Medical Devices Reforms and the Landscape in India

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Global Medical Device Market

Geography Wise Sale of Medical Devices (2015)
- Western Europe: 27%
- Americas: 45%
- Asia: 21%
- Eastern Europe: 4%
- Middle East and Africa: 3%
- Others: 6%

Segment Wise Medical Device Sale Globally (2015)
- Diagnostics: 24%
- Imaging: 26%
- Consumables: 15%
- Patient Aids: 10%
- Dental Products: 6%
- Others: 6%
- IV: 24%

Total: 59.28 USD Bn
Indian Medical Device Market

India is one of the top medical device markets in the world, contributing 4% of the Indian healthcare market which is pegged at USD 96.7 bn (INR 6.29 Lakh Crores), in 2015.

The Indian medical device sector is worth USD 5.5 Billion and is growing at 15% CAGR.

The industry estimate suggests that the Indian medical device market will grow to USD 8.16 bn (INR 53,053 crore) in 2020 at a CAGR of 16%.

India is one of the top 20 global medical device markets and the 4th largest medical device market in Asia.
Medical Device Clusters in India

**Haryana**

**Players:** Boston Scientific Corp., Becton Dickinson India, Hindustan Syringes, Narang Medicals, Poly Medicure, BL Life Sciences

**Gujarat**

**Players:** 3M Co., Bayer AG, Meril Life Sciences, Envision Scientific, Invent Bio-Med, Sahjanand Medical Technologies

**Maharashtra**

**Players:** Johnson & Johnson, Smith & Nephew, Philips Healthcare, Siemens, Nipro Corp., Danaher Corp, Trivitron Healthcare, Remi Laboratories

**Karnataka**

**Players:** GE Healthcare, Biocon, Medived, Skanray, Bigtec Labs, Skanray Technologies, Prognosys Medical, Opto Circuits, Biorad Medisys, Vascular Concepts, Confident Dental Equipments

**Delhi (NCR)**

**Players:** Hindustan Syringes and Medical Devices, Mediray Healthcare, 3M Co., Boston Scientific, Danaher Co.

**Telangana**

**Players:** St. Jude Medical, Relysis Medical Devices, B Braun (Hyd.), Medtronic (Hyd.)

**Tamil Nadu**

**Players:** Roche, Trivitron Healthcare, Opto Circuits, Perfint Healthcare, Cura Healthcare, Appaswami Associates, Phoenix Medical Systems, Schiller
Foreign Direct Investment and Other Investment in Indian Medical Device Sector

- FDI in medical devices has grown by 25.4% from USD 131.4 mn in FY12 to USD 164.7 mn in FY1615.

- In January 2015, Government of India modified the FDI regulations allowing 100 per cent FDI under automatic route in Greenfield and brownfield projects in medical device sector.

- The Indian medical device sector has received an investment of USD 505 mn from 27 M&A transactions and around 43 venture capital/private equity investment in last five years.

- Indian medical device sector has witnessed around 7 inbound, 8 outbound and 13 domestic merger and acquisition tractions in the last five years.

- In the last five years around 9 angel/seed funding deals was witnessed in medical device companies.
13.11 **Make in India**: Towards furthering “Make in India”, the private domestic manufacturing firms/industry could be engaged to provide customized indigenous **medical devices** to the health sector.

14. **Regulatory Framework**: The regulatory role of the Ministry of Health and Family Welfare- which includes regulation of clinical establishments, professional and technical education, food safety, **medical technologies**- medical devices, clinical trials, registration, and implementation of the health related laws.

14.5 **Medical Devices Regulation**: The policy recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical devices in India. The policy supports harmonization of domestic and international regulations.

14.7 **Pricing- Drugs, Medical Devices and Equipment**: The regulatory environment around pricing requires a balance between the patients concern for affordability and industry’s concern for adequate compensation.

18. **Availability of Drugs and Medical Devices**: The policy accords special focus on production of Active Pharmaceutical Ingredient (API) which is the back-bone of the generic formulations industry. Recognizing that over 70% of the medical devices and equipments are imported in India, the policy urges for国产izing.

19. **Aligning other policies for medical devices and equipment with public health goals**: For medical devices and equipment, the policy recommends and prioritizes establishing sufficient labeling and packaging requirements on part of industry, adequate medical devices testing facility and effective norms.

16 **Medical Technologies**: India is known as the pharmacy of the developing world. However, its role in new drug discovery and drug innovations including bio-pharmaceuticals and bio-similars for its own health priorities is limited. This needs to be addressed in the context of progress towards universal health care. Making available good quality, free essential and generic drugs and diagnostics, at public diagnostics for chronic diseases and outsourced subsidized.

22. **Health Technology Assessment**: Health Technology assessment is required to ensure that technology choice is participatory and is guided by considerations of scientific evidence, safety, consideration on cost effectiveness and social values. The National Health Policy commits to the development of institutional framework and capacity for Health Technology Assessment and adoption.

25.4 **Research Collaboration**: The policy on international health and health diplomacy should leverage India’s strength in cost effective innovations in the areas of pharmaceuticals, medical devices, health care delivery and information technology. Additionally leveraging international cooperation, especially...
Regulatory Landscape:
Government Support & Initiatives for Medical Devices Sector

Regulatory Landscape Strengthening
- Materio-vigilance Programme of India
- Delinking of Schedule M-III
- Significant experience for Manufacturing Supervisor
- Prescription of Shelf-life for medical devices
- Exemption for Custom Made Medical Devices
- Clarification of Standards for medical devices
- Drugs and Cosmetic (Amendment) Bill, draft for stakeholder views
- Draft National Medical Device Policy, 2015

Subsidies and exemptions to MSMEs
- Corrections in the Inverted Duty Structure to boost domestic manufacturing of medical devices
- Budget initiatives

Tax/ Duty Modifications
- ‘Make In India’ Campaign to boost domestic manufacturing
- Setting up of Medical Device Parks in three states
- Setting up of Medical Device Testing Labs in two states

Infrastructure Boost
- Exemption from Phase I clinical trials for medical devices
- Development of ICMED scheme for certification of medical devices

Other Favourable Initiatives
Make in India campaign: launched with focus on 25 sectors including medical devices

100 per cent FDI allowed: The medical device sector was carved out from the pharmaceutical sector thereby allowing 100 per cent FDI under the automatic route, for brownfield as well as greenfield set-ups.

Draft National Medical Device Policy, 2015 released: The DoP recently issued the draft National Medical Device Policy, 2015, which sets out the regulatory structure for medical devices.

Formation of Task Force: The DoP constituted a task force to identify issues relating to the promotion of domestic production of high end medical devices.

Draft Drugs & Cosmetics (Amendment) Bill, 2015 released: The bill proposes to expand the scope of the Act to cover new areas and will “regulate the import, manufacture, distribution and sale of drugs, cosmetics, medical devices”. The amendment is likely to be approved soon.

The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and WHO Guidelines to comply with best international practices.

Funding approval to AMTZ: AMTZ receives approval for funding by the state cabinet on 1st June, 2016 for setting up Asia’s first dedicated medical device park at Visakhapatnam.
Honourable Finance Minister Budget Speech

We propose to amend the Drugs and Cosmetics Rules to ensure availability of drugs at reasonable prices and promote use of generic medicines.

New rules for regulating medical devices will also be formulated. These rules will be internationally harmonised and attract investment into this sector. This will reduce the cost of such devices.

‘India Pharma 2017’ & ‘India Medical Device 2017’: for responsible Healthcare

Aim to Project India as an Attractive Investment Destination and Global Hub for Pharma and Medical Devices Sector: Shri Ananth Kumar

The Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, is organizing ‘For Responsible Healthcare’, the 2nd International Health & Medical Devices Summit, from 11th to 13th February, 2017, in Bengaluru.

Addressing the media during the Curtain Raiser & Fertilizers and Parliamentary Affairs, Shri Ananth Kumar, stated that the event will provide global potential for the Indian healthcare opportunity to project India as an attractive investment destination in these sectors.

Further, the Minister informed that this year the ‘India Pharma 2017’ Summit will bring together the best minds from the global Pharma & Medical Devices sector to network and learn about the latest developments in the sector.

The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices. Only 15 categories of medical devices are, at present, regulated as drugs and to that extent, the current regulatory practices in India were not fully geared to meet the requirements of the medical devices sector in the country. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.
Medical Device Rules, 2017

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- The new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and conform to best international practices.
- The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.
- Medical devices will, under the new Rules, be classified as per GHTF practice, based on associated risks, into:
  - Class A (low risk)
  - Class B (low moderate risk)
  - Class C (moderate high risk)
  - Class D (high risk)
- The manufacturers will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.
- Through these Rules, a system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged. The Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB).
- The Rules also seek to evolve a culture of self-compliance by manufacturers of medical devices and, accordingly, the manufacturing licences for Class A medical devices will be granted without prior audit of manufacturing site.
- Manufacture of Class A and Class B medical devices will be licensed by State Licensing Authorities concerned after Quality Management System audit by an accredited Notified Body.
- For all manufacturing sites, Quality Management System will need to be aligned with ISO 13485.
- Manufacture of Class C and Class D medical devices will be regulated by the Central Licensing Authority and, where required, assistance of experts or notified bodies will be taken.
- Import of all medical devices will continue to be regulated by CDSCO.
- Separate provisions for regulation of Clinical Investigation (clinical trials) of investigational medical devices (i.e. new devices) have also been made at par with international practices and, like clinical trials, these will be regulated by CDSCO.
- There will be no requirement of periodic renewal of licences.
- Accordingly, manufacturing and import licences will remain valid till these are suspended or cancelled or surrendered.
- Further, the entire process starting from submission of application to grant of permission/licence will be processed through online electronic platform.
- Timelines have been defined for most activities at the regulators end.
- These Rules envisage creation of a robust eco-system for all stakeholders including innovators, manufacturers, providers, consumers, buyers and regulators.
- The Rules will provide a conducive environment for fostering India specific innovation and improving accessibility and affordability of medical devices across the globe by leveraging comparative cost advantage of manufacturing in India.
- The objective, transparent and predictable regulatory framework will boost the confidence of investors and, as a consequence, the quality and range of products and services will improve and business burdens will be reduced.
Registration & Certifications

Medium and small scale enterprises (MSME) is the segment representing and fostering the promotion and growth of micro, small & medium Enterprises in the country.

Certifications are trademarks of quality processes and thereby quality products.

R&D and Intellectual Property
Human Resources and Skills
Product Range

Medical devices manufacturing

The ability of eco-system

Situational

1. Approximately 52.22% organizations could be re-source whereas 4% sector.
2. Programs of skill build force in – on the job-1 remains the goal

Inference: Urgent need to work force is the need of dimensions on which skill explored in consultation with

The products range from wound closure pads to stents and IVD machines to MRIs.

Situational Analysis Findings

1. 79.03% of the surveyed firms have product range between 1 to 10.
2. 9.67% had more than 10 but less than 20 products, while 11.29% of the firms had more than 20 products in their manufacturing portfolio

Inference: The range of products depicts the technological and financial bandwidth of manufacturing firms. There are no schemes that support product diversification exclusively. A need for product diversification mechanism is a long pending requirement for Indian med tech markets to expand.

Work in Progress

- Setting up of Medical Technology Industrial Parks, linked with Industrial Corridors are in the making, with lead being taken by Andhra Pradesh Med Tech Zone, a newly formed Public Sector Unit under government of Andhra Pradesh.
Initiatives for Promotion of Medical Device Industry

Scheme for Financing Common Facility Centres (CFCs) at Medical Device Parks:

- Proposal for scheme for “Development of Common Facilitation Centres for Medical Devices” in medical device parks under the Umbrella scheme for “Development of Pharmaceuticals Industry” thus creating an Eco System for High End Medical Device Manufacturing and Import Substitution with an eye for Export Market
- This sub-scheme proposes for Financing Common Facility Centres (CFCs) at Medical Device Parks in the country at a total cost of Rs. 250 crores.

Corrections in the Inverted Duty Structure:

a. Raised import duty on 67 ITC Categories of Medical to 7.5 per cent

Medical Device Promotion Council:

- Proposal under consideration for establishment in co-operation with Andhra Pradesh MedTech Zone Ltd. (AMTZ) at Vishakhapatnam.

Preferential Market Access:

- Proposal under consideration for giving preference to domestic industry in purchase of medical devices by all government agencies.

Uniform Code For Medical Device Marketing Practices (UCMDMP):

- Draft Uniform Code for Medical Device Marketing Practices (UCMDMP) was prepared.
- It was decided to consult UCMDMP with the stakeholders.
- Two meetings in this regard were held with the stakeholders for incorporating their suggestions and further course of action in the matter.
- xi. Other facilities commonly required in manufacturing of medical devices
Assessment of the National Regulatory Authority (NRA) of India
Ensuring quality, safety and efficacy of vaccines

“Pharmacovigilance” is one of the core functions in the WHO global NRA benchmarking tool

The WHO NRA re-benchmarking exercise, from 13-17 February 2017, was aimed at assessing the status of the India vaccine regulatory system.
Materiovigilance Programme of India (MvPI)

- Ministry of Health and Family Welfare, Government of India and National Health Systems Resource Centre (NHSRC) in collaboration with WHO Country office for India formally announced the commencement of NHSRC, as the **WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy**.

- Technical support will be provided by National Health System Resource Centre (NHSRC) for MvPI.
Launch of the Joint WHO-AMTZ-DoP-DIPP Medical Device Report
Thank you!

Disclosure - No Conflict of Interest