

**NEW REGULATIONS FOR MEDICAL DEVICES IN INDIA- TAKING THE INDUSTRY TO NEXT LEVEL****\*Prashant Soni<sup>1</sup> and Prof. (Dr.) S.K.Gupta<sup>2</sup>**

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**ABSTRACT**

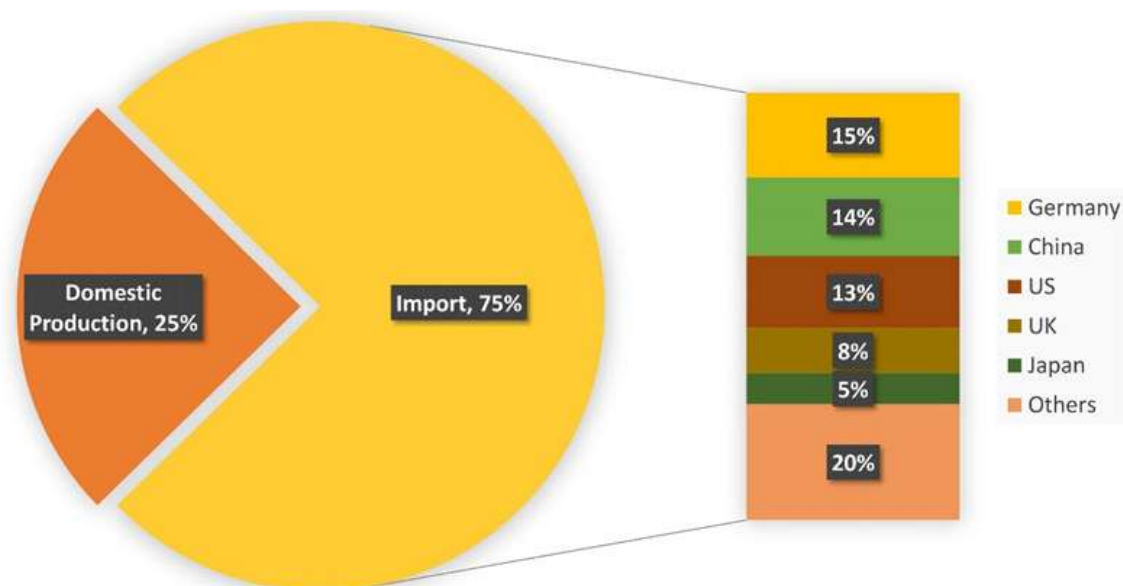
In India, the medical technology sector is pegged at USD 6.3 billion, which is small as compared to rest of the global business but rapidly growing annually at CAGR of 15 percent. In India, the medical devices sector is mostly import driven with approximately 75 percent of devices are imported. There were lots of complaints about the overcharging of medical devices in hospitals by various governmental and non-governmental organizations (NGOs). Because of this, Maharashtra Food and Drug Administration (FDA) conducted a six-month long inquiry against major importing companies. The report of FDA exposed that, there is an exaggeration of around 300-700 percent from the price of stents at which they were imported. In spite of

chances of very huge potential and growth, the Indian Medical device industry is full of challenges like import dependency, non adequate regulatory standards and the absence of tax incentives. There are a series of measures taken by the government like 100 percent foreign direct investment (FDI), hike in basic customs duty by 5 percent of imported medical devices, and providing funds for functioning of medical equipment in public health facilities. Task force constitution and draft National Medical Device Policy-2015 (NMDP-2015) were the other steps to promote domestic production. Access, affordability and return on innovation are the three pillars of medical device industry, which should be balanced to get fruitful result. Sufficient resources are present to open the right doors of opportunities and present India as a global hub for innovation and technology.

**KEYWORDS:** Medical Devices, FDI, National Pharmaceutical Pricing Authority, equipment, implants, diagnostic.

## INTRODUCTION

Medical device industry globally is around USD 200 billion<sup>[1]</sup>, which is involved in the development and manufacturing of various equipment ranging from smaller or cheaper devices like thermometers to larger or costlier ones like x-ray machines and pacemakers. In India, the medical technology sector is pegged at USD 6.3 billion, which is small as compared to rest of the global business but rapidly growing annually at CAGR of 15 percent.<sup>[2]</sup> According to 'Medical Technology: Vision 2025' report of CII-BCG, India keeps on being a developing business sector in the medical device space, is yet to advance in the field of market opportunity and creating a hub for innovation and development.<sup>[3]</sup> As per the Confederation of Indian Industry (CII), this sector has the potential to reach USD 50 billion<sup>[4]</sup> by 2025, an upsurge of approximately 800 percent<sup>[5]</sup> from the current value. This will only be possible if this medical technology sector in India gets the right direction in terms of policies and regulations by government and health care industry.

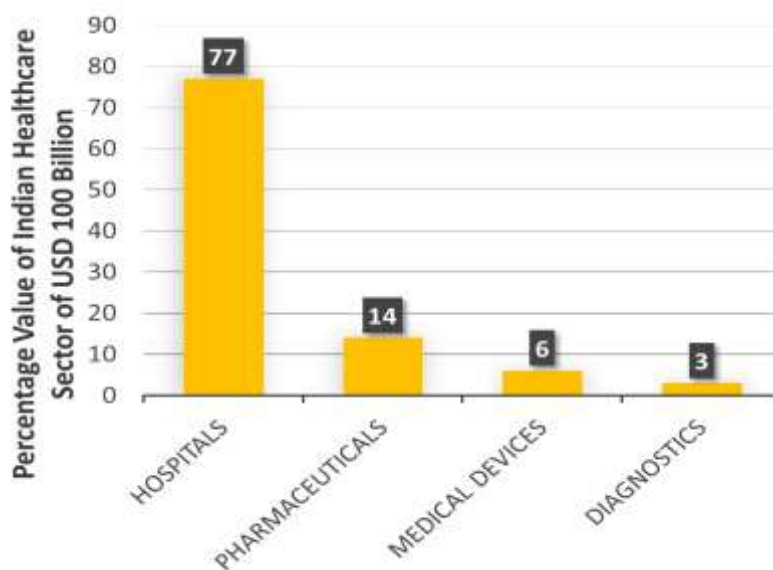


**Figure: 1 Import Vs Domestic Production of Medical devices**

**Source: RNCOS 2012**

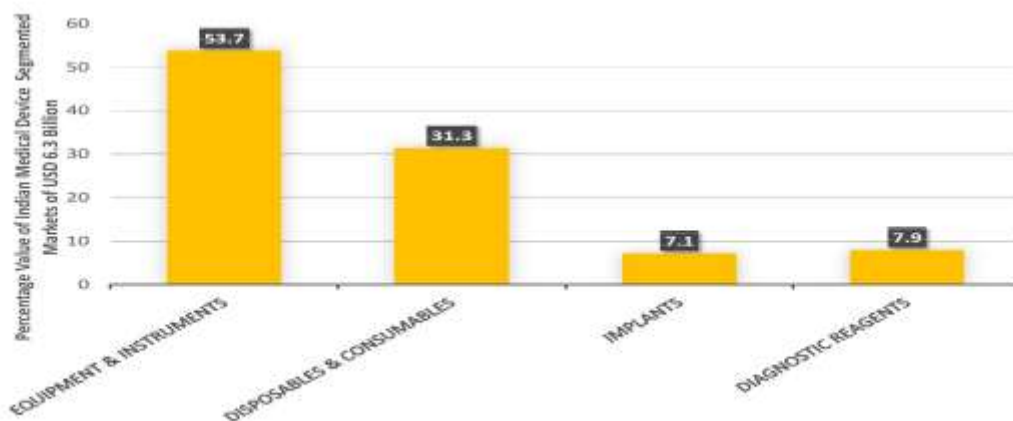
In India, the medical devices sector is mostly import driven with approximately 75 percent of devices are imported (Figure-1). The customs duty on devices and equipment are far less than that of raw materials. This encourages the dependence on imports rather than manufacture. The domestic industry is highly fragmented with the total of 65 percent of local

manufacturers comes under the SME category i.e. Small & Medium Enterprises<sup>[6]</sup>. They predominantly manufacture lower margin products like disposables. Class I & II devices (classification as per USFDA) i.e. devices which are not viewed as risky and do not require large-scale clinical trials before approval are generally manufactured in India. Indian healthcare sector valued at USD 100 billion is divided into four categories which are hospitals, pharmaceuticals, medical devices and diagnostics. Hospitals attract the maximum shares of 77 percent. Medical devices are contributing to 6 percent of spending on health care as compared to 14 percent shares of pharmaceuticals (Figure-2).



**Figure: 2 Indian Healthcare Sector-USD 100 Billion**

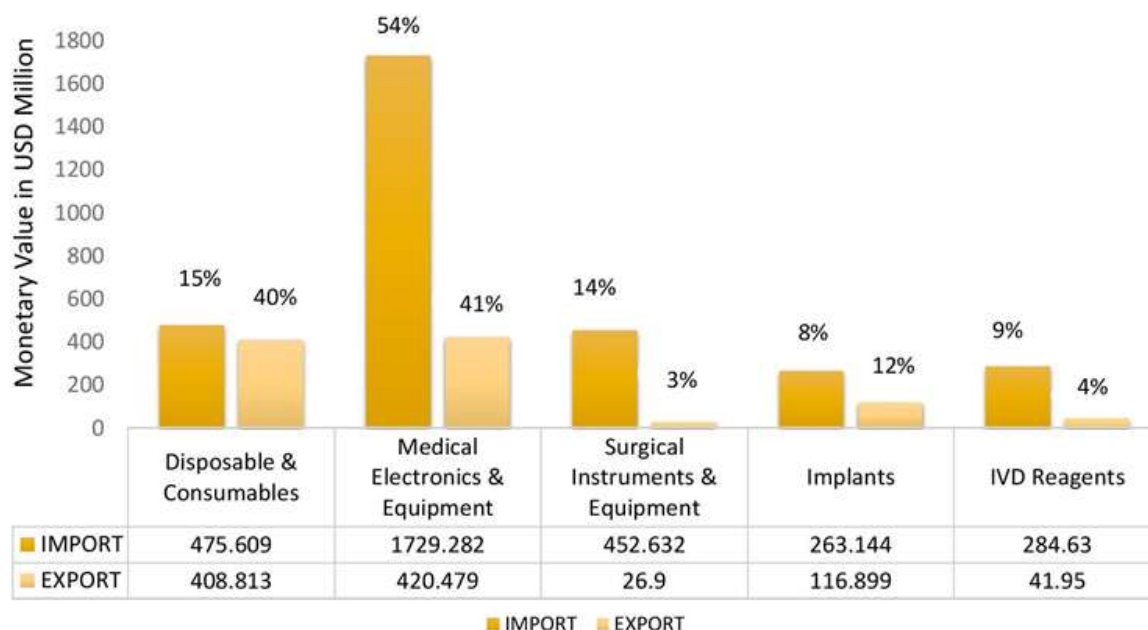
**Source: India Brand Equity Foundation (IBEF) Healthcare Report, 2015**



**Figure: 3 Indian Medical Device Market Segmentation--USD 6.3 BILLION**

**Source: O3 Capital<sup>[6]</sup>, NMDP-2015<sup>[23]</sup>**

The medical device industry is broadly classified into four segments- a) medical disposables and consumables, b) medical equipment and surgical instruments c) implants and d) diagnostic reagents (Figure-3). Medical disposables and consumables, like bandages & dressings, suturing materials, syringes, needles, and catheters, is the second largest segment of the Indian medical device sector which covers the 31 percent shares in the market. Medical equipment and instruments that form the largest part of medical devices with the market size of 54 percent include X-ray machines, ultrasound machines, CT scanners, MRI machines, ECG machines, etc. Diagnostic reagents and implants cover the 8 percent and 7 percent of the market respectively. Implants market is expected to grow much faster than other segments in the coming years. Equipment and implants categories are responsible for more than 50 % of import in India. The current scenario of export and import of various categories of segments of the markets is shown in figure (Figure-4). Around 2000 medical devices are locally sold from surgical needles to ultrasound machines. Only 22 of them are presently regulated as “Drugs” under Section 3, Clause (b), Sub-clause (iv) of Drugs & Cosmetics Act, 1940<sup>[7]</sup> (Figure-5). The Ministry of Health and Family Welfare, Govt. Of India has specified this by various Gazette notifications.



**Figure: 4 Medical Industry Current Export & Import Scenario, Values in USD Million.**

**Source: Task Force Recommendation, AIMED**

S.No.	Name of the Device	S.No.	Name of the Device
1	Disposable Hypodermic Syringes	12	Scalp Vein Set
2	Disposable Hypodermic Needles	13	Orthopaedic Implants
3	Disposable Perfusion Sets	14	Internal Prosthetic Replacements
4	In-vitro Diagnostic Devices for HIV, HBsAg and ACV	15	Blood Grouping Sera
5	Cardiac Stents	16	Skin Ligatures, Sutures, and Staplers
6	Drug Eluting Stents	17	Intra-Uterine Devices (Cu-T)
7	Catheters	18	Condoms
8	Intra-Ocular Lenses	19	Tubal Rings
9	I.V. Cannulae	20	Surgical Dressings
10	Bone Cements	21	Umbilical Tapes
11	Heart Valves	22	Blood/Blood Component Bags

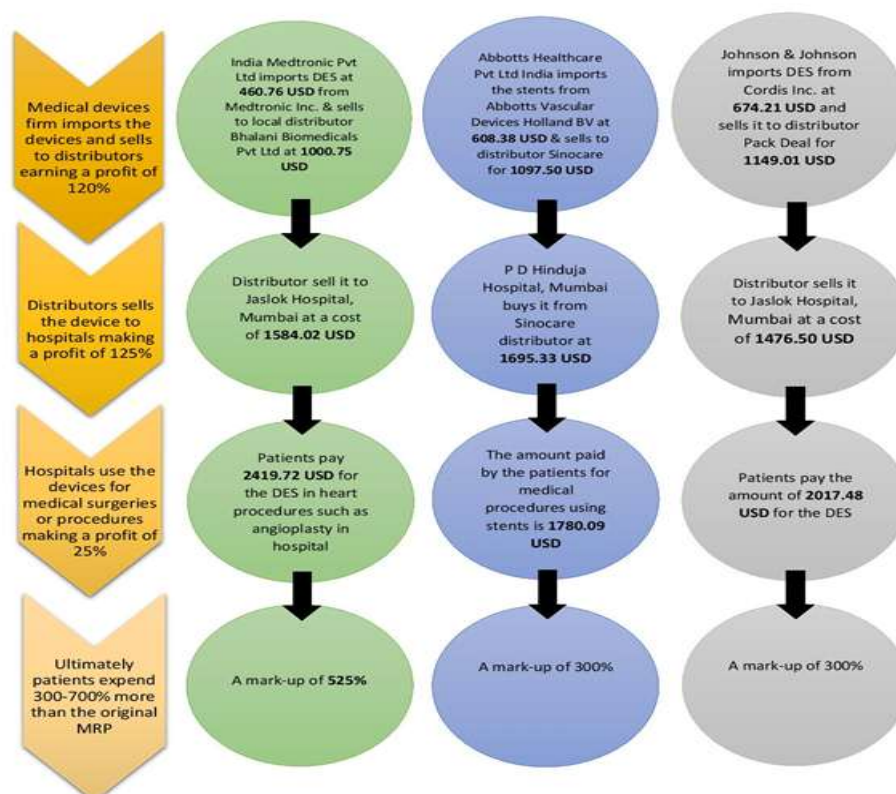
**Figure: 5 List of Notified Medical Devices in India**

**Source: CDSCO Website<sup>[7]</sup>**

### **CURRENT SCENARIO OF INDIAN MEDICAL DEVICE MARKET**

In India, primarily cardiac and orthopaedic procedures attract maximum revenue. Every year around 1 lakh people undergoes knee-replacement surgeries and 3 lakhs undergo heart procedures. Total cost for each patient comes in the range of 1500 USD and 7500 USD.<sup>[8]</sup> There were lots of complaints about the overcharging of medical devices in hospitals by various governmental and non-governmental organizations (NGOs). Because of this,

Maharashtra Food and Drug Administration (FDA) conducted a six-month long inquiry against major importing companies, distributors, and hospitals in Mumbai, Pune, and Nashik division.<sup>[9]</sup> It revealed that the patients are paying almost three to four times the imported cost of various devices like cardiac stents. These stents were sold with the huge mark-ups of 250-400 percent.<sup>[10]</sup> The FDA reported the details of overcharging by Medtronic, Abbott and Johnson & Johnson.<sup>[11]</sup> At each level of supply chain, i.e. importers, distributors and hospitals, everyone keeps their profit margins before selling it to the next level. Thus, at the end level of the chain, i.e. patient gets the stents at a much-inflated price. The report of FDA exposed that the importer companies sell the stents to distributors after making a minimum profit of 120 percent. The importers decide the MRP of the stents. Distributors supply the stents to client hospitals at a price including their profit in a range of around 120-125 percent. Also, hospitals earn the profit of 25 percent by selling the stents to patients. In this whole process.<sup>[9]</sup> Hence, there is an exaggeration of around 300-700 percent from the price of stents at which they were imported. Some examples are cited in the figure to show the unregulated chain process.<sup>[12-14]</sup> (Figure-6).



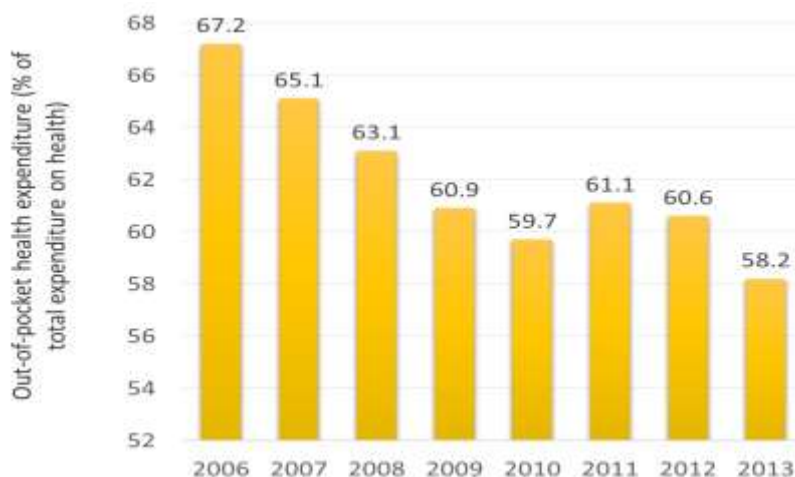
**Figure: 6 Unregulated Supply Chain of Medical Devices**

Source: The Times of India<sup>[12-14]</sup>



## REGULATIONS GAP

In spite of chances of a huge potential and growth, the Indian Medical device industry is full of challenges like import dependency, inadequate regulatory standards, and the absence of tax incentives. Although medical devices save the life of many people in India for many years, still there is no price control or any particular regulations for it. As per the figure, medical devices manufactured in India only cover the 30 percent of the country's needs. Manufacturing units are small in size and do not voluntarily comply with GMP standards. Because of this, there are many fraudulent practices in its marketing<sup>[15]</sup> and since the dependency has increased on imported medical devices, their prices have climbed up massively in the past few years. In the absence of any specific, regulatory body to control the prices of medical devices or equipment, importer company, distributors, hospitals, and doctors charge the patient exorbitantly i.e. thrice the import price and make money as commission.<sup>[12]</sup> Distributors for medical device companies use their money to influence doctors for prescribing or using the devices made by their company in the future, so that the market share of the company can expand.<sup>[11]</sup> Currently, medical devices are covered under the Drugs and Cosmetics Act with the same provisions of drugs. However, they are not included in the Drug Price Control order (DPCO) due to which it is difficult to control and monitor the prices of drugs.<sup>[13]</sup> National Pharmaceutical Pricing Authority (NPPA), under the Ministry of Chemicals and Fertilizers, which monitors the prices of the drug also regulates the prices of medical devices. As the specific policy or guidelines for regulating the prices of medical devices are not available, NPPA fails to limit their prices as it does for drugs.<sup>[16]</sup> Unlike drugs, there is no such surety of MRP of medical devices as they are not available in the retail stores. There is Hobson's choice for patients, i.e. either to take it or leave it, as they are helpless during emergency care in hospitals.<sup>[17]</sup> In India, where out of pocket expenditure on health care is high i.e. around 58 percent of total expenditure on health in 2013, these high prices will cause a great burden on the pockets. Despite the fact that the out of pocket expenditure has decreased from 67 percent in 2006 to till date, as per the world bank data, but it is still very high enough to create a barrier in affordability. (Figure-7) There is a total of 10 percent duty on devices while 27 percent on their raw materials.<sup>[18]</sup> Although the government has allowed 100 percent FDI through automatic route, this duty structure is one of the major reasons steering medical device industry away from the local manufacturing. This unpropitious duty structure is making locally manufactured devices more expensive than the least priced imported ones.



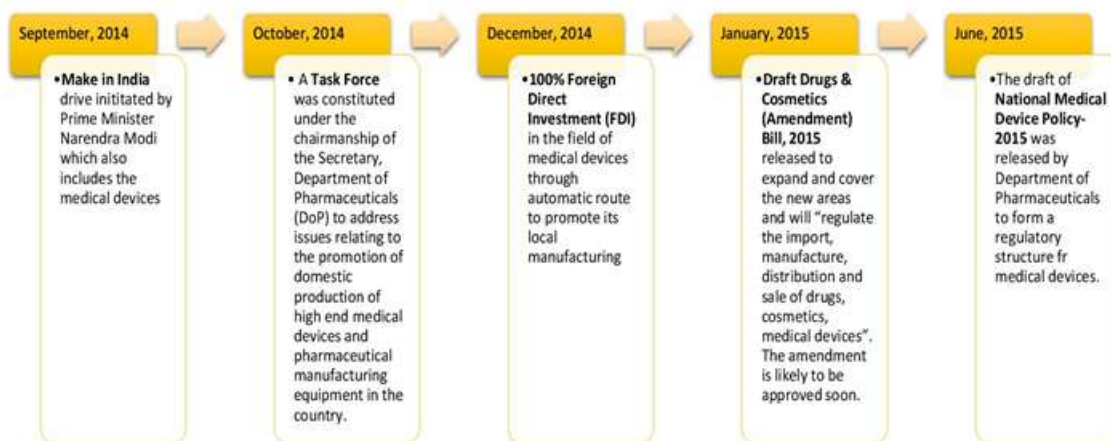
**Figure: 7 Out-of-pocket health expenditure (% of total expenditure on health)**

**Source: World Bank Data**

### **REGULATORY CONTROL BY THE GOVERNMENT**

There are a series of measures taken by the government and regulators to give the country's medical device sector a complete transformation. (Figure-8) The government has allowed the 100% foreign direct investment (FDI) in the field of medical devices through automatic route to promote its local manufacturing and to reduce the over-dependence on imports.<sup>[4]</sup> The key source countries for FDI inflow includes the USA, Europe, and Japan. Medical implants, equipment and consumable segments of the market have a very broad scope for FDI. Their next step, the government issued a notification regarding the labelling of medical devices to control the regulatory environment of the sector. The labels of devices carry very few details only and some key information is missing. As per the notification, labels should disclose the complete name of the medical device, name & address of the manufacturer, date of manufacture and expiry, net quantity in terms of weight, measure, volume, number of units and the other details which will be necessary to identify the device and its use.<sup>[15]</sup>





**Figure: 8 Changes in Regulatory Regime in India to Support Medical Device Sector Growth.**

The government is also planning to hike the basic customs duty by 5 percent on imported medical devices so that the locally manufactured devices could be used more than the imported ones. Presently, the customs duty on medical devices is in the range of 5 percent to 10 percent. For high-end medical equipment like an X-ray machine, CT scanners and MRI machines, which are mostly used in radiology laboratories or in hospitals, the customs duty is around 5 percent, while disposables like catheters, needles, syringes have 10 percent customs duty. Stents and pacemakers like implants also have 5 percent customs duty. However, according to industry people, hike in customs duty would not benefit the manufacturing. Instead, it would cause an increase in the prices of medical devices as most of the devices used in India are imported. The price increase will eventually upsurge the total health care costs for patients and the government's FDI policy will also go in vain.<sup>[19]</sup>

NPPA has written to the top medical device companies to keep a check on prices from time to time and not to hike the price beyond 10 percent in a year as per the paragraph 20 of Drugs (Prices Control) Order, 2013, according to which no manufacturer/importer/distributor should increase the MRP more than 10 percent during the preceding 12 months and if the price hike goes beyond 10 percent, the company would have to reduce it within limits. Also, that manufacturer/importer/distributor should deposit the overcharged amount along with interest thereon from the date of the increase in price in addition to the penalty.<sup>[20]</sup>

NPPA had also asked the companies to provide the list of all devices they manufacture or import and their current prices to investigate the violation of prices in notified medical devices.<sup>[13]</sup> Further, NPPA has reminded the companies to issue a price list and

supplementary price list in Form V of schedule II of DPCO, 2013<sup>[20]</sup> from time to time to all dealers (including retailers), state drug controllers and government as well as NPPA carrying the proper name of the product, its composition, the pack size (inclusive of applicable duties) and its maximum retail price as per the paragraph 25 of DPCO, 2013.<sup>[21]</sup>

The Government is trying to provide special funds to states for the development and functioning of Medical Equipment Maintenance Agencies to bring life to around 1500 Million USD worth of non-functioning medical equipment in public health facilities. This agency will take care of every equipment from small weighing machine to a big CT scanner, X-ray machine or Dialysis machine. A comprehensive maintenance program has been initiated by the state government from April 1st, 2015 for this from primary care centres to large hospitals. The government has estimated around 60 million USD<sup>[22]</sup> for this program. A toll-free number will be there in each state to register complaints regarding dysfunctionality of equipment. Anyone, from a nurse or ward boy to radiologist can register the complaint, which will track electronically and addressed as per priority basis.

#### **DRAFT OF NATIONAL MEDICAL DEVICE POLICY-2015**

To upsurge the growth of medical device sector, a task force was constituted under the chairmanship of the Secretary, Department of Pharmaceuticals (DoP) with the objective to address issues related to the promotion of domestic production of medical devices. The representatives of the task force also include the members of the Ministry of Commerce and Industry, department of industrial policy and promotion (DIPP), the Ministry of Health and the confederation of Indian Industry (CII). The task force studied the sector, its regulatory structure and its policy and infrastructure thoroughly and released their report in April 2015. The report includes the recommendations from all sub-groups of task force covering eight areas of medical device sector. (Figure-9) These recommendations are the base of draft National Medical Device Policy-2015 (NMDP-2015).



**Figure -9: Recommendations of the Task Force on the Medical Devices Sector in India-2015**

**ICMR- Indian Council of Medical Research, DBT-Department of Biotechnology, CSIR- Council of Scientific and Industrial Research, DeitY-Department of Electronics and Information Technology and DoP-Department of Pharmaceuticals.**

The draft NMDP-2015 was released on 3rd June 2015 by Department of Pharmaceuticals, Ministry of Chemicals & fertilizers, Government of India with the objective of strengthening the 'Make In India' drive (started by Prime Minister Narendra Modi) in the medical devices sector by reducing the dependence on imports and setting up a strong base for medical devices in terms of affordability and availability for patients. Even though the implementation details are not widely described, it still forms a broad structure of the regulatory framework. It has proposed to create a new regulatory body under the Department of Pharmaceuticals and to be named as "National Medical Device Authority" (NMDA).<sup>[23]</sup>

This autonomous body will only promote the medical device industry in India by making the industry self-dependent and globally recognized in production and innovation. This authority will also be responsible for building and monitoring Medical Devices Mega Parks, networking with national/international organizations within and outside India primarily to facilitate scientific cooperation, exchange of information, coordination of activities, exchange of expertise and implementation of joint projects. NMDA will also remove any trade barriers and collect and analyse the relevant data. It will provide complete support to access foreign markets, face competition and find new business partners outside India. This authority will issue the guidelines to develop methodologies for risk assessment and spread the awareness regarding medical device safety and quality standards.

As per the policy, the incentives will be given to both Greenfield and Brownfield units by the government on the recommendations of NMDA. The incentives include preference in government procurement for devices manufactured in India; support for research and development by agencies such as the Indian Council of Medical Research (ICMR), Council of Scientific & Industrial Research (CSIR), Department of Pharmaceuticals (DoP), Department of Electronics and Information Technology (DeitY) & Department of Biotechnology (DBT); low cost funding and concessional power price. Other proposed incentives include seed capital, viability gap funding and co-fund start-up projects; commercialization support to new innovations; promotion of local manufacturing by designing tax/duty structure; export promotion; either zero or minimum duty for importing the raw materials needed to manufacture medical devices and limitations on using and importing second-hand devcies.<sup>[23]</sup>

NMDP-2015 also takes into account the issue of safety and quality control for different categories of medical devices to strengthen the Made in India marking (BIS). It proposes the setting up of medical device testing centres in a public-private partnership. Centres of Excellence like Bureau of Indian Standards (BIS), Department of Electronics and Information Technology (DeitY), Central Institute of Plastics Engineering (CIPET), Defence Research and Development Organization (DRDO) etc. are needed for the validation and safety and efficacy testing of medical devices. The policy also includes the recommendation for setting up a skill development committee under NMDA, which will perform various activities like online/e-learning modules; engaging with vocational training providers, ITIs, polytechnic and

other such institutes; satellite training camps and counselling to candidates to check any skill gaps and upgrades it.

To address price control, the draft proposes to create a separate pricing division under NPPA and include the devices as a separate entry under the Essential Commodities Act. A separate Medical Devices Prices Control Order (MDPCO) will also be announced and implemented soon by the government.<sup>[23]</sup>

## DISCUSSION AND CONCLUSION

The government ought to support and promote local manufacturing through some incentives and infrastructure along with the price regulation. Providing access to large, globally developed companies in India will provide a strong competitive environment to local medical device manufacturing units and improve their manufacturing capabilities. In the meantime, the Health Ministry should keep a check on the quality of raw materials used in the manufacturing of devices so that the Indian branded products gain maximum profit in International markets. The Good Manufacturing Practice (GMP) must be made compulsory for all medical device manufacturing units and timely auditing should be done to ensure that units are following the guidelines properly.

The Ministry of Consumer affairs, as well as the Ministry of Finance, needs to consider some steps to control the retail price increment because of the tax structure. Because of the duties levied on these devices as well as on raw materials for their manufacturing, prices of them are touching sky high. There is also a need for detailed classification of medical devices. National Product Classification for Manufacturing Sector (NPC (MS)) could simplify and expedite this process<sup>24</sup>.<sup>[24]</sup> Association of Indian Medical Device Industry (AIMED) suggests that the government should first understand the medical device industry from inside out and study the economics of devices right from its manufacturing till the patient pay for that device as the NPPA or DPCO are not sufficient to regulate the price.<sup>[25]</sup>

The prices of the devices, the highly debated issue, should be predictable and transparent. Profit margins for importing companies, distributors and hospitals should be fixed to decrease the price burden and make the medical treatment, including such devices economical and affordable to a common man. Currently, the prices of only two devices, i.e. intrauterine devices and condoms are under the government's control besides other 348 essential medicines, as they are enlisted under the National List of Essential Medicines (NLEM). The risk of cardiac diseases is more in Indian Population, thus, the demand for stents are growing.



The Government plan to cap the price of all devices will provide relief from thousands to lakhs of patients, but it is just a single step towards the biggest milestone of creating an independent medical device regulator in India, which is yet to achieve. The government is leaving no stones unturned to accomplish this task. Recently, the central government announced its plan to set up the India's first medical device park in Gujarat<sup>[26]</sup> to complement 'Make In India' drive. This park will create a base, which will then build up the component ecosystem and greatly improve the domestic production of the high-end medical device. National Institute of Pharmaceutical Education and Research (NIPER) will be the nodal institute for all research and development in that industrial park.

Access, affordability and return on innovation are the three pillars of medical device industry, which should be balanced to get fruitful result. Obviously, the situation is very different now than it was 10 years prior. Sufficient resources are present to open the right doors of opportunities and present India as a global hub for innovation and technology.

### CONFLICT OF INTEREST

No conflict of interest, financial or other, exists.

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