

LEAD AGENCY



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India's Medical Device & Pharma Machinery Sector

STRATEGY PAPER TO BOOST EXPORTS



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INTRODUCTION

Medical Device & Equipment sector is the next sunrise sector in India, which is having a growth potential even more than IT Sector boom. The cost of manufacturing pharmaceutical machinery in India is the lowest in the world, therefore, giving us the leading edge in world's markets. Backed by India's strong English Speaking man power, competitive skills, after sales service, etc. India is having a clear edge over China. The global medical device market is consistently shifting to adopt new treatment, budgets and increase in demands.

EEPC India with Yes Bank as the "Knowledge Partner" has prepared a strategy paper for the promotion of medical device and pharma equipment sector. An effort has been made to define the medical device sector, the report also incorporate the feedback of short term and long term strategy to be adopted for the promotion of the sector, the inherent competence and strength of the medical device sector and the way forward. The financial support in the form of fiscal benefits, technological advancements and policy changes are bound to create a strong opportunity for India to build global competitive edge in the healthcare sector. With several changes in the anvil, including the Drugs & Cosmetics (Amendment) Bill, 2013, the sector is poised for major developmental and regulatory changes. The pharma machinery has been taken up as a separate segment and the issues and concerns of the industry have been placed forward.

It is hoped that this report would be useful to the industry, major stakeholders and Government of India and will provide useful insight into charting a road map for developing a strategy to promote the export of medical device and pharma machinery.

Special thanks to Shri Rajeev Kher, Addl. Secretary & Shri Sudhanshu Pandey, Joint Secretary, Ministry of Commerce & Industry for spearheading and providing valuable inputs for preparation of the report.

The contribution and support of Confederation of Indian Industry, Exim Bank, ECGC, Association of Indian Medical Device Industry, Indian Pharmaceutical Machinery Manufacturers Association, Ministry of Commerce & Industry, Department of Science & Technology, Department of Pharmaceuticals, Pharmexcil, Capexcil, Plex Council, Yes Bank and the various consulting organizations who have provided data/information for the study is gratefully acknowledged.



METHODOLOGY

EEPC INDIA under the directions of Ministry of Commerce & Industry, Government of India was assigned as the nodal agency to prepare the strategy paper on India's exports of medical device and pharma machinery sector alongwith the other stakeholders and EPCs. EEPC INDIA has tried to adopt a comprehensive approach in preparing the strategy paper.

As a first step, a committee was formed for the preparation of the paper. Members of the committee were

1. Representative from CII
2. Representative from AIMED, New Delhi
3. EEPC India Chairman on Instruments – all types panel
4. Representative from Exim Bank
5. Representative from ECGC
6. Representative from Pharmexcil
7. Representative from CAPEXCIL
8. Representative from PLEX Council
9. Yes Bank (as Knowledge Partner)

A briefing meeting of the committee was conducted where the background was given which included a brain storming session on the approach towards the report.

Yes Bank was appointed as the “Knowledge Partner” for the preparation of the strategy paper. The appointment was also seconded by the members of committee. Yes Bank has a separate division of Life Sciences and Information Technology Knowledge Banking and Mr. Siddharth Dhodi, Senior Manager was directly involved in the preparation of the report alongwith his team members.

EEPC India devised a questionnaire to obtain the feedback from all the stakeholders and this was circulated to the committee members. EEPC India also identified the top exporters of the medical device sector and their feedback was obtained.

A series of interactions with the major associations, leading companies operating in the medical device sector in India was conducted alongwith Yes Bank. Secondary analysis by the team was conducted in order to develop strategic recommendations for the paper.

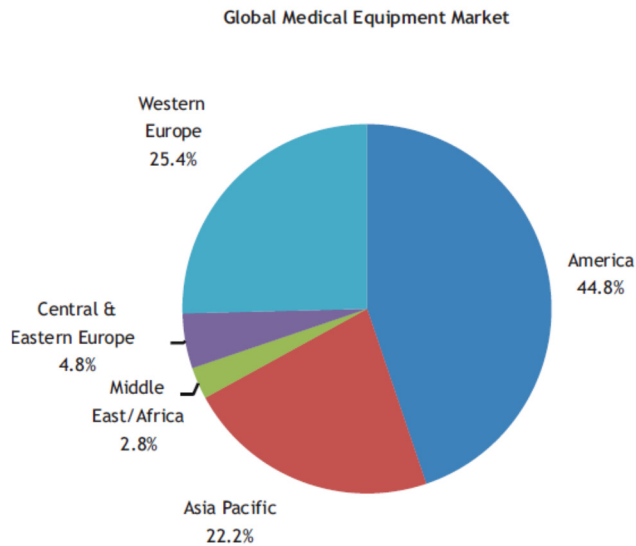
For the pharma machinery sector, inputs were taken from Indian Pharma Machinery Manufacturers Association (IPMMA) and their feedback was incorporated in the report.

To conclude the report indicates the short term and long term strategies which may be adopted by the sector for the promotion of medical device and pharma machinery.



GLOBAL MEDICAL DEVICE INDUSTRY

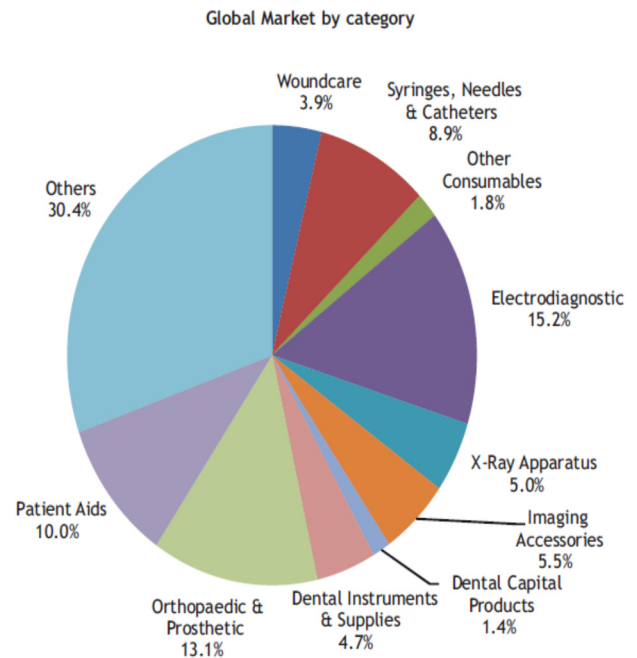
The Global Medical Device market was estimated to be around USD 270 billion in 2011 and was observed to grow at a growth rate of 5.3%. The market has been primarily dominated by US and Europe which cater to 75% of the market while the Asia Pacific contributes to nearly 22%.



Source : Espicom Report 2011

In terms of industry segments, Orthopedic & Prosthetic and Electro diagnostic emerge as the largest category with a total market share of nearly 30% of the total medical device market. The dental products amass to a total of 6-7%. The consumables which include the Syringes, Needles, Catheters etc constitute to ~ 11%. This consumables space is primarily as low value high volume space and has witnessed a domination of the emerging economies. The High technology 'patent driven' space has been a stronghold of the US and Europe.

Although through Technical innovation and extreme emphasis on R&D the medical technologies in the developed nations have fairly evolved. The last decade has seen an evolution of the Asia Pacific medical device industry. This region has slowly emerged as the growth hub. Many factors which include cost arbitrage, manufacturing excellence, engineering skills etc have contributed to this sudden impetus.



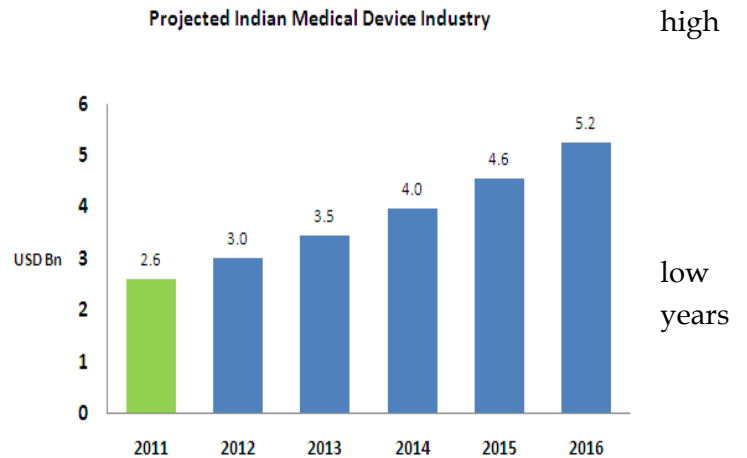
Source : Espicom Report 2011

INDIAN MEDICAL DEVICE INDUSTRY: AN OVERVIEW

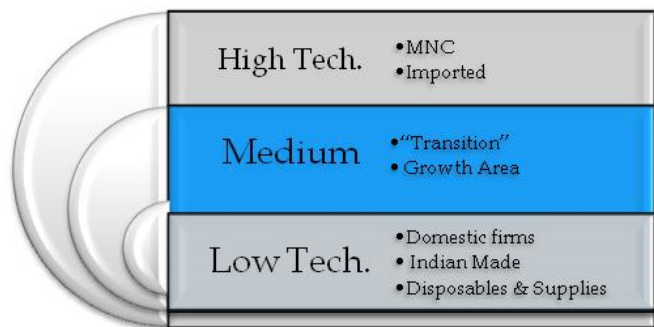
The Indian Medical Device industry is currently valued at around USD 3.5 billion. The market in comparison to the Indian Pharmaceutical Industry remains disproportionately small despite strong growth rates. The Indian Medical device Industry is expected to grow at a CAGR of 15% and touch the USD 5 billion mark by 2016. The present landscape is primarily import driven with import contributing close to 75% of the market. The domestic market caters to low-value disposables and supplies space, whereas importers dominate the costly and end medical equipments with extensive service networks.

The Indian medical device industry is highly fragmented with close to 1000 domestic firms primarily manufacturing technology products. However in the recent there has been a paradigm shift in the approach and companies have expanded operations to produce cost-effective, medium end medical devices. Opto Circuits

is a classical example of Indian companies becoming technology intensive thereby producing high quality, cost-effective medical devices. Opto’s focus towards knowledge intensive medical device development is showcased by its patent portfolio , It has an impressive 168 patents granted and 53 pending patents.



YES BANK research reveals that owing to huge cost pressures and completion from China and Asia-pacific countries, the Indian companies have started transitioning up the value chain into the “Medium Technology” segment. This augurs well for Medical devices future in India as this would imply Technology innovation and high margin product portfolio. The “High Value” space would still be governed by MNCs e.g. GE, Siemens ,Becton Dickinson etc. and these products would be primarily imported into India.



Challenges

However , there are certain challenges for the growth of the Medical device Industry . One of the major challenges being the absence of a separate Legal entity for Medical Devices The medical device industry is currently regulated by the Drug Controller general of India (DCGI). The DCGI till date has notified 14 devices, these devices would be classified as drugs under the Drugs and Cosmetics Act.

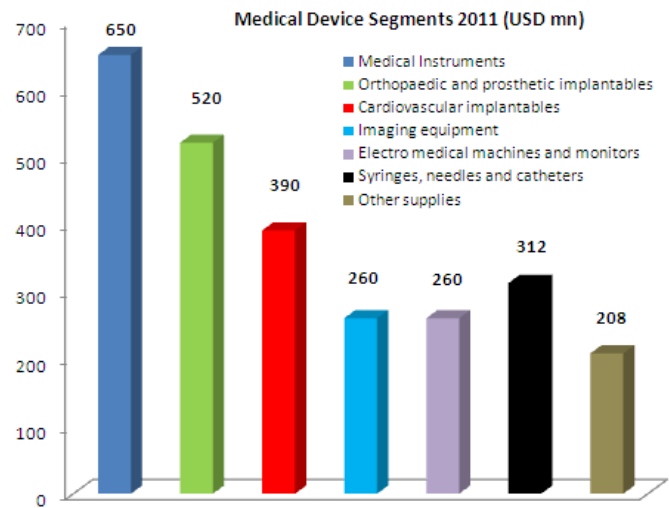


This has amounted to many ambiguities as these regulations are sometimes not applicable for the Medical Devices. Apart from this DCGI is often riddled in giving regulatory clearances to devices which are un-related by functionality or application to the devices mentioned in the list. A separate regulatory entity for Medical devices would go a long way in ensuring quality, safety and performance of medical devices and would strengthen the industry.

Another impediment in the growth of the domestic Medical Device industry is the duty structure for import and exports. The prevalent duty structure favours Medical device imports , This higher import duties for raw materials than finished goods has established an **‘Import-Export Anomaly’** whereby devices manufactured in India become expensive owing to high raw material cost making them uncompetitive against Chinese low priced goods. In addition to this unlike China, Indian government does not provide any incentive on setting up Medical device production bases. Steps to overcome these anomalies would boost the domestic Medical Device Industry and would decrease our high dependence on exports.

Market Segmentation

The majority of Indian Medical Device market is dominated by medical instruments catering to Ophthalmology, Hearing Aids, Dental. Apart from this a significant portion of the market comprises of Orthopaedic/ Prosthetic goods. Cardiovascular implants emerged as high growth segment owing to increased incidences of cardiovascular diseases. Another area of high-relevance to India has been the Diagnostic kits. With a major emphasis on 4A’s of Healthcare Affordability, Awareness, Accessibility and Availability there has been a radical shift towards Point-of-care (PoC) diagnostic kits. This has been well supported by the increased network of initiatives like the National Rural Healthcare Mission. With repeated onsets of communicable and infectious diseases in India such PoC kits would be quite relevant for Indian settings.



has the



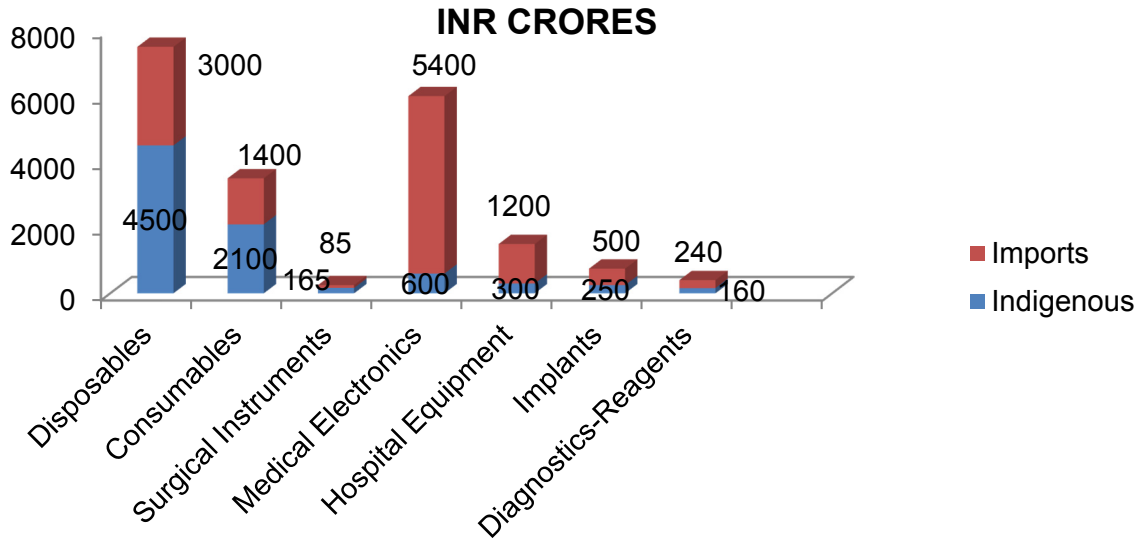
Despite some challenges YES BANK research believes that with India's burgeoning middleclass, growing medical tourism industry, swelling private-sector healthcare investment, aging population, and heightened government commitment to provide health services to the rural population, the domestic medical device industry is expected to grow at 15% each year to reach \$ 5 billion by 2016.

Indian Medical Device Industry is a sunrise segment in the Healthcare space. With focus on technology, innovation and a conducive regulatory framework, this sector would attract investments from the Private sector. This would give further impetus to growth and Indian companies would become originators rather than traders.

RECENT TRENDS IN INDIAN MEDICAL DEVICE INDUSTRY

The Indian Medical device industry is the 4th largest in Asia ;The market is primarily dominated by MNC products while the indigenous products form 20-25% of the market share. Majority of the products in the categories of Medical electronics, implants and other high to medium end technologies are catered through imports and foreign technologies.

The graph below shows a comparison of import versus indigenous for different product types :



The Indian Medical space is disorganized and ~90% of the manufacturers have a turnover of less than 50 Crore. These major manufacturers are in the low-technology and consumables space.

Industry Profile	
Estimated 750 Manufacturers Nationwide	
Turnover	% Distribution
0-10 Cr.	70
10-50 Cr.	20
50-100 Cr.	5
100-500 Cr.	3
500 + Cr.	2

India is now in 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 recession are looking to tap opportunities in the emerging markets as these markets are perceived to be the growth engines of the future. Companies in the West are transforming business models to cater to the needs of the emerging markets which make up a majority 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 prerogative is 'performance over price' while in India the emphasis 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 capital 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 is higher than the finished products. Therefore, we need to be able to raise investments with a realistic time frame and calibrate expectations of time. The advanced infrastructure and technical competence to offer services at a competitive cost. Our capability covers design, development of electro mechanical diagnostic and therapeutics devices besides implantable devices 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 areas.

We have the expertise to provide the required regulatory compliance documentation for medical devices manufacturing quality management systems. 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.



REGULATORY LANDSCAPE

At present the medical devices are covered under the Drug and Cosmetics Act (D&C Act) , there is no single comprehensive specific law regulating medical devices. As the devices are governed in line with drugs , the regulatory compliance becomes quite challenging.

The lack of regulatory clarity in terms of market entry, capital infusion, approval processes, labeling and classification does not augur well for the growth of the Indian Medical device industry.

The CDSCO/DCGI is the principal authority regulating medical device under the Ministry of Health and Family Welfare. The companies should register their products with DCGI before they products are introduced in the country.

The Central License Approval Authority serves as a main body that classifies medical devices while the D&C act regulates the import, manufacture, sale and distribution of the notified medical devices. This mechanism of applying D&C to medical devices leads to delays in the approvals of medical technologies.

The Indian manufacturers face 6-12 months in obtaining the manufacturing which follows a hierarchical approval process going through the State Drugs licensing authority , then to the CDSCO Zonal /Sub Zonal offices and finally to the DCGI. Just to add to the woes, the Indian manufacturers needs to take approval for each brand. In China , the approval is taken for a generic product and not a brand thereby reducing the time window and making them more competitive.

Industry and regulatory authorities have for long felt that provisions related to drugs can't be applicable entirely for medical devices. Hence, a recently tabled Drugs and Cosmetics (Amendment) Bill, 2013 has been under wide discussion. It is an attempt towards specifying provisions specific to medical devices.

The medical device sector has been largely unregulated for the and functioning in absence of any standards for the devices used in the healthcare sector. The draft bill introduced aims at providing an impetus to the industry but there are multiple flaws which would decelerate the growth. The flaws should be addressed before finalizing the bill.

Some of the short-coming of the tabled bill include

- ✓ Medical devices and significantly different from Drugs

Drugs	Medical Devices
Drugs are evaluated on parameters of : <ul style="list-style-type: none"> • Efficacy • Quality 	Medical device is evaluated on the following : <ul style="list-style-type: none"> • Performance • Engineering
Drugs get metabolized and can be checked for outcomes	Devices are available for testing even after implant
Drugs usually don't need professional to administer	Devices require professional intervention for implant or usage
Drugs have 12-20 years life cycle	Device have 2-3 years or lesser life cycle
Drug's action and adverse reaction can be ascertained	Device's outcome could be attributed to the device and also to the user
Drug clinical trials could be performed on a larger population	Clinical trials depend on bench study, bioavailability study and minimal human study due to non-availability of subjects and expensive nature of therapy
QA test is feasible for checking post landing in recipient country	QA test not practical owing to special need of Equipment's and test procedure

- ✓ **Need exclusive law for Medical devices**

Medical devices should not be viewed through the same laws as that of drugs . Drug regulators should not bring the same set of regulations for both medical devices and drugs.

The proposed amendment to existing D&C act with inclusion of all medical technology under one law and extrapolating laws applicable to drugs to medical technology, if notified without modification will result in huge impact to both local and global manufacturers as well as healthcare providers and therefore , needs separate act. Government needs to tread a thin line and should not move from having virtually no laws for the past 65 years for med-tech to an overkill for a nascent sector.

The Indian manufacturers wishes that the government paves the way for passing a Bill on Regulation of Medical Devices and Patient Safety by a National Regulatory Authority under the Ministry of Health. The current CDSCO's role could be enlarged with more autonomy and could be renamed as the Indian Healthcare Products Regulatory Authority (IHRA) with decentralized Divisions for Drugs, Cosmetics, Medical devices and Diagnostics.

Given the vast diversity of Technologies and varying risk profile of Medical Devices, Regulatory Controls could be shared and split

As an example :

Official Body	Responsibility
National Regulator	Policy, Licensing & Registration of Manufacturers/Importers/Exporters for enabling a single window and harmonized controls
CAB's - Conformity Assessment Bodies	the task of factory audits of Indian and Overseas Manufacturers for Compliance to Good Manufacturing Practices/ Quality Management Systems
State Regulatory Authority	Licensing and Registration of Traders Distributors/Dealers/Warehousing Sub Contractors/Retailers etc for regulating logistics and Sales

A mechanism similar to this would provide an ease in the regulatory process and circumvent the delays for medical devices.

✓ **Punitive clauses**

The proposed amendment bill is extremely tough on the non-compliance and every error (minor/major) is being treated with severe penal provisions. This would have an adverse impact on the budding medical device industry.

The punitive clauses under the Bill recommends penalty and punishment is flat for all levels of Non-conformance - Minor/ Moderate/Major. However, best practices across the globe have provisions of CAPA (Corrective and Preventive Action) and progressive penalties starting with commercials.. The discretionary powers in determining contraventions of the act compounded by punitive actions prescribed will be deterrent for the Industry

✓ **Standards of Quality of Medical Devices**

The Standards of Quality of Medical Devices are not clearly defined. It only talks about Misbranded, Adulterated and Spurious form of medical devices, whereas these terms are applicable for drugs. Instead, consistent and globally harmonized standards would offer significant benefits to patients and consumers and to Regulatory Authorities as well

CURRENT TREND OF INVESTMENTS IN MEDICAL DEVICE

The Indian medical devices industry forms a very small part of the total manufacturing industry accounting for only 0.2% of all certified facilities. The high-tech end of the medical device market is currently led by multinationals with extensive service networks; whereas low end equipment and disposables are led by domestic manufacturers because of their cost effective innovations. Collaborative trends across these two segments are visible through deals and acquisitions, setting up of local manufacturing by large international players and other technical alliances. MNCs in this field are also using India as a manufacturing base by either setting up facilities of their own or by acquiring domestic manufacturers.

Local manufacturing impetus by foreign players over the last few years:

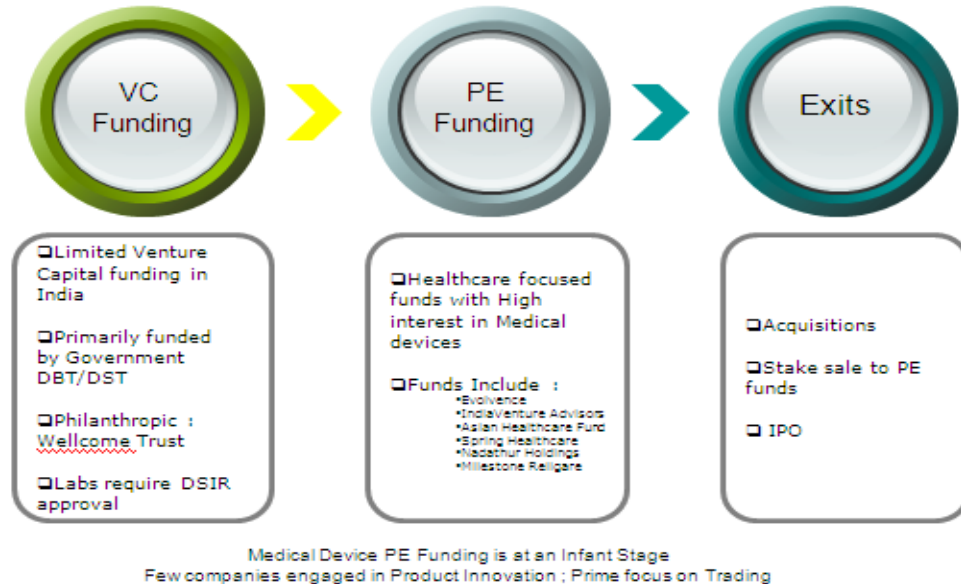
Company	India Story
GE Healthcare	<ul style="list-style-type: none"> Established a 50,000 sq.ft . R&D facility in Bangalore Developed a portable ECG machine that produces ECG@ 10 Rs
Siemens Healthcare	<ul style="list-style-type: none"> Manufactured Imaging and ultrasound systems in India for more than 50 yrs Building mobile diagnostics units with integrated X-ray, ultrasound & pathology systems
Nipro Corp	<ul style="list-style-type: none"> Setting up a manufacturing facility at Pune to produce medical devices, especially equipment to support haemodialysis treatment process
Hollister's	<ul style="list-style-type: none"> Made significant investments in setting up its manufacturing facility for healthcare products in Haryana
B Braun	<ul style="list-style-type: none"> Besides its suture manufacturing plant in Chennai, B Braun acquired a controlling stake in Hyderabad-based medical devices manufacturer Oyster Medisafe
Terumo	<ul style="list-style-type: none"> The Company has set up a strong manufacturing base in India for blood bags, seals, component extractors, storage and transfusion sets and services blood centres across the globe

Even though the country seems to have lost some of its attractiveness as an investment destination, the medical technology space has seen a spate of partnerships/ acquisitions and collaborations despite the fact that the regulatory landscape for drugs (which includes medical devices) has been a deterrent. According to DIPP, FDI inflows into India in the medical and surgical appliances segment amounted to US\$ 717.61 million during April 2000- August 2013, accounting for 0.36 percent of the total inflows coming during this period.

Investments – Venture Capital /Private Equity

The medical-device industry, struggling to adapt to a thriftier health-care system, is getting squeezed by a venture-capital drought. Investment in the medical-device and equipment industry is on pace to fall to \$2.14 billion this year, down more than 40% from 2007 and the sharpest drop among the top five industry recipients of venture funding, according to an analysis of data compiled by PricewaterhouseCoopers and the National Venture Capital Association. Venture money received by the biotechnology sector declined 28% over the same period, while software startups recorded a 75% increase.

Medical Device : Funding Value Chain



As a result, the industry responsible for making prosthetic hips and other devices has to get creative. Entrepreneurs are taking on more debt and looking for cash in unusual places, including family investment funds overseas and high net worth individuals in the U.S., people in the industry say. One of the biggest shifts has been entrepreneurs and their financial backers are approaching potential acquirers much earlier than in the past. Some firms are striking funding deals with larger established companies, often in exchange for board seats and future acquisition rights. The upside is reliable financing and industry expertise. But such deals can curb the start-up's upside potential if it finds success and becomes an acquisition target: The device firm can't seek multiple bidders and run up its acquisition price.

Recent investments through PE/VC route are as under:

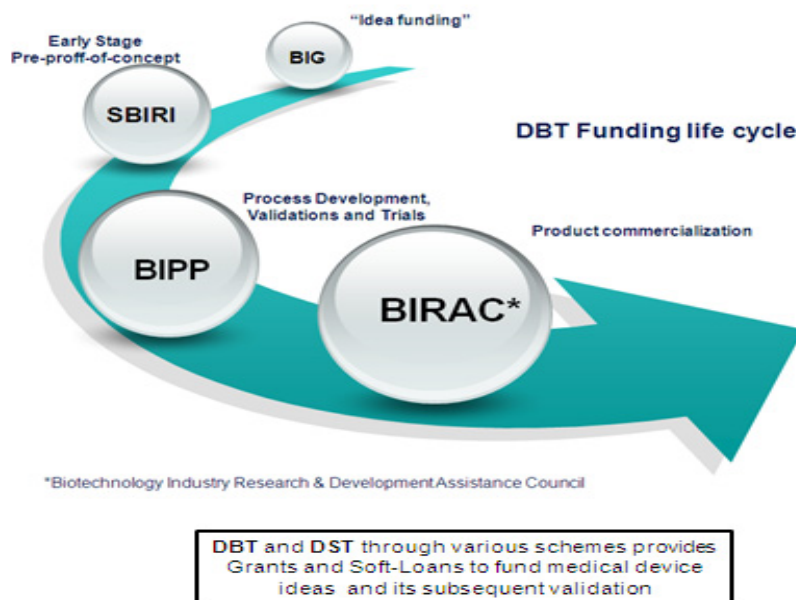
Company	Details
Medtronic	<ul style="list-style-type: none"> • Medtronic increased its Indian field force from 200 to 800 individuals • R&D Centre in India
CardioDx	<ul style="list-style-type: none"> • CardioDx partnered with India's Core Diagnostics to distribute its coronary artery disease test in the country's burgeoning market. • Core will administer the Corus CAD test to patients in India, shipping samples back to CardioDx's lab in California for analysis and turnaround.
Smith & Nephew	<ul style="list-style-type: none"> • Smith & Nephew acquired Indian trauma business Adler Mediequip Private Limited and with it, the brands and assets of Sushrut Surgical Private Limited, a leader in mid-tier, orthopaedic trauma products for the India market to supplement their organic growth through acquisitions, and to bring forward a mid-tier offering for these region.
Cardiac Science	<ul style="list-style-type: none"> • Cardiac Science sells diagnostic cardiology product line to Mortara Instruments for \$21M
Perfint Healthcare	<ul style="list-style-type: none"> • Norwest Ventures invests \$11m in Perfint Healthcare for commercialization of its recently launched products, new product development and for expansions into new markets •
BPL Medical technologies	<ul style="list-style-type: none"> • Goldman Sachs picks up 49% stake in BPL Medical technologies for INR 110 crore. The fresh infusion will be used to further expand the company's medical device business into areas such as imaging and neo-natal care.
Villgro Innovations	<ul style="list-style-type: none"> • Villgro Innovations invests in healthcare technology start-up Windmill Health. Villgro Innovations supports and incubates innovators and social entrepreneurs for their early stage of growth.
Biosense	<ul style="list-style-type: none"> • Medical devices start-up Biosense secures \$500K from GSF India & Insitor Fund. The funds will be primarily used to launch a series of products for the healthcare sector.
Sutures India	<ul style="list-style-type: none"> • TPG invests USD 23million in Sutures India which manufactures and exports surgical sutures through its FDA approved facilities. The deal has been one of the largest private equity transaction in the Indian medical devices and consumables space so far

Government funding

The setting up of a separate Department of Biotechnology (DBT), under the Ministry of Science and Technology in 1986 gave a new impetus to the development of the field of modern biology and biotechnology in India. In more than a decade of its existence, the department has promoted and accelerated the pace of development of biotechnology in the country. Through several R&D projects, demonstrations and creation of infrastructural facilities a clear visible impact of this field has been seen.



The department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry.



Few BIPP Projects Funded Medical device projects

POC detection of infectious disease using handheld microPCR
Immunodiagnostic kits for detection of autoimmune diseases
Establishment of vitro phamacological Assay platform for biosimilars
Development of low cost rapid quantitative PCR technology for molecular diagnosis
Multiplex Fast-PCR based diagnosis and prognosis of Tubercululosis
Flow analyzer
Affordable fluorescence reader for point-of-care diagnostics
3rd Generation HIV (Antibody) & 4th generation (HIV Antigen and Antibody) immunoassay test

Guidelines for FDI:

Pharmaceutical sector in India is open for 100 percent FDI via automatic route in case of Greenfield investments. However, in case of brownfield investments, FDI is allowed through FIPB approval route. This was done keeping in view the fact that taking over of production process of critical drugs by foreign entities would have denied availability of drugs at affordable prices. The medical



devices segment also comes under the pharmaceutical industry, and a demarcation of FDI policy for the former is essential. This is because the medical device segment in India is at a very nascent stage and in order to grow and thrive in future, it needs to get access to new technologies. India's own demand for medical devices has been burgeoning, which necessitates better technological process and diversified product range. Hence, a separate FDI policy for the segment is required.

Increasing FDI by MNCs for accessing greater domestic market and for having closer proximity to customers is expected to lower the import burden on the country over time. These MNCs would also help domestic players to access new cutting edge technology.

SWOT ANALYSIS FOR INDIAN MEDICAL DEVICE SECTOR

Strengths

Cost Competitiveness,
 Mass production
 Economies of scale
 Trainable large Labor Pool
 Technology Access - no conflicting national interest .
 Strong in Mechanical ,Software ,Biotechnology Engineering Areas.
 Well developed supporting industries like microelectronic, telecomm, software precision engineering

Weakness

Low R&D base
 Reliance on High Cost imported inputs
 High Cost Multiple Taxes
 Limited products regulated
 Quality perception low- middle end
 Absence of Government Promotional policies (Brand India Engineering campaign will give the much needed impetus to the sector)
 Weak link between industry & academia
 No distinct status for the industry
 Relaxed import policies
 Monopoly of MNCs in government sector due to FDA and CE certifications as mandatory requirements in tenders

Opportunity

Value for money competitiveness,
 high growth sales in global markets
 Huge domestic market with increased income & changing lifestyle

Threat

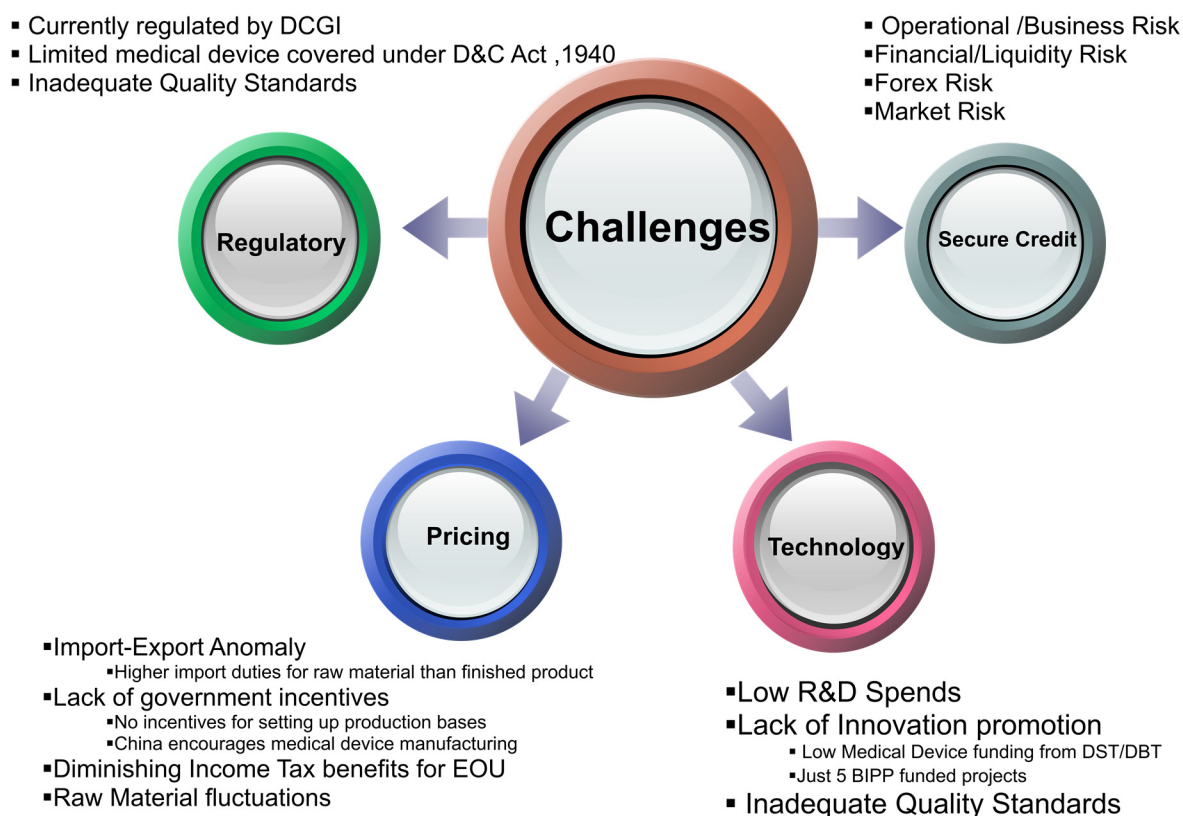
Increased dependency on imports
 Low recognition of Brand India for the sector
 Regulations limiting market access if used as Protectionist Non Tariff Barrier



CHALLENGES FOR THE INDIAN MEDICAL DEVICE INDUSTRY

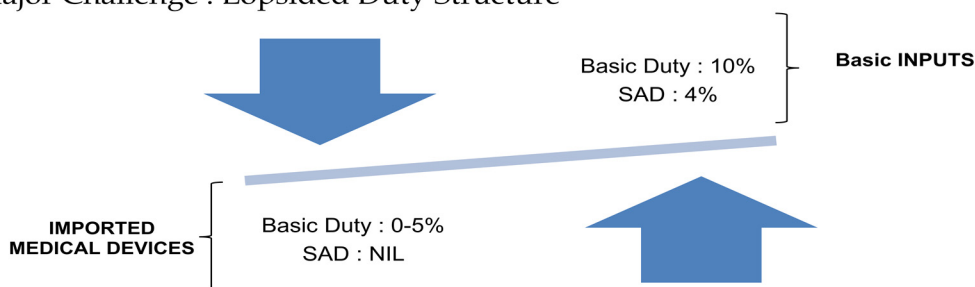
The domestic medical device has not been able to grow significantly and there is a huge reliance on imports some of the major impediments that lie in the ways of the growth have been the following:

Adverse regulatory policies: The limitation of medical device falling under the preview of D&C act has been the major deterrent for the growth of the sector. The time delays and hassles makes business non-viable and non-lucrative. For e.g. implantable medical devices has to be routed through Central and state governments, a process which often takes 24-48 months. This delay due to the absence of a Single window clearance hinders new product development.



Capital and Fiscal Policy: Majority of medical devices in India are imported so there is vast opportunity for import substitution and local manufacturing. The current fiscal environment and the **lopsided anomalous duty structure** whereby the Basic duty on imported medical Devices is Zero to 5 % with Nil SAD compared to 10% Basic Import Duty and 4% SAD applicable. This import-export anomaly encourages Indian industry towards trading rather than getting into manufacturing.

- ✓ 75% Imports ; Vast opportunity for import substitution and Local Manufacturing
- ✓ Capital requirement is not a major challenges
 - ✓ Debt funding from Commercial Banks
 - ✓ Attractiveness of sectors for PE funding
- ✓ Major Challenge : Lopsided Duty Structure



- ✓ Incentives and Subsidies to be provided to set-up Medical Device Manufacturing Units

Low R&D Spends: Indian medical device industry has a low R&D base and has a heavy reliance on reverse engineering. The government should introduce the automatic use of fiscal benefits for companies that invest in R&D.

The significant incentives under this could be , deductions from income tax and social contributions on net profits from expenses on R&D (between 60% and 100%); reductions in the tax on industrial products for purchasing machines and equipment for R&D ; economic subsidies for scholarships of researchers in companies

RISK	DESCRIPTION	RISK MITIGANTS
Operational Risk	<ul style="list-style-type: none"> Limited product range Primarily low value products Stretched operating cycle <ol style="list-style-type: none"> large inventory Delayed export realization <p>Resulting in Devolvement of LCs and delays in payment of statutory dues</p>	<ul style="list-style-type: none"> Need to undertake LC backed export orders and guarantee from superior credit rated International banks Efficient working capital management and ensuring comfortable liquidity Need to undertaking backward integration so as to develop cost-efficiencies
Financial/Liquidity Risk	<ul style="list-style-type: none"> High Level of work in progress Delayed export realization causes CF mismatched 	<ul style="list-style-type: none"> Easy and Securing financing for exports to UN/WHO funded agencies Prudent Working capital to fund debtors and raw material Bill discounting to ensure short term liquidity
Forex Risk	<ul style="list-style-type: none"> Foreign Currency payments Large Time to Deliver 	<ul style="list-style-type: none"> Hedging export receivables Forward booking/derivative contracts
Market Risk	<ul style="list-style-type: none"> Stringent norms for manufacturing Stringent norms for Marketing products in US and EU Exports relatively easier : <ol style="list-style-type: none"> Third-world countries Semi-regulated Un-regulated markets Low brand recognition <ol style="list-style-type: none"> Low sales realization for exports 	<ul style="list-style-type: none"> CE Mark registration for EU Markets Better Margins in regulated markets Sales Predictability in Third-world, Semi and Unregulated markets <ol style="list-style-type: none"> Bulk Orders from UN/WHO Agencies
Regulatory Risk	<ul style="list-style-type: none"> Need to obtain license to manufacture and export Irrational tax structure (Import-Export anomaly) 	<ul style="list-style-type: none"> Easing Regulatory Hurdles Tax structure rationalization and duty cuts to provide level playing field Government to offer cheaper credit (Based on LIBOR) for exporters on lines of China and other South East Asian Countries
Technology Risk	<ul style="list-style-type: none"> Technology obsolescence risk Low R&D expenditure 	<ul style="list-style-type: none"> Financial incentives by the government in term of tax exemptions Increased R&D Support from government

INTERNATIONAL MARKETS DYNAMICS

India has made major progress in exports to various markets. Its export in Asian countries of China, Thailand, and Belgium in Europe has witnessed high growth to the tunes of around 25 percent and 18 percent respectively. Even African countries like, South Africa has earned the highest CAGR of 32 percent during the five year span. India's export performance for Medical Devices is recorded below.

Growth in India's Exports of Medical Devices (Value in US\$ mn)			
Country	2008	2012	CAGR (2008-12) (%)
United States of America	154.39	170.19	2.46
Singapore	71.82	88.64	5.40
China	29.47	71.07	24.62
Germany	53.14	69.84	7.07
United Arab Emirates	20.60	42.09	19.56
Bangladesh	20.47	36.92	15.90
France	23.00	36.80	12.47
South Africa	10.13	30.79	32.03
Brazil	15.15	30.69	19.30
Japan	41.01	27.70	-9.35
Thailand	7.69	18.28	24.18
Turkey	7.82	16.13	19.84
Belgium	7.34	14.39	18.30

HS codes: 3005, 3006, 4005, 4014, 4015, 4017, 4818, 5601, 9012, 9018, 9019, 9020, 9021, 9022, 9025, 9026, 9027, 9402 & 9619
Source: UN Database

Product code	Product label
3005	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES (FOR EXAMPLE, DRESSINGS, ADHESIVE PLASTERS, POULTICES), IMPREGNATED
3006	MISCELLANEOUS PHARMACEUTICAL GOODS
4005	COMPONDED RUBBER UNVULCANISED IN PRIMARY FORMS/IN PLATES SHEETS/STRIP
4014	HYGROSCOPIC/PHARMACEUTICAL ARTICLES (INCLUDING TEATS) OF UNVULCANISED RUBBER OTHER THAN HARD RUBBER WITH/WITHOUT FITTINGS OF HARD RUBBER
4015	ARTICLE OF APPAREL AND CLOTHING ACCESSORIES (INCLUDING GLOVES, MITTENS AND MITTS) FOR ALL PURPOSES OF VULCANISED RUBBER NOT HARD
4017	HARD RUBBER (FOR EXAMPLE, EBONITE) IN ALL FORMS, INCLUDING WASTE AND SCRAP; ARTICLES OF HARD RUBBER
4818	TOILET PAPER OR SIMILAR; PULP/CELLULOSE WADDING/WEBS OF CELLULOSE FIBRES USED IN HOME/HOSPITAL/INDUSTRIAL/ APPLICATIONS OF WIDTH ≤36 CM OR CUT TO SIZE
5601	WADDING OF TEXTILE MATERIALS AND ARTICLES THEREOF; TEXTILE FIBRES, NOT EXCEEDING 5 MM IN LENGTH (FLOCK), TEXTILE DUST
9012	MICROSCOPES OTHER THAN OPTICAL MICROSCOPES; DIFFRACTION APPARATUS
9018	INSTRUMENTS AND APPLIANCES USED IN MEDICAL, SURGICAL, DENTAL/VETERINARY SCIENCES, INCLUDING SCINTIGRAPHIC APPARATUS ELECTRO-MEDICAL APPARATUS AND SIGHT-TASTING INSTRUMENTS
9019	MACHINERY-OTHER APPLIANCES; MESSAGE APPARATUS; PSYCHOLOGICAL APPARATUS-TESTING APPARATUS; OZONE THERAPY, OXYGEN THERAPY, AERIAL THERAPY, ARTIFICIAL RESPIRATION APPARATUS ETC
9020	OTHER BREATHING APPLIANCES AND GAS MASKS, EXCLUDING PROTECTIVE MASKS HAVING NEITHER MECHANICAL PARTS NOR REPLACEABLE FILTER
9021	ORTHOPEDIC APPLIANCES, ARTIFICIAL PARTS OF THE BODY; HERNIA BANDS AND OTHER APPLIANCES WHICH ARE WORN/CARRIED/IMPLANTED IN THE BODY TO COMPENSATE DEFECT/D
9022	OTHER APPLIANCES OF HEADING 9021 BUT A/GMA RADIATIONS INCLUDING RADIO THERAPY APPARATUS, X-RAY TUBE AND GENERATORS, HIGH TENSION GENERATORS, SCR
9025	HYDROMETERS AND SIMILAR FLOATING INSTRUMENTS, THERMOMETERS, PYROMETERS ETC, RECORDING/NOTING AND ANY COMBINATION OF THESE INSTRUMENTS
9026	INSTRUMENTS AND APPARATUS FOR MEASURING/CHANGING THE FLOW, LEVEL, PRESSURE/OTHER VARIABLES OF LIQUID/GASES EXCLUDING APPARATUS OF HEADINGS 9014, 9015, 9028/90
9027	INSTRUMENTS AND APPARATUS FOR PHYSICAL OR CHEMICAL ANALYSIS (FOR EXAMPLE, POLARIMETERS, REFRACTOMETERS, SPECTROMETERS)
9402	MEDICAL, SURGICAL, DENTAL/VETERINARY FURNITURE ETC BARBERS' CHAIRS AND SIMILAR CHAIRS; PARTS OF THE FOREGOING ARTICLES
9619	SANITARY TOWELS (PADS) AND TAMPONS, NAPKINS AND NAPKIN LINERS FOR BABIES AND SIMILAR ARTICLES, OF ANY MATERIAL

In many of the categories, India has not been able to increase its export and in some cases, exports have even reduced drastically. India's exports of Apparatus based on the use of alpha, beta/gamma radiations for medical use (HS code: 902221) and Apparatus based on the use of X-rays for other uses (HS code: 902219) has drastically reduced over the years. Below is a list of all products where India's exports haven't increased substantially over the years.

Product Categories where India's exports have not picked up (Value in US\$ millions)					
HS Code	Category Name	2008	Share (%)	2012	Share (%)
4017	Hard rubber in all forms,including waste&scrap;articles of hard rubber	4.18	0.51	2.79	0.23
3005	Dressings packaged for medical use	33.32	4.07	37.12	3.04
4014	Hygienic/pharmaceutical art of vulcanised rubber	64.49	7.87	40.76	3.33
9022	Apparatus based on the use of X-rays/of alpha, beta/gamma radiations	194.37	23.71	198.12	16.21
Total Medical Codes_4 digit		819.68	100.00	1222.55	100.00

Source: UN Data Base

The following markets are where India's CAGR of export in medical devices segment during the period 2008-12 is less than the CAGR of country's imports from the world during the same period. Hence, potential for penetration exists in these countries.

Prospective countries for market diversification (Values in US\$ million)						
Country	Countries' world imports			India's export to countries		
	2008	2012	CAGR (%)	2008	2012	CAGR (%)
United States of America	42079.21	50693.07	4.77	154.39	170.19	2.46
Japan	11210.86	16223.81	9.68	41.01	27.70	-9.35
United Kingdom	12103.32	11512.49	-1.24	29.38	27.35	-1.77
Canada	7697.15	9666.06	5.86	5.91	4.98	-4.18
Russian Federation	6681.94	8934.98	7.53	10.39	10.39	0.00
Korea, Republic of	4084.52	5822.29	9.27	7.54	9.86	6.95
Singapore	2942.21	5073.89	14.60	71.82	88.64	5.40
Mexico	3775.29	4958.98	7.06	9.87	9.72	-0.37
Hong Kong, China	2945.08	4099.48	8.62	5.46	6.00	2.35

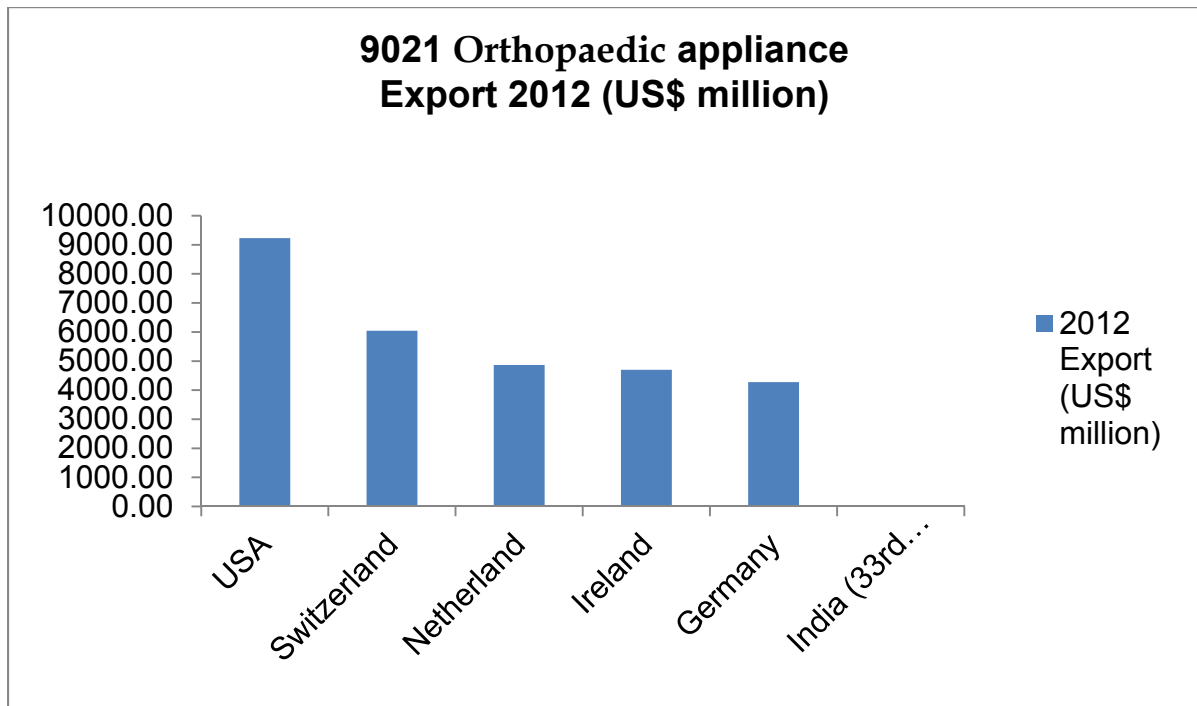
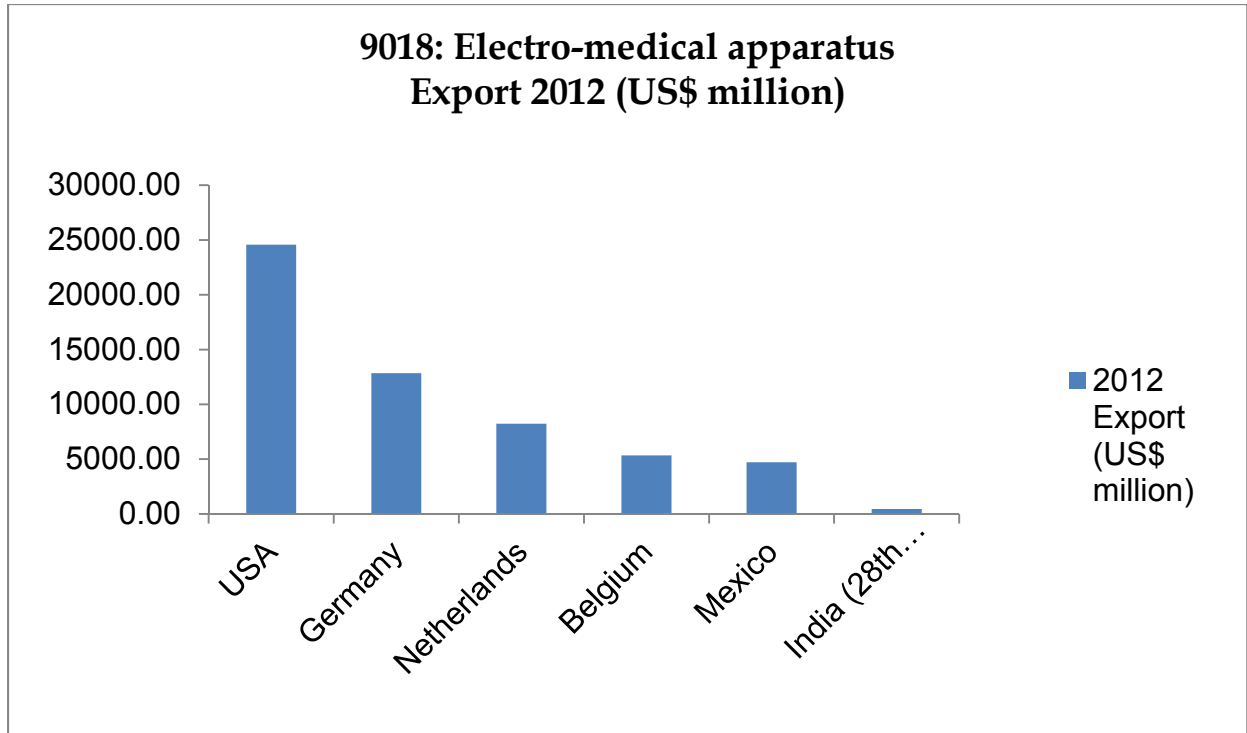
Taipei, Chinese	1965.21	2602.69	7.28	1.69	1.76	0.96
Saudi Arabia	153.61	2347.66	97.72	8.69	9.74	2.89
Finland	1263.63	1375.76	2.15	0.98	0.79	-5.06
Portugal	1441.29	1299.92	-2.55	1.60	1.33	-4.53
Colombia	811.30	1257.10	11.57	3.85	5.85	11.04
Israel	1087.00	1236.05	3.26	13.95	12.37	-2.97
Hungary	1069.87	1018.98	-1.21	1.63	0.40	-29.42
Kazakhstan	704.07	937.22	7.41	0.50	0.61	5.25
Egypt	522.80	703.51	7.70	9.76	12.73	6.86
Panama	179.58	358.33	18.85	0.95	0.59	-11.10
Lebanon	194.25	326.73	13.88	2.05	1.05	-15.42
HS codes: 3005, 3006, 4005, 4014, 4015, 4017, 4818, 5601, 9012, 9018, 9019, 9020, 9021, 9022, 9025, 9026, 9027, 9402 & 9619						
Source: UN Database						

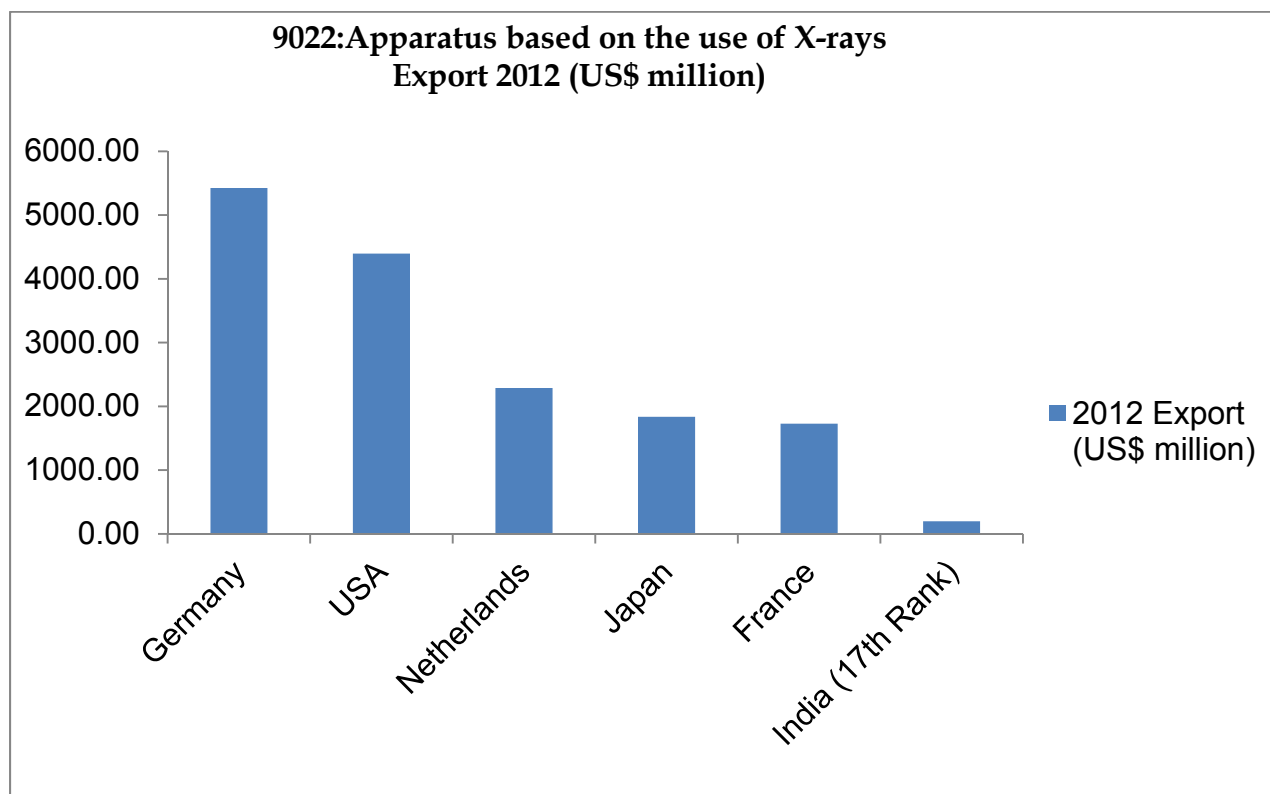
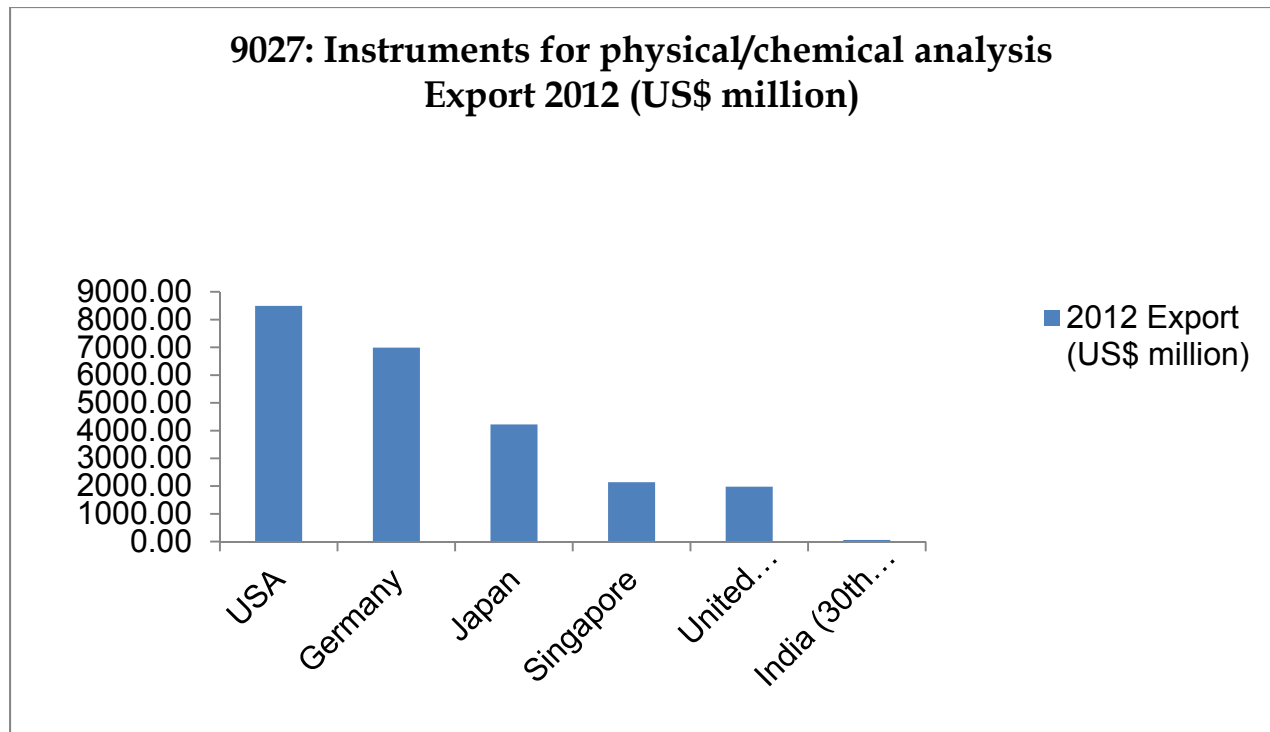
The Medical Device items capturing high export share among all the medical devices in the world market are identified and listed below. The following items cover almost 80% of the total medical devices exported in the world.

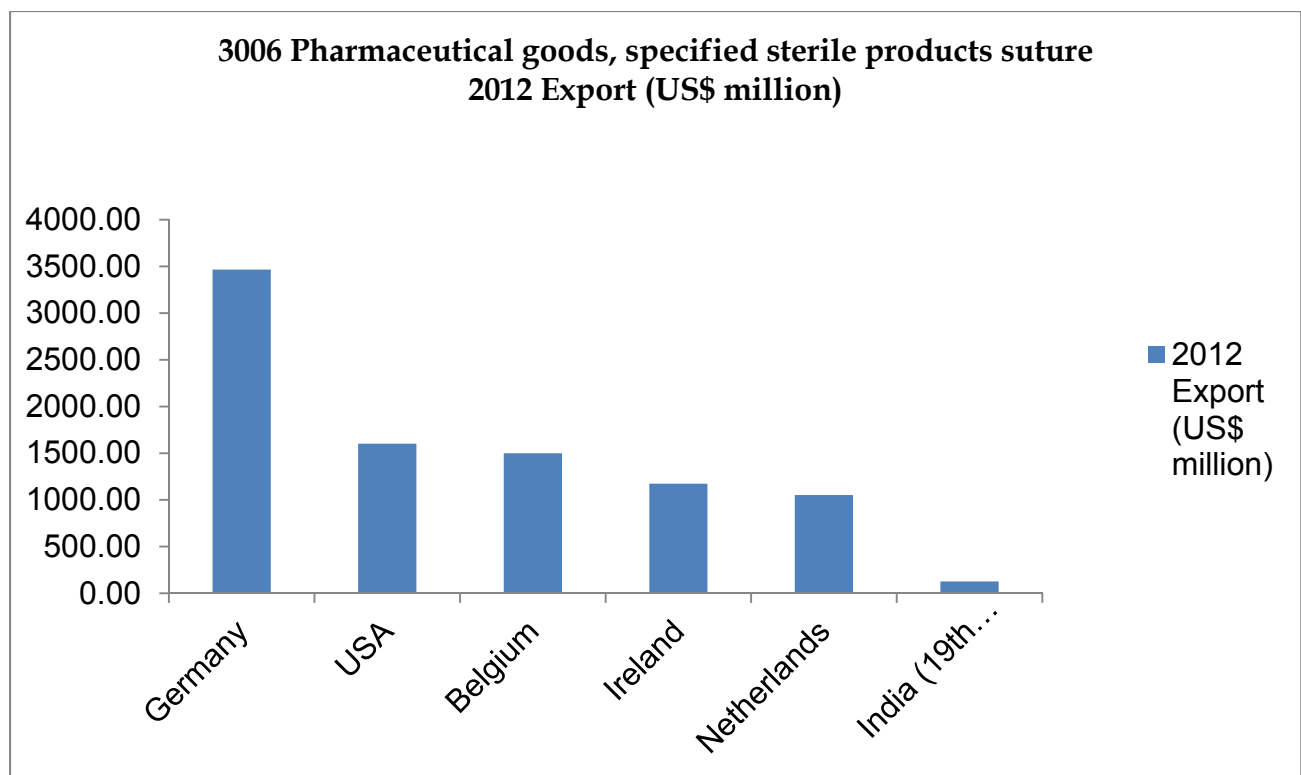
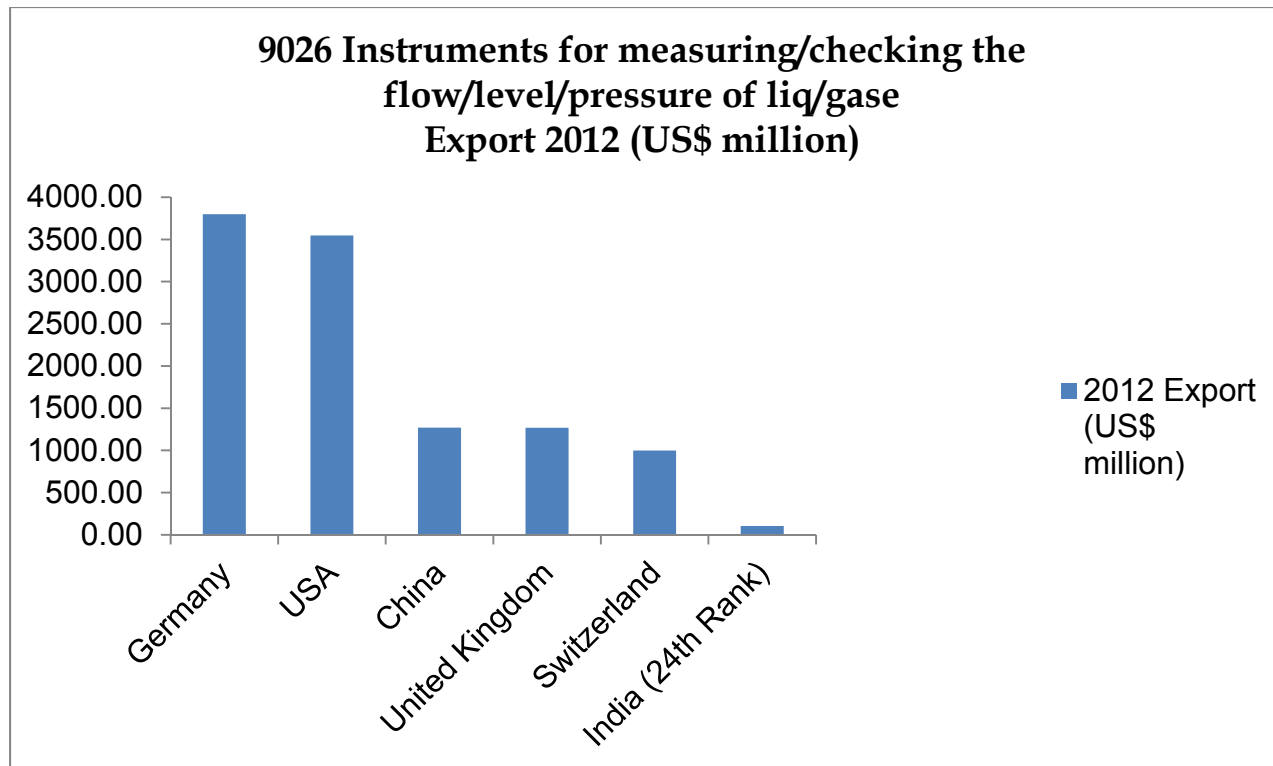
Product code	Product label	Exports to the World in 2012 (US\$ million)	Export share
9018	Electro-medical apparatus (electro-cardiographs, infra-red ray app, sy	99067.7	31.99
9021	Orthopaedic appliance (crutche/surgical belts & trusse)	46121.09	14.89
9027	Instruments for physical/chemical analysis;inst for viscosity,heat,etc	37100.27	11.98
9022	Apparatus based on the use of X-rays/of alpha, beta/gamma radiations	22353.52	7.22
9026	Instruments for measuring/checking the flow/level/pressure of liq/gase	18892.33	6.10
3006	Pharmaceutical goods, specified sterile products sutures, laminaria,	15234.06	4.92
9619	Sanitary towels (pads) and tampons, napkins and napkin liners for babies,	12799.74	4.13

The graphs below indicate India as compared to the Top-5 exporters for the above major product categories.









LIST THE GLOBAL STANDARDS FOR MEDICAL DEVICE SECTOR & ALIGNMENT OF INDIAN STANDARDS TO THE GLOBAL STANDARDS.

- CE is the standard being used towards import of Medical equipment in Europe
- FDA is the standard being used towards import of Medical equipment in USA
- BIS is the standard being used towards the Electrical and Mechanical safety of the equipment and applicable in India and neighbouring countries.
- AERB is the standard being used towards the Radiation safety of the equipment and applicable in India and other oversea countries.
- Indian standards like BIS and AERB are not considered in Europe as well as USA when it comes to their regulatory requirement and such, we again face a challenge in this stream too.
- The important global standards for medical device sector are ISO 13485:2003, IEC 60601, ISO 15223-1:2012 and ISO 14971.

In term of regulation, medical device regulations are the key challenge faced by device manufacturers in the Asian region, followed by new product development and price pressure. Mid-sized and large companies struggle with regulatory issues more than smaller companies. This may be due to the fact that larger companies are more likely to sell in markets with less transparent regulatory systems. The industry is of the opinion that some of the global standards which are in practice in the industry may be adopted by the Indian medical device industry (after slight modifications) instead by creation of new standards.

STRATEGY FOR THE PROMOTION OF MEDICAL DEVICE EXPORTS FROM INDIA

The government should undertake some measures which would propel the medical device exports from India. These measures should be part of a two pronged strategy initiative comprising of both short-term and long-term initiatives.

Short term Strategies

- ✓ Correction of the lop-sided duty structures
 - Reverting of SAD from 0% back to 4%
 - Increase basic duties on devices to ~ 10%
 - Decrease basic duties on parts of devices to 7.5%

- ✓ Changes to the D&C (Amendment bill) , 2013
 - Medical devices significantly different from drugs
 - Exclusive laws for Medical devices
 - Punitive clauses to be changed to Corrective and Preventive actions and progressive penalties
 - Global harmonization of standards to quality for medical devices

- ✓ Finalization and issuance of time bound guidelines on
 - Application and grant of manufacturing licenses
 - Initial factory audit of QMS & Infrastructure
 - Export labeling
 - Application of additional brand
 - Application of Free sale certificate
 - Import of non sterile assembled devices
 - Clinical evaluation
 - Adverse event reporting

- ✓ Incentives from DGFT and Ministry of commerce to exporters
 - On Medical products exports, China provides 17% subsidy, as against a subsidy of 2-3% provided in India
 - Time delay in sanction and disbursement of subsidies in India

- ✓ Encourage brand India and the Indian manufacturers
 - Price benefit in public health tenders for product of Indian companies and Indian origin products
 - Accelerated depreciation at double rates for income tax calculation due to high capital cost for ISO 13485 Indian manufacturers
 - Initiation of a modernization fund to provide minimal interest loans for plant up gradation and setting up of clean room facilities
 - Launching Brand India Engineering campaign in the Medical Device sector & its promotion in overseas market.

- ✓ Export promotion councils and promotion initiatives
 - Medical devices to be a sector of focus for the next two years. Dedicated personnel and subject matter expert at EEPC which would act as the promotion body for medical devices
 - MDA benefits from EEPC should be extended to flourished exporters who had crossed the defined Export turnovers also so that with some MDA benefits which are passed to the exporters, they should be encouraged to participate and advertise well.
 - Participation in Overseas Tenders with Joint support from Ministries with the help of Indian exporters
 - Incentivizing the participation in major medical device trade fairs MEDIFEST, MEDICA, ARABHEALTH. Specialized Indian delegation representation in such platforms
 - Some relaxation on the Payment terms like export proceeds to be realized with one year or more from the date of export instead of 180 days at present will surely help the exporters to penetrate in the market as nowadays it is in trend that competitors offer relaxed payment terms and attract the customer with deferred payment period.

- ✓ Indian Govt. initiates Medical Aid to various oversea countries through a planned process. Countries like China, Brazil, Argentina, Russia, USA, Europe etc also provide Aids to various countries but they ensure that the country of origin of the products supplied under that Aid should be of their respective country. The same policy should be strictly followed in the Aid given to overseas by India
 - Replication of the Africa centric PRPFAR US AID

- ✓ Policy intervention to safeguard the local industry and incentivizing the Indian manufacture to flourish and cater to the Domestic need as well as export to the oversea market
 - Quality standards should be followed to restrict the import of cheap / sub standard products from China, Korea etc
 - Government tenders should not follow a mandatory note of FDA in all government tenders
 - Government R&D support for manufacturing high-end medical equipments like CT, Pet CT, MRI , Cath Lab etc in India

- ✓ Addressing the internal Non-tariff barriers , this is in-lieu of the fact that there is no mandate to the Drug Controller of India to regulate exports of Drugs and Exports and Medical device exporters face an internal Non Tariff barrier stifling and delaying export of devices. Few of the concerns which needs to be addressed as a short-term strategy include :
 - Time delay in approvals for Brand approvals to manufacture under overseas customer brand
 - Renewal licenses takes very long time (Extending even more than an year)
 - Time delay by the Assistant Drugs Controller (India)-Port in sampling and dispatching of material
 - Time bound clearance for time sensitive consignments like Controls/ Calibrators
 - Paucity of space/Infrastructure/ Manpower at the major ports

Learning's from the Pharmaceutical Sector

The Pharmaceutical Sector underwent similar growth-curve with multiple-incentive scheme to boost exports. Some of the moves taken by the government include

- ✓ **Export Impetus post TRIPS**
 - Consolidation of Pharma sector
 - Operation efficiencies
 - Price Competitiveness
- ✓ **Export Promotion agency like Pharmexcil**
- ✓ **Government Aided Credit Security schemes**
 - Export Credit Guarantee Corporation Scheme
- ✓ **Non-government aided credit facilities for exporters**
 - Gold-card schemes : Extended Lines of credits for exporters
- ✓ **Government support to Innovation**
 - Tax-Incentive for R&D Investments(DSIR approved)
- ✓ **Government Rebates**
 - Export Promotion Capital Goods Scheme : Duty free capital goods import
 - Market Access Initiative : Reimbursement of registration /litigations
 - EOU Schemes : Service tax waive-off

Long term Strategies

Some of the long term strategies for promotion of Indian exports include :

- ✓ **Separate regulatory Infrastructure for Medical devices:** An Ordinance may be passed to remove Medical Devices from the definition of Drugs in the Drugs and Cosmetics Act. This would pave the way for passing a Bill on Regulation of Medical Devices and Patient Safety by a National Regulatory Authority under the Ministry of Health
 - The current CDSCO's role could be enlarged with more autonomy and could be renamed as the Indian Healthcare Products Regulatory Authority (IHRA) with decentralized Divisions for Drugs, Cosmetics, Medical devices and Diagnostics
 - Given the vast diversity of Technologies and varying risk profile of Medical Devices, Regulatory Controls could be shared and split. For e.g.
 - National regulator – For policy , licensing and registration
 - Conformity Assessment Bodies (CABs) – For Factory audits as per GMP/QMS
 - State Regulatory Authority -- Licensing and Registration of Traders Distributors/Dealers/Warehousing Sub Contractors/Retailers

Similar regulatory model is being followed in Europe, Canada and now Australia and New Zealand are reviewing. Such a mechanism would allow for a single window clearance for the approval process.

- ✓ **Setting up of Medical Devices SEZ or Medical Devices excise benefit zones in India:** . Specific in and out SEZ to be developed with proximity to metros. Development of industrial clusters specifically for the medical devices industry would provide an impetus to the sector.
 - Similar strategies have worked well for the Indian Pharmaceutical sector , where excise-free zones like Baddi and Poanta sahib have emerged as major Pharmaceutical manufacturing hubs
 - Development of industrial clusters specifically for the medical devices industry would provide an impetus to the sector. In this regard, Gujarat government intends on developing of a specialized pharmaceutical machinery cluster in the state. More central and state government initiatives would go a long way in improving Indian capabilities within the segment.
 - As per the industry feedback, a few of the domestic clusters which can be set up for medical devices & equipment are Faridabad, Gurgaon, Ahmadabad, Chennai & Bangalore.
- ✓ **Cross-border research linkages:** Joint R&D activities can be organized through cooperation of Government of other nations. For instance Israel has taken up many bi-national funds for development of R&D in technology, such as Bi-national Industrial R&D Foundation (BIRD).

BIRD is a catalyst for joint R&D between American and Israeli companies. Any pair of companies, one Israeli and one American, may jointly apply for BIRD support as long as they have the combined capability and infrastructure to define, develop, manufacture, market, sell and support an innovative product based on industrial R&D. Typically, one of the two companies is involved in the development of cutting edge technologies, while the other company offers large-scale product development and commercialization. The BIRD Foundation offers conditional grants for joint development projects on a risk-sharing basis. The Foundation funds up to 50 percent of each company's R&D expenses associated with the joint project. Repayments are due only if commercial revenues are generated as a direct result of the project.

Apart from this, Israel has other similar bi-national funds as well-

- SIIRD- The Singapore-Israel Industrial R&D Foundation
 - CIIRDF- Canada Industrial R&D Foundation
 - KORIL-RDF- The Korea-Israel Industrial R&D Foundation
 - US-Israel Science & Technology Commission and Foundation
- **Industry-Academia linkages:** Existing students and researchers engaged in biomedical engineering courses need to be geared towards research suited to development of medical devices in India through proper incentives. Through incentivising research, India can diversify its product basket within the industry. This would help India move away from the status of large volume, low value products towards products with higher value in the international market. In promoting partnerships between industry and academia, India can take inspiration from the Innovation law and Good law of Brazil.

Innovation Law was enacted to strengthen the university-industry research relationship, promoting the shared use of science and technology infrastructure by research institutions and firms, allowing direct government grants for innovation in firms and stimulating the mobility of researchers within the S&T system. Public resources could be transferred as nonrefundable funds for enterprises, sharing the costs and risks of innovative activities. The law permitted the creation of the Economic Subsidy Program, created in 2006 and coordinated by FINEP, which provided resources for research and development (R&D) activities performed by industrial firms.

Good Law was enacted in Brazil for authorizing the automatic use of fiscal benefits for companies that invest in R&D. The significant incentives under this were: deductions from income tax and social contributions on net profits from expenses on R&D (between 60% and 100%); reductions in the tax on industrial products for purchasing machines and equipment for R&D (50%); economic subsidies for scholarships of researchers in companies; an exemption from the Contribution for Intervention in the Economic Domain (CIDE) carried to payments of patent deposits. It also includes funding for firms who hire employees with Masters Degrees and PhDs

- ✓ **FDI policy:** Presently the FDI in Medical devices is in the same lines as that of the Pharmaceutical industry. Majority of MNCs which are entering the Indian market are using this 100% advantage but end up doing trading activities.

The FDI policy should be designed in such a way that these companies availing the 100% advantage should be given a time period to establish sales/distribution base. After the stipulated time the MNCs should start some manufacturing in India as well. This would provide a level playing ground for Indian companies as compared to MNCs

- ✓ **Inadvertent advantage to Imports:** The present scenario gives an inadvertent advantage to MNC imports into the country. The government should have a long term view to make it a level playing field both for MNC as well as the local manufacturers, some of the different which needs to addressed include :

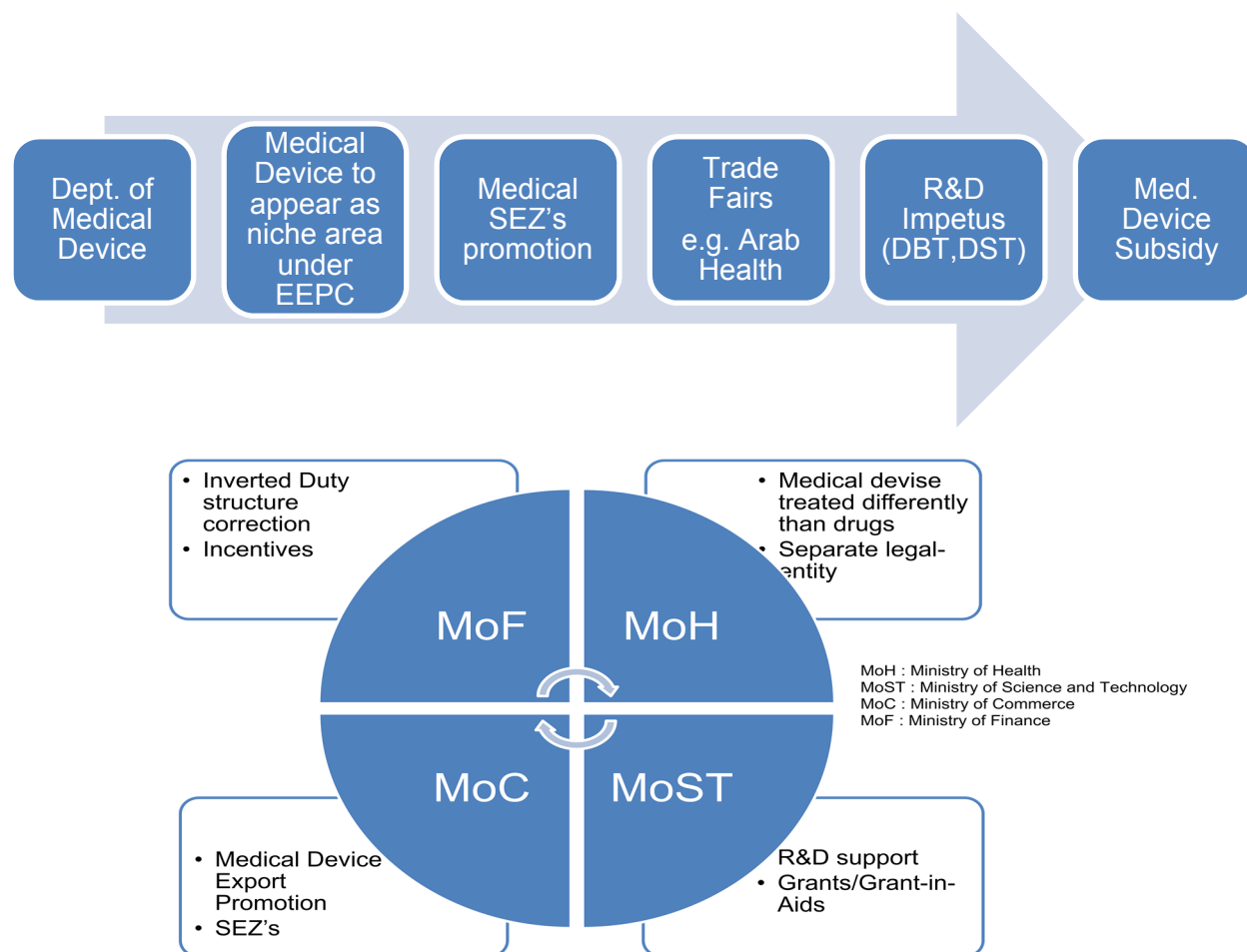
Imports to India	Local Manufacturing
Single window licensor (CLAA)	Manufacturing application at three levels (STATE,ZONAL,CLAA)
No Inspection	Joint Inspection
Compliance to ISO 13485 & TECH FILE Review	Ambiguous Guidelines with time delay
Approval time : 3 to 6 months	Approval time :1 to 3 years
Lack of Unambiguous Written System/Response Mechanism For Mfrs.,& Exporters	Free Sales Certificates, Brand Addition, NOC's

- ✓ To encourage more participation in the production process, Government must resort to promotional measures for the entrepreneurs. India can take cue from Technological Incubators Program which was established in 1991 in Brazil wherein for a period of two years, entrepreneurs are provided with R&D and marketing grants, infrastructure, technological and business guidance, legal and regulatory advice and administrative assistance. Projects need to be approved by the Incubators Committee. Israel has also taken a remarkable step in promoting entrepreneurs. TNUFA is a national pre-seed fund of Israel. It assists individual inventors and nascent start-up companies during the earliest stages of their projects. This includes evaluation of the technological and commercial potential of a project, filing for a patent, building a prototype, drafting a business plan and initial business development. Grants of up to 85 percent of approved expenses are available to a maximum of approx. USD 65,000 per project.

- ✓ Skill and Capability development
 - Up-gradation of test labs
 - Access to low cost testing
 - Accreditation of Labs
 - Training of Regulatory requirements
 - Short term courses at NIPMER
 - Distance e-learning
 - Encourage Academia - Industry interaction

In addition to this the DCGI office is inadequately staffed and the concerned ministry should take steps to increase the people and knowledge base so that the approval process could be fastened.

Strategies for Promotion of Exports have to be followed aggressively with a cohesive effort coming from the Government and the Industry. The government should provide adequate support to the budding sector in order to make it a success like the Indian Pharmaceutical Industry



IDENTIFICATION OF NICHE MARKETS FOR EXPORT PROMOTION EFFORTS

- Markets like Indonesia, Bangladesh, Dubai, Egypt, South Africa etc. are some of the potential markets which do not have trade barriers or limitation to “Indian origin equipments” and the same should be incorporated in FMS countries so that exporters may be given opportunity to explore more in these markets
- Semi regulated markets like Middle East, CIS and Africa are easy for promotion of exports. Specific markets like Turkey, Egypt, Iran, etc. can be targeted.

INDIAN PHARMA MACHINERY SECTOR: CURRENT STATUS, CHALLENGES, IDENTIFICATION OF KEY MARKETS & THE WAY FORWARD

1. Current Production: The estimated business revenue from this sector which includes processing, packaging, utility equipments and other ancillary products is around Rs. 6,000 crores
2. Current Export: Rs. 1,800 crores accounts for exports. HS Code: (Refer Annexure - 001)
3. Current Imports:
4. Related statistical status & trends over past 4 - 5 years in pharma machinery market segment with regards to above three:
 - The Pharma Machinery Industry is growing 15-20% annually.
 - In India there are around 800 pharmaceutical machine manufacturing and allied utility service units in the small and medium sector.
 - An entire range of manufacturing facilities is being catered by the Indian pharmaceutical machinery industry including Processing (Tablet / Capsule / Liquids / Injectibles / Ointments / Dry Syrups), Packaging (Filling / Sealing / Labelling / Cartoning) Material Handling, R&D Equipment & Instrumentation, and API / Bulk Drug Plant Machineries.
 - IPMMA today has more than 300 registered member companies, exporting to 80 countries internationally.
5. List of major Indian players in the sector:
 - Accu Pack Engineering Pvt. Ltd.
 - Accurate Machines
 - Ace Technologies & Packaging Systems Pvt. Ltd.
 - ACG Worldwide
 - Adam Fabriwerk Pvt. Ltd.
 - Alliance Machines Pvt. Ltd.
 - Ambica Pharma Machines Pvt. Ltd.
 - Anchor Mark Pvt. Ltd.
 - Bectochem Consultants & Engineers Pvt. Ltd.
 - Brothers Pharmamach (India) Pvt. Ltd.
 - Cadmach Machinery Co. Pvt. Ltd.
 - Chitra Machineries Pvt. Ltd.
 - Crystal Automation Pvt. Ltd.
 - Electrolab India
 - Elmach Engineering
 - Fabtech Technologies International Pvt. Ltd.
 - Fluidpack
 - Gansons Ltd.
 - Harikrushna Machinetech Pvt. Ltd.
 - Hydropure Systems
 - IMA PG India Ltd.
 - Ion Exchange India Ltd.
 - Jicon Machines
 - Klenzaid
 - Machine Fabrik Pvt. Ltd.

- Maharshi Udyog
 - Newtronic Lifecare Equipments Pvt. Ltd.
 - Nilsan Nishotech Systems Pvt. Ltd.
 - NPM Machinery Pvt. Ltd.
 - Parle Elizabeth Tools Pvt. Ltd.
 - Pharmachine India
 - Pharmalab India Pvt. Ltd.
 - Progressive Instruments Pvt. Ltd.
 - Propack Technologies Pvt. Ltd.
 - Rapid Pack Engineering Pvt. Ltd.
 - RP Products
 - Saan Engineers Pvt. Ltd.
 - SK Pharma Machinery Pvt. Ltd.
 - SSPM Systems & Engineers
 - Tapasya Engineering Works Pvt. Ltd.
 - Thermolab
 - TSA Process Equipments
 - Wraptech Machines Pvt. Ltd.
6. Challenges facing from China and Korea, we need support from Government to promote the Indian pharma machinery in terms of Road Shows, Seminar, Buyer – Seller Meet, etc. in various countries
 7. To apply anti dumping duty on Chinese Machineries to prevent the in-flow of Chinese Machineries
 8. Considering as a industry, similar to Agro, Textile, Chemical, request to recognise the pharma machinery sector as one of the industry
 9. Regulatory Frame Work: The pharma machinery should meet the WHO – GMP standards set for the pharma manufacturing process. However, in addition to this, while supplying the products / machines to European Union, CE Mark is desirable.
 10. Major Industrial Clusters in Pharma Machinery Sector: The major clusters are located at Mumbai and Ahmedabad to Vapi industrial corridor. The remote clusters are at various locations including – Hyderabad, Bangalore, New Delhi.
 11. Key Markets: Africa (Kenya, Nigeria, Uganda, Tanzania, Ethiopia), Asia (Sri Lanka, Nepal, Philippines, Malaysia, Vietnam, Thailand), Middle East (Dubai, Oman, Yemen, Iran, Iraq, Syria, Jordan), East Europe (Hungary, Poland, Yugoslavia, Slovakia, Czech Republic, Romania).
 12. Emerging Markets: Africa (Ghana, South Africa, Algeria, Egypt, Morocco), Asia (Bangladesh, Pakistan, Myanmar), Middle East (Turkey, Lebanon, Israel, Palestine, Sudan), Latin America (Brazil, Argentina, Chile, Peru, Ecuador, Venezuela, Costa Rica), Central America (Panama, Guatemala), CIS (Whole CIS zone).
 13. Key Improvements:
 - [a] Removal of CST, Road Permit, Way Bill, etc. and single point GST
 - [b] Single Point Taxation
 - [c] Financial support for project expenses as our people lose business to China as China offers loans on capital equipment at an interest rate of 3% p.a.
 - [d] Proper HS Code No. vis-à-vis DEPB benefit
 - [e] No service tax and / or TDS - PAN Card hassle for sending overseas sales commission

[f] Include our products in bilateral agreements with LAC countries and European as well as other countries for duty free imports at buyer's end

[g] Pursue removal of embargo by Pakistan on pharma machinery

14. WAY FORWARD:

As the Global Pharmaceutical Industry is on a growth and healthcare will remain the focus for any developing nation, India can play a major role to partner with them and support on setting up turnkey projects for manufacturing pharmaceutical. The industry needs a boost from the government policy in following areas:

1. R&D Support
2. Export Promotion Schemes and benefits
3. Focus market scheme extended to their products
4. Funding for foreign market development
5. Financing and risk coverage for exports to under developed countries
6. Relaxations for import of design and technology
7. Education on Patent laws and procedure to protect our designs
8. Anti Dumping duty on Pharmaceutical machinery from China to protect the local manufacturers
9. Organising Buyer Seller meets
10. Technical programs to upgrade the knowledge of the industry

Annexure I - Comprehensive list of HS Codes Arrived for Medical device industry**EEPC & Plexconcil**

9018	INSTRMNTS AND APPLNCS USED IN MDCL,SURGCL, DNTL/VTRNRY SCNCS,INCL SCNTGRPHC APPRTS ELCTRO-MDCL APPRTS AND SIGHT-TSTNG INS
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Pharmexil

3005	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES (FOR EXAMPLE, DRESSINGS, ADHESIVE PLASTERS, POULTICES), IMPREGNATED
3006	MISCELLANEOUS PHARMACEUTICAL GOODS
5601	WADDING OF TEXTILE MATERIALS AND ARTICLES THEREOF; TEXTILE FIBRES, NOT EXCEEDING 5 MM IN LENGTH (FLOCK), TEXTILE DUST

Capexil

4014	HYGNC/PHRMCTL ARTCLS (INCL TEATS) OF VALCNSD RUBR OTHR THN HARD RUBR WTH/WITHOUT FITTINGS OF HARD RUBBER
4015	ARTCL OF APARL AND CLOTHING ACCESSORIES (INCL. GLOVES, MITTENS AND MITTS) FOR ALL PURPOSE OF VULCANISED RUBR NOT HARD
4005	CMPNDED RUBR UNVULCNSD IN PRMRY FORMS/IN PLATES SHEETS/STRIP
4017	HARD RUBBER (FOR EXAMPLE, EBONITE) IN ALL FORMS, INCLUDING WASTE AND SCRAP; ARTICLES OF HARD RUBBER

EEPC India

9018	INSTRMNTS AND APPLNCS USED IN MDCL,SURGCL, DNTL/VTRNRY SCNCS,INCL SCNTGRPHC APPRTS ELCTRO-MDCL APPRTS AND SIGHT-TSTNG INS
9019	MCHNO-THRPHY APLNCS;MSGE APRTS;PSYCHOLGCL APTTUD-TSTNG APRTS;OZON THRPHY,OXYGN THRPHY,AERSL THRPHY,ARTFCL RSPRTN APPRTS ETC
9020	OTHER BREATHING APPLIANCES AND GAS MASKS, EXCLUDING PROTECTIVE MASKS HAVING NEITHER MECHANICAL PARTS NOR REPLACEABLE FIL
9021	ORTHPDC APLNCS,ARTFCL PRTS OF TH BODY;HRNGAIDS AND OTHR APLNCS WHICH ARE WRN/CRRD/ IMPLNTD IN THE BODY TO CMPNST DEFT/D
9022	OTHER APPLIANCESOF HEADING 9021 BTA/GMA

	RADITIONS INCL RADIOTHRPY APPRTS,X-RAY TUBEANDGNRTRS,HGH TNSN GNRTRS,SCR
9025	HYDROMETERS AND SMLR FLOATING INSTRUMENTS, THERMOMETERS,PYROMETERS ETC,RCORDNG/NT AND ANY CMBNTN OF THESE INSTRMNTS
9402	MEDCL,SURGCL,DENTAL/VETRNRY FURNITR ETC BARBERS' CHAIRS AND SMLR CHAIRS;PRTS OF THE FOREGOING ARTICLES
9012	MICROSCOPES OTHER THAN OPTICAL MICROSCOPES; DIFFRACTION APPARATUS
9026	INSTRMNTS AND APRTS FR MSRNG/CHKNG THE FLOW,LEVL,PRSR/OTHR VARIABLES OF LIQUID/GASES EXCL APPRTS OF HDG 9014,9015,9028/90

Suggested by Exporters/associations

9027	INSTRUMENTS AND APPARATUS FOR PHYSICAL OR CHEMICAL ANALYSIS (FOR EXAMPLE, POLARIMETERS, REFRACTOMETERS, SPECTR
9619	SANITARY TOWELS (PADS) AND TAMPONS, NAPKINS AND NAPKIN LINERS FOR BABIES AND SIMILAR ARTICLES, OF ANY MATERIAL
4818	TOILT PAPR OR SMLR; PULP/CELULOS WDG/WEBS OF CELULOS FBRS USD IN HOME/HSPTL/SNTRY/ APPRL OF WIDTH <=36 CM OR CUT TO SIZE

Annexure II: Composition of Members of Consultative Committee**1. AIMED**

Mr. Rajiv Nath
Forum Coordinator
Association of Indian Medical Device Industry (AIMED)

2. Yes Bank Limited

Mr. Siddhartha Dhodi
Life Sciences and Information Technology, Corporate Banking
Yes Bank Limited

Mr. Shrikant Ganduri
Executive Vice President,
Head Life Sciences and Information Technology

3. Confederation of Indian Industry

Mr. Pavan Choudary
Chairman - CII Medical Equipment Division

Mr. Himanshu Baid
Co-Chairman, CII MLED

Ms. Elizabeth Jose
Deputy Director
CII

4. EEPC INDIA - INSTRUMENTS ALL TYPES

Mr. C. S. Shukla
Convenor
Instruments all types panel
EEPC India

Mr. Shaily Grover
Managing Director
Paramount Surgimed Ltd.

5. PHARMEXCIL

Dr. P.V.Appaji,
Director General,



Pharmexcil

Mr. Raghuvveer Kini,
Executive Director,
Pharmexcil

Mr. Abhay Sinha,
Regional Director,
Pharmexcil

6. EXIM BANK

Mr. Sriram Subramaniam,
Resident Head
Exim Bank India

7. CAPAEXIL

Mr. VR Chitalia
Director
CAPEXIL (WR),

Debjani Roy
Executive Director
CAPEXIL

Mr. S. Mukhopadhyay
Director, Northern Region
CAPEXIL

8. PLEX COUNCIL

Mr. Sanjiv Rai Dewan
Regional Director
The Plastics EPC

9. ECGC

Ms. Tapasi De
Regional Manager (North)
ECGC of India Ltd



India's Medical Device &
Pharma Machinery Sector

STRATEGY PAPER TO
**BOOST
EX**PORTS



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ENGINEERING THE FUTURE

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