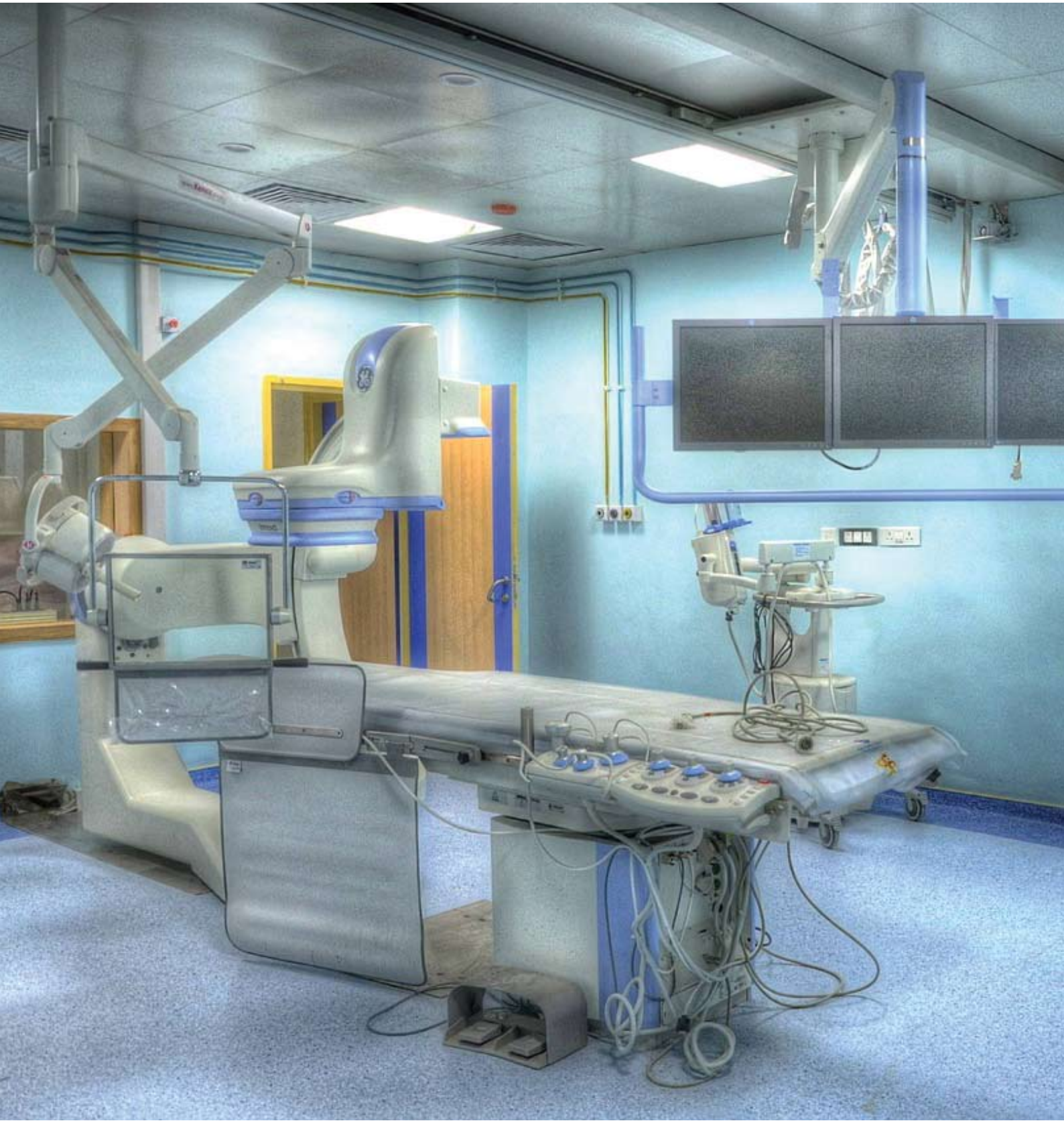
RECOMMENDATIONS OF THE TASK FORCE ON THE MEDICAL DEVICES SECTOR IN INDIA - 2015

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India



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Acknowledgements

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1. Department of Commerce (DoC)
2. Department of Health & Family Welfare
3. Drugs controller DCGI
4. Niti Aayog (formerly Planning Commission)
5. Department of Electronics & IT
6. Department of Science and Technology
7. Indian Council of Medical Research (ICMR)
8. Department of Industrial Policy and Promotion (DIPP)
9. National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad
10. Association of Indian Medical Device Industry (AIMED)
11. Confederation of Indian Industry (CII)
12. The Federation of Indian Chambers of Commerce and Industry (FICCI)
13. The Associated Chambers of Commerce of India (ASSOCHAM)
14. Organisation of Pharmaceutical Producers of India (OPPI)
15. The Boston Consulting Group (BCG)
16. PHD Chamber of Commerce and Industry
17. IMS Health and Consulting Information Services (IMS Health)

Background

Medical devices' industry is a multi-product industry, producing wide range of products. Manufacturing and trade in medical devices is also growing quite steadily. Double digit growth rates indicate its importance in health care. Medical devices' industry mostly depends on imports. Most hi- tech innovative products and technology originate from a well-developed eco-system and innovative cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

The 'Make in India' campaign of Hon'ble Prime Minister Narendra Modi's government has a mandate to boost the medical device manufacturing sector in India for all types of medical devices and equipments used in manufacturing of Pharmaceuticals. To implement the initiative a Task Force was constituted under the chairmanship of the Secretary, Department of Pharmaceuticals (DoP) to address issues relating to the promotion of domestic production of high end medical devices and pharmaceutical manufacturing equipment in the country. The Terms of Reference (ToR) for the Task Force is attached in Appendix 1.

The first meeting of the Task Force was held on November 27, 2014 and attended by the representatives of the member departments, Ministries and various industry associations. The need to address various basic concerns facing the industry including human resources, finance, market, ease of doing business, promotion of R&D and innovation etc was identified. Specific issues that have to be deliberated upon intensively were identified and more focused sub-groups were formed to address these issues in the subsequent meeting of the task force held on December 18, 2014:

Sub-group 1: Sector overview
Sub-group 2: Policy & Infrastructure
Sub-group 3: Regulatory

The respective ToRs of different sub-groups are attached in Appendix 2-4.

Subsequently multiple meetings were conducted by each sub-group and detailed recommendations on the identified areas were formulated as attached in Appendix 5-7

Further meetings of the Task Force were conducted on January 29, 2015 and March 03, 2015.

All the recommendations from different sub-groups were reviewed, collated and a concise actionable set was created. However participation of the industry / stakeholders from manufacturing equipment used in pharmaceutical was lacking and the Task Force did not receive inputs from them despite all attempts.

The ensuing sections provide an overview of the device industry and the different elements required to build the envisioned harmonized ecosystem.

Medical Devices Sector Overview

Medical devices sector in India is very small by size as compared to the rest of manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the 4th largest market in Asia after Japan, China and South Korea. Although accurate data is not available, an educated guess would place the retail market at Rs. 60,000-70,000 Crores.

Segments

The Medical Devices market can be classified into two major categories:

– Devices that do not require any external energy source.

– Devices that require external energy source to be operational (powered).

Powered devices are further divided into three product categories:

a. Equipments,

b. Implants, and

c. Disposables.

a. Equipments

Equipments account for the largest share of the total market followed by medical implants and disposable segments respectively. This segment is also the fastest growing and is largely dependent on imports currently.

This can be further segmented into the following categories –

- Surgical Equipments:
  Prominent factors that drive demand are advancements in surgery and surgical device designs, availability of high skilled surgeons, growing breed of corporate hospitals and advanced surgical facilities like advanced robotics, minimally invasive surgical techniques and imaging.
- Diagnostics:
  Increase in the prevalence of diseases, their complexity and the need for quick diagnosis has created a high demand for diagnostic services and devices like Cardiac imaging, CT scans, X-ray, Molecular Imaging, MRI and Ultrasound-imaging including hand - held devices.
- Life Support:
  As life support technologies evolve and improve, use of equipments like ventilator and automated external defibrillator outside of the hospital environment has increased. Also, as consumer spending power increases demand for such systems is expected to grow.

b. Implants

The market for implants is witnessing some amount of innovations in terms of catering to large unmet needs in certain disabilities e.g. blindness. A microchip retina implant is under trial which will allow blind patients to read letters & recognize foreign objects.

c. Disposables

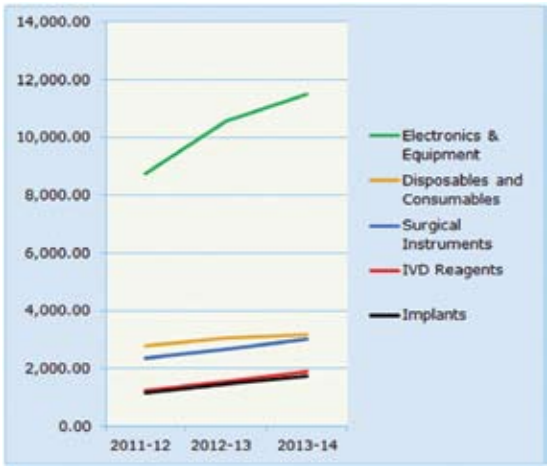
Medical disposable products for medical electronic equipment are used by all hospitals and private nursing homes in the country, including diagnostic and pathological laboratories. The market is becoming increasingly competitive due to low entry barriers (for MNCs), increasing number of players and an expanding consumer base. Examples include disposable medical and electronic probe assemblies for minimally invasive applications, disposable catheter cables, disposable EEG sensors/lead wires, disposable SpO2 sensors, panel mount receptacles, etc.

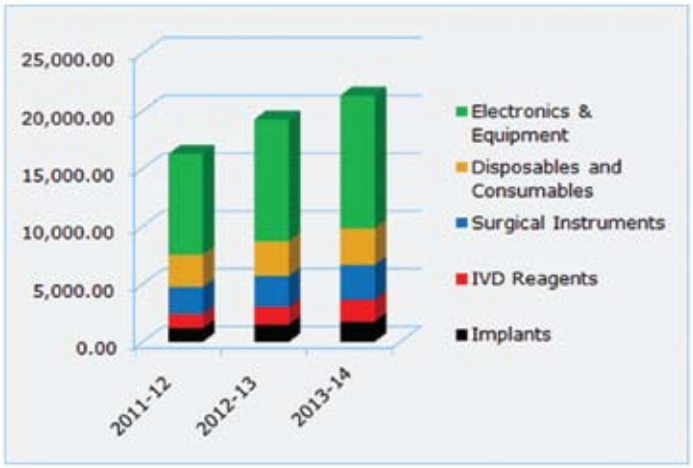
Present status

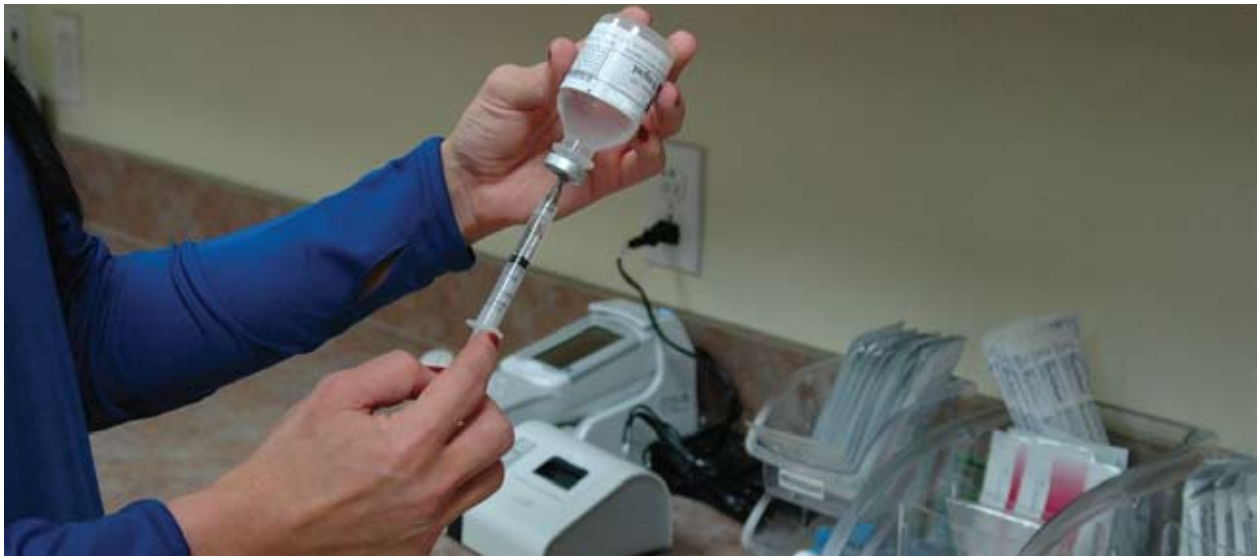
During the period 2011-12 to 2014-15 both import and export of medical devices have grown at more than 10% rates.

Import as well as export of Medical Electronics and Hospital Equipment has been the highest amongst all the devices in terms of value. Along with surgical instruments they form more than 50% of total sales with majority being imported (87.4%).

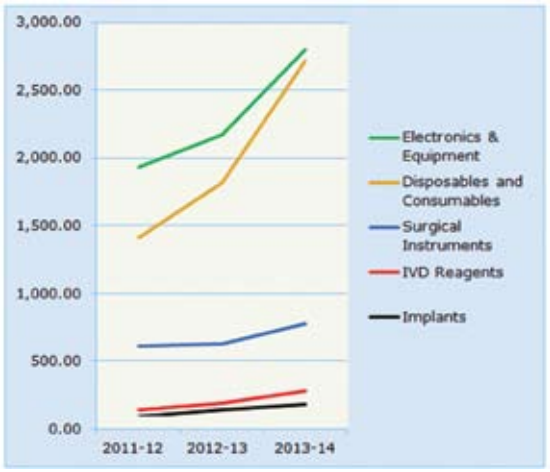
Summary of Imports of Medical Devices in India (All values in Rs. Crore)

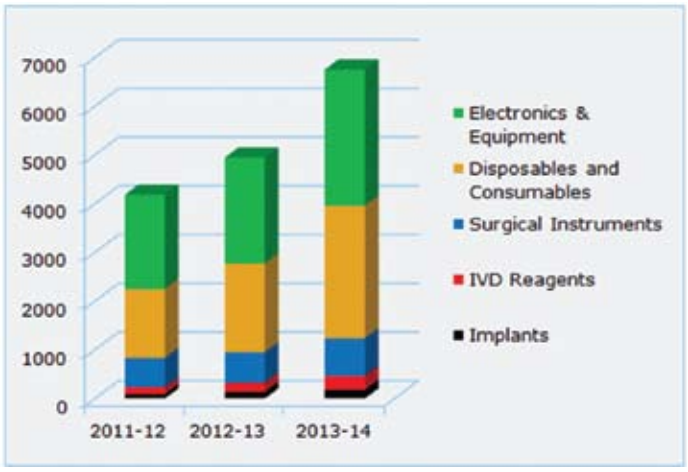




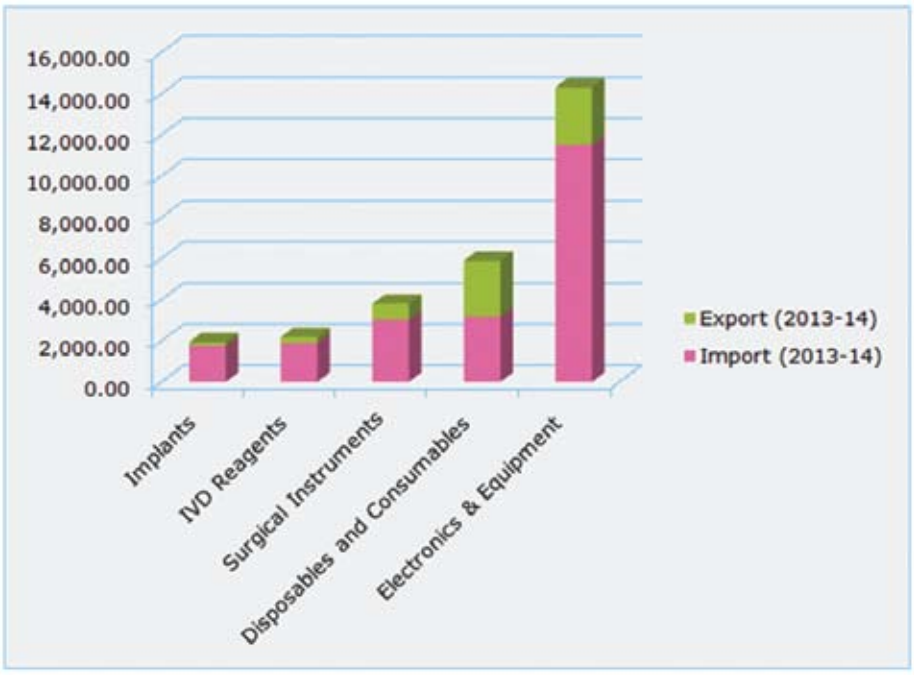


Summary of Exports of Medical Devices in India (All values in Rs. Crore)





Summary of Sales of Indigenous versus Imported Medical Devices in India in 2013-14 (All values in Rs. Crore)



Factors driving the growth of medical devices sector

1. Market Factors – Growing population, ageing, income base and associated disposable income, increasing socio-economic inclusion of rural and deprived in mainstream economy, heightened manufacturing innovation to create customized products to meet the needs of all income segments, changing disease prevalence pattern (e.g. early onset of diabetes and heart diseases) and growing awareness among the middle class to focus on early detection and disease prevention.

2. Non-market Factors – Development of infrastructure, favorable regulations, FDI inflow, outsourcing of manufacturing and R&D activities to India, government initiatives to improve healthcare access through insurance schemes such as RSBY (Rashtriya Swasthya Bima Yojana), Aarogyasri, etc.

The lack of regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices etc. are affecting the medical devices industry adversely.

Recommendations

Policy support

1. Create necessary bodies to drive the policies

1.1. Facilitating body

1.1.1. Set up an independent body with a permanent office and support staff to promote and facilitate the medical device industry with representatives from all related government departments as well as Industry.

1.1.2. It would function as

- A single window to facilitate for medical technology sector
- Create benchmarks as per international best practices and update all the stakeholders on global development.
- Develop knowledge networks with partners from industry
- To identify and prevent creation of unnecessary and unjustified technical barriers to trade especially by new or changing technical regulations.
- To support and prepare Indigenous businesses face competition, access foreign markets, and find new business partners abroad.

  Going international increases SMEs' performance, enhances competitiveness, and reinforces sustainable growth.

1.1.3. The inter-ministerial task force may continue to function till the facilitating body is able to independently service and facilitate the industry.

1.2. Administrative Department

Department of Pharmaceuticals be strengthened and rechristened as Department of Pharmaceuticals and Medical Devices. Necessary revisions in the scope of services along with creation of a separate post of Director in the department to deal with issues related to the Medical devices sector.

2. Preferential treatment in government procurement

2.1. Since medical devices will be manufactured in the country on a large scale for the first time, the conditions of tender documents such as experience for last three/ five years etc. can be suitably relaxed for new manufacturers.

2.2. Preference may be given to medical devices which are being manufactured in India with an additional preference for medical devices manufactured under MSME sector.

Infrastructure

1. **Set up manufacturing hubs/ clusters in PPP mode**

   The government can develop necessary infrastructure with recurring expenses borne by the private industry as per usage.

2. **Set up Medical device parks**

   With the right infrastructure in places that are conducive to medical device manufacturing.

   To promote start ups right from incubation to product development and market reach out.

   To begin with, one such park may be promoted near Chennai.

3. **Financing support**

   3.1. R&D should be supported/ coordinated by agencies like ICMR, DBT, CSIR, DIETY & DoP through the single window facilitating body.

   3.2. Low cost funding like interest subsidy to MSME

5. **Other support**

   Concessional power tariff for up to 5-10 years

Facilities for efficacy and safety testing

1. **Medical device testing centers should be set up preferably in the PPP mode**

   Common medical device testing facilities can be set up by government in major medical device manufacturing hubs to facilitate testing/ evaluation of medical devices. Recurring expense can be borne by the industry.

2. **Designate "Centers of Excellence" (CoE) for supporting product development and validation**

   2.1. These centers having existing requisite facilities and expertise for different categories of medical devices (Example: DEITY, BIS, IIT-M, IIT-D, IISc-B, CIPET, DRDO)

   2.2. They would support:

   - Product development – design and prototyping
   - Validation and certification of the medical use of devices
   - Adopt, implement and advocate policies on efficacy and safety testing

3. **Strengthen a made in India marking (BIS) specific to Medical devices**

   in line with international standards like CE and FDA

Skill development

Set up a Skill development committee with representatives from Medical devices industry, academia (NIPERs) and Healthcare Sector Skill Council (HSSC) under National Skill Development Council (NSDC)

The committee would:

- Identify skill gaps and reduce shortages

- Design curriculum and explore possibilities for on-line/ e-learning modules to meet specific requirement of medical device segment
- The committee would engage with HSSC affiliated Vocational Training Providers as well as potential ITIs, Polytechnic and other institutes for skill development
- Set up satellite training campus around manufacturing hubs for skill upgrading
- Liaise across the Medical devices industry for job placements
- Provide counseling to candidates seeking skill development and address issues like student loan, scholarships, job placements etc.

R&D capability

1. Set up a system for IP exchange

Since medical devices sector is highly innovation and technology intensive, it is recommended to create a system where Industry may place/ make available their IP in non-core activities available to the exchange which may help technological up-gradation of the sector.

2. Set up/ promote Incubation centers

through appropriate incentive structure/ cost sharing.

Such centers would address gaps in capabilities within R&D infrastructure, testing calibration etc.

3. Provide requisite financing support

3.1. Provide seed capital, viability gap funding and co-fund start-up projects

3.2. Support commercialization of innovations

3.3. Provide longer term view (10 years window) for 200% weighted tax deduction on approved expenditure on R&D as the gestation period in high in this industry.

4. Promote industry specific "independent software vendor" by extending similar benefits

Policy for pricing

1. Separate price control order for medical devices

Once the proposed exclusion of medical devices from the definition of drugs under the Drugs and Cosmetics Act (and hence from the Drugs Prices Control Order issued thereunder) is implemented, the medical devices may be included separate from drugs in the Essential Commodities Act and regulated under a separate Medical Devices (Prices Control) Order (MDPCO).

2. Price control body

Empower NPPA for fixation and monitoring of prices under a separate vertical.

3. Pricing & reimbursement policy

3.1. Pricing of medical devices should be different from that of drugs. It should be done in such a manner to ensure sufficient incentives in terms of returns on investment.

3.2. Costs of complete basket of medical devices may be considered while deciding the prices to keep the

industry viable as the industry cross subsidises its products.

3.3. Transparent, predictable evidence based policy on core principle of “value for money”. Create enough opportunity to provide appropriate return on investment for all stakeholders.

3.4. Liaise with IRDA & the Payer (Health insurance) industry in the country to cover new technology on risk based pricing models.

Duty structure

Tax/ duty structure to be designed to promote local manufacturing of quality medical devices and diagnostic equipment

1. Discounts on import duties

Minimum/ zero duty on the import of raw materials and manufacturing equipments for production of medical devices.

2. Restrictions on import of second hand diagnostic equipment/ tools

2.1. It should be prohibited or made more stringent.

2.2. Higher taxes after 5-7 years of usage for imported second hand devices

3. Incentivize and promote exports in the medical devices sector.

The manufacturers with newly established set ups would be able to offset some of their initial setup costs.

4. Taxes should be levied with reference to MRP

as a disincentive to peg MRPs at a very high level.

Regulatory

1. Formulate “Medical Device Regulatory Act”

1.1. Medical devices should be treated distinctly from drugs and a separate chapter for medical devices should be made in the existing Drugs & Cosmetics Act.

This will provide a dedicated, predictable, transparent, globally harmonized and appropriate regulations for medical devices and will ensure that medical devices are only subjected to device relevant laws and not to those relevant to drugs.

In addition to updated definitions, the new legislation would simplify import procedures and affect change across many areas including: manufacturing, sales, distribution and clinical trial of medical devices based on international benchmarks

1.2. A distinct regulatory pathway to be created for clinical trials of Medical devices

It should not be same as those for drugs.

1.3. Formulation of a risk based regulatory system for medical devices based on justified regulatory control mechanisms.

A risk based classification of medical devices into different categories based on safety and usage in Humans would permit requisite regulation while avoiding unnecessary hindrance to growth in the sector.

It could be formulated as more stringent regulation for high risk devices, regulation of medium risk devices by notified bodies and self-regulation and conformance to standards for lowest risk category of medical devices.

Notified bodies would be defined/ recognized and incentives provided to them for setting up and, thereafter, for their up-gradation.

1.4. Harmonization with regulations guiding radiation-emitting medical products with the help of bodies like AERB

Regulation of radiation-emitting medical products such as lasers, x-ray systems, ultrasound equipment, CT Scan, MRI, PET scans and cathlabs can be reviewed and integrated with the Medical devices regulations.

1.5. A policy on safety, efficacy and adverse reaction reporting based on international quality standards

Should be defined in consultation with concerned bodies like BIS and National Health Systems Resource Centre (NHSRC)

1.6. Penal provisions to be made moderate for Medical devices

It should not be as stringent as drugs

1.7. Labeling of MRP on Unit packs on imports should be made mandatory

with details of country of origin, date of manufacturing and shelf life. Bodies like CDSCO may advise on the process.

1.8. Design a system to restrict usage of diagnostic equipment beyond their shelf life

Design and implement policies to scientifically phase them out.

2. Designate regulatory bodies for medical devices

2.1. Regulatory body for medical devices

An independent vertical within the existing regulatory framework be set up.

2.2. 2.2. Regulatory clearances to be provided by single window

Personnel from other agencies can be co-located and development of online and time bound system of clearances

2.3. Regulatory officials to be positioned across the regulatory landscape in

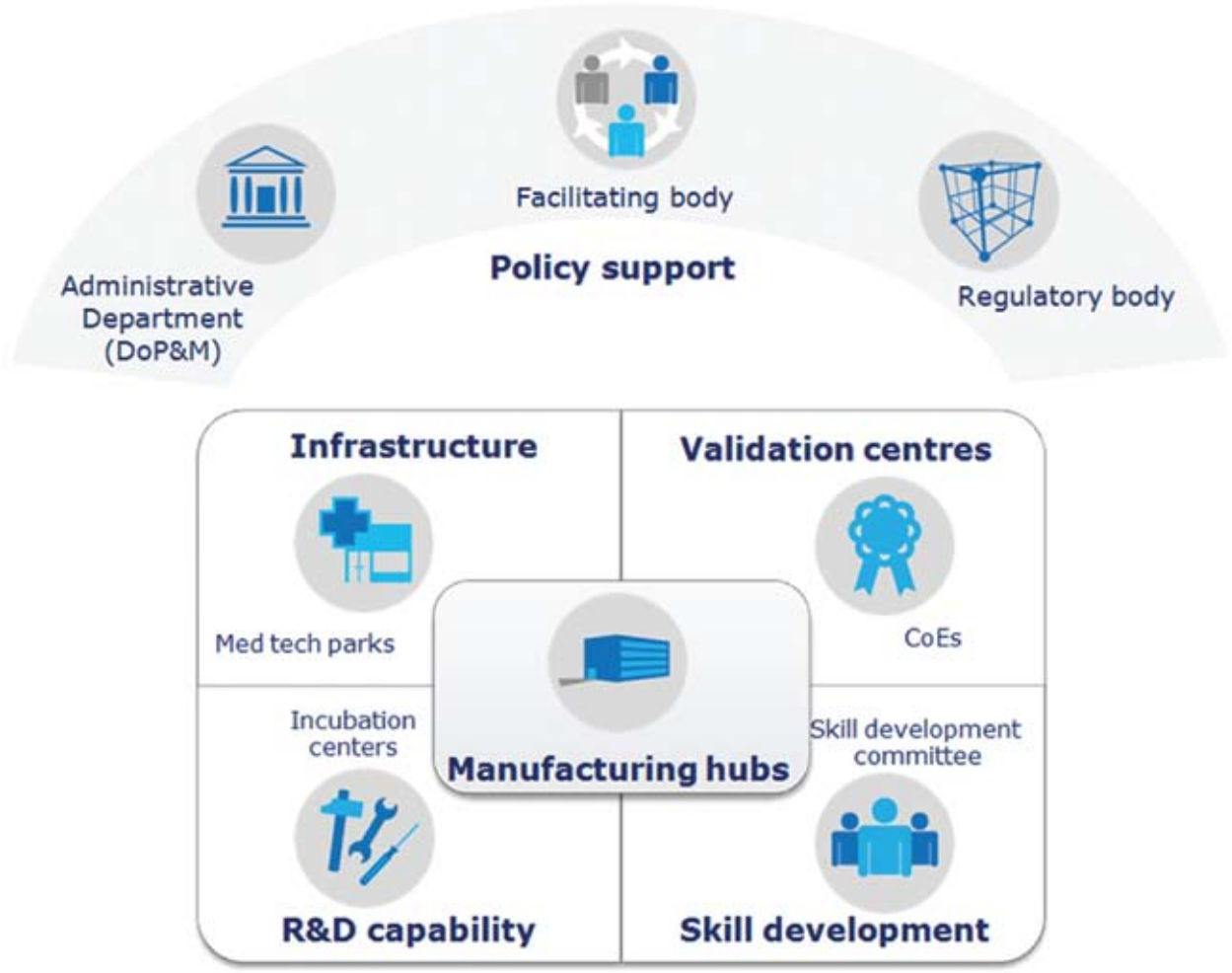
- CDSCO
- States (preferably)
- Medical devices manufacturing hubs

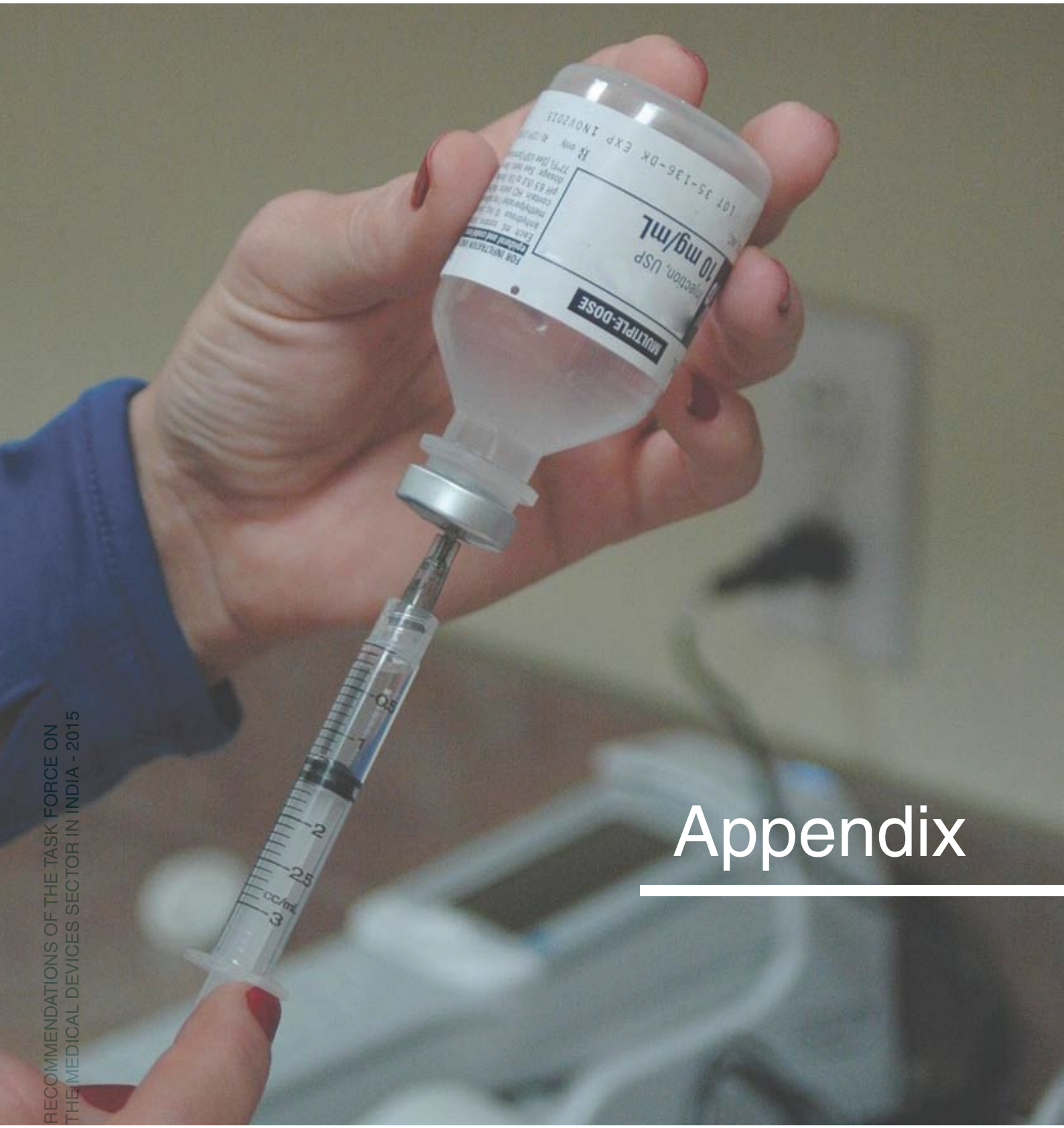
2.4. Continuous training of regulatory staff at centre as well as state level

to ensure proper interpretation and consistent implementation of regulatory approval processes

The envisioned ecosystem

- Medical Device Regulatory Act
- Pricing control policies
- Tax discounts
- Financing support





Appendix

Appendix 1 | Terms of Reference (ToR) for the Task Force

To identify issues relating to the promotion of domestic production of high end medical devices and pharmaceutical manufacturing equipment in the country, it was decided to constitute a Task Force in the Department of Pharmaceuticals in compliance of the E-samiksha monitoring system related action point.

Scope of work:

1. Ascertaining the present status and share of domestic production and imports in different categories of medical devices and equipment used in the manufacture of pharmaceuticals.
2. The impediments that exist in making India self-reliant in domestic production of medical devices and equipment used in manufacture of pharmaceuticals.
3. The steps necessary for promotion of domestic production of high end medical devices and pharmaceutical manufacturing equipment.

The Task Force was supposed to submit its findings in three months.

Composition:		
1.	Secretary, D/o Pharmaceuticals (DoP), Government of India	Chairman
2.	Representative of D/o Health & Family Welfare, GoI (Not below the rank of Joint Secretary)	Member
3.	Representative of D/o Health Research, GoI (Not below the rank of Joint Secretary)	Member
4.	Drug Controller General of India (DCGI) or his representative	Member
5.	Representative of D/o Commerce, GoI (DoC) (Not below the rank of Joint Secretary)	Member
6.	Representative of D/o Industrial Policy and Promotion (DIPP) (Not below the rank of Joint Secretary)	Member
7.	Representative of D/o Electronics & IT (DEITY) (Not below the rank of Joint Secretary)	Member
8.	Representative of Industry Division of Niti Aayog	Member
9.	Representative of Association of Indian Medical Devices (AIMED)	Member
10.	Representative of Federation of Indian Chamber of Commerce and Industry (FICCI)	Member
11.	Confederation of Indian Industry (CII)	Member
12.	PHD chamber of Commerce and Industry	Member
13.	The Associated Chambers of Commerce of India (ASSOCHAM)	Member
14.	Federation of Pharma Entrepreneurs (FOPE)	Member

Appendix 2 | ToR for Sub group 1

Scope of work:

1. To ascertain present status of the medical devices and equipment industry in the country along with share of domestic production and imports in the different categories of medical devices and equipment used in manufacturing of pharmaceuticals ; and
2. To review the present situation of demand in the country for medical devices and pharmaceuticals manufacturing equipment.

Composition:

Representatives from the following Department / Organizations:

1. Department of Commerce
2. Ministry of Health and Family Welfare (dealing with Health Insurance issues)
3. NITI Ayog (formerly Planning commission)
4. Health Associations viz Organisation of Pharmaceutical Production of India (OPPI), Bulk Drug Manufacturing Association (BDMA), Indian Pharmaceutical Association (IPA), Association of Indian Medical Devices Industry (AIMED), CII, Indian Drug Manufacturing Association (IDMA), FICCI, PHD Chamber of Commerce and Industry

Co-opted Members:

1. Smt Chandni Raina, Director, DIPP
2. Sh Awadhesh Kumar Choudhary, Director, Deptt. Of Pharmaceuticals

Appendix 3 | ToR for Sub group 2

Scope of work:

The subgroup would analyse the present status and way forward for promotion of domestic production of high end medical devices and equipment used in manufacturing of pharmaceuticals with focus on policy and infrastructure related issues facing the sector. The group will in particular look at factors like:

- The policy support
- Infrastructure
- Facilities for efficacy and safety testing
- Trained personnel with sufficient technical & pharmacy-based knowledge
- R&D capability with interdisciplinary approach
- Policy for pricing of Medical Devices

Composition:

- Chaired by: Department of Pharmaceuticals (DoP)
- Members consisted of representatives from Department of Health Research, CDSCO, Niti Aayog (Planning Commission), Department of Electronics and all Associations. The subgroup would also co-opt Member if needed.

Appendix 4 | ToR for Sub group 3

Scope of work:

The subgroup would make recommendations on the regulatory issues as also on issues relating to duty structure for promotion of domestic production of high end medical devices and equipment used in manufacturing of pharmaceuticals.

Composition:

- Chaired by: MoHFW
- Members will consist of representatives from CDSCO, DOC, DIPP and all Associations. The subgroup may also co-opt Member if needed.

Appendix 5 | Recommendations of Sub group 1

Medical Devices Sector Overview

India has experienced significant growth in the health care sector in the past decade. However, it faces constant challenge to make high quality health care affordable and accessible. Medical devices form an important pillar in the health care system along with health care providers, pharmaceuticals and health insurance industry in India. Medical devices are used to enhance the quality of patient care by restoring function and aiding in the diagnosis, prevention, treatment and management of diseases and disabilities. Medical devices industry in India is very small by size as compared to manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the 4th largest market in Asia after Japan, China and South Korea.

The Medical Devices market can be classified into two major categories:

1. Devices that require external energy source to be operational (powered) and
2. Those that do not require any external energy source.

Powered devices are divided into three product categories-Equipments, Implants and Disposables. Equipment accounts for the largest share of the total market followed by medical implants and disposable segments respectively.

Equipments –

The 'Equipments' segment is also the fastest growing segment and is largely dependent on imports. This can be further segmented into the following categories –

- Surgical Equipments: Prominent factors that drive demand are advancements in surgery and surgical device designs, availability of high skilled surgeons, growing breed of corporate hospitals and advanced surgical facilities. Advanced robotics, minimally invasive surgical techniques and imaging are expected to be key enabling technologies for developments.
- Diagnostics: Increase in the prevalence of diseases, their complexity and the need for quick diagnosis has created a high demand for diagnostic services and devices in the country. Advances in diagnostic categories such as Cardiac imaging, CT scans, X-ray, Molecular Imaging, MRI and Ultrasound-imaging including hand - held devices are market movers.
- Life Support: As life support technologies evolve and improve, their use outside of the hospital environment has increased. For example, patients with ventilator support are increasingly staying at home with the device, increased presence of automated external defibrillator in nursing homes and residences, etc. As consumer spending power increases demand for such systems is expected to grow.

Implants –

The market for implants is witnessing some amount of innovations in terms of catering to large unmet needs in certain disabilities e.g. blindness. A microchip retina implant is under trial which will allow blind patients to read letters & recognize foreign objects.

Disposables –

Medical disposable products for medical electronic equipment are used by all hospitals and private nursing homes in the country, including diagnostic and pathological laboratories. The market is becoming increasingly competitive due

to low entry barriers (for MNCs), increasing number of players and an expanding consumer base. Examples include disposable medical and electronic probe assemblies for minimally invasive applications, disposable catheter cables, disposable EEG sensors/lead wires, disposable pulse oximetry sensors, panel mount receptacles, etc.

The growth of medical devices sector depends on the following two factors-

- **Market Factors –** Growing population, ageing, income base and associated disposable income, increasing socio-economic inclusion of rural and deprived in mainstream economy, heightened manufacturing innovation to create customized products to meet the needs of all income segments, changing disease prevalence pattern (e.g. early onset of diabetes and heart diseases) and growing awareness among the middle class to focus on early detection and disease prevention.
- **Non-market Factors –** Development of infrastructure, favorable regulations, FDI inflow, outsourcing of manufacturing and R&D activities to India, government initiatives to improve healthcare access through insurance schemes such as RSBY (Rashtriya Swasthya Bima Yojana), Aarogyasri, etc.

Status of Medical Devices Manufacturing in India

At present, the Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Requirement for high end medical equipments are met by multinational companies. It is estimated that there are about 800 manufacturers in the country and based on their turnover, the industry profile of these manufacturers are as given in table 1 below.

Table 1: Industry Profile

Turnover	% Distribution
0-10 Cr	65
10-50 Cr	25
50-100 Cr	5
100-500 Cr	3
500 + Cr	2

Source: Association of Indian Medical devices Industries (AIMED)

Medical devices Industry in India is predominantly import driven accounting for over 65% of the medical equipment market. Domestic firms generally participate in the low priced, high volume market segment wherein competition is intense. MNCs do not operate in low tech device segment where local manufacturers are involved in intense price competition. On the brighter side, some manufacturing companies are now shifting their focus from capturing the market share to market creation. They are discovering innovative products for market niches.

During the period 2011-12 to 2014-15 both import and export of medical devices have grown at more than 10% rates. Import and export during this period were as depicted in Table 2 and Table 3 below.

Table 2: Summary of Imports of Medical Devices in India (All values in Rs. Crore)

S No.	Description / HS Code	2011-12	2012-13	2013-14	2014-15 (April to Oct.)
1	Disposables and Consumables (HS Code 9018, 9020, 9021, 9027, 3006, 4818)	2,782.19	3,035.02	3,164.11	2,170.12
2	Electronics & Equipment (HS Code 9018, 9019, 9021, 9022, 9027, 9402)	8,734.50	10,547.30	11,504.48	6,799.44
3	Implants (HS Code 9018, 9021)	1,160.57	1,482.68	1,750.63	1,092.10
4	Surgical Instruments (HS Code 9018)	2,342.92	2,662.82	3,011.25	1,881.92
5	IVD Reagents (HS Code 3006, 3822)	1,249.67	1,534.59	1,893.57	1,084.54
	GRAND TOTAL	**16,269.84**	**19,262.42**	**21,324.04**	**13,028.12**

Source : Department of Commerce, MOC&I

Table 3: Summary of Export of Medical Devices in India (All values in Rs. Crore)

S No.	Description / HS Code	2011-12	2012-13	2013-14	2014-15 (April to Oct)
1	Disposables and Consumables (HS Code 9018, 9020, 9021, 9027, 3006, 4818)	1 ,414.78	1,820.06	2,719.73	1,723.02
2	Electronics & Equipment (HS Code 9018, 9019, 9021, 9022, 9027, 9402)	1,934.86	2,174.37	2,797.34	1,778.22
3	Implants (HS Code 9018, 9021)	92.61	138.95	178.96	125.97
4	Surgical Instruments (HS Code 9018)	606.18	625.05	777.70	437.02
5	IVD Reagents (HS Code 3006, 3822)	136.63	187.42	279.08	118.60
	GRAND TOTAL	**4,185.06**	**4,945.84**	**6,752.82**	**4,182.83**

Source : Department of Commerce, MOC&I

It is assumed that out of Rs. 6800 Crore of exports during the year 2013-14 approx 30%, i.e 2,000 Crore is from Re -Export of imports (an insignificant value addition). Therefore Rs. 4,800 Crore is produced indigenously. It is further assumed that exports are in the range of 30-35% of indigenous production. So production (including reprocessing of imports for exports) is estimated at Rs.16,400 Crore. (This corresponds to an average turnover of Rs. 20.50 Crore x 800 manufacturer). Therefore the industry size is estimated to be approximately Rs. 30,900 Crore (US $ 5 billion) during the year 2013-14.

Assuming that out of the total supply of Rs. 30,900 Crore, over 70% is for private sector and below 30% is for Govt. sector, the split is approx Rs.21,600 Crore for Private Sector and Rs. 9,300 Crore for Govt. Assuming the price of indigenous manufactured goods as well as imported goods which is supplied to Govt. and its agencies is in the range of 1.5 - 2.00 times Ex-Factory/ CIF price and price at retail / corporate hospital of indigenous manufactured goods as well as imported goods is 2 to 2.5 times the Ex-Factory /CIF price, the total Market Size at retail level may be estimated to be over Rs. 61,800 Crore (US $ 10 billion).

Overview of the medical devices industry for 2013-14 is indicated in the Table 4 below.

Table 4: Industry Profile 1 (All estimated values in Rs. Crore)

	Total Sales (Import + Indigenous)	**Percentage share of the Total Sales (%)**	**Indigenous Sales Rs.**	**Percentage (%)**	**Imports**	**Percentage (%)**
Disposables & Consumables	9,650	31.3	6,500	67.3	3,150	32.7
Medical Electronics, Hospital Equipment, Surgical Instruments	16,600	53.7	2,100	12.6	14,500	87.4
Implants	2,200	7.1	450	20.5	1,750	79.5
Diagnostics Reagents	2,450	7.9	550	22.5	1,900	77.5
Total	**30,900**	**100**	**9,600**		**21,300**	

Source : AIMED

Share of different segments of medical devices in imports and exports for the year 2013-14 is summarized as under in Table 5 below.

Table 5: Industry Profile 2 (All values in Rs. Crore)

S No.	Description	Import in India	Share	Export from India	Share
1	Disposable & Consumables	3164.11	15%	2719.73	40%
2	Electronics & Equipment	11504.48	54%	2797.34	41%
3	Surgical Instruments & Equipment	3011.25	14%	178.96	12%
4	Implants	1750.63	8%	777.70	3%
5	IVD Reagents	1893.57	9%	279.08	4%
	GRAND TOTAL	**21324.04**	**100%**	**6752.81**	**100%**

Source : AIMED

Various sources expect the Medical Electronics industry to reach around USD 2+ Billion in 2015 growing at a CAGR of 17% for the last five years from a size of USD 850+ Million in 2009. It is believed that the growth will not only sustain but increase beyond 17%.

Appendix 6 | Recommendations of Sub group 2

Policy Support

- Set up a corporate body / registered society consisting of representatives from Government agencies and business; with a permanent office and support staff who would keep all stakeholders apprised of the best practices and global development in the sector.
    - This will ensure percolation and spread of learning from experience of other countries/trade blocks like ASEAN and facilitate adoption of international templates for regulation in medical device industry, clinical investigation on medical devices, etc.
- Introduce a policy for preferential treatment in government procurement for medical devices in which significant value addition is made in India.
- As of now, there is no designated nodal government agency responsible for the sector. Allocation of Business Rules may be suitably revised to make Department of Pharmaceuticals as the nodal Department concerned with the sector and it may be rechristened as Department of Pharmaceuticals & Medical Devices.
- Department of Pharmaceuticals to be suitably strengthened to enable it to effectively take up the additional responsibility.
    - To begin with, a post of Director for Medical Devices along with support staff may be created in DoP.
- Separate medical device regulatory act should be drafted and introduced in view of the specificities of the sector
- Set up an independent regulatory body with specialized regulators for medical devices; **alternatively,** create separate wing within the existing regulatory set up that would exclusively focus on Medical Devices and have manpower with relevant expertise.
- A risk-based regulatory approach to clinical research requirements may be adopted in accordance with global regulatory principles
- Appropriate training be imparted to the regulatory staff especially at the state level to ensure consistent interpretation of regulatory approval processes.
- Make labeling of Max. Retail Price on Unit Pack on Imports mandatory.
    - Label should also provide details on Country of Origin, shelf life and date of manufacturing on Unit Pack.

Infrastructure

- Rationalise the adverse / inverted duty structure in medical devices segment with minimum / zero customs duty for import of raw materials and manufacturing equipment's for the production of medical devices and max. on finished products.
- Set up Medical Devices Parks with the right infrastructure in places that are conducive to medical device manufacturing.
- Provide access to low cost funding through capital/interest subsidy to spur investments and to make the business case attractive.
- Designate 'Centers for Excellence' for different categories of Medical devices that have requisite infrastructure expertise and facilities. These Centres would:

- Update BIS standards & set up Validation facilities with the International available standards and compliance mechanisms.
- Certify the medical use of a device.
- Providing support to product development including assistance for Design, Prototyping and validation of High-end Product development in line with Global standards.

HR Development

- Set up a committee with representatives from medical devices industry and academia especially NIPERs for:
  - Identifying the skill needs of the sector and design curriculum to address such needs appropriately.
  - Exploring the possibility for setting up satellite campus of NIPERs around manufacturing hubs to create training hubs for skill up gradation.
  - Explore the possibilities of providing on-line courses / e-Learning modules to meet the specific requirements of this segment.
  - Engaging with the it is and polytechnic training institute to skill the manpower to the requirements of the sector
- Facilitate training of medical and paramedical staff by supporting such efforts by the Medical Devices sector.

R&D Capability

- Provide seed capital, viability gap funding, co-fund start-up projects and support the commercialization of innovations.
- Develop 'Knowledge Networks'
- Promote 'independent software vendor' catering to the need of this sector by extending similar benefits.
- Facilitate setting up of IP Exchange
- Provide a longer term view (10 yrs window) for 200% weighted tax deduction on approved expenditure on R&D activities as the gestation period is high in this industry.
- Set up / promote incubation centres through appropriate incentive structure / cost sharing.
  - Incubation centres would address the capability shortfall in R&D infrastructure, testing, calibration etc which limits the extent of investment in innovation in India.

Policy for Pricing of Medical Devices

- Amendment of the Essential Commodities Act to insert 'Medical Devices' after the entry 'drugs'.
  - Consequent to proposed amendment of the definition of Drugs under the Drugs and Cosmetics Act excluding medical devices.
- A policy for control of prices of medical devices.
- Give powers relating to fixation and monitoring of prices of medical devices to NPPA.
- A transparent, predictable, evidence based reimbursement and pricing policy with the core principle of "value for money." may be adopted. Create enough opportunity to provide an appropriate return on investment for all stakeholders.
- The pricing of medical devices requires a different model from drugs

Appendix 7 | Recommendations of Sub group 3

1. Medical devices to be treated distinctly from drugs. Separate provisions to be made in the Drugs & Cosmetics Act to provide for a dedicated, predictable, transparent, globally harmonized and appropriate regulations for medical devices/ IVDs. This will ensure that medical devices are only subjected to device relevant laws and not to those relevant to drugs.
2. Separate/ dedicated set of regulatory officials to be positioned in CDSCO and preferably in the states for the medical devices.
3. Need to regulate medical devices should be linked to risk with more stringent regulation for high risk devices, regulation of medium risk devices by notified bodies and self-regulation and conformance to standards for lowest risk category of medical devices. However, the regulatory staff can and shall test-check conformance to standards.
4. Notified bodies would be set up/ recognized and incentives provided to them for setting up and, thereafter, for their up-gradation.
5. Medical devices manufacturing clusters to be set up so that regulators could also be positioned in those places to facilitate cases clearances.
6. Medical device testing centers or labs to be set up to facilitate testing/ evaluation of medical devices preferably in PPP mode. This could be done closer to the medical device manufacturing clusters. Requisite incentives to be provided for setting up of such units including soft loans/ interest subvention.
7. Common medical device testing facilities can be set up by government in major medical device manufacturing hubs to facilitate testing/ evaluation of medical devices. Recurring expense can be borne by the industry.
8. A clear regulatory pathway to be developed for conduct of clinical investigation of new medical devices and it should not be the same as clinical trials in case of drugs.
9. Training of Regulatory personnel both from the Centre and the States in the field of medical devices to be organised.
10. Penal provisions in respect of medical devices should not be made as stringent as drugs.
11. Import of second hand diagnostic equipment / tools should be prohibited or at least made more stringent as such equipment not only cause high radiation but also give misleading results thereby impacting the quality and course of the treatment.
12. Diagnostic equipment should not be used beyond their shelf life and a system should be evolved to scientifically phase them out.
13. Clarity, objectivity, transparency and predictability will need to be ensured in the rules to regulate medical devices which will supplement the Drugs, Medical Devices and Cosmetics Act.
14. Regulation of process of medical devices should be done in such a manner that it ensures sufficient incentives in terms of return on investment.

15. Tax/ duty structure should be designed to promote local manufacturing of quality medical devices and diagnostic equipment rather than encourage second hand refurbished and doubtful quality equipment. A clear message needs to go that after five/ seven years, the imported devices will attract higher taxes.

16. Centres of excellence for promoting innovation should be set up and funded by the Central Government.

17. Research and Development facilities should be supported by funding agencies such as ICMR, DBT, CSIR

18. Taxes should be levied with reference to Maximum Retail Price (MRP). This will serve as a disincentive to peg MRPs at a very high level.

19. Feasibility of all regulatory clearances being provided from one organization viz. CDSCO., where personnel from other agencies can be co-located and development of online and time bound system of clearances should be evolved.

20. Since medical devices will be manufactured in the country on a large scale for the first time, the conditions of tender documents such as performance over last three/ five years etc. should be suitably modified.