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Review Article

Indian Medical Device Sector - Blue Print & Regulatory Policy Roadmap

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Abstract

Good quality, affordable and comprehensive healthcare to all its citizens is the new age universal mantra in Government lexicon. While healthcare infrastructure and indigenous medical device manufacturing are the areas in which most countries have achieved self-sufficiency, the medical device sector in India with about 80% import dependency needs focused attention and policy interventions to achieve self-sufficiency. In 2015, Government of India included medical device sector in its ambitious *Make in India* program. Since then, there have been various policy initiatives by the Government to address ecosystem requirements including rolling out of the Medical Device Rules 2017 to regulate devices, introduction of 100% FDI policy to attract foreign investments, addressing infrastructure gaps by setting-up Medical Device parks, incubators, accelerators, boosting innovation by supporting start-ups etc. The policies in this sector are evolving, changing frequently which brings in unpredictability and lack of confidence in manufacturers and importers e.g. notification of medical devices to be regulated as drugs, price capping etc. Indigenously developed medical devices lack credibility due to lack of comprehensive regulation of devices. The medical device industry in India is at its surge with about 800 manufacturers and 1000+ start-ups. The industry has expectations in terms of policy roadmap for catalyzing this sector and making it self-sustainable. This article covers key policy initiatives to boost medical device sector by the Government of India, highlights medical device industry expectations and the envisaged roadmap for developing a conducive ecosystem for fostering this sector in India with immense growth potential.

Keywords: Medical Device, In Vitro Diagnostics, Regulation, Policy, Medical Device Rules, Medical Device Industry, CDSCO, DCGI, FDI, CE mark, MDI, Government of India (GoI)

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1. Introduction

Medical Device Industry (MDI) is a multi-product diversified engineering industry ranging from simple tongue depresssors and glucometer strips to large radiology & electronic modules. (1) Global market for medical devices is over USD 220 billion[1]. The Medical devices industry in India is presently valued at USD 5.2 billion and contributes 4-5% to the USD 96.7 billion Indian health care industry. (2) The market size for this sector in India through retail sales is estimated to be over USD 10.00 billion (Rs. 61,800 Crore) in 2013-14, growing steadily at a rate of over 15-17% CAGR, currently about USD 15 billon. (3) The sector is highly import dependent with about 80% of the requirements being met through imports. (4) Considering huge import dependency and immense growth potential, Government of India (GoI) has included medical device sector in its flagship Make in India initiative to give this sector a structured push and policy impetus. All Medical Devices are not regulated in India and therefore in absence of holistic regulatory regime, Made in India medical devices lack credibility and market acceptance. The regulatory policies in the country are evolving and are being closely monitored by the world. This paper covers the status of Indian medical device industry as it stands today and includes various policy initiatives taken by the Government on one side and the requirements towards comprehensive regulations and enabling ecosystem of medical devices for ensuring patient safety and consumer protection being sought by the Industry. Based on the extensive experience of the authors and representing the Association of Indian Medical Device Industry (AiMeD), a roadmap and policy framework has

been proposed which could be relevant to the policy makers and other medical device stakeholders.

Data sources Study selection

The data for this study has been taken from the Government of India websites including from Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Ministry of Health and Family Welfare, Central Drugs Standard Control Organization (CDSCO), Make in India, Ministry of Commerce etc.

Some reports and policy papers published by globally recognized consultants and Industry associations have also been referred to in this article. Policy documents published by Association of Indian Medical Device Industry (AiMeD) have been referred to for including the perspective of Indian medical device industry.

2. Current Status of Indian Medical Device Industry Sector

In India, within MDI, the broad product classifications that exist are: i) Disposables & Consumables; ii) Surgical Instruments & Implants; iii) Equipment & Electronics & iv) Diagnostic Reagents. (4) Domestic manufacturing in India is concentrated around low cost devices such as intra-ocular lenses, catheters and syringes, with some success in development and production of implants. Some growth spikes have also been achieved in manufacturing of radiology and ultrasound products, Cath labs and linear accelerators. (5)

It is estimated that there are about 800 -1000 manufacturers in the country with average turnover of USD 5 million & average export turnover of USD 1.5 million. (1) The key Medical device manufacturers/ facilitators in the country are located as medical device clusters in various states. Figure 1 shows the key medical device clusters in India. (6)

As per the estimates by the Ministry of Commerce (MoC), Government of India (GoI), imports in the country crossed INR 43,365.9 Cr (USD 6.2 Bn) in 2018-19, as per the data compiled by Kalam Institute of Health Technology (KIHT) from MoC website, based on 153 HS codes and as per the data on imports based on 137 HS codes compiled by AiMeD, the imports crossed INR 38,837 Crores (USD 5.13 Bn) (Figure 2) and exports crossed 2.3 Billion USD (Rs. 16,300 Cr.) in year 2018-19. Market Share of imported medical devices in the country is estimated to be about 80% and about 90% for Medical Electronics. (7,8)

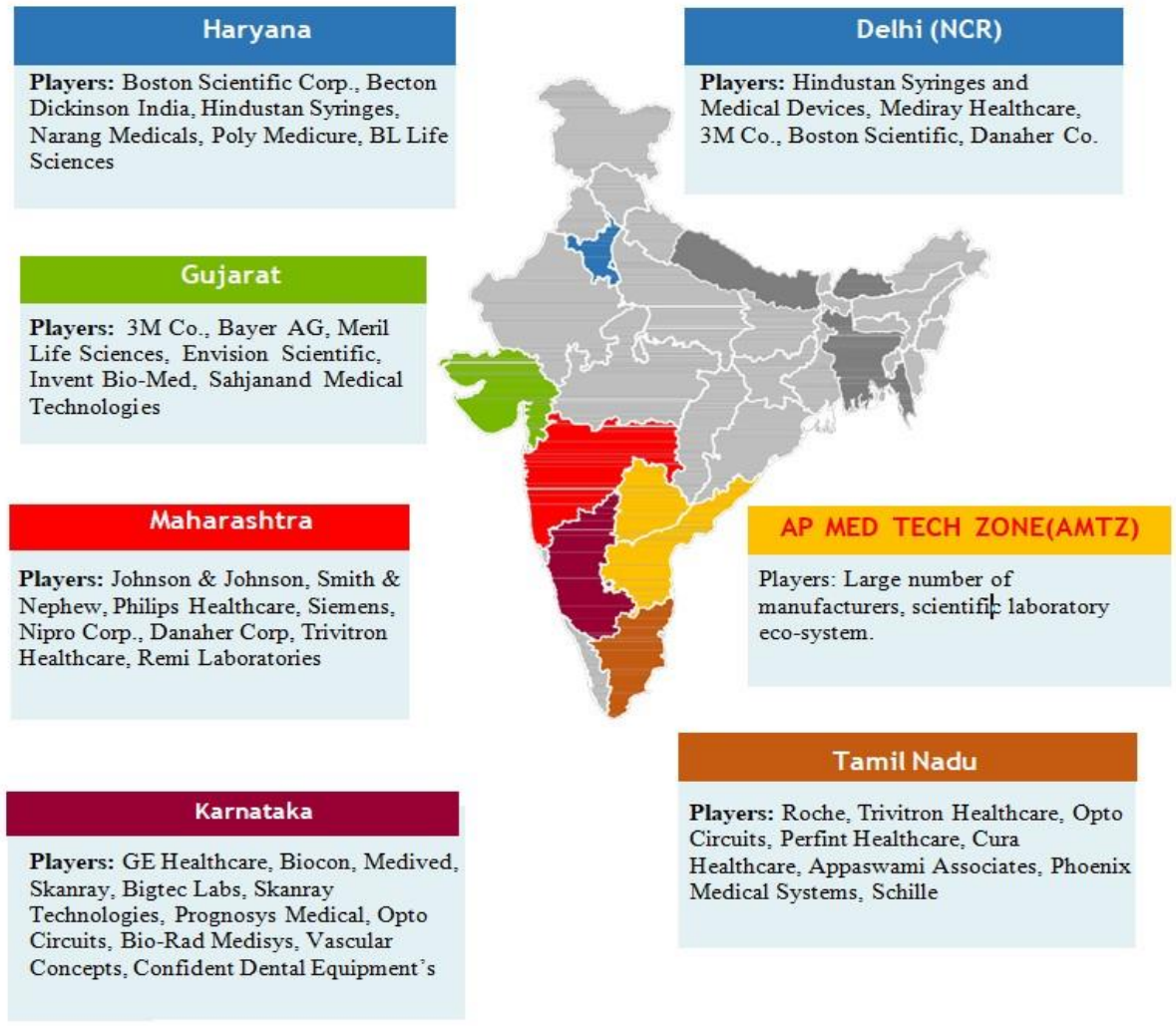

Figure 1. Medical Device Clusters in India (6)

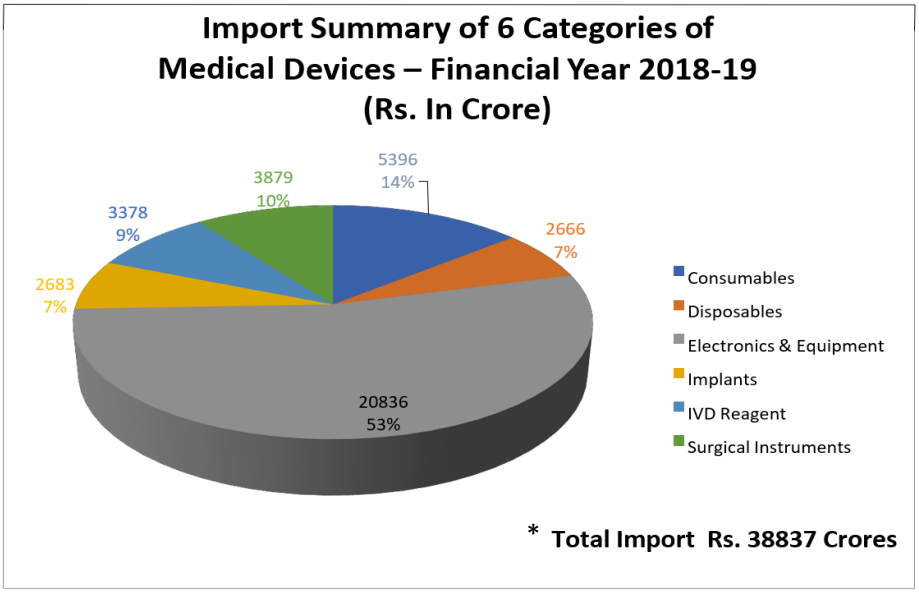

Figure 2. Category-wise Import Summary of Medical devices (2018-19) (7,8)
**(Data from 137 HS codes from MoC website compiled by AiMeD)*

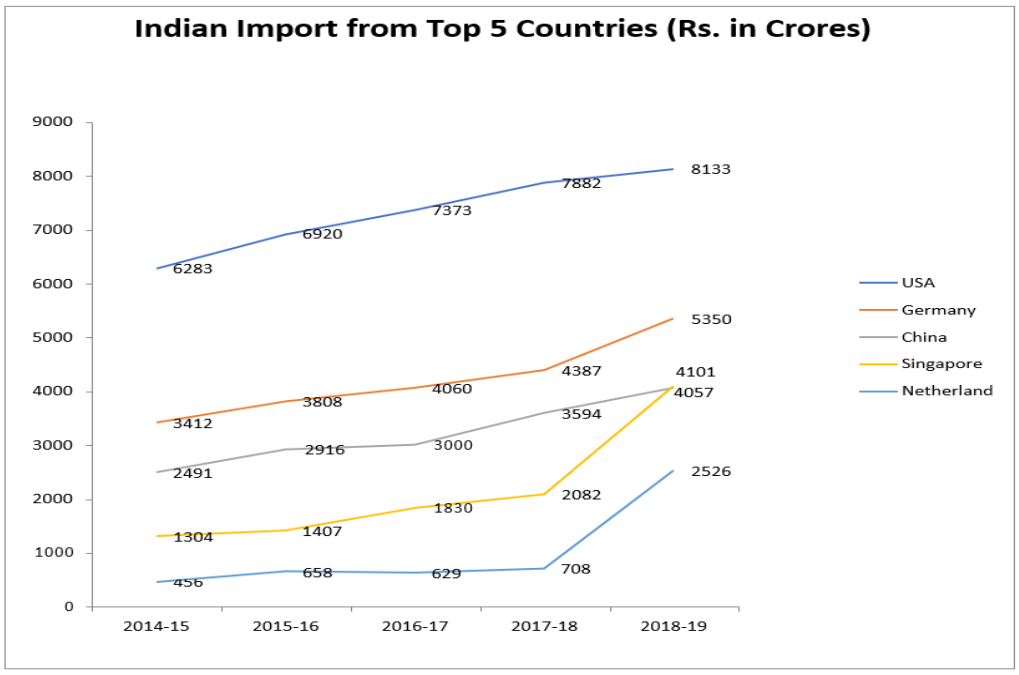

Figure 3. Year-wise status of imports in India for medical devices from top 5 countries (7,8)

India is a big market for Medical device imports by five (5) countries, viz. USA, Germany, China, Singapore and Netherland (7,8) (Figure 3)

The major share of medical device imports in the country is from USA while Germany stands second in terms of highest quantum of import of medical devices. (7)

There are six (6) broad categories of medical devices which are imported in India including Surgical Instruments, IVD Reagents, Implants, Electronics Equipment, Disposables and Consumables. Electronics equipment form a large section of imports from all the five countries as depicted in Figure 4. (7,8)

As per the import-export analysis in the medical device sector recorded by Ministry of Commerce, GoI between FY12 to FY16, the import of medical devices in India has increased by 16.8 per cent, whereas export increased by 25.7 per cent. Amongst the exporters' portfolio, USA was the chief destination for exports and contributed close to 15 per cent of the export trade. Singapore, Germany and China were other leading export destinations with shares of 7.0 per cent, 6.7 per cent and 6.4 per cent respectively. (7,8)

The European Union (including Germany) cumulatively constitutes 21.7% of the total export trade from India. USA, Germany, China, Japan and Singapore constitute the five largest exporters of high technology medical

equipment to India. Figure 5 highlights the exponential increase in the export of medical devices from India to other countries. (7,8)

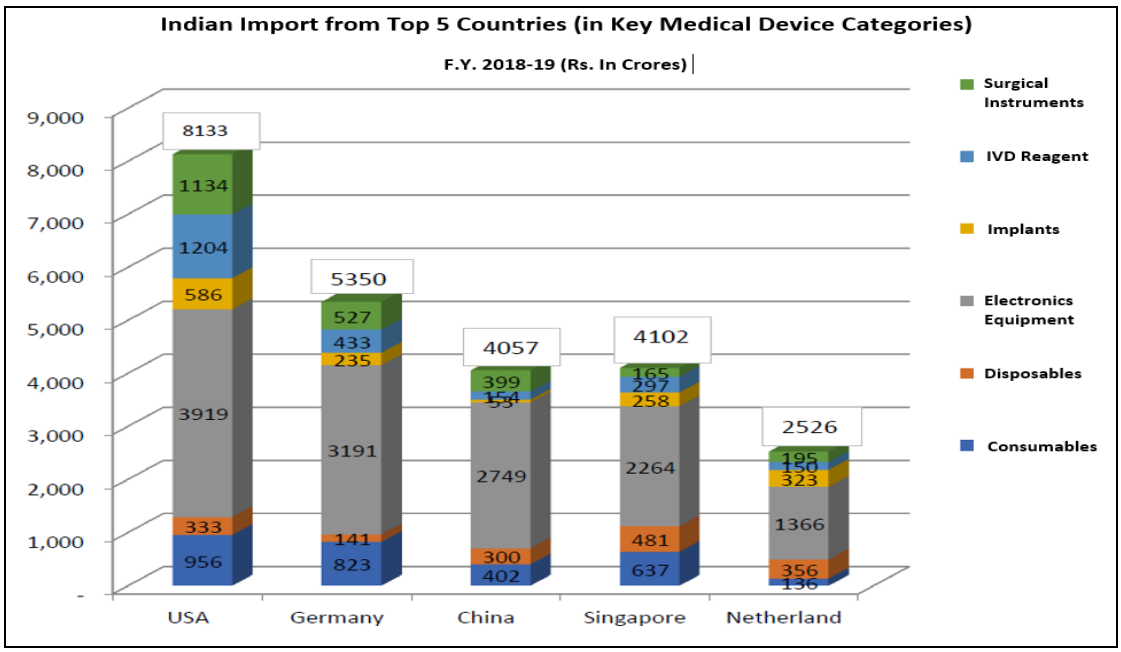

Figure 4. Country-wise status of imports in India for six (6) medical device categories (7,8)

Diagnostic imaging medical device import trade has grown by 24.9 per cent from USD 833.5 million (Rs.5,826.7 crore) in FY18 to USD 1.04 billion (Rs. 7,277.53crore) in FY19

Medical Consumables import trade has grown by 24.7 per cent from USD 624.9 million (Rs. 4,368.06 crore) in FY18 to USD 779.3 million (Rs. 5,447.51 crore) in FY19

In-vitro Diagnostic devices import trade has grown by 25.7 per cent from USD 512.5 million (Rs. 3,582.6 Crores) in FY18 to USD 644.4 million (Rs. 4,503.4 Crores) in FY19

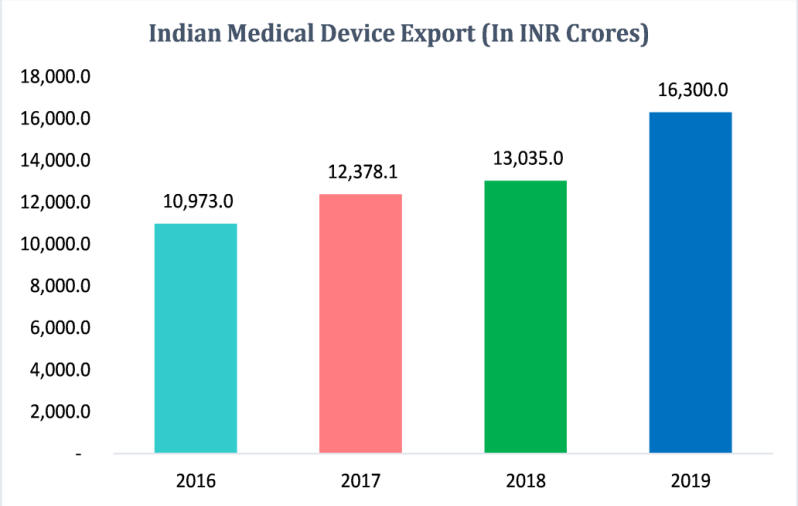

Figure 5. Year-wise status of export of medical devices from India (7,8)

This exponential increase in export of medical devices may be because of the limitation in the enabling policies in India for medical devices manufacturing and trading within the country. The medical devices of India with stringent safety and quality profile have acceptability in USA which is a highly regulated market. (7) Moreover; there is an increase in the exports in recent past which shows credibility of devices exported from India. (7,8)

While MDI in India faces a classical set of challenges, primary among them being lack of motivation to manufacture medical devices with non-viable margins due to ease of low cost imports (including pre-owned equipment) coupled with absence of robust regulatory framework for medical devices. Other key challenges faced by the MDI in India includes lack of avenues for pooling and bridging of adequate fresh talent into the sector, lack of pathways for uptake of innovations in supply chain; lack of subsidies and incentives appropriate to the levels of providing a bonus to the industry. (7)

Steps have been taken by the Indian Government to address some of these challenges such as introduction of Medical Devices Rules 2017; classification of

occupational standards under Health Sector Skill Council; Competency mapping of biomedical engineers under IBSC (Indian Biomedical Skills Consortium) incentives for export promotion by Department of Commerce, Government of India (GoI); Preferential Procurement Order guidelines for procurement by public healthcare institutes under GoI, setting-up and operationalization of Andhra Pradesh Medtech Zone (AMTZ) medical devices park in Andhra Pradesh and establishment of Kalam Institute of Healthcare Technology (KIHT) to accelerate indigenously developed technologies and Government's decision to have more IITs for speeding up research in the country. (9,10)

Some of the areas however are still unattended to, and require more concentrated and comprehensive approach. While many of these steps have been comprehensive efforts from various Government of India (GoI) Ministries and Departments including from Ministry of Health & Family Welfare; Ministry of Science and Technology, Department of Biotechnology, Ministry of Commerce & Industry and Quality Council of India; Department of Pharmaceuticals, NITI Aayog and Ministry of Electronics, however, a need for central information pooling and coordination mechanism has been felt by the Government and the Medical device industry, however, it is yet to take-off through suitable policies.

3. Key Policy initiatives by the Government of India

Envisaged Ecosystem

To deliberate on some of the challenges faced by the Industry, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India (GoI) constituted a specialized Task Force. The task force elucidated a set of recommendations for boosting growth of MDI in India in its report on 8th of April 2015 (Figure 6). (4) The Government envisaged addressing some of these issues to create enabling ecosystem for medical device development in the country. Some of the components of the envisaged ecosystem with key policy initiatives are given below:

Coordinating & Facilitating Agency

To promote indigenous manufacturing of quality medical devices and attract investments in the sector, the government has set up a facilitation body called the "National Medical Devices Promotion Council (NMDPC)". Created under the aegis of Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India and with its technical secretariat at the Andhra Pradesh MedTech Zone (AMTZ) it has been providing necessary facilitation and coordination to various departments and ministries for promotion and development of the Indian Medical Devices Industry. Some broad activities undertaken by the council includes policy facilitation, strategic forums (to discuss Policy Interventions, Best Practices, Partnerships), dissemination of International Norms, Industry Support (Manufacturing, Regulatory Challenges, etc.) and Market Access. It has been playing an instrumental role to urge Public Procurement Agencies (both from State and Central Govt.) to adhere to transparent procurement norms as per the DPIIT's Public Procurement Order 2017. Additionally, NMDPC has advised the government to clear payments of manufacturers or suppliers, especially those which are stuck for years together with State / Central Health Corporations and Procurement Agencies, as such delays may not only dampen the spirits of Make-in-India but also land these manufacturers into bankruptcy.

Infrastructure creation

The Union cabinet on 21st March 2020 has approved a scheme on promotion of medical device parks for financing common infrastructure facilities in four medical device parks with financial implications of Rs 400 crore, and approved the Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices with financial implications of Rs 3,420 crore," it said. Under the sub-scheme for promotion of medical device parks, common infrastructure facilities would be created in four medical device parks, which is expected to reduce manufacturing cost of medical devices in the country. "The PLI scheme for promoting domestic manufacturing of medical devices would boost domestic manufacturing and attract large investments in the medical device sector, particularly in the identified target segments. It will lead to expected incremental production of Rs 68,437 crore over a period of five years".

Intellectual Property & Skill building

The policy envisages the support of Indian Patent Office for transfer/operationalization of Intellectual Property, for facilitating voluntary technology uptake and up-gradations through established commercial models creating enabling protective measures to protect outright purchase of patents from research institutions and start-ups based in India. For assisting product development and regulatory compliances, there is a need for developing capabilities in testing of medical devices in the country. The existing laboratories need to be upgraded and accredited while ensuring low cost testing for doing research on IVD with tested blood samples. Laboratories in certain Universities with bio technology courses can be encouraged to provide antigens and antibodies and sero-conversion panels to IVD industry which currently depends totally on imports. Working with stakeholders such as National Skill Development Agency (NSDA) for promotion of occupational and vocations standards for training of engineering workforce for medical devices industry will also be helpful and should be suitably pursued. (4)

A huge demand for certified & skilled manpower to serve the healthcare industry e.g., to export medical equipment to other countries like USA or Europe and to install high end equipment Indian biomedical engineers need licences or certification which is recognized in respective country. To address this, AMTZ in partnership with AiMeD and QCI created IBSC. It was launched during February 2018 in an event hosted by the Department of Pharmaceuticals at Bengaluru. IBSC developed an institutional mechanism for having a

registry for more than the two lakh Biomedical Engineers in the country. IBSC is deemed as a Government of India Sector specific Skill Council to certify clinical & biomedical engineers across hospitals, manufacturing units, R & D etc. Reputed academic institutions and organizations has partnered with IBSC. IBSC has also signed the MoU with Association for the Advancement of Medical Instrumentation (AAMI), USA, were certified candidates will have equal opportunities to practice biomedical profession globally. In addition to the skill certification, IBSC designed & developed five qualification packs and these skill programs were approved by National Skill Qualification Committee (NSQC) and listed in National Skill Qualification Frame Work (NSQF) under Ministry of Skill Development and Entrepreneurship (MSDE).

Quality Promotion

Given that quality of product has implications on their acceptability and applicability and therefore a direct bearing on their markets, policy impetus is required for facilitation and promotion of industry specific quality standards and benchmarks in consonance with national and international best practices, creation and/or adoption of medical device industry specific manufacturing standards and best practices, technology upgrades in manufacturing, knowledge sharing platforms, and other events for quality promotion of medical devices manufacturing sector. There is also a need for creating general awareness on medical devices safety, standards and facilitate sharing of all such relevant information with general public, medical professionals, all other stake holders and setting-up of medical device testing laboratories for pre-market approvals and standardization. The Government may also consider selection and designation of "Centers of Excellence" for product development, validation, and design improvement and improving their access to medical device industry and establishing technical and financial frameworks for such initiatives. The Indian Medical device industry also urges the Government to promote regulatory standards, standards of Bureau of Indian Standards (BIS), any voluntary standards as adopted by the medical device industry in India for building confidence and credibility to this industry sector. (4)

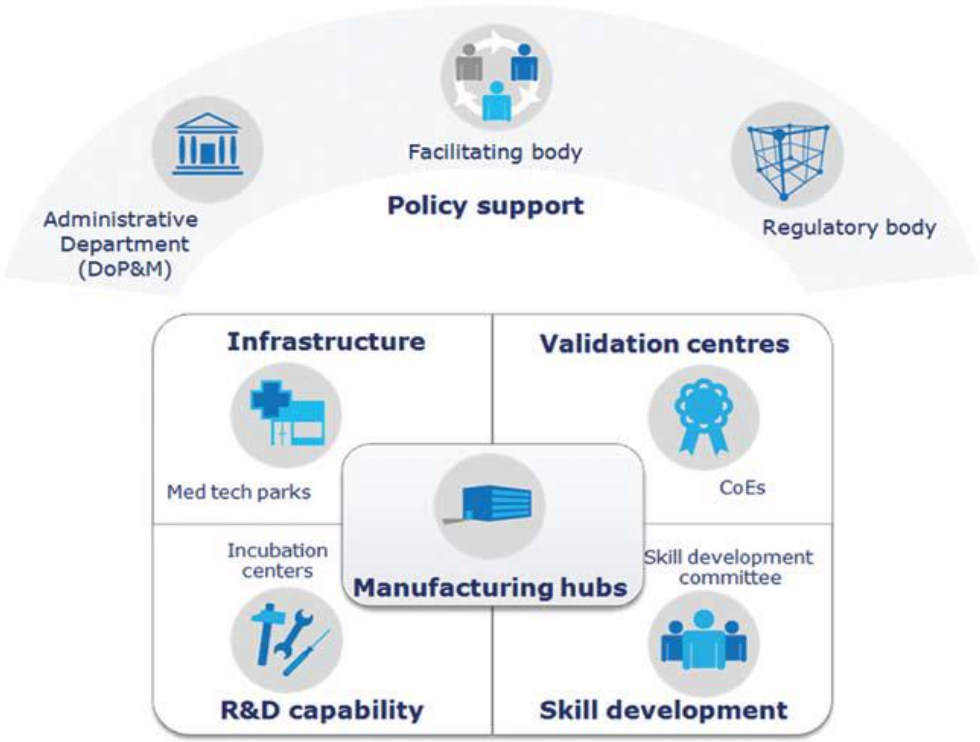

Figure 6. The envisioned ecosystem of DoP, Government of India (4)

4. Key Policy Interventions by the Government of India to boost Medical Device Sector-The Journey so far

To foster foreign investments in the medical device sector in the country, in January 2015, The Government modified the FDI regulations allowing 100 per cent FDI under automatic route in Greenfield and brownfield projects in this sector.

The sector has received an investment of USD 505 mn from 27 M&A transactions and around 43 venture capital/ private equity investments in the last five years. The sector has witnessed around 7 inbound, 8 outbound and 13 domestic mergers and acquisitions tractions in the last five years (2011-2016). In this period only, around 9 angel/ seed funding deals were also witnessed in medical device companies showing keen interest of investors in this sector. (10)

5. Key Achievements-Central Drugs Standards Control Organisation (CDSCO)

With the release of the MDR17, to expedite examination and increase transparency in evaluation of applications, the application process at the CDSCO has been made online through the *Sugam* Portal. New online system for medical devices is now functional for uploading the applications for Import licensing and Manufacturing license of Medical devices and IVDs for

post approval changes, registration of medical device testing laboratories, clinical investigation etc. The key regulator, CDSCO in consultation with the medical device expert group has finalised the classification of Medical Devices and IVDs which can be reviewed and accessed by the medical device industry stakeholders through the CDSCO website. The new online system for Medical devices is now functional for the registration of Notified bodies also. Six notified bodies have been registered for assisting CDSCO for ensuring regulatory compliance. Grouping of Medical Devices and IVDs along with essential principle checklist has been finalized in consultation with the stakeholders which has been made available by CDSCO for ease of adoption by the medical device industry. (11)

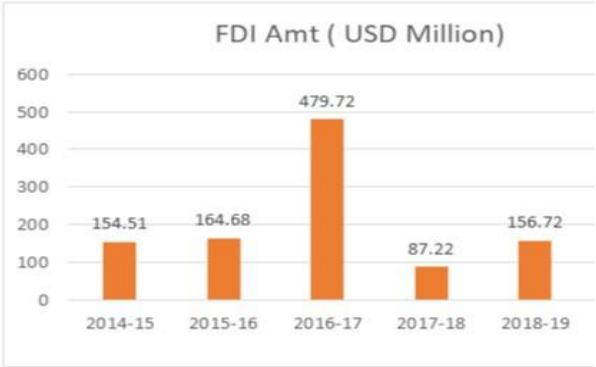

Figure 7. FDI Trends in Medical Device Sector in India

To address the skill and testing infrastructure gap in this sector, notifications for manpower recruitment including Medical device officers and Medical Device testing laboratories have been published and CDSCO envisages recruiting a number of officers for implementing medical device regulations. For addressing various questions on regulatory practices in medical devices, Frequently Asked Questions (FAQ) on medical devices and in vitro diagnostics (IVDs) have been prepared and are available online for reference and adoption of the MDR17. Specific guidance documents on performance evaluation of in-vitro diagnostic medical devices have also been prepared and made available for use by the industry. Guidance document for stability study and post marketing surveillance of IVDs has also been prepared and shared with the stakeholders for their comments. As a proactive approach, CDSCO has also set-up a Public Relation Office which is acting as a single window to guide, assist and provide information to the innovators regarding regulatory requirements. CDSCO has also launched support cells for WHO Performance, Quality and Safety (PQS) process for IVDs to provide guidance to the Indian manufacturers for achieving WHO Pre-qualification of In-Vitro Diagnostics programme in India. (11)

To monitor Medical Device-associated Adverse Events (MDAE), to create awareness among healthcare professionals about the importance of MDAE reporting and generate independent credible evidence-based safety data of medical devices, a Materio-vigilance program was successfully launched by the Government on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad. Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram acts as National collaborating centre fo implementation of this program. National Health System Resource Centre (NHSRC), New Delhi, acts as Technical support partner to the CDSCO in successfully implementing this programme. (11)

Policy support sought by the Medical device Industry

Incentivizing quality products from India, giving preference to locally manufactured products and implementation of a robust and dynamic 'Preferential Market Access Policy' is the key to boost indigenous manufacturing, as per the Government of India's Public Procurement Order 2017, which is quintessential to achieve Make-in-India. The public procurement order prescribes the following percentages of minimum local content for various categories of medical devices and for preference in public procurement:

Table 1 Medical Device, their Current and Envisaged Local Content

Category of Medical Devices	Minimum Local Content	Local content to be increased in phased manner over next 3 yrs
Medical disposables and consumables	50%	50% to 70%
Medical electronics, hospital equipment, surgical instruments	25%	25% to 45%
Implants	40%	40% to 60%
Diagnostic Reagents	25%	25% to 45%

Also, accordingly the Department of Pharmaceuticals (DoP) is the Nodal Agency for carrying out strategic market access programs with the support of National Medical Devices Promotion Council.

The Indian Medical device Industry urges the GoI to consider introducing policies in line with globally accepted policies for catalysing indigenous manufacturing through Preferential Market Access. The Public Purchase Order for Preferential Market Access with GFR 153 and WTO / GATT Compliant Preferential Pricing (e.g. as per World Bank Terms) may be benchmarked for suitable inclusions in Indian Public Healthcare Tenders.

The Indian Medical device industry envisages that the public healthcare system needs to move from lowest price basis to UN system of Sustainable supply chain basis and penalize suppliers with a poor track record of service and delivery and reward those with proven services as well provide opportunity to new entrants and startups.

Suitable policies should also be drafted by the Government for promoting activities supporting technology transfers, increase in market access and commercialization of innovations. There is a need for application of international best practices in evidence-based industry promotion strategies including manufacturing incentives such as interest subsidies, concessional power tariffs, provision of seed capital and/or viability gap funding. To boost the indigenous *Make in India* for medical device sector, the Government may consider providing tax liberalization measures including but not limited to - higher weighted tax deduction on approved expenditure on R & D to cater to high gestation period; extension of R&D tax benefits to limited liability partnerships; tax and regulatory/non tax barriers on import of pre-owned medical devices, wherever found necessary/applicable; incentivizing export of medical devices; and formulating guidelines for mergers and acquisition in this sector to protect the interest of medical devices industry. (12)

Other policy interventions may include drafting a planned and predictable tariff policy to enable business viability to make investment in this sector attractive and provide protection in a phased manner. (12) To provide further impetus to this sector, the GoI may consider increasing the basic import tariff from 0-7.5% to 15% for Medical devices and duty on components to be 7.5% as a *Make in India* enabler. Concessional duty on medical grade raw materials may be retained at 2.5% for now, for next few years. Industry also needs a supportive clinical environment for clinically validating the safety of their products. Policy to encourage government hospitals & medical colleges that would partner with domestic manufacturers in clinical evaluation as per regulatory requirements and HTA (Health technology assessment) studies with reasonable charges, publication of studies of clinical outcomes as incentive to healthcare professionals are some of the interventions expected and needed by the medical device industry. (12) To ensure patient safety, there is also a need for policies imposing restriction on import of pre-owned medical equipments until India has a robust regulatory framework to ensure patient safety and calibration. (12)

6. Regulations to ensure Patient Safety & Consumer Protection:

The Indian Medical Device industry seeks comprehensive regulation of medical devices and a predictable policy regime. The industry looks forward to suitable policies to ensure patient safety and build competence and competitiveness whereby Government should incentivize voluntary Indian Certification for Medical Devices by QCI (Quality Council of India) and expedite legislation for Regulation of all Medical Devices outside the ambit of the Drugs & Cosmetics Act at one go with a defined transition period for enabling capacity building for the manufacturers and regulators. (12)

The Government should consider necessity to unbundle regulations and create a regulatory framework consisting of a revamped and more competent Indian Healthcare Products Regulatory Authority with separate divisions for Medical Devices or an independent National Regulatory Authority to regulate the registered manufacturing or subcontracting sites in India or globally and the Market Access Authorization Holder (MAAH) whether it's a manufacturer, importer, agent or a marketing company. With the assistance of 3rd Party Certification Bodies accredited by National Accreditation Board for Certification Bodies (NABCB), the medical device companies should be able to get the necessary compliances. The State regulators may be mandated to regulate all the domestic resellers whether wholesale, dealer, retailer or healthcare provider (Figure 8). (12)

Table 2 Risk based classification of Medical Devices

Class	Risk Level	Device Examples
A	Low Risk	Surgical retractors / tongue depressors
B	Low-Moderate Risk	Hypodermic needles / suction equipment
C	Moderate-High Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

Central Drugs Standard Control Organization (CDSCO) is responsible for regulating the registration and sale of notified medical devices in India. Indian medical devices market regulators have distributed another draft list of medical devices which explains how they are classified by the Medical devices rules 2017. CDSCO headed by Drug Controller General of India (DCGI) classifies medical devices into four classes (A, B, C, and D) as per the regulation.

To bring credibility to the Indian Medical Devices through regulations, the medical device industry proposes to have a system of Voluntary compliance backed by 3rd Party ICMED Certification from QCI to be considered as a compliance option with reduced oversight enabling Ease of Doing business. There is a need for policy to financially support all manufacturers to attain ISO/ICMED13485 Certification and CE Mark. To ensure patient safety, suitable policy is needed to restrict reuse of devices labeled as single use. Rules are also needed for reprocessing of medical devices. Rules for misleading advertisements and claims on performance; e.g. Provision of Bio Medical engineers in hospitals to play corresponding role of Pharmacists in hospitals for good warehousing practices, maintenance and calibration of equipment are also additional requirements to be considered by the Government. (12)

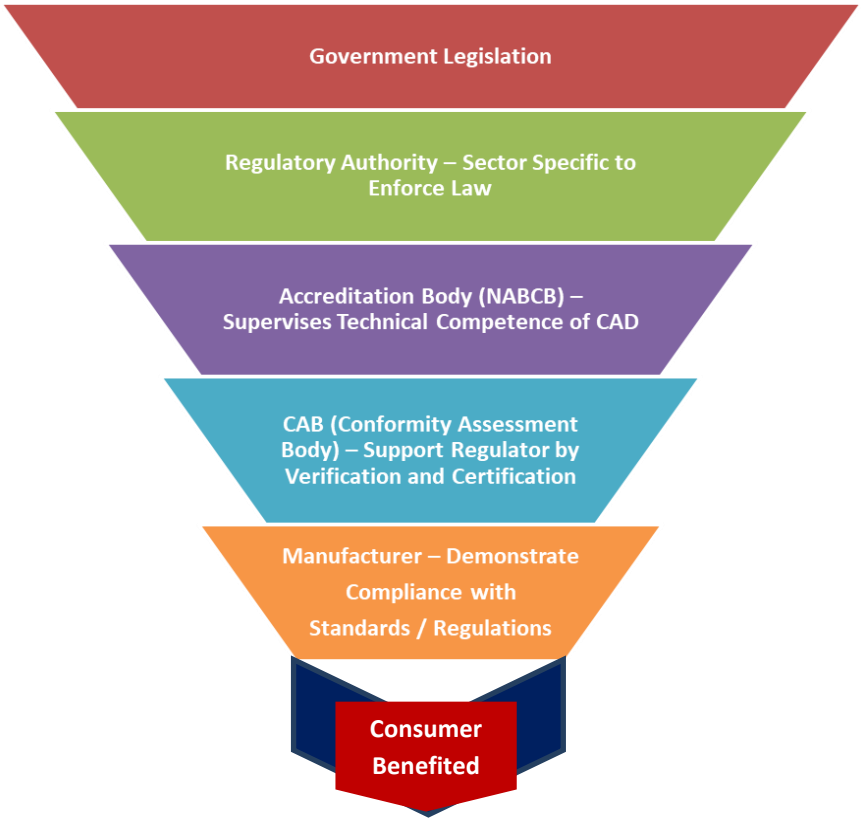

Figure 8. Proposed Regulatory Framework for Comprehensive Regulation of Medical Devices

7. Policy Roadmap and Way Forward

Many of the medical devices like equipments, analyzers, instruments etc. used in various healthcare facilities for diagnosis, treatment and mitigation are currently out of scope of regulation under The Drugs and Cosmetics Act. Concerns have been raised from time-to-time in different fora regarding safety, quality and performance of non-notified medical devices. Comprehensive regulation of Medical Devices is important for ensuring safety and well-being of patients using such Medical devices. Keeping in view the need for such comprehensive regulation of all medical devices, Ministry of Health and Family welfare had constituted a committee vide order No.11035/61/2019-DR dated 04.02.2019 to work out a roadmap on regulation of all Medical Devices and for creating Medical Devices vertical in the CDSCO, the key regulator in the country. (13, 14)

The roadmap needs to be implemented in a phased manner wherein the first phase of implementation will include issuance of notification for including all medical devices by their technical definition and provisions for exemptions to obtain import / manufacturing license and permission for clinical investigation till 30 months for class A and B category of devices and 42 months for class C and D categories. This will be followed by registration of all non-regulated Medical Devices on SUGAM portal for obtaining voluntary registration (in the form of registration number) on voluntary basis within 12 months from the date of notification for class A and B devices, followed by compulsory registration within 24 months for class C and D devices. (15)

The Second phase will include requirement of registration (by number) of Class A & B devices which shall be followed by mandatory licensing within 12 months after 18 months of voluntary registration period.

CDSCO envisages that as per the roadmap, after 12 months period, no person, company and organization should be allowed to manufacture, import, and sale or distribute Class A & Class B Medical Devices without prior license under the Medical Devices Rules, 2017. (15)

The Third phase shall include registration (by number) of Class C & D critical medical devices allowing voluntary registration within 18 months of notification by CDSCO followed by mandatory licensing within 24 months. After the 24 months period, no person, company and organization should be allowed to manufacture, import, sale or distribute Class C & Class D Medical Devices without prior license under the MDR17. (15)

A separate vertical for Medical Devices will be created within the CDSCO for regulating medical devices. To effectively manage this vertical, huge recruitments of the order of more than 700 posts will be advertised to recruit professionals from regulatory, laboratory and medical specialisations. Officials in various disciplines of medical devices are proposed for recruitment and are under active consideration for incorporation at advanced stage as per procedures.

To give special focus to this sector and deliberate on the key challenges for proposing suitable interventions, the Government has constituted MDTAG (Medical Devices Technical Advisory Board) which includes experts from various Govt. Departments & various medical devices national and international Associations in order to discuss the various issues/ concerns related to medical devices and IVD kits. (16) To protect consumers and ensure ethical marketing policies, regulatory price controls are sought that discourage unethical practices to induce hospitals and retailers to push brands to patients on the basis of high trade margins. This will create a disincentive to label Medical devices with exorbitant retail prices and will also help boost domestic ethical manufacturing.

8. Conclusion

A National Medical Device Policy framework needs to achieve time bound growth of medical device industry by supporting measures to promote manufacturing as part of *Make in India* and enabling improved affordable access to medical devices for general public with the objective of **"Sabka Saath Sabka Vikas***"* meaning **"Collective Efforts, Inclusive Growth"**.

To give special attention to this sector and introduce comprehensive regulation of medical devices, the Medical Devices (Safety, Effectiveness, and Innovation) Bill, 2019 has been drafted by NITI Aayog. As per the draft bill, NITI Aayog, has proposed regulation of medical devices through a separate Act, with separate regulatory framework apart from Drugs, and a separate regulatory authority under Ministry of Health to regulate all medical devices. NITI Aayog envisages addressing Patient safety concerns and including key elements to foster *Make in India* of Medical Devices for providing access to safe, innovative Devices to users through this Bill which is under stakeholder consultation. The medical device industry and other stakeholders nationally and globally are closely monitoring how the policies are evolving for addressing enabling ecosystem requirements of this sector to leapfrog and reach newer heights.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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