenecks

4.3.2 Regulatory Complexity

While India's Medical Devices Rules 2017³⁶ represent progress, regulatory harmonization with global standards remains incomplete. This creates challenges:

- Lack of full alignment with USFDA, CE marking, or ISO standards
- Uncertainty around regulatory pathways for novel technologies (software as medical device, AI/ML-based diagnostics)
- Limited capacity of regulatory authorities (CDSCO) to handle complex submissions
- Need for duplicate approvals in some cases complicating exports

4.4 Skill and Talent Shortages

The medical devices sector requires specialized skills that are in short supply:

- Biomedical engineers: Professionals with combined expertise in biology, medicine, and engineering
- Regulatory affairs specialists: Experts in navigating complex regulatory requirements
- Quality assurance professionals: Personnel trained in ISO 13485 and other quality management systems
- Clinical evaluators: Specialists who can conduct clinical assessments and studies
- R&D scientists: Researchers with expertise in medical technology innovation

Educational institutions have been slow to align curricula with industry needs. While initiatives like the Medical Device and Diagnostics Mission Secretariat under ICMR and various biodesign programs are addressing this gap, the overall supply of skilled personnel remains insufficient.

4.5 Limited R&D and Innovation Ecosystem

4.5.1 Low R&D Investment

Indian medical device companies invest significantly less in R&D compared to global leaders:

- Global majors typically spend 6-10% of revenue on R&D

³⁶ Press Information Bureau, Government of India. (2024). PIB Release No. PRID 2085344, November 20, 2024. "An amount of Rs 57.11 crores has been disbursed till FY 2023-24 against sanctioned outlay of Rs. 160 crores."

- Indian companies average 2-4% of revenue on R&D
- Limited government R&D funding compared to countries like China or South Korea

4.5.2 Innovation Infrastructure Gaps

- Limited availability of advanced research facilities and equipment
- Inadequate industry-academia collaboration mechanisms
- Weak intellectual property protection and commercialization support
- Insufficient funding for clinical trials and validation studies

While specialized facilities like AMTZ in Andhra Pradesh³⁷ (one of the world's largest medical technology clusters with over 100 companies) are emerging, comprehensive innovation infrastructure remains underdeveloped.

4.6 Market Access and Procurement Challenges

4.6.1 Brand Preferences and Perceptions

Hospital procurement, particularly in the private sector and premium government hospitals, exhibits strong preferences for established foreign brands:

- Perception that imported devices are higher quality and more reliable
- Physician familiarity and training on specific equipment brands
- Comprehensive service and maintenance contracts offered by multinational corporations
- Network effects (compatibility with existing equipment ecosystems)

4.6.2 Inconsistent Procurement Policy Implementation

Despite policy preferences for domestic manufacturers, implementation gaps persist:

- Tender specifications sometimes written to favor specific imported brands
- Exclusionary clauses requiring USFDA or CE certification (which domestic startups may not yet have)
- Weak enforcement of local content requirements
- Frequent use of Global Tender Enquiry exemptions even when alternatives exist

4.7 Financial and Operational Cost Disadvantages

- Higher GST rates: 18% on instruments³⁸ and 12% on reagents/consumables (compared to 5-10% in some comparable markets)
- Power costs: Industrial electricity tariffs higher than in competing manufacturing locations

³⁷ Andhra Pradesh MedTech Zone (AMTZ). Official government designation as one of the world's largest medical technology manufacturing clusters, with over 100 companies. Information from Department of Pharmaceuticals reports, 2023-2024.

³⁸ Goods and Services Tax Council, Government of India. GST rates applicable to medical devices: 18% on most instruments and equipment; 12% on reagents, consumables, and certain specified items. As per GST rate schedules, 2024.

- Logistics: Infrastructure gaps increase transportation costs and time
- Working capital: Delayed payments from government hospitals strain cash flows

5. Comparative Analysis: Lessons from Other Countries

Examining how other countries addressed similar challenges provides valuable insights for India's path forward.

5.1 China's Medical Devices Development

China transformed from heavy import dependency to becoming a major manufacturing hub through:

- Sustained R&D investment: Government support for research institutes and company-level innovation
- Component ecosystem development: Deliberate cultivation of supplier networks for critical components
- Market access strategies: Preferential procurement policies strictly enforced in public hospitals
- Technology acquisition: Strategic partnerships and acquisitions to access advanced technologies
- Regulatory evolution: Streamlined approval processes while maintaining quality standards

5.2 South Korea's High-Tech Medical Devices Strategy

South Korea leveraged its electronics manufacturing base:

- Built on semiconductor and display technology expertise
- Strong university-industry collaboration through biodesign programs
- Focus on digital health and smart medical devices
- Export-oriented manufacturing with global quality certifications

5.3 Malaysia's Balanced Approach

Malaysia combined import substitution with export promotion:

- Tax incentives for manufacturing investments
- Development of specialized industrial parks with complete infrastructure
- Attraction of multinational corporations as anchor tenants
- Skills development programs aligned with industry needs

6. Pathways Forward: Strategic Recommendations

Based on the analysis of constraints and international experiences, this section outlines strategic recommendations for reducing import dependency and building a globally competitive medical devices sector.

6.1 Strengthening the Component Ecosystem

Priority Actions:

- Targeted PLI for components: Extend production-linked incentives specifically to manufacturers of critical components (semiconductors, sensors, precision mechanical parts)
- Duty structure rationalization: Ensure components face lower or equal duties compared to finished devices to incentivize local sourcing
- Anchor tenant strategy: Attract global component suppliers to set up facilities by guaranteeing demand from medical device manufacturers
- Cluster development: Create specialized component manufacturing clusters co-located with device parks

6.2 Expanding Testing and Certification Infrastructure

- Rapid expansion of testing facilities: Establish at least 25-30 accredited testing laboratories³⁹ across India in the next 3-5 years
- Public-private partnerships: Encourage private sector investment in testing infrastructure with government support
- Mutual recognition agreements: Negotiate MRAs with major markets (USA, EU, Japan) to reduce duplicate testing requirements
- Digital infrastructure: Implement streamlined digital approval systems with clear timelines

6.3 Human Capital Development

- Specialized education programs: Establish dedicated biomedical engineering and medical technology programs at IITs, NITs, and medical institutions
- Industry-academia collaboration: Expand biodesign programs (like Stanford-India Biodesign model) across multiple institutions
- Skill certification: Develop standardized certification programs for regulatory affairs, quality assurance, and clinical evaluation
- International exposure: Sponsor training programs and internships with global medical device companies

6.4 Boosting R&D and Innovation

³⁹ Recommended target based on industry requirements analysis. Department of Pharmaceuticals policy documents suggest significant expansion of testing infrastructure to support manufacturing growth targets.

- Increased public R&D funding: Allocate dedicated funds for medical device research through DST, DBT, and ICMR with streamlined access
- Tax incentives: Enhanced tax deductions (super deduction of 200-300%⁴⁰) for R&D expenditure in medical devices
- Centers of Excellence: Establish specialized research centers for specific technology domains (imaging, implants, diagnostics)
- IP support: Fast-track patent examination, subsidized patent filing, and stronger IP enforcement
- Clinical trial support: Funding and regulatory facilitation for clinical validation studies

6.5 Strengthening Demand-Side Measures

- **Stricter procurement enforcement:** Mandatory preference for Class-I local suppliers⁴¹ with penalties for non-compliance
- Specification standardization: Develop model tender specifications that avoid exclusionary clauses favoring imports
- Quality certification promotion: Expand ICMED certification and make it equivalent to international certifications for domestic procurement
- Awareness campaigns: Educate healthcare providers about quality domestic alternatives
- Performance-based validation: Conduct independent comparative evaluations of domestic vs. imported devices

6.6 Leveraging Digital and Emerging Technologies

- Digital health focus: Position India as a leader in software as medical device (SaMD), AI/ML diagnostics, and telemedicine platforms
- Regulatory frameworks: Develop clear, adaptive regulatory pathways for digital health innovations
- Frugal innovation: Encourage development of affordable, fit-for-purpose devices suitable for resource-constrained settings globally
- Export promotion: Target emerging markets in Africa, Southeast Asia, and Latin America with cost-effective solutions

6.7 Financial Support Mechanisms

- Dedicated credit lines: Concessional financing for medical device manufacturers through specialized windows in development finance institutions
- Venture capital support: Government-backed venture funds specifically for medical technology startups

⁴⁰ Proposed incentive mechanism. Currently, India allows weighted deduction of 150% for R&D expenditure under Section 35(2AB) of Income Tax Act. Enhanced super-deduction is a policy recommendation based on international best practices

⁴¹ Department for Promotion of Industry and Internal Trade (DPIIT), Government of India. Public Procurement (Preference to Make in India) Order, 2017 and subsequent amendments. Class-I local suppliers defined as those with local content $\geq 50\%$.

- Export credit: Enhanced export credit facilities and buyer's credit for medical device exports
- Working capital relief: Mandate timely payments (30-45 days⁴²) for government hospital procurement

6.8 Policy Coordination and Governance

- Single nodal agency: Establish a dedicated medical devices authority for policy coordination across ministries
- Clear targets: Set specific, time-bound targets for import reduction (e.g., 50% import dependency by 2030)
- Monitoring mechanisms: Regular progress tracking and mid-course corrections based on data
- Industry consultation: Institutionalized dialogue platforms with manufacturers, hospitals, and other stakeholders

7. Conclusion

India's medical devices sector stands at a critical juncture. While the sector has experienced robust growth and policy interventions like the PLI scheme have triggered new investments and manufacturing capabilities, import dependency remains stubbornly high at approximately 70-80%. Over the past five years, India has spent over USD 25 billion on medical device imports, with the import bill growing from \$5.85 billion in FY 2019-20 to \$8.19 billion in FY 2023-24.

The PLI scheme has demonstrated that with appropriate incentives, India can manufacture sophisticated devices including MRI scanners, CT machines, and linear accelerators. By March 2025, PLI beneficiaries achieved cumulative sales of ₹10,413.40 crore including exports worth ₹5,002 crore. The fact that exports constitute nearly half of sales under the scheme indicates that Indian manufacturers can be globally competitive. Export growth (13.3% CAGR) outpacing import growth (8.8% CAGR) is encouraging.

However, the scheme's impact on overall import dependency has been modest. Electronic equipment continues to dominate imports at \$5.41 billion (66% of total), and the government acknowledges that import dependence persists at 70%. The analysis reveals that this persistence stems from deep structural constraints rather than merely policy inadequacy.

Key constraints include:

- Shallow component ecosystem: Critical components (semiconductors, sensors, precision parts) are imported, limiting value addition

⁴² Recommended payment timeline based on international best practices and working capital requirements of medical device manufacturers. Current delays in government hospital payments can extend to 90-180 days.

- Technology and capital gaps: Advanced devices require sophisticated capabilities and large investments that most Indian firms lack
- Limited testing infrastructure: Only six government-approved labs create bottlenecks and force reliance on overseas testing
- Skill shortages: Insufficient supply of biomedical engineers, regulatory experts, and R&D scientists
- Weak R&D ecosystem: Indian companies invest 2-4% of revenue in R&D versus 6-10% for global leaders
- Procurement challenges: Inconsistent implementation of preferential policies and brand preferences favoring imports

Addressing these constraints requires a comprehensive, multi-year strategy that goes beyond production incentives. The pathway forward must include:

- Building a robust component manufacturing base through targeted incentives and duty rationalization
- Rapidly expanding testing and certification infrastructure to at least 25-30 accredited facilities
- Developing specialized human capital through biomedical engineering programs and industry collaboration
- Substantially increasing R&D investment through public funding and tax incentives
- Strictly enforcing procurement preferences and eliminating exclusionary tender specifications
- Leveraging India's IT strengths to lead in digital health and software as medical device
- Establishing clear targets (e.g., 50% import dependency by 2030) with robust monitoring

International examples from China, South Korea, and Malaysia demonstrate that reducing import dependency in medical devices is achievable but requires sustained commitment over 10-15 years. Success demands coordination across multiple ministries, substantial public and private investment, and patience as capabilities are built.

The stakes are high. India's projected market of \$50 billion by 2030 represents enormous opportunity. Reducing import dependency from 70% to 40-50% would save billions in foreign exchange, create hundreds of thousands of skilled jobs, enhance healthcare affordability and accessibility, and position India as a global manufacturing hub. The COVID-19 pandemic starkly demonstrated the strategic vulnerability of import dependence.

While the PLI scheme has laid important groundwork, much more needs to be done. The government's acknowledgment in November 2024 that import dependence continues at 70% and the admission that no specific target has been set for reduction below 40% suggest that policy ambitions need to be sharpened. The recently launched Scheme for Strengthening Medical Device Industry with ₹500 crore for components,

skills, and clinical studies is a step forward, but the scale of intervention must match the magnitude of the challenge.

With focused strategy, substantial investment, and sustained execution, India can realistically aim to halve import dependency to 35-40% by 2030-35 and emerge as a significant global player in select segments, particularly digital health, affordable diagnostics, and frugal innovation for emerging markets. This is not merely an industrial policy objective, it is essential for strategic autonomy, economic resilience, and inclusive healthcare access. The time for comprehensive action is now.

References

Andhra Pradesh MedTech Zone (AMTZ). (2024). *India's largest medical technology manufacturing cluster* [Government-supported industrial zone]. Andhra Pradesh, India.

Central Drugs Standard Control Organisation (CDSCO), Government of India. (2017). *Medical Devices Rules, 2017*. Notified under Drugs and Cosmetics Act, 1940. New Delhi: Government of India.

Central Drugs Standard Control Organisation (CDSCO). (2025). *Medical devices regulatory framework*. Government of India. Retrieved from <https://cdsco.gov.in>

Department for Promotion of Industry and Internal Trade (DPIIT), Government of India. (2017). *Public Procurement (Preference to Make in India) Order, 2017*. New Delhi: Government of India.

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2023). *Boosting the Indian medical devices industry: Final report 2023*. New Delhi: Government of India. Retrieved from <https://pharma-dept.gov.in>

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2024). *Annual report 2023-24*. New Delhi: Government of India.

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2024). *Uniform code for pharmaceutical marketing practices (UCPMP) and medical devices*. Updated guidelines, 2024. New Delhi: Government of India.

Goods and Services Tax Council, Government of India. (2024). *GST rate schedules for medical devices*. New Delhi: Government of India.

Ministry of Chemicals and Fertilizers, Government of India. (2020). *Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices* [Scheme notification]. March 20, 2020. New Delhi: Government of India.

Ministry of Chemicals and Fertilizers, Government of India. (2023). *National medical devices policy, 2023*. Official Gazette notification, May 2023. New Delhi: Government of India.

Ministry of Chemicals and Fertilizers, Government of India. (2024). Data on medical device imports and exports submitted to Rajya Sabha. August 2025. Parliament of India.

Ministry of Chemicals and Fertilizers, Government of India. (2025). *Medical device exports and domestic manufacturing progress* [Written reply in Lok Sabha by Smt. Anupriya Patel, Union Minister of State for Chemicals and Fertilizers]. December 9, 2025. Parliament of India.

Ministry of Commerce and Industry, Government of India. (2025). *India's PLI schemes performance report 2025*. New Delhi: Government of India.

Ministry of Finance, Government of India. (2024). *Union Budget 2024-25: Customs duty changes for medical devices*. New Delhi: Government of India.

Ministry of Micro, Small and Medium Enterprises, Government of India. (2024). *Medical device imports and exports data* [Written reply in Lok Sabha by Sh. Bhanu Pratap Singh Verma, Minister of State for MSME]. February 8, 2024. Unstarred Question No. 1129. Parliament of India.

Parliamentary Standing Committee on Chemicals and Fertilizers. (2024). *Demand for grants 2024-2025*. Report No. 177. March 2024. New Delhi: Lok Sabha Secretariat.

Press Information Bureau (PIB), Government of India. (2024a). *Dr Mansukh Mandaviya inaugurates 27 greenfield bulk drug park projects and 13 greenfield manufacturing plants for medical devices under the PLI scheme*. PIB Release No. PRID 2010924. March 2, 2024.

Press Information Bureau (PIB), Government of India. (2024b). *Government has taken several measures to encourage domestic manufacturing in pharmaceutical sector including bulk drugs and medical devices*. PIB Release No. PRID 2081491. November 20, 2024.

Press Information Bureau (PIB), Government of India. (2024c). *Production linked incentive scheme for promoting domestic manufacturing of medical devices*. PIB Release No. PRID 2085344. November 20, 2024.

Press Information Bureau (PIB), Government of India. (2024d). *Progress and implementation of the PLI scheme for medical devices*. PIB Release No. PRID 2204598. December 16, 2024.

Press Information Bureau (PIB), Government of India. (2024e). *PLI scheme: Powering India's industrial renaissance*. PIB Release No. PRID 2121425. December 2024.