



AiMeD Annual Report 2016

India is growing as a Key Market for Medical Devices and Diagnostics. It is currently the fourth largest Market in Asia and is worth over 10 Billion \$ at Retail & Institution Sales level. At Production value level, i.e. at Ex-factory and Import Landed Price (Pre Duty) level its estimated at over 5 Billion \$ of which Imports are at 25000 Crores and Exports at 1.1 Billion \$. The Industry had earlier seen tremendous growth over the last decade of 15-20% but is currently growing at a slower rate of 10-15% though the Market is growing more rapidly at 15-20% which indicates a declining share of Domestic Industry. Hence now is the time for a Policy review so that Domestic Industry growth exceeds 20-25% increasing its share in the Domestic & International Market.

Preface : India is now the limelight for its expertise in some segments of the Medical Devices space. The Industry's inherent Engineering strengths are being recognized by Global majors who are now looking to tap the emerging Market opportunities to augment growth. India is well placed in the outsourced contract design, development and manufacturing space because of its Engineering capabilities in a wide spectrum of areas. Typically, there are two Market opportunities in contract design and development of Medical Devices. One is that Companies in the US and Europe can offload a whole range of existing Medical Device Products to India to maximize the cost advantage. India has been proving to be a reliable and dependable source for this capability.

The second is that Global Companies can look at India as a Hub in the Asian Region to undertake contract design, develop, manufacture and package the Medical Devices.

A visible trend is that all International Companies in the wake of the Global Economic slow down are looking to tap opportunities in the emerging Markets. These are the Markets of the future. Companies in the West are transforming Business Models to cater to the needs of the emerging Markets which make up 4/5th of the Global demand. The Companies have begun to re-device the Business Strategy primarily because emerging Markets are Price sensitive.

Therefore Companies would look at Alliances and Joint Ventures with Indian Enterprises in these Regions. In the US, the issue is 'Performance over Price' as against India where it is 'Price over Utility'. Therefore International Companies need to look at the 'Design to Cost' factor to make Medical Devices available in India. This is where Global Majors will now have to look at design and Manufacturing Hubs in Asia and India, in particular, to tap the Quality-Cost advantage which will help improve gross margins. There is need for innovative thinking and India is now building its capability to be a Platform for such prospects and the challenge for Medical Device Companies is to raise funds and be able to repay within a realistic time frame. In this business, cycle time is longer. Therefore, both the Investor and Management have to be patient. There is also the issue of Global Sourcing of Raw Materials and dealing with Imports because of inconsistent levy of Import Duty on Raw Materials which was being higher than the Finished Products in some Medical Devices. Recently for nearly 60% of the Medical Devices this Tariff anomaly has been corrected. Therefore, we need to be able to raise investments with a realistic time frame and calibrate expectations of time.

Our Capacity covers design, development of low cost Disposables and Consumables, Electro Mechanical Diagnostic and Therapeutics Devices besides Implantable Devices like Stents and active Implantable like Pacemakers. We are gearing up to offer our expertise across all Segments in Medical Devices from Electrical –



Electronics – Mechanical Engineering to Software. These include high precision Machining of Components, Sub Assemblies to printed Circuit Boards Assembling, Sourcing of Implantable Grade Materials and Sterile Packaging, Global Sourcing of Bio Gradable Materials which are Implantable Grade Materials Steel, Noble Metals, Novel Biomaterials like Nitinol, Polymers, Silicones, Epoxy etc. of Medical Grade. This is possible because of our State of the Art ISO 13485 Compliant in house Multi- Disciplinary Engineering and Manufacture Infrastructure that includes Micro Electronics, Polymer Sciences, Bio Mechanical, Laser Welding Hermetic Sealing which is supported by Classified Clean Room and complex Device Assembly area.

We have the Expertise to provide the required Regulatory Compliance documentation for Medical Devices Manufacturing Quality Management Systems which has been proven by the recent release of the International Class ICMED Voluntary Certification Scheme by QCI. This will bring International respect to Medical Devices made in India. The future holds immense potential for the Medical Devices Industry. This is because of the strong growth of the Healthcare space. India can score over China in the Medical Devices space and grab the contract design and development orders.

The Country has a sound record in adherence to IPR which is vital for Medical Devices because it follows English Law which is also referred to as the Contract Law of the Common Wealth Countries. International Courts uphold the English Law. There are Multi-Disciplinary R&D efforts and Engineering capability in multiple Sciences of Electronics, Chip design, Software Mechanical and Medical Engineering which are complex.

The Country has already made a mark in Pharmaceuticals, development of new Chemical Entities and Clinical Research. The time has now come for India to take its place in the Medical Devices space. This Medical Device Engineering opportunity is bigger than the Information Technology (IT) boom and we need to capitalize.

Actionable points.

Most of the policy decisions taken in past have been based on White Papers published at behest of MNC's who are ruling the roost in CII & FICCI – (Importers with Overseas Manufacturing Facilities) who are comfortable to access the large unregulated Indian Market with Minimal Tariff Barriers and while they make right sounding noises they have been opposing most of the 5 corrective strategic actions suggested by AiMeD that could strengthen Make in India or help make Indian Manufacturers more competitive and thereby increase their Market Share, such as :

- 1- **Tariff Correction**, with the plea that it effects affordability and accessibility to poor Patients. Our contention being to make Manufacturing viable and profitable as before and reverse ongoing trend of Manufacturers becoming Importers / Traders. Later Domestic Competition will bring down prices.
- 2- **Regulations, (Short Term Correction of Amending Rules , Schedule Mill , Guidelines ,etc.)** with the plea that it would lead to further confusion and affects accessibility and better to wait till a Law is passed. Our contention being to use the available short term solutions of administrative circulars and of executive orders rather than delay till availability of lengthy Legislative process.
- 3- **Mandatory MRP & Price Capping** – With the plea that it will scare away investment. Our contention being that affordability and Competition is getting skewed - not lower Ex-Factory Price but higher Retail Price wins and Consumers are suffering from Artificial Inflation and Domestic Manufacturers suffer from loss of Market Share unless they match ever increasing MRP and Trade Margins.



4- **ICMED – Self Certification and Self Regulation** , With the plea that it creates a Parallel Mechanism with CDSCO so better to have only one control and are afraid it could be used as a Non-Tariff Barrier in due course. Our contention being it provides credibility to Indian Products and Low Cost access to Local Certification rather than getting expensive Overseas Certification for CE / ISO 13485 etc. and respect for Indian Brand, a Law to Regulate all Devices may not be there for few years and a Law can permit Voluntary Certification.

5- **Preferential Market Access** – With the plea that it restricts access to Quality Products in absence of Regulations. Our contention is it will Boosts Domestic Manufacturing and will also stop Usage of USFDA Compliance as a Mandatory Qualifying Criteria in Many Tenders. Why should Indian Manufacturers be denied access to our own Indian Market unless they Comply with a Foreign Country Regulatory Approval of CE / USFDA ? It's unfair.

We needed the following National Medical Device Policy decisions in 2016 ; Progress Report :

i) **Govt. to Revise Basic Duty on Import of Medical Devices to 10% Basic**, as earlier (now 7.5% on Jan 19th for 78 items , 21 pending)

- Govt. to Revise Special Additional Duty on Medical Devices to 4%, as earlier to enable business viability (Done on Jan 19th 2016 for 78 items, rest 21 to be covered)

- **Govt. puts Tax based disincentive for addressing Artificial Inflation & enabling Consumer Protection** 1% Excise Duty Cess (on MRP) - Pending

ii) Govt. introduces **ICMED 13485 Quality Certification System** as a precursor to Medical Device Regulations for enabling confidence in quality of Indian Products (Done on 15th March 2016).

iii) Govt. Releases a **Preferential Market Access** Buy Indian Policy to Indian Manufactured Product for Public Health Procurement having over 40% value addition and ICMED Certification to boost Domestic Production of Quality Devices - *awaited*.

iv) Govt. gives a 15% **Preferential Pricing** for Indian Origin Medical Devices (like being done for World Bank Financed Tenders) to counter Chinese Subsidy of 17% - *awaited*

v) Govt. creates a **Separate Medical Device Regulations** Act (based on International Best Practices) in India, independent of D&C Act for ensuring Patient Safety- *intention announced* - opportunity to Make in India and not allow traders to be incorrectly defined as Manufacturers - *awaited* .

vi) Govt. pulls back its Auto Approval Brownfield FDI Policy -retains this for 100% Green Field Projects for manufacturing , not trading - for ensuring choice of Indian Brands to Indian Consumers

vii) Govt. assists **creation of Medical Device Parks** in Andhra Pradesh, Maharashtra, Gujrat & Karnataka and aids existing Clusters in NCR, Gujrat & Maharashtra Mumbai – Pune, Bangalore & Chennai with a 'Revenue Support Model' with Common Testing & Manufacturing

Facility Centre – No Capital Subsidy, for Making India Hub of Medical Devices (AMTZ launched on August 19th, next Nagpur under consideration, DOP suggested Policy pending)



viii) Govt. creates a **Medical Device Export Promotion and Import Substitution Council (MDEPISC)** under Medical Device Dept. in a New Ministry of Life Sciences to enable balance of Facilitation & Regulation

There are 3 types of Potential Manufacturers in India.

1- **MNC Importer** - Fence Sitters - used FDI to put up shop in India, displaced their Distributors and busy entrenching their Brands. They will put up Plants if they think they will lose market share due to above Policy announcements or if you offer attractive SOPS to compete with Ireland etc. can you ?

2- **OEM exporters** - Subcontracting to MNC s - their wish list to have Export benefits to match China's of 17% . Some success Stories are there.

3- **Indian MSME and mid sized co** . Irony is no one is even having 1000 Crores of mfg turnover and many shifted to imports - their wish list is to consider most of schemes of MSME available to Medical Devices without Cap - they have survived the adverse Manufacturing environment and brutal competition from deep pocketed MNC's, they have ambitions to place Brand India Globally. Many success stories. Please Help them.

Depending upon Govt. of India urgency and resources and limitations Dept. of Pharmaceuticals can decide wisely what incentives you can give (or not) to each of these 3 categories but most important is either announcing a comprehensive medical device policy Or taking action on above recommendations 1 by 1 and enclosed To Do checklist (enclosed) Appendix 1 for each Ministry, as soon as possible.

We can go incrementally or we can leapfrog ,depends upon implementation of above and response from investors - Indian & Foreign - more important, please aim to turn Traders into Manufacturers as was historically the case till a decade ago.

Impact of Actions Taken :

Impact Assessment of 78 Medical Devices of Notification No. 4/2016 Dt : 19.01.2016											
										Value in Rs. Crore	
S No.	HS Code							Import - 2015-16			Import - 2016-17
		(April to June) (Rs. In Crore) Q1	(July to Sep) (Rs. In Crore) Q2	(Oct to Dec) (Rs. In Crore) Q3	Average Q1 to Q3	(Jan to Mar) (Rs. In Crore) Q4	(April to June) (Rs. In Crore) Q1				
1	9018	1,993.70	2,198.81	2,258.20	2,150.23	2,247.33	2,066.27				
2	9022	894.04	900.80	997.67	930.84	815.08	877.22				
3	9019	133.20	133.35	185.94	150.83	148.72	164.89				
4	9020	11.44	13.49	23.44	16.13	13.97	16.25				
5	9021	757.52	707.60	699.55	721.56	743.04	742.51				
	TOTAL	3,789.91	3,954.06	4,164.79	3,969.58	3,968.14	3,867.13				
	Gross Total										



(i) The positive Impact Assessment on 78 items covered under Notification No. 4/2016 – Customs Dt : 19.01.2016 whereby Basic Duty covers of 5% (or 0%) was withdrawn and reinstated to 7.5% and similiary for SAD reinstated from 0% to 4%.

We may assume that there may be No / Minimum Impact in the 4th Quarter data i.e. January 2016 to March 2016 as the Notification came only on 19th January, 2016.

While it may be too early to see a significant impact for each of the 78 items however their average for the 3 Quarter of 2015-16 (April to June, July to Sept and Oct to Dec) was Rs. 3969.58 Crore. This reduced marginally to Rs. 3968.14 Crore in Jan to March 2016 but more significantly the downward trend continued to Rs. 3867.13 Crore in April to June 2016.

Upon further analysis, we can see that the Quarterly Import of April to June 2016-17 is significantly lower at 2066.77 than the average of the previous year for HS Code 9018 at 2247.33 & for 9022 at 877.22 down from 930.84.

This is a clear indication of positive impact of beginning of slow down of imports. **We are now requesting that for 67 of these 78 items whose Exports are over 5 Crore, the Basic Duty may be increased to 10%.** This will accelerate the Import Substitution and decrease Market Share of imports. Further to boost Component Manufacturing, the Basic Duty on Components used to make these 67 items may be increased to 5% (from 2.5%) Next Year and 7.5% thereafter. The Basic Duty of 2.5% may be retained on Raw Materials for now, for Next 3 Years at least.

The other Major impact of the Tariff Notification of 19th January was the focus and positive mood of investment this Sector is now generating, with Andhra Pradesh Govt. announcement of AMTZ Project in Feb'16 and Foundation Stone laid recently on 19th August. Thereafter Gujarat, Maharashtra, Telegana, Tamilnadu, Haryana & Himachal Pradesh State Govt's are considering similarly to set up Medical Device Parks. If Duty are nominally increased as recommended by us this will accelerate investment & Import Substitution as investors will find it viable and profitable to invest in India.

(ii) **ICMED Certification** : One Certifying Body (Intertek) have been accredited by QCI for Certifying Manufacturer for Compliance to ICMED 9000 & ICMED 13485 Schemes. Another six, UL India, BSI, Tuv Sud, TuV (Intercert), DNV and ICS, their application is under process.

5 Manufacturers have got ICMED Certification and another 20 are expected to get this in 2-3 months. In 2017, we expect over 100 Manufacturers to have ICMED Certification. Its important to reward them for their efforts by expediting Preferential Market Access Policy for these Certified Manufacturers.

(iii) **On the Regulatory Front** : In April this year (2016) the Schedule M III of Drugs and Cosmetics Rules which had listed requirements for Plant & Equipment & Infrastructure for 3 Medical Devices was updated to include Quality Management System (Good Manufacturing Practices) and aligned with IS / ISO : 13485 Certification. This will hopefully address the confusion and overkill whereby Medical Sterile Disposable Manufacturer were being asked to comply needlessly with requirements for Sterile Injectable and parentals on arbitrary basis. For the first time there is confidence generated that Medical Device Regulators will be treated separately from Pharmaceutical. Thereafter in May (2016) the Group of Ministers decided to rescind amendment to D&C Act and instead of having a Separate Chapter for Medical Devices to have entirely Separate Regulations for Medical Devices.



(iv) **Medical Device Park** : AMTZ opened its booking of plots on October 2nd. 10% of the plots have been booked by November 3rd week. To make this venture a success its imperative for Dept. of Pharmaceuticals to expedite Policy Measures as requested above and coordinating with respective Ministries enclosed in Appendix 1 for motivating fence sitter importers to invest in Manufacturing Plants in India. Other States will be motivated to follow based on success of AMTZ.

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Enclosed :

- 1) Appendix 1 – Action Points
- 2) Appendix 2 – Import / Export Data for 2015-2016 & 2014-2015