MEDICAL DEVICES INDUSTRY IN INDIA

LOCAL MANUFACTURING AND TRADE

RIS
Research and Information System
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विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

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by

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I

Introduction

The three integral industry pillars of modern healthcare technology systems are drugs, vaccines and medical devices (Kale & Weild, 2018). Medical devices include a range of products from bandages and syringes to sophisticated devices that incorporate bioinformatics, nanotechnology, engineered cells and artificial intelligence. These are designed for use by practitioners, patients and healthy individuals in a variety of settings: hospitals, surgeries and private homes. Over the last decades, India has made significant progress in developing local pharmaceutical and biotechnology capacity mainly owing to concerted state policy initiatives and supportive institutions (Dinar, et al., 2013). This has resulted in increased access to affordable drugs and vaccines to people in India and other countries, both developing and developed. However, the same cannot be said about medical devices. About 75 percent of medical devices needs are met through imports from developed countries (Datta, et al., 2013). This is because consumables and disposables make up the major share of products manufactured by the Indian Medical Device Industry (MDI). Therefore, to meet the healthcare needs of the population, expensive medical devices are imported (Datta, et al., 2013).These medical devices at times are inappropriate for use in developing countries due to environmental and operating conditions such as climate, access to water, electrical supplies and transportation conditions (WHO, 2010). A World Bank review of the Bank's investment in medical devices from 1997 to 2001, globally, found that about 30percent of sophisticated equipments remained unused, while those in operation had 25percent to 35percent equipment downtime because of weak capacity to maintain the equipment (World-Bank, 2003). In India, studies show that major medical devices were 'non-usable', 'idle' or had 'low utilization' rates (Mahal, 2006) (Mahal & Karan, 2009). Besides, devices developed in the high income countries cater mostly to users in advanced countries (WHO, 2012), where healthcare priorities focus primarily on ageing and the management of chronic diseases (Cheng, 2007) (Singh & Abrol, 2014). In 2014, taking note of the need to address these issues, MDI was recognised as a key industry under the 'Make in India' initiative (Ministry of Commerce & Industry, 2014). It has since been nick-named the "Sunshine Sector" of 'Make in India' (Department of Pharmaceuticals, 2015). The new government's 'Vision for the Decade', has once again identified medical devices as a salient sector (Budget Speech, 2019).

Given India's unique health and socio-economic challenges and needs medical devices can offer cost effective treatment options for leading causes of disability and mortality as they detect diseases earlier (Urdea, et al., 2006). It has been seen that innovation in medical technology and devices appears correlated to the trend of improved health outcomes for most countries in the world where patients are able to live longer, be healthier, and be more productive over their lifespan (Cutler & McClellan, 2001) (Fuchs & Sox, 2001). A robust medical device sector is, therefore, imperative to sustain government's key health programmes such as Ayushman Bharat. Numerous policy initiatives have been implemented to create synergies for health-industry collaboration. This is critical for Research & Development (R&D) and innovation. As it has been seen that unlike high-income countries where technology drives R&D and innovation, in developing countries demand constitutes the principal stimulus for innovation (Mackintosh, et al., 2016).Against this backdrop, this paper takes an ecosystem approach to study MDI. It includes a broad multi sectoral approach to include industrial, science & technology (S&T),and healthcare policy interventions. This wide-ranging approach is vital as only when policy measures are concurrently implemented across sectors will India achieve its "Vision" of simultaneously nurturing an enabling ecosystem for medical device manufacturing and providing equitable healthcare.

1.1 Methodology

This paper is based on literature review, secondary data analysis, a detailed survey, and one to one interaction with key stakeholders. Desk review involved an extensive review of journal articles, reports of industry associations, consultancies, and autonomous government bodies and official documents available on government websites. For secondary data analysis ASI unit level data was used to examine the structure of local manufacturing. Trade trends of medical devices were studied using CMIE trade database. Based on the desk research and personal interactions with academia, industry personnel and government officials, an Internet survey was designed and circulated to stakeholders. Personal visits to industrial parks and industry establishments were also made. The draft findings were discussed in a meeting of stakeholders before finalising the present report.

1.2. Literature Review

Majority of the studies in developing countries has focused on development and access to pharmaceuticals and vaccines (Dinar, 2010). The scant literature on medical devices focuses on issues related to manufacturing and access for resource poor setting (WHO, 2012), (World-Bank, 2003), (Singh & Abrol, 2014), and (Mori, et al., 2011). Harper provides evidence of pre-used medical devices being imported into the country (Harper, 2003).

Studies highlight numerous barriers in building local capacity and capabilities for manufacture of medical devices (Wield & Dinar, 2018). These range from the absence of a comprehensive regulatory framework for medical device manufacture to lack of adequate ecosystem for R&D and innovation. Moreover, on the demand side, public expenditure on health is abysmally low at 1.15 per cent of the total GDP (Centarl Bureau of Health Investigation, 2018). Wield & Kale (2018) have identified the overall lack of 'organised reflective public policy' between diverse public and private institutions as the main challenge to local production of medical devices. The complex nature of technology mix associated with medical devices makes its challenging for policymakers to understand and grasp these technologies to enable the establishment of appropriate supportive institutions. Moreover, due to disconnect between healthcare objectives and industrial and technology policy there has been a lack of appropriate governance

mechanism (*ibid*). The poor communication and collaboration among different key stakeholders in the public health system including the absence of systemic and cross-sectoral linkages between manufacturers, practitioners and policy makers act as a disincentive for local firms and entrepreneurs (*ibid*). This has severely hampered both development of national technological capabilities and the provision of affordable health care (*ibid*).

Wield and Dinar (2018) underscores the need of a robust regulatory system. They claim that the absence of a standalone regulatory system for product specifications to address the nuances of the medical device industry is a key obstacle in accessing the poorly regulated and fragmented market. Under the current regulatory system medical devices are governed by the Drugs and Cosmetics (D&C) Act, 1940. Since the D&C Act caters to "drugs'', medical devices are also regulated as 'notified drugs'. However, medical devices, unlike pharmaceuticals, are dependent on a mix of technologies such as engineering, electronics, material sciences and information technology (Kale & Weild, 2018).

Literature on standards and regulations on medical devices suggest a strong need to set up 'optimal' regulations and standards that match local context rather than conforming to standards set by advanced countries (Mackintosh, et al., 2016). For developing countries, reference to a standards system not only helps medical device administration, it is also important for industrial and economic developments. There is an increasing realisation that a standardised infrastructure is a basic requirement for the success of economic policies that will improve productivity, market competitiveness and export capability. ISO13485 and ISO13488 are specific ISO quality systems standards for medical device manufacturing (Patel, 2017). Some argue that the lack of stringent device certification processes, similar to that of FDA in United States and CE in European Union, will continue to remain India's weakness (Vendoti, 2018).

Studies on innovation highlight that globally, innovation in healthcare has been enabled by close interaction with local medical practitioners, links to global S&T and global regulatory requirements (Gardner, et al., 2007). The dearth of institutionalised platforms to promote these interactions and partnerships acts as an impediment for R&D and innovation in medical devices (Dinar, n.d.). In addition, there is a shortage of adequate human resources to support innovation. Data from Global Health Observatory highlights that the density of biomedical engineers and technicians in India per thousand of population has decreased from 0.32 (2014) to 0.31 (2015) to 0.23 (2017) (WHO, 2018). Bio-medical engineers are essential human resources who collaborate with doctors and researchers to develop innovative technological solutions and ensure the correct deployment of medical equipment or devices. They are an integral part of the research ecosystem and the shortage has implication for development and growth of the industry.

On the demand side, issues highlighted by Jarosławski&Saberwal focus on the lack of a transparent and formalised Health Technology Assessment (HTA) for healthcare. This creates inconsistencies in demand for goods and services associated with medical devices (Jarosławski & Saberwal, 2013). Moreover, the absence of national evidence-based guidelines for use of medical devices and of compulsory continuous education for medical practitioners has created barriers for appropriate and adequate use of medical devices (*ibid*). Strengthened medical councils and associations with continuous medical education and national medical guidelines for medical practitioners would facilitate market access for innovative products (*ibid*).

More recently, there have been studies to examine trends in manufacturing, trade and utilization of medical devices (Datta &

Selvaraj, 2019) (Datta, et al., 2013) (Mahal & Karan, 2009) (Mahal, 2006). These studies highlight issues related to availability of data to conduct a comprehensive study on medical devices manufacturing using ASI. Since 2010, ASI has been using the Central Product Classification (CPC), which serves as the reference classification for all products within the international economic classifications system put in place by the United Nations (Annual Survey of Industries, 2014). It therefore, allows a consistent categorisation of products over the years. Building on the previous work by Pritam *et al* 2013, this study takes the opportunity to examine the status of local manufacturing and trade in India. Moreover, it examines if there has been some form of indigenisation of this sector.

II

Evolution of Medical Devices Industry in India

Drugs, vaccines and medical devices have several unique features that differentiate them from other consumer products. The asymmetry of information between the provider of healthcare and patient necessitates the need for appropriate regulations to ensure the safety, quality and effectiveness of the healthcare product. Regulations allow for market acceptance as it enables consumers to build trust in the healthcare systems, the professionals involved and products offered to them. However, unlike drugs and vaccines, medical devices lacked the required regulatory scrutiny and policy support. Even in developed economies, besides France, Germany, the UK and USA, medical devices were not regulated prior to 1990 (EU Regulations, 2017).These countries are major producers and exporters of medical devices globally. Against this backdrop, the evolution of the Indian medical device sector is studied through the regulatory, industrial, S&T and healthcare policy since independence in 1947. There have been four major periods.

2.1 Independence to Pre-Liberalisation Period: 1947-1991

Since independence and prior to pre-liberalisation period, industrial policies were mainly focussed on self-reliance. Barring 'life saving' devices which could be imported duty free, medical devices faced tariffs ranging from 40 to 60 per cent. In the early 1990s, domestic market of medical devices was small. It was estimated at Rs 0.76 billion, (at 1999-2000 prices) of which approximately 15 per cent was imported (Baru, 1998). The responsibility of healthcare provision was mainly through the state system focussed on communicable diseases (CDs) (EpiTrand, 2014).

On the R&D front, S&T Plan in 1974 and the subsequent Technology Policy Statement (TPS) in the 1980s identified 24 sectors such as Nuclear Energy, Space Sciences, Pharmaceuticals, and heavy engineering to build capability and augment R&D. This was aimed at import substitution, adaptation of imported technology, building indigenous capacity, enhancement of industrial productivity and export promotion. Some of these sectors made remarkable progress and supported innovation in medical devices. In 1968, the Jaipur foot was launched by designer Ram Charan Sharma and surgeon Pramod Sethi. It was supported by 60per cent of funds from donations, 30 per cent from government and 10 per cent from earned income. Similarly, Dr. Valiathan, a cardiac surgeon started work on the development of the first Indigenous mitral valve in 1974. He collaborated with National Aeronautics

Space Limited and Vikram Sarabhai Space Centre (VSSC) and launched an indigenous mechanical heart valve at a third of the cost of imported values in 1990. Some of the challenges highlighted by Dr. Valiathan were the lack of local biomedical engineering industry and absence of collaborative network of research institutes. He further highlighted the absence of a regulatory framework for medical devices with consequent challenges to gain market acceptance. Though indigenously produced, the valve was approved by international regulatory authority which delayed the project and increased cost of product development (Kale & Weild, 2018).

In India, the Drugs and Cosmetics (D&C) Act, 1940 and D&C Rules, 1945 regulate pharmaceuticals. In 1989, for the first time, the government notified disposable syringes, needles and perfusion sets to be considered drugs under the Act. This endeavour was not so much to promote local industry, but could have been due to the global recognition of the linkage of HIV to the use of contaminated syringes emergence. Bureau of Indian Standards under the Ministry of Consumer Affairs, Food and Public Distribution laid the standards for other devices. Of these, only two devices, thermometers and x-rays required mandatory certification.

2.2 Post-Liberalisation Era: 1991-2005

Post 1991, India's economic liberalisation policies changed the respective role of the public and private sector enterprises. Imports on medical devices were de-licensed and import tariffs were reduced to 15-30 per cent. The market for medical devices reached $680 million in 1995 growing at 15-20 per cent per year (Kedar & Priestley, 1997). In 1995, of nearly 90 firms, 22 firms dominated production, joint venture and collaboration with overseas firms (Kale, et al., 2018). Imports increased considerably. Between 1994 and 1996, imports from US increased by 19 per cent and constituted about 40 per cent share of medical device market (Kedar & Priestley, 1997). The inverted duty structure whereby finished goods were exempted from custom duty and raw material for manufacture of medical devices attracted custom duty, led to imports dominating local production (Wield & Dinar, 2018). MNCs were primarily involved in distribution of medical devices on the pretext of unavailability of human resources and supporting industry (*ibid*).

Increases in life expectancy, non-communicable diseases (NCDs), health awareness, rising income and medical tourism contributed to demand side pressures (Mahal, 2006). Moreover, the increased participation of the private sector in the provision of healthcare significantly helped boost demand for medical devices (*ibid*). In addition, hospitals also adopted latest innovation to attract patients and leading medical professionals who might otherwise chose to work somewhere (Baru, 1998). The return of many non-resident Indians familiar with modern diagnostic methods also added to market demand during this period (*ibid*).

On the regulations front, 'D&C (IIndAmendment) Rules, 1994, incorporated Schedule MIII to regulate manufacture and imports of medical devices. *In vitro* diagnostic devices for HIV, Hepatitis B Virus (HBsAG) and Hepatitis C Virus were added to the list of devices to be regulated. It was linked to Schedule M that regulated Pharmaceuticals. This caused a challenge for MDI as the Rules were implemented keeping in mind the pharma sector. For example, mandatory 'clean room conditions', such as standard of flooring and air-flow is required to minimize impurities for drugs but these conditions need not be applied to medical devices as instruments can be sterilised in the hospital before they are used.

2005–2014

In 2005, the National Health Mission was launched to address the disparities in healthcare access by additional grants to the states

to expand the reach of its programmes. Numerous central and state health insurance schemes targeted at Below Poverty Line (BPL) households were rolled out in the following years. These allowed empanelment of private healthcare providers for providing tertiary healthcare services. These initiatives along with the growing incidence of NCDs, burgeoning middle class and the use of medical technologies by medical professionals for diagnosis and treatment lead to an expanding medical device market.

The Indian government continued to reduce import duties to 12.5 per centby 2004 and 5 per cent by 2013 (Mahal & Karan, 2009). By 2013-14, the local MDI was estimated at INR 44.7 billion with net import of INR 103.5 billion (EPW, 2019).However, due to the overall regulatory neglect of medical devices there was no national policy to oversee device safety. In 2004, Jamshedjee (JJ) Hospital in Mumbai used unapproved drug eluting stents on 60 high-risk cardiac patients leading to a grave situation. These stents, manufactured by a Netherland based company, were not approved for use in EU markets. Subsequently, in 2005, the Mumbai High Court ordered the government to set rules and standards for the MDI. This brought a new focus on the state of regulation and industrial policy for medical device manufacturing and imports in India. In June 2005, ten medical devices, namely, cardiac stents, drug eluting stents, catheters, intra ocular lenses, I.V. cannula, bone cement, heart valves, scalp vein set, orthopaedic set, orthopaedic implants and internal prosthetic replacements were brought under the ambit of the D&C Act. Further, blood grouping sera, ligatures including sutures and staplers, intra uterine devices, condoms, tubal rings, surgical dressings, umbilical tapes, blood or blood component bags were regulated as drugs under D&C Act & Rules.

The growing medical devices market prompted MNCs to set up joint ventures and subsidiaries with local manufactures (Kale & Weild, 2018). In 2007, over 25 MNCs received licences to import medical devices through their subsidiaries (Delloitte, 2010). Some subsidiaries such as Phillips and General Electric established their R&D centres in India and developed affordable and appropriate devices for the Indian market. For example, an ECG machine at 60per cent lower cost than a traditional ECG machine. The National Policy on Electronics, 2012, provided a policy framework for electronic medical devices. These initiatives were further enhanced through collaborations between international funders such as the Wellcome Trust and Department of Biotechnology (DBT)to launch the "Affordable Healthcare Initiative'', a joint fund to support biomedical research through a series of fellowships programmes. Similarly, in 2007, All India Institute for Medical Sciences (AIIMS),

Stanford University and DBT set up research collaboration to encourage local entrepreneurship for developing medical devices specific to developing countries. The initiatives lead to the development of the 'Jaipur knee' a prosthetic joint that cost only $20 compared to the $10,000 cost of titanium replacement (*Time*, 2009).

2015 onwards

In 2014, 'Make in India' programme was launched. It identified medical devices as a key sector. The same year, Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilizers, formed a multi stakeholder task force to highlight concerns and provide policy recommendations for cost-effective manufacture of safe and efficacious medical devices. The key recommendations included measures to strengthen regulatory landscape, modify inverted duty structure with financial incentives to include tax subsidies, create infrastructure for industry and to promote synergies for healthcare collaboration. These suggestions have been taken forward through major initiatives that include fiscal incentives

to creation of infrastructure, promotion of R&D and innovation and measures to ensure a market for locally produced goods (Pharmaceticals, 2015).

In January 2015, Schedule MIII for medical devices under the D&C Act, 1940 was amended and delinked with Schedule M for pharmaceuticals. This established compliance of ISO 13485 as the Quality Management System for manufacture and import of medical devices. It also allowed 100 percent Foreign Direct Investment (FDI) under the automated route for brown field as well as green field medical device companies (GOI, 2018). FDI in medical devices grew by 25.4 per cent from USD 131.4 million to 164.7 million from 2012-16 with USA, Europe and Japan being the key source for FDI flow (DIPP & WHO, 2017). The equipment, instruments, consumables and implants segments have attracted the most FDI (*ibid*). In the subsequent year, the import duty on 67 categories of medical devices was raised from 5 to 7.5 percent. The special additional duty (SAD) exemption on these devices was withdrawn, and a 4 percent SAD was levied. Simultaneously, basic customs duty was reduced from 7.5 percent to 2.5 percent along with full exemption from SAD on raw materials, parts and accessories for manufacture of medical devices falling under headings HS 9018 to HS 9022 (Ministry of Finance, 2016). It was envisaged that these changes would allow for local manufacturing and eventually import substitution.

Nearly all of the financing in medical devices manufacturers is through venture capital or private equity (Wield & Dinar, 2018). Government support is provided through numerous schemes and subsidies under different ministries to support medical devices manufacturing in India. For example, Departments of 'Medium and Small Enterprises' and Electronics and Information Technology under the Technology and Quality upgradation support provide benefits to MSME (MEITY, 2018). These include nearly 25 percent of the project cost as subsidy by Government of India, and the balance amount to be funded through loans from Small Industries Development Bank of India (SIDBI) and other financial institutions (*ibid*.). In addition, a 75 percent subsidy support to MSME manufacturing units towards licensing of product to national or international standards is also provided (*ibid*.). The maximum assistance by the government allowed per MSME is INR 1.5 lakh for obtaining product licensing or marking to national standards and INR 2 lakh for international standards. Modified Special Incentive Package Scheme (M-SIPS) was started in July 2012 by the Department of Electronics and Information Technology to provide incentive package to promote large-scale manufacturing in the Electronic System Design and Manufacturing (ESDM) sector (*ibid*.). This scheme supports both new projects and expansion of existing projects. It would provide capital subsidy of 20 percent in Special Economic Zones (SEZ) (25 percent in non-SEZ) for units engaged in electronics manufacturing (*ibid*.). For the non-SEZ units' provision for reimbursements of countervailing duties or excise for capital equipment are available. Other provisions and initiatives under the National Electronics Policy, 2012 include reimbursement of excise duties for capital equipment in non-SEZ units, exemption from central taxes and duties for ten years in high tech facilities, and fund allocation of USD 2 billion to promote R&D, product commercialization and nano-electronics (*ibid*).

The government has taken measures to create infrastructure for medical device manufacturing. It proposed to establish three industrial parks in Andhra Pradesh, Maharashtra and Gujarat (Ameel, 2015). It was envisaged that this would result in 50 percent reduction in cost of manufacturing medical devices. Andhra Pradesh MedTech Zone (AMTZ) was established in 2016, in Visakhapatnam, under Government of Andhra Pradesh. The park spans across 270 acres and provides modern state-of-the-art common

facilities such as specialised laboratories, warehousing, and testing centre apart from 150 independent manufacturing units (*ibid.*). These parks have in-house manufacturing units and facility for consolidated raw material procurement. In addition, they provide access to quality control units; have import and export facilitation centres; regulatory offices and engineering services. In 2017, with funding from Department of Biotechnology, Kalam Institute of Health Technology (KIHT) was established at AMTZ (Ameel, 2017). The KIHT provides R&D support for innovation, enable technology transfer and promote market access. The institute is also mandated to auction patents and prototypes available with government funded academic research institutions to promote commercialisation of the products through a web based portal. The parks complement each other - Visakhapatnam will focus on electrical devices (in which India is 90 per cent import dependant), Maharashtra will have a cluster for production of consumables, orthopaedic implants and surgical instruments, and Gujarat will concentrate on disposables. It is expected to function on a Public Private Partnership model (*ibid*). Similar medical device park was inaugurated in Sultanpur, Telangana. This park would work closely with Indian Institute of Information Technology, Hyderabad (IIIT-Hyderabad) for R&D and innovation in medical technology (Ameel, 2017). It is envisaged that the proximity of the academic institutes with the cluster would provide an enabling environment for academia-industry collaboration and promote R&D and innovation. However, the pace of work is slow and major timelines have been missed.

The Ministry of Electronics and Information Technology has established infrastructure to support R&D for electronic devices such as MRIs, Electronic Health Records and assisted devices. Examples include the National Resource Centre for telemedicine and Bio Medical Informatics at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, and medical electronics lab for calibration, repair and maintenance of medical electronics equipment at National Institutes of Electronics & Information Technology (NIELIT) at Imphal, Aizawl, Agartala, Shillong and Kohima. Moreover, a facility for batch fabrication of Linac Tubes at SAMEER, Khargar Campus Navi Mumbai and an ICT centre of excellence on Tactile Graphics at IIT Delhi was also set up (MEITY, 2018). Various schemes have also been proposed to support electronic medical devices manufacturing in the recent National Policy on Electronics, 2019.

Further to support testing and ensure safety and efficacy of medical devices the Union government proposed to set up two dedicated medical device testing laboratories in the country at Vadodara in Gujarat and Noida in Uttar Pradesh, based on a survey conducted by National Health Systems Resource Centre (NHSRC) (IMT News Desk, 2017). The medical device testing lab in Gujarat would be the first and the only dedicated biomaterials and implants testing lab in the country. The lab at Noida will be set up primarily to test electrical and electronic medical devices in the country. Such type of testing labs will allow manufacturers to overcome deficiencies in their products and enhance product value in the market. These labs will be accredited to the National Accreditation Body for Certification Laboratories. However, there have been delays in the realisation of these projects.

A concerted effort has been made to promote innovation to address the healthcare challenges and needs specific to the Indian population. According to the G-Finder report, the world's most comprehensive analysis of neglected disease research investments for drugs, vaccines and diagnostics highlights that India's substantial increase of nearly 38 percent to $76 million in 2017 (Chapman, et al., 2017). In 2018, Government of India and the World Bank signed a $125 million agreement to support India in developing an innovative biopharmaceutical and medical devices industry. The 'Innovate

in India for Inclusiveness Project (I^3)' awarded to Biotechnology Industry Research Assistance Programme (BIRAC), would support innovative start-ups through collaborations and strategic partnerships (World Bank, 2017). The programme has been launched as the National Biopharma Mission. Some of BIRAC's earlier flagship schemes include Biotechnology Ignition Grant (BIG), Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP), Contract Research and Services Scheme (CRS) and Social Innovation Programme for Products: Affordable and Relevant to Societal Health - SPARSH has resulted in more than 30 Products, 20 Technologies, 16 Early Stage-Technologies, 2 Process Innovations, 40 IP (BIRAC Annual Report, 2017-2018).

The Stanford–India Biodesign programme of Department of Biotechnology continued for twelve years. The complete value chain from product innovation to commercialisation has been facilitated and resulted in nearly 40 medical devices and diagnostics, some of which have received USFDA clearances (Min. S&T,GOI, n.d.). As an outcome, more than 100 innovators have been trained (*ibid*). Several national and international patents have been filed. Some of the 'Fellows' of this programme have established their start-up companies for further refining, testing, validating and converting the prototypes into the products. Building on the success of the Stanford-India Biodesign Programme, the Indigenous International Innovation Fellowship - 'i-Fellowship' was launched by AIIMS, and Indian Institute of Technology (IIT), Delhi in collaboration with QUT Australia and Hiroshima University, Japan. The objective was to train a large number of medical technology innovators to support frugal medical technology innovation. The i-Fellowship is an interdisciplinary, team-based, experiential hands-on training programme where physicians, engineers, designers, entrepreneurs and researchers come together to identify needs of the healthcare system in India to develop affordable solutions using a frugal approach (School of International Biodesign, n.d.). Fifteen technologies have been commercialised and twelve Start Ups have been established by Fellows trained under the programme.

A Healthcare Technology Innovation Centre (HTIC) at IIT-Madras was established with the help of DBT (HTIC, n.d.). This centre has delivered innovations and technologies that have been commercialised through government and industry partnerships to benefit society at large. Some of the technologies developed under HTIC are: a) Eye-PAC, the comprehensive ophthalmic image computing platform; b) ARTSENS™, the vascular screening technology; c) an improved design for a Neonatal Transport Unit, d) a highly efficient, practical and useful technology for performing accurate contouring of surgical plates used in reconstruction surgery; e) to evaluate feasibility and appropriateness of Liquid Based Cytology (LBC) in cervical cancer screening in resource-constrained settings of India; and f) wearable health status monitor for Chronic Obstructive Pulmonary Disorder (*ibid*). The HTIC has established collaborations with various industries.

Accelerating Growth of New India's Innovations (AGNI) is a national initiative of the Government of India spearheaded by a dedicated team under the Principal Scientific Adviser to the Government of India. It is an initiative that aims to support the ongoing efforts to boost the innovation ecosystem in the country by connecting innovators across industry, individuals and the grassroots to the market and helping commercialise their innovative solutions. It provides a platform for innovators to bring their market ready products and solutions to industry thereby helping propel India into a new era of inclusive economic growth. Innovation in medical devices has also been possible under this programme, for e.g., the Self-Actuating 3D Printed Expandable Prosthetic Arm (Accelerating Growth of New India's Innovations, GOI, n.d.).

Until 2016, there was an absence of a mandatory quality certification system for medical devices sold in India. To fill the regulatory vacuum, the Association of Indian Medical Device Industry (AIMED) in collaboration with National Accreditation Board for Certification Bodies (NABCB) under Quality Council of India rolled out a voluntary quality certification scheme for medical devices called Indian Certification for Medical Devices (ICMED) (Ameel, 2017). Prior to ICMED, Indian manufacturers were forced to seek CE (European) certification or USFDA certification, to gain some level of credibility to convince public and private healthcare professionals to buy their devices. USFDA certification is prohibitively expensive, even for low-risk devices and cost of getting a pre-market approval is currently INR 1.5 crore which will be over INR 2 crore (Patel, 2017).

The implementation of the Medical Device Rules 2017 provided the much-needed regulatory framework for medical devices. These Rules came into effect on 1st January, 2018 (MoHFW, 2017). Under this initiative, for the first-time regulations specifically pertaining to manufacture and import of medical devices were issued. The new Rules have been framed to conform to Global Harmonisation Task Force (GHTF) framework which classifies devices into four categories (A, B, C and D) depending on the risk associated from low risk to high risk. The Global Harmonisation Task Force (GHTF), founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America provide guidelines to meet standards for safety and quality of medical devices (WHO, 2020). Similar to global practices, these regulations incorporated provisions of third-party audit by Notified Bodies (NB) appointed by the Central Licensing Body. The National Accreditation Board for Certification Bodies (NABCB) under Quality Council of India (QCI) has been tasked to certify these notified bodies. These NBs will undertake assessment of Quality Management System for manufacturers of Class A and B category devices. The objective is to remove regulatory bottlenecks and promote MDI while also ensuring patient care and safety. As of 31 July 2019, six notified bodies have been registered with the Central Drugs Standard Control Organization (CDSCO) to carry out audit of medical device manufacturing units (Central Drugs Standard Control Organization, 2019). Only 23 medical devices were included in MDR, 2017. In February 2020, the Rules were amended and it further included 14 additional devices to monitor a total of 37 devices. It was also decided that all medical devices over a period of three and half years will need to comply with BIS standards (CDSCO, 2019).

In 2015, the first policy specific to medical devices, the Draft Medical Device Policy 2015, recommended significant steps to give a fillip to the local manufacturing of medical devices. Some of the provisions include - creation of an autonomous body 'National Medical Device Authority' (NMDA) to provide a single window mechanism and a supportive framework for the local medical devices industry; incentives for both greenfield and brownfield units like interest subsidy, concessional power, favourable tax/ duty structure, minimum duty on import of raw materials/ parts etc; institutional frameworks such as common testing centres, 'Made in India' marking (BIS) and Skill Development Committee for Medical Device Manufacturing; establishment of 'Centres of Excellence' (CoE) for supporting product development and validation/ certification; price controls for devices including surgical instruments, implants and diagnostic equipment by notifying a separate Medical Devices Prices Control Order (MDPCO) (Department of Pharmaceuticals, 2015).The Medical Devices Technical Advisory Board was constituted on 22 July 2019. This body advises both central and state regulatory authorities (Director Genaral of Health Services, 2019).

On the demand side, numerous healthcare programmes have been expanded to support locally produced goods. In 2015, under National Health Mission, a new scheme for providing physical aids and assisted living devices for senior citizens living below the poverty line was launched (Ameel, 2015). Subsequently, in 2016, the 'National Dialysis Services Programme' was launched to provide dialysis services in 219 district hospitals with 2039 machines via PPP model. The program was free for people below poverty line but provided services to other patients at a subsided rate. Under 'Free Diagnostics Programme', INR 759.10 crore was approved for 29 States/UTs to provide pathology and radiology services (Ameel, 2017). The Ayushman Bharat program that was launched in 2018 provides free essential drugs and diagnostics through its 1.5 lakh health and wellness centres. Again, the National Health Protection Scheme (NHPS) that aims to cover secondary and tertiary care hospitalisation for over 10 crore poor and vulnerable families would create an effective demand for medical devices (MoHFW, 2018). Moreover, since the government is the largest individual buyer of any given product, there has been provision to give preferential procurement to locally produced goods under the government's e–market portal. In 2017, 'Public Procurement Order', was issued by Department of Industrial Policy and Promotion (DIPP). It designated the Department of Pharmaceuticals (DoP) to implement the policy. DoP has proposed that depending on the category of the device, domestically sourced components must contribute to 25-50 per cent of the cost of medical devices to qualify for public tenders. The per cent is expected to increase incrementally over the years. This initiative is similar to measures taken by other emerging economies such as Brazil for public procurement to support domestic production of health technologies (Mackintosh, et al., 2016).

The institutionalisation of Health Technology Assessment (HTA) under ICMR by creation of the Medical Technology Assessment Board (MTAB) is a landmark development towards evidence-based health policy making in India (Prinja, et al., 2018). HTA assists in the prioritisation of health resources. It is the international gold standard for utilising health economic principles to comparatively assess evidence for cost, clinical effectiveness, safety, and equity to provide evidence as to whether an intervention is a cost-effective investment within a given health system. The UK's National Institute for Health and Care Excellence (NICE) is an example to emulate how HTA and public procurement can be linked. This has also meant an assured demand for goods and services associated with medical devices.

To monitor the safety of medical devices in the country, the Drug Controller General of India launched the Materiovigilance Programme of India (MvPI) on 6th July 2015. The central government has allocated Rs 1 billion for MvPI which includes four surveillance programs - materiovigilance, pharmacovigilance, biovigilance and heamovigilance. Key institutions and respective roles have been clearly enumerated. While the Indian Pharmacopoeia Commission (IPC) will function as the national coordination centre, the biotechnology wing of Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) in Thiruvananthapuram, will act as National Collaborating Centre; the National Health Systems Resource Centre (NHSRC) under the Ministry of Health & Family Welfare will collaborate and provide technical support. The program has been piloted in ten medical colleges across the country and will be implemented along the lines of the existing pharmacovigilance and haemovigilanceprogrammes (IPC, 2018).

While numerous multi sectoral policy initiatives have been taken to provide a conducive ecosystem for the development and growth of the medical device sector, there are many shortcomings that still remain.

III

Industry Profile: Trends and Trajectories

The time period of the study for local manufacturing was from 2010-11 to 2015-16. This is the largest and latest ASI data available which uses international economic classifications system for products manufactured. ASI is designed to obtain 'comprehensive and detailed data' of key features of registered manufacturing sector to allow for formulation of industrial policies (Annual Survey of Industries, 2014). Under ASI, National Industry Classification (NIC) is an activity classification. Based on the principal product manufactured, NIC defines the appropriate industry groups. In this manner a unit gets classified in one and only one industry group even though it might be manufacturing products belonging to different industry groups. For this study, four-digit level of classification is inadequate to identify medical device industries due to the diverse range of products that make up medical devices. Therefore, NIC 2008 at the highest level of disaggregation (5-digit) was used to categorize medical devices manufacturing industries. Table 1 in Annexure provides eleven NIC 2008 industries that have been selected for our analysis.

The key indicators of interest at the unit (NIC 2008) level were – per cent share of medical devices and non-medical devices produced; value of 'sale of goods sold in same condition as purchased'; and per cent of indigenous and imported inputs used in medical device industry. In addition to NIC, ASI utilises the National Product Classification for Manufacturing Sector (NPC-MS), 2011 to categorize commodities that are associated with the manufacturing sector. This classification applies to commodities used as 'inputs' for manufacturing, as well as 'outputs' generated by the factories. NPCMS is based on Central Product Classification (CPC) which serves as the reference classification for all products within the international economic classifications system put in place by the United Nations (Annual Survey of Industries, 2014). At the product (NPCMS) level, indicators of interest include products manufactured and 'indigenous' and 'imported' input used for manufacturing. Using ASI has its limitations. As medical devices consist of diverse set of products the current system of identifying medical devices is limited in scope. Our study is, therefore, limited to only 11 NIC groups of industries that have selected. Other commodities not related to medical devices are also produced in these industries. Therefore, the overall size of the industry gross output is likely to be overestimated.

Under CMIE trade database, Indian Trade Classification (ITC) is based on 'Harmonised

System (HS) of Coding' for global trade. For our analysis, eight-digit ITC (HS) is used to identify commodities that constitute medical devices. This is the highest level of disaggregation to meet national trade requirements. HS 2007 version was used. A total of 144 products were identified as medical devices in the CMIE data. Further, for measuring trade flows, only the total value of trade has been considered. This is because there is inconsistency in the data when measured in terms of volume. For example, for some products such as electro-cardiographs (HS-90181100) and 'Apparatus based on use of x-rays for dental use' (HS-90221300), data is recorded as number of items. However, for other product categories, such as appliances identified for 'ostomy' (HS-30069100) and X-ray tubes (HS -90229000), the data are given in kilograms.

The key driver of the medical device industry is technology. The data sources used for the study do not allow for analysis on international technology transfers or appropriateness of the technology coming into the country. This information is essential to ensure that a robust medical device industry can address the health needs of the country. Therefore, an effort has been made to categorise products using the matrix employed by Kale *et al* (2017) to map technology intensity and local production capability. Figure 1 represents the matrix used. In this matrix, devices with low risk are categorized under low technology while devices with medium or high risk are taken as medium and high risk respectively. Local production capability refers to domestic production of medical devices. This analysis will help gauge how much of the domestic needs are addressed through imports. Products have been classified into electronic devices, diagnostics, implants, instruments and appliances, and consumables and disposables in descending order of risk associated with the devices. Table 2 in Annexure gives the NPCMS and HS concordance of medical devices under each category.

Numerous industry reports and market analysis undertaken by consultancy firms such as McKinsey, Delloitte, PwC, Frost and Sullivan and healthcare industry associations such as Nat Health underscore the importance of medical devices in healthcare and focus on status and composition of medical device sector, its growth potential, export and import of medical devices, merger and acquisitions, private equity and venture capital in medical device. As per these reports, India is currently one of the top twenty markets for medical devices in the world (Sehgal & Bose, 2016). It ranks the fourth largest market in Asia after Japan, China and South Korea (Department of Pharmaceuticals, 2015). The Indian industry has grown from USD 2.02 billion in 2009 to USD 3.9 billion in 2015 at CAGR of 15.8 per cent (Stirling & Shehata, 2016). This is approximately 1.7 per cent of the global medical device market in the same year (DIPP & WHO, 2017).It is expected to reach approximately $25-30 billion in 2025, having a reported compound annual growth rate (CAGR) of 16 percent, significantly higher than the global industry growth of 4-6 percent (Sehgal & Bose, 2016). In terms of cost, it is estimated that the share of medical devices stands at about 4-5 per cent to the overall healthcare (DIPP & WHO, 2017). However, when taken together with the healthcare services, they could add up to a 25 per cent of the healthcare cost. It is also estimated that medical devices can amount to about 30-40 percent of the cost of setting up a tertiary care hospital (Sehgal & Bose, 2016).

As per our analysis, in 2016, there were about 759 registered manufacturing units under the selected group of industries. They comprise 0.31per cent of all manufacturing units in the country. Of these, 620 units were operational. Over 50per cent of the units were situated in the four states of Gujarat (14.7per cent), Maharashtra (14.4per cent), Tamil Nadu (13.7per cent) and Uttar Pradesh (11.5per cent). About 73per cent of the manufacturing units were present in urban areas. This sector

is predominantly dominated by private sector enterprises (68per cent). Table 3 in Annexure gives some basic characteristics of medical device industry in the study period. These include the number of workers employed, total output produced, average wage of workers, exports in this sector.

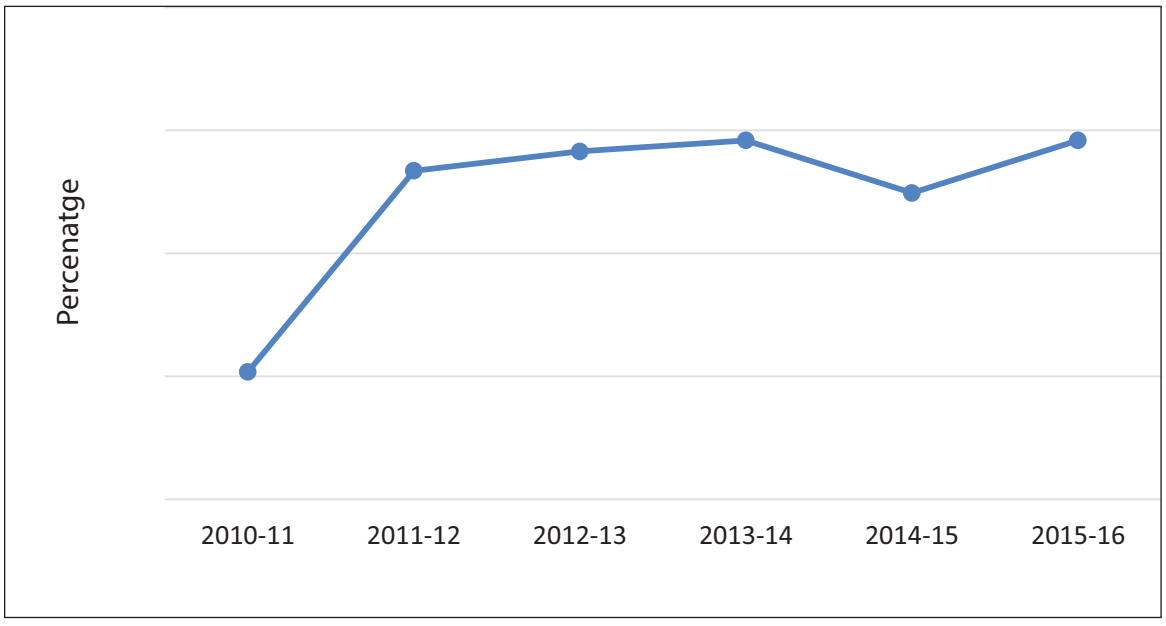
In 2016, total output generated by this sector was INR13634crore, which amounted to about 0.20percent of output generated in the manufacturing sector. Based on output generated, the profile of the industry is given in Table 4 (Annexure). Of the 620 medical devices manufacturers, output generated ranged from INR 20 to 100 crore for 92.8 per cent of the firms. Only 7.92 per cent firms had an output over INR 100 crore.

Medical device industry is complex. The industry produces goods other than medical devices. For example, in 2015-16, NIC32504, produced needles and dental instruments but also produced scraps of stainless steel and plastic as by products which are not used in the healthcare industry. A total of 395 products that were produced by the selected units could be classified under NPCMS. Of these, 218 were categorised as medical devices. Table 5 in Annexure shows the share of total value of medical, non-medical and other products (not classified under NPCMS) produced in 2015-16. Trends seen in Graph 1 below indicates that the medical device industry is becoming more specialised in the manufacturing of medical devices, as the percentage of medical device produced has increased from 75per cent to 94per cent from 2010 to 2015 respectively.

3.1 Traded Vs. Manufactured Goods

Anecdotal evidence suggests that medical devices are often assembled (or repackaged) and sold. The value for 'sale of goods sold in the same condition as purchased' in ASI can be used as a proxy to quantify traded rather than manufactured goods. Trends of goods assembled and marketed (AMGs) for total manufacturing sector *vis-a vis* MDI (2010-11 to 2015-16) is represented in Graph 2. In 2014-15, it has been observed that AMGs are about 68 percent higher in value terms when compared to total manufacturing sector.

Graph 1: Medical device production as percentage of total production of firms(2010-11-2015-2016)



Source: Annual Survey of Industries (2011 -2016)

In 2016, it was observed that 65.18percent of all goods traded took place in NIC 32505, which manufacture measuring instruments such as thermometers, etc., followed by NIC 26600, industries that manufactured irradiation, electro medical and electrotherapeutic equipment at 38.91per cent. Table 6 (Annex) shows the per cent of goods assembled and marketed (AMG) in 2015-16.While AGMs may be of less risk than manufactured goods, high share of AMGs cannot be considered healthy for the industry and public health on account of the dependency on global supply chains which can get disrupted for various reasons and affect supplies.

3.2 Indigenisation of Medical Device Sector

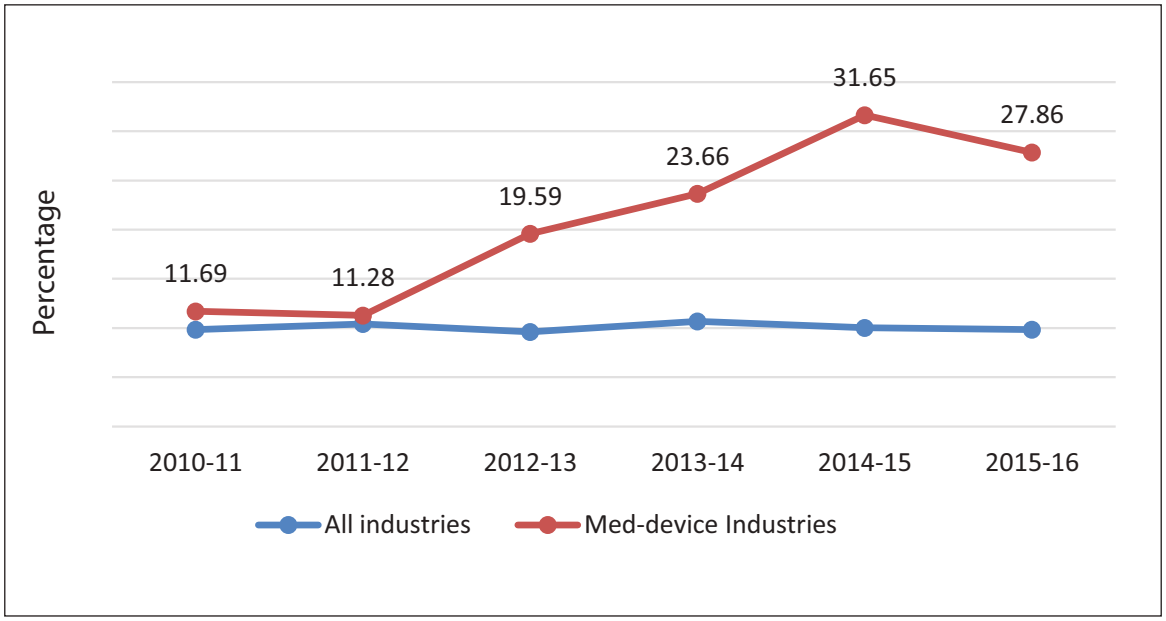
In the medical device sector, many inputs are used to create a product. Some of these inputs are imported while others are domestically produced. Table 7(Annex) gives percentages of indigenous and imported inputs used in selected medical device units in 2015-16. On an average, imported goods constitute 29 per cent of total inputs consumed by the sector.

In 2016, top three industries that were most dependent on imported inputs included NIC 30922- Manufacture of invalid carriages with or without motor, NIC 32503 - Manufacture of medical, surgical, dental or veterinary furniture and NIC 32509 Manufacture of dental fillings and cements. As compared to total manufacturing sector, the per cent of imported inputs is higher in the medical device sector. However, there has been decreasing trend over the study period from 46.76 to 29.73 per cent, reflecting more indigenisation.

3.3 Range of Products Manufactured

Table 8 in Annex shows the top twenty products manufactured in India by percentage share in 2015-16. Retainers, sterilizers, disposable

Graph 2: Goods Assembled and Marketed (AMGs) for Total Manufacturing Sector vis-a vis MDI (2010 to 2015)



Source: Annual Survey of Industries (2011 -2016)

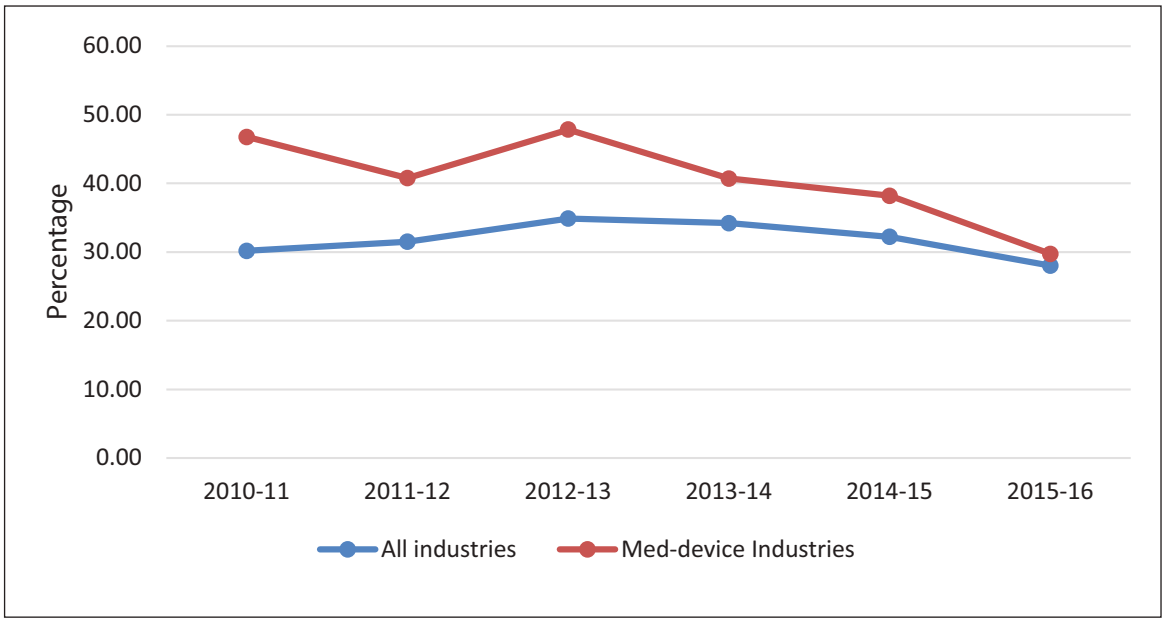
syringes and bone instruments make up nearly 60 per cent of goods that are produced during the study period. Graph 4 represents share of medical device by category produced from 2010-11 to 2015-16. It has been seen that the share of implant manufacture has grown consistently after 2011-12 from 10.42 per cent to 39.60 per cent over the study period. Demand side pressures for more affordable devices coupled with increasing demand could be a major reason for this.

Graph 5 shows the growth of output of MDI during the period of study compared to the overall manufacturing sector. There has been a spike in the growth during years 2011-2012, with incremental growth in the following two years. The year 2014-15 saw negative growth in MDI. The compound annual growth rate (CAGR) for study period for MDI was 4.93. Production in consumables and diagnostic devices grew during the study period.

3.4 Trade in Medical Devices

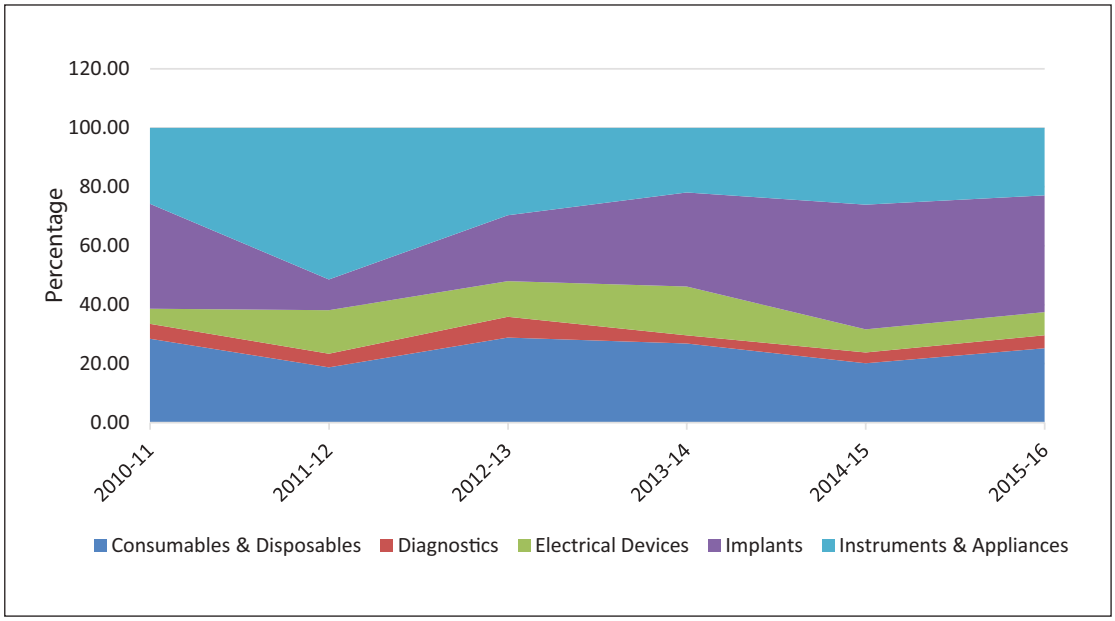
In 2015-16, India's total trade value amounted to approximately INR42, 06,689.94 crore. Of these, medical devices stood at around INR 37,117.958 crore. The share of medical devices in the overall trade value has increased from 0.62 per cent in 2010-11 to 0.88 in 2015-16. While there has been growth of both export and import of medical devices, the pace of import of medical devices has also been substantial. In 2015-16, medical devices export and imports were valued at INR 9096.8 crore and INR 28,021.15 crore, respectively. Further, the trade deficit has increased nearly 117 per cent for the period of study (INR 8740.171 to INR 18,924.342 crore).

Graph 3: Represents the Share of Imported Inputs (2010-11-2015-16)



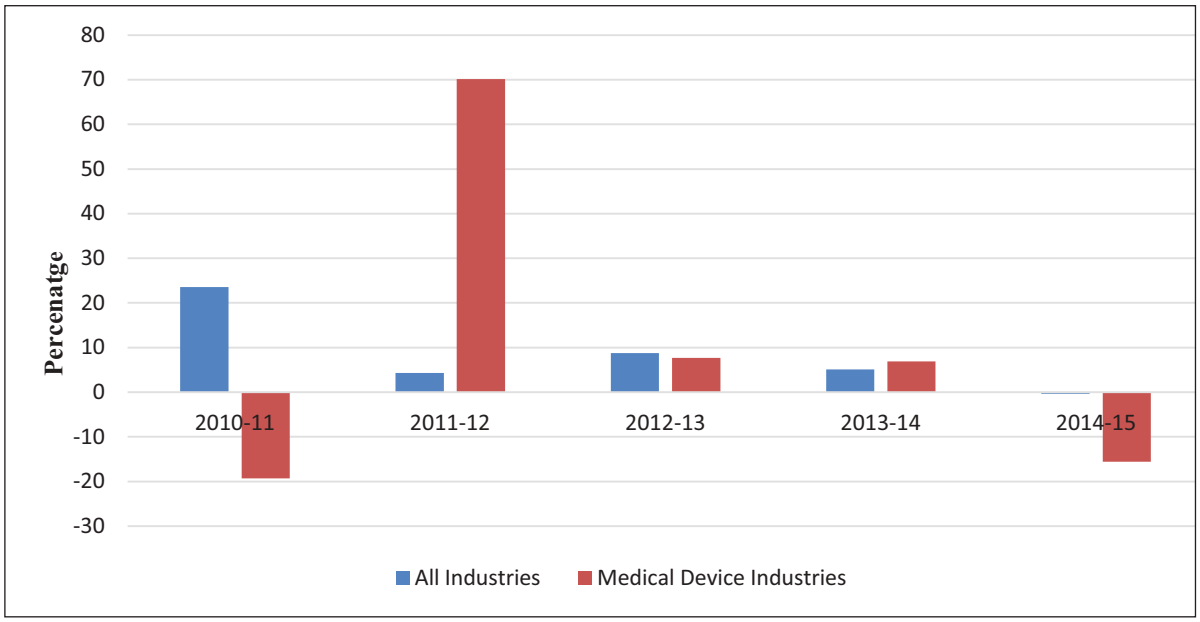
Source: Annual Survey of Industries (2011 -2016)

Graph 4: Percentage Share of Medical Device Production by Category (2010-11 to 2015-16)



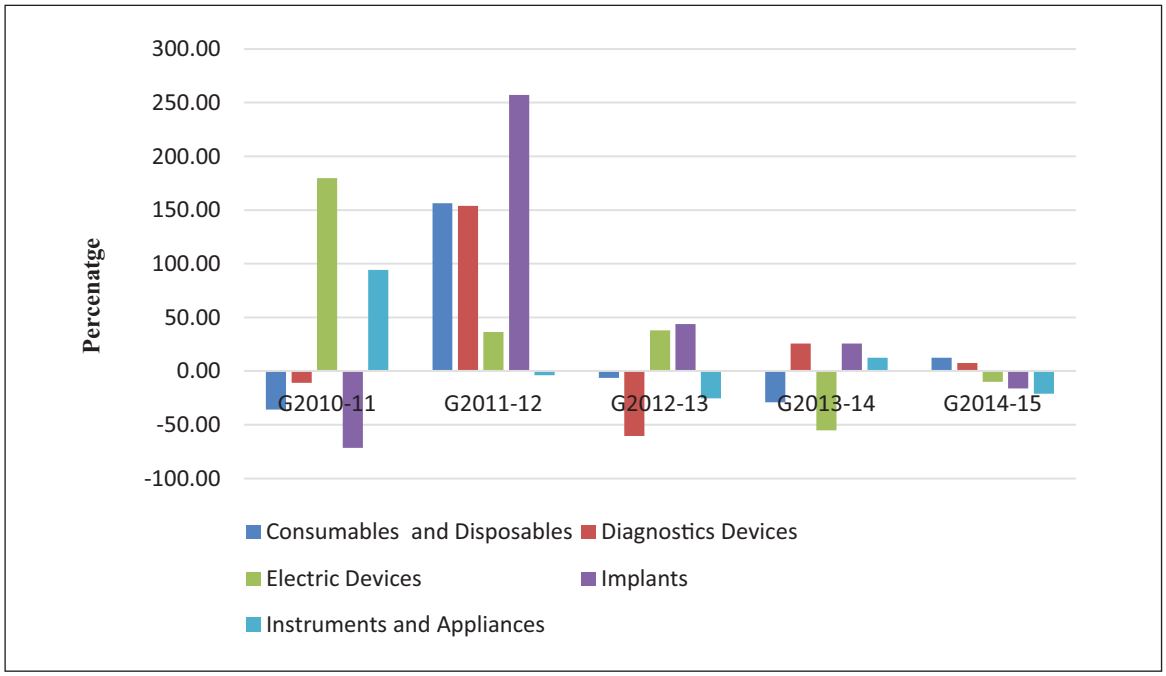
Source: Annual Survey of Industries (2011 -2016)

Graph 5: Growth of Output (2010-11 -- 2014-15)



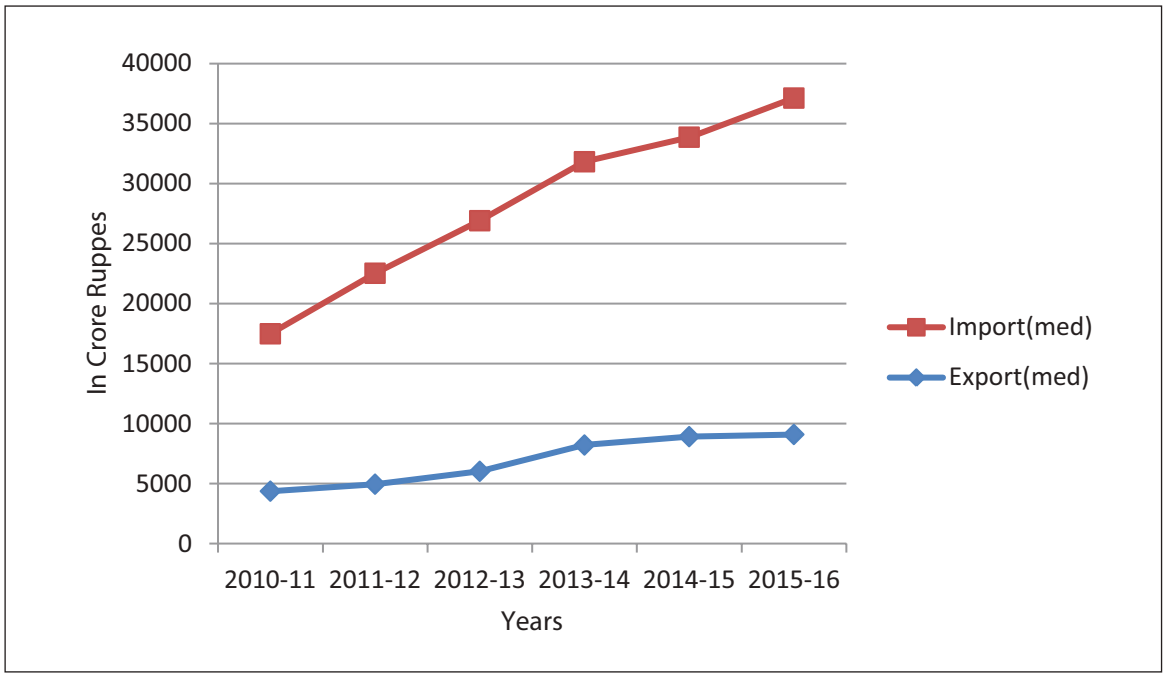
Source: Annual Survey of Industries (2011 -2016)

Graph 6: Growth of Output by Different Categories of Medical Devices (2010-11 -- 2014-15)



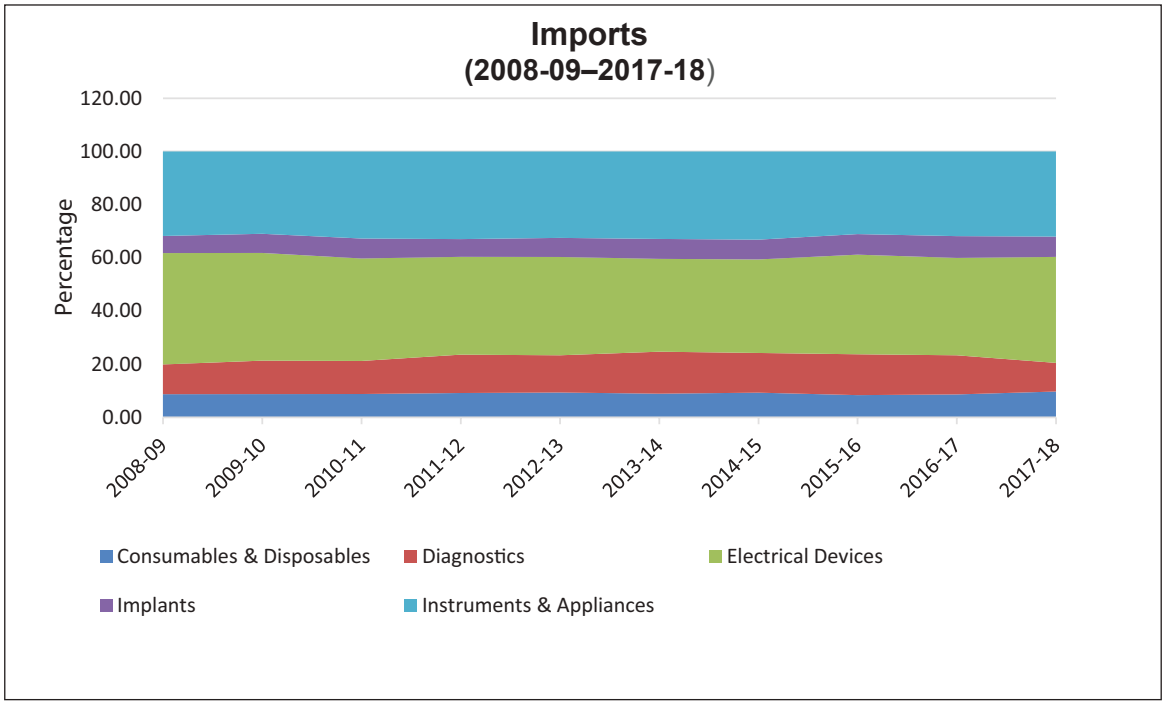
Source: Annual Survey of Industries (2011 -2016)

Graph 7:Trade in Medical Devices from 2010-11 to 2015-16

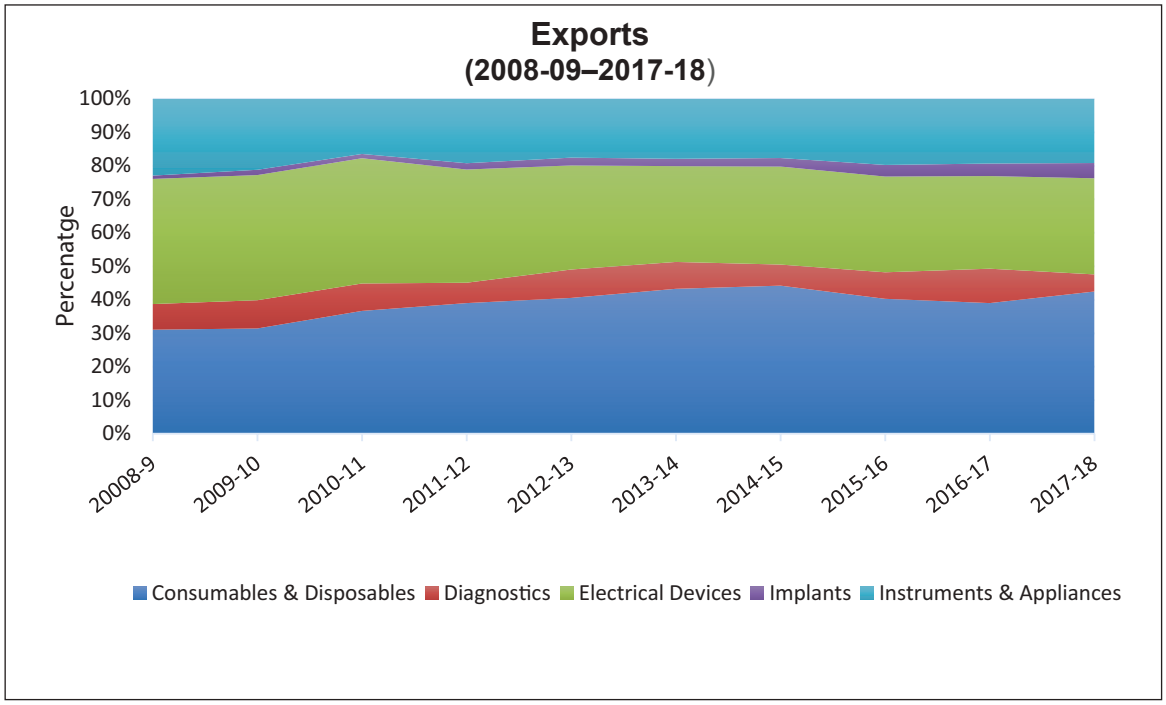


Data Source: Comtrade

Graph 8: Imports Export of different categories of medical devices from 2008-09 to 2017-18



Data Source: Comtrade



Data Source: Comtrade

The above two graphs demonstrate that higher technology products such as electronic and electric devices form the major share of import into the country, while low technology and low value consumable and disposables constitute major exports from India. These findings are consistent with the literature on trade of medical devices. This leads to the conclusion that policies will have to focus more on infusing high technology products into the sector through innovations and inter-sectoral linkages.

The top five sources for import of medical devices in 2018 are USA, China, Germany, Japan, and Singapore. Nearly 80 per cent of the total requirements are imported. The dependency is near total in areas of cancer diagnostics, medical imaging, ultrasonic scans, and PCR technologies. The country needs to pay more attention to innovation and entrepreneurship in the area of medical devices to bring down its dependency at least in areas of life saving devices like ventilators.

3.5 Innovation in Medical Devices

Similar to pharmaceuticals, the medical devices industry is also supply driven and technology intensive. Technology is a key driver and determines competitiveness in the sector. It, therefore, influences local manufacturing and access. A guide to the state of innovation is the number of patent applications. Under the International Patent Classification (IPC) medical devices fall under A 61. A study into the applications received in the Indian Patent Office during the last 5 years under this class except for the subclasses of A61D regarding veterinary instruments, tools or methods and A61Q about specific use of cosmetics or similar toilet preparations, show that the number of applications that were published annually declined for medical devices - from 245 in 2015 to 99 in 2016, to 30 in 2017, to 15 in 2018 and 10 in 2019.In the matter of granted patents, the status is better, the numbers have been steadily rising from 16 in 2015 to 34 in 2016 to 62 in 2017 to 61 in 2018 and to 132 in 2019. This is the overall picture including foreign applicants[1]. This pattern is in sharp contrast to earlier period from 2005 to 2015 when the number of published applications was generally steadily growing. Without a detailed examination it is difficult to access the reasons for such decline. However, there are anecdotal cases of indigenous innovations in medical devices that appear periodically in the media.

IV

Challenges and Way Forward

4.1. Challenges and Way Forward

A survey was conducted to elicit the views of key stakeholders which included mostly industry. As per the survey, about 95per cent of the firms had a turnover of less than INR100 crore and were registered as MSMEs. All firms were ISO 13485 certificated and had import export codes. The spending on R&D activities ranged between 1-6 per cent. The products produced are diverse and range from simple bandages to stents.

The survey and interaction with the industry highlighted a number of factors that need to be addressed to build and boost local manufacturing of medical devices. They include non-availability of low cost financing, inadequate domestic demands, lack of national quality certification, unfavourable duty structure, and so on. There are also concerns about macro-economic issues of overall business environment and tax enforcement mechanisms. As could be seen from the previous sections, a number of measures had been taken in the past to redress many of these grievances, and a great impetus provided by the Make in India, which the industry acknowledges, but it does feel more can be done to support the industry. The key issues and action areas highlighted by the industry fall under the following themes:

- Domestic manufacturing
- Human Resources
- Public Procurement
- Regulations and regulatory bodies
- R&D and Innovation
- Trade.

A. Domestic Manufacturing

Since products currently manufactured are mostly low technology goods, medical technology (Medtech) parks should focus on high end and innovative devices through access incentives, reduced tax rates and linkages with medical and engineering colleges. In accordance with WHO recommendations, a list of National List of Essential Medical Devices should be identified similar to the National List of Essential Medicines. Measures should be taken to ensure that domestic capacity and capability is present in the manufacture of these products. Moreover, priority setting to build indigenous should be based on burden of disease for mortality and morbidity. Every year a list of twenty disease conditions would be identified. Against these conditions 100 therapies are selected. These therapies are further matched with key devices that are needed. This eventually leads to a list of about 500 devices. This exercise is followed by an

analysis of trade data. Products with HS codes that are only imported into the country are selected. This list is juxtaposed with the earlier list that includes the devices selected on the basis of burden of disease to form the list for priority medical devices for R&D. Further, critical components are identified to outline priorities for innovative technologies and fund R&D for unmet needs.

Measures should also be taken to develop internationally accredited and recognized laboratories for device testing to prevent duplicity of testing and reduce overall local product development costs. These should include pre-clinical, *in-vitro* and *in vivo* testing of medical devices during device development phase. Further, Capex subsidy on new investment of 15 to 25 per cent would incentivise local manufacturing. These measures have been taken in China and Ireland to promote local manufacturing of medical device sector in the respective countries (Sehgal & Bose, 2016). Exemption of medical equipment associated accessories and spare parts like monitors from Compulsory Registration Scheme maybe considered. Moreover, the formulation of guidelines for mergers and acquisition, through provisions under Section 3(5) of Competition Act, 2002 in the sector would be useful to ensure adequate and timely supply of medical devices as well as to protect the interest of local industry.

The National Pharmaceutical Pricing Authority (NPPA) of Department of Pharmaceuticals applies formulae under the Drug Price Control Order (DPCO), 2013 for controlling price of certain notified medical devices. The formula has been developed keeping in mind the pharmaceutical market. It calculates the cost price by averaging the price at which the devices are sold to the retailer by different manufacturers. However, medical devices are never sold to the retailer but directly to a distributor who sells them to a hospital or doctor. Moreover, the manufacturer has to incur additional cost in skill development and training so that the device is used correctly. There is a need to revise the pricing regime and develop specific regulations for price fixation for medical devices that are different from those for pharmaceuticals.

In the context of duty structure, measures to correct inverted duty for medical devices such as dialyzers which have not been considered earlier would be beneficial to boost local manufacture. In addition, policies to increase tax and regulatory barriers on import of pre-owned medical devices, where applicable, maybe considered.

Enhancing availability of capital by allowing CSR and philanthropic institutions to fund investments in social business is likely to encourage domestic manufacturing and enhance access to affordable medical devices.

Since India is a large potential market, measures to encourage collaboration of academic and research institutions with medical device industry be set in motion. They may include fast lanes for finances and regulatory approvals as well as tax rebates.

B. Human Resources

There is a critical need for human resource development to build skill and capacity in biomedical engineering. With less than 20 courses related to biotechnological engineering currently available, the country needs to offer more courses to increase the number of graduates in this field. The inclusion of life science as a mandatory subject for bachelors' programme at all IITs, Indian premier engineering colleges, is a welcome step in this direction (Editorial, 2018). Diaspora outreach and engagement could also be another strategy to address the dearth of human resources. The "Thousand Talent Program" of the Chinese Academy of Science launched in 2008 is a major programme in recruiting outstanding talents from overseas (Chinese Academy of Sciences, 2019). In 2017, a similar programme called VAJRA (Visiting Advanced Joint

Research) Faculty Scheme was launched under Department of Science and Technology for overseas scientists and academicians to work as adjunct / visiting faculty for a specific period of time in Indian Public funded academic and research institutions (Department of Science & Technology, 2017).

C. Public Procurement

To support import substitution, the Public Procurement Order, 2017 has made provision to give preference for domestically produced medical devices. However, as health is a state subject, public procurement agencies at the state level still lack clarity on the implementation of this order. Building awareness among state level procurement agencies is imperative.

The current system of public procurement based on the lowest price quoted in the tender does not favour Indian companies since they find it difficult to compete with low prices offered by Chinese companies. Measures should be devised to base the selection from the tenders based on quality. For this to happen, a robust health technology assessment system should be put in place to make public procurement decisions.

The delayed payments from government are a substantial burden for Indian manufacturers as they are mainly MSMEs. Effort should be made to ensure a faster timeline for payments.

An innovative method to procure Medtech devices which have high recurring costs on maintenance and operation would be to procure equipment with a clause that would include maintenance costs over the life cycle of the device. It should also ensure that a person from the community is trained to maintain the equipment by skills imparted by the Medtech firm.

D. Regulations and Regulatory Bodies

A general perception is that the Medical Devices Rules, 2017 are inadequate (Nishit Desai Associates, 2018). These Rules come under the Drugs & Cosmetics Act, 1940. As such, they are regulated as drugs. Nowhere in the world are medical devices regulated as drugs. It is detrimental to overall growth of sector to regulate hypodermic needles, catheters, etc. as drugs. These regulations must be drafted to specifically address the nuances of MDI. It would be a good idea to incorporate the American Society for Testing and Materials (ASTM) standards in the Rules in view of the global acceptance of the same, as this is vital component of any medical devices especially implantable devices such as stents.

The Rules have made provision for third party Notified Bodies (NB) to oversee Class A and Class B medical devices. These NBs have to be accredited by the National Accreditation Board for Certified Bodies (NABCB) or an International Accreditation Forum ensures quality. The NBs accredited by NABCB are registered with the CDSCO and the list is available on the CDSCO website. However, list of NBs that have international accreditation are not available. This has led to instances of fraud by unauthorised NBs that claim to have an international accreditation. It is recommended that a list of all NBs be made available to check the credibility of the NBs.

There have been concerns about the regulatory capacity of the CDSCO and State Regulatory Authority (SRA) in the regulation of medical devices as these organisations have been mostly regulating drugs. Regulators for drugs possess expertise related to field of chemistry. Medical devices on the contrary require biomedical engineers. A robust team of biomedical engineers with close coordination between the CDSCO and SRA is required to support adequate implementation of the Rules.

E. R&D and Innovation

To support R&D activities many platforms have been created to allow collaboration between various government institutions such as DRDO and MEITY. However, there are avenues to

further these partnerships through additional grants and human resource development such as dual MD and PhD programmes that combine medical and engineering sciences.

Under the tax liberalisation measures available the current weighted tax reduction on approved expenditure on R&D is 150 per cent. It is recommended to increase this to 200per cent as was suggested in the budget keeping in mind the high gestation period of medical devices (Moorthy, 2016). Extension of R&D tax benefit should also include Limited Liability Partnerships.

There is a provision under Para 32 of DPCO 2013 to exempt those medical devices from price control for five years which are developed through indigenous research and patented under the Indian Patents Act, 1970 (Department of Pharmaceuticals, 2013). The Department of Pharmaceuticals is considering a proposal to ensure this. If this should happen, it will provide added incentive for R&D and innovation in the country. So far, Merril Lifesciences has been provided waiver for the stents.

Funding support for R&D has to be on a different footing than normal grants. R&D will involve both fundamental research and product innovation. There is always uncertainty about the outcome and also about the time period. Funds are needed for both pilot projects and later scaling up. This has to be done in a sustained way and should not be stopped midway.

Clinical validation is an aspect that can be boosted by identifying and incentivising institutions for the same. The regulatory certification process may also be expedited so that validated products can enter the market at the earliest.

F.Trade

HS Codes: The current Harmonisation System (HS) to monitor the import of medical devices is inadequate. More than 50per cent of the goods are imported under the 'others' category. Therefore, initiatives to address inverted duty structures through tariffs are insufficient as goods are imported under the 'others' category. It is therefore essential to expand HS codes to include a wider range of products to help monitor the import of products into India to allow for evidence based policy making. However, the industry should not be penalized for using the 'others' category until an appropriate HS system is implemented.

Export Certification: The key issue with export of medical devices is the 'Free Sales Certificate (FSC)'. Medical device manufacturers are required to register with the foreign country and seek approval from their regulatory authorities for permitting import of medical devices into that country. The Regulatory Authority requires a FSC from the 'Country of Origin (COI)' – with the understanding that if a product is freely sold within the COI it is safe for use and therefore of acceptable quality to be imported. As a routine, Medical Device Regulatory Authorities desire this FSC to be issued by Ministry of Health or the Regulatory Authority of the exporting country. Currently, the Ministry of Health and Family Welfare provide FSC for only 23 notified medical devices. FSC for all the other medical devices is issued by Director General of Foreign Trade (DGFT) considering them as consumer goods and engineering items. Many countries including China and those in South and Central America do not recognize the Certificate issued by DGFT and insist on Certificate by MoH for a medical device. This creates a barrier for registration to allow Indian manufacturers to access markets abroad. It is, therefore, imperative to devise a mechanism by which FSC certificates be issued either by DGFT under the authorisation of MoHFW for medical devices not notified as drugs, or CDSCO issues these certificates which have IS/ICMED/ISO 13485 QA Certification.

Currently, there are different ministries involved in the regulation, labelling and

packaging, pricing and obtaining marketing approvals for medical devices, making it difficult for the business community in India. The Medical Devices Promotional Council under the DoP could be designated as the coordination agency to address the various issues faced by the medical device industry.

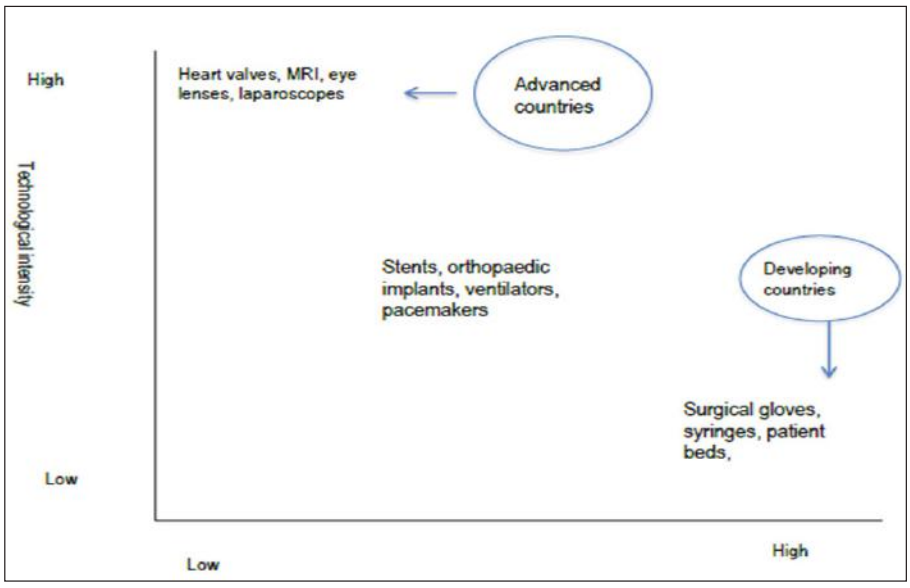
4.2. Conclusion

In the recent past a number of policy measures have been undertaken to ensure the sustainable and substantial growth of the industry. However, growing public healthcare requirements demand faster growth of the sector than in the past. It is also imperative to make parallel investments in the healthcare system since the two sectors are complementary. India's public health spending is abysmally low at 1.15 per cent of GDP (National Health Policy, 2017). This should be increased to at least 2.5 to 3per cent of GDP. Moreover, branding and marketing have a key role in promoting local manufacturing and export of medical devices produced in India. It is critical to raise awareness about the high-quality medical devices that are produced in the country. The overall aim should be to assure providers and patients that domestically produced medical devices which are available at a fraction of a cost are equally safe and effective as those that are imported. It is ultimately, the demand that will drive supply and support locally produced goods in an ever-evolving medical device market.

Endnote

1. The above data accessed from ipindiaservices.gov.in/public search.

Figure 1: Mapping Medical device capability



Source: Social Innovation paper by Kale Dinar, 2017

List 1: Notified Medical Devices

LIST OF NOTIFIED MEDICAL DEVICES

The Ministry of Health and Family Welfare, Govt. of India under following Gazette notifications has notified the following devices to be considered as drugs under Section 3, Clause (b) , Sub clause (iv) of the Drugs and Cosmetics Act: -

S.No	Name of the device	Notification Number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopaedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005

Note: Further, the following products are regulated as 'Drugs' under Drugs & Cosmetics Act & Rules there under: -

1. Blood Grouping Sera
2. Ligatures, Sutures and Staplers
3. Intra Uterine Devices (Cu-T)
4. Condoms
5. Tubal Rings
6. Surgical Dressings
7. Umbilical Tapes
8. Blood/Blood Component Bags

Source: (Drugs Controller General, 2017).

Table 1 NIC selected for Study

	NIC 2008 5 digit	Description
1	21006	Manufacture of medical impregnated wadding, gauze, bandages, dressings, surgical gut string etc
2	26600	Manufacture of irradiation, electro medical and electrotherapeutic equipment. It includes manufacture of MRI scanner, CT scanner, medical ultrasound equipment, pacemakers, hearing aid, electrocardiographs and irradiation apparatus. Irradiation apparatus contain beta-rays, gamma-rays, X-rays, or other ionizing radiation
3	23104	Manufacture of laboratory or pharmaceutical glassware
4	30922	Manufacture of invalid carriages with or without motor
5	32501	Manufacture of dental fillings and cements (except denture adhesive or cement), dental wax and other dental plaster preparations; manufacture of dental laboratory furnaces, dental instruments, artificial teeth, bridges, etc., made in dental labs
6	32502	Manufacture of laboratory apparatus (laboratory ultrasonic cleaning machinery, laboratory sterilizers, laboratory type distilling apparatus, laboratory centrifuges etc.)
7	32503	Manufacture of medical, surgical, dental or veterinary furniture such as operating tables, examination tables, dentists' chairs etc.
8	32504	Manufacture of measuring instruments such as thermometers etc.
9	32505	Manufacture of bone plates and screws, syringes, needles, catheters, cannula, etc
10	32506	Manufacture of orthopaedic and prosthetic devices
11	32509	Manufacture of other medical and dental instruments n.e.c

Source: National Industrial Classification (NIC 2008), Ministry of Statistics and Program Implementation (MOSPI)

Table 2 Concordances Mapping of Medical Devices Manufactured and Traded by NPCMS and HS Codes

NPCMS	COMTRADE HS
Implants	
3529004,3529013,3544003,4815099,3544004,4831102,4831103,3529032,4961099	90183920,90189094,90189091,90213900,90212900,90212100,90213100,90215000
Electronic devices	
3529018,4834103,4812100,4815015,3529048,4811000,4721500,3529006,4714010,4832200,4423201,4731401,4831406,4721400,4695099,4714099,4715099	90181990,90181290,90189019,90181300,90181100,90181400,90181910,90181920,90223000,90221490,90229090,90221410,90229040,90221200,90221900,90221300,90222900,90221420,90229010,90278090,90272000,90273090,90275090,90273010,90273020,90278020,90278040
Diagnostics	
3529003,4825300,3711205,3719999,4826102,3719599,4824306,3711105,4812204,3529014,4826199,4828400,3529033,4815002,3711204,4828200,3719505,4815006,4826101,4815003,4332009,3719399,4696000	30062000,38220090,38220019,38220011,38220012,30029020,30029030,30029090,30021011,30021012,30021013,30021014,30021019,30021020,30021091,30021099

Instruments and Appliances	
4817100,4611202,4392203,4992199,4813000,4481899,3529007,4481801,4831501,4731499,4693999,4816000,3529030,4721103,4814000,3870210,4815014,4812299,4992203,4421105,4818000,3529099,3526086,4323005,3529017,4812202,4992201,4323099,4694005,4462200,4812203,4993099,4342002,4722300,4911901,4912999,4812201,4128501,4292124,4992204,4421102,4731500,4992202,4824400,4291303,3729100,3811101,2669008,4832400,4342099,2669013,2669020,4825100,4482400,3899399,4831599,3529037,4824999,4653199,4291299, 4325101,4824303,4824901,4824305,4993003,4141303,4481608,4352005	90189099,90189022,90189029,90185090,90189031,90189044,90184900,90189023,90182000,90189092,90181210,90189041,90185010,90189093,90189011,90189021,90189042,90189098,90184100,90185030,90189024,90189012,90189097,90189025,90189096,90189095,90185020,90189033,90192090,90191090,90192010,90191010,90211000,90219090,90214090,90214010,90222100,90229020,90229030,90279090,90271000,90279010,90279020,90278010,90275020,90278030,90275010,90275030,94029090,94029010,94021010,90251110,90251910,84239010
Consumables and Disposables	
3529001,3529005,4291301,3529008,4621500,3529011,3529012,3544099,3694011,3529026,3529028,3527099,3529035,3719503,3694036,4815007,4815008,3711206,3525098,3633008,2825099,2686000,3527057,3529041,4324009,3417001,3423114,3544001,3626031,3527041,3529031,3529042,3421012,3424053,3526072,4291399,3529043,3533299,3527027,3529016,3532321,3541010,2824303,3415003,4151603,3526099,3626027,4826699,3424025,3627008,1520001,1520009,3549099,3626028,4299708,4299707,3633017,3527017,3527036,3529027, 3527016,4291302,4826999,3870203,3219399,3213199,2713099,3812107,4823300,3416039,3214902,2616000,3270099,3641099,2952000,3641005,3649001,2826903,325004,4781400,4461201,3417015,4299705,3641008,2715001,3416033,2799207,4834299,3626022,3529020,2951000,2933099,3626029,2823802,2792299,3892299,3511075,3511077,4291401,3692002,2719099	90183990,90183930,90189032,90183100,90183910,90183210,90183290,90183220,90183230,90189043,90200000,90219010,30066010,30066020,30069100,30061010,30063000,30064000,30067000,30065000,30061020,30066030,48189000,48185000,40141010,40141020,40149010,40149020,30051010,30051020,30051090,30059010,30059020,30059030,30059040,30059050,30059060,30059070,30059090

Source: Annual Survey of Industries and Center for Monitoring Indian Economy Data

Table 3: Basic Features of Medical Device Industry

Year		2011	2012	2013	2014	2015	2016
No of Units	All Industries	211660.00	217554.00	222120.00	224576.00	241030.20	247906.70
	Medical device industries	619.99	616.22	685.19	774.56	742.62	759.90
	per cent Medical Device	0.29	0.28	0.31	0.34	0.31	0.31
No of Workers	All Industries	9905059.81	10441586.61	10052354.00	10444404.43	10760276.77	11136790.47
	Medical device industries	34590.69	29028.46	36893.11	45961.64	44767.18	43836.04
	per cent Medical Device	0.35	0.28	0.37	0.44	0.42	0.39
Average Wage	All Industries	86491.71	95662.29	110324.70	121114.10	130637.50	140083.60
	Medical device industries	105173.30	109217.30	133243.00	205247.60	130684.50	128424.90
	per centwage differential	21.60	14.17	20.77	69.47	0.04	-8.32
Total Inputs	All Industries	385500000.00	480396832.00	502977088.00	550073984.00	573928448.00	560531456.00
	Medical device industries	725736.88	579641.13	1008012.75	1113803.38	1191816.75	944096.38
	per cent Medical Device	0.19	0.12	0.20	0.20	0.21	0.17
Total Outputs	All Industries	467831808.00	577845120.00	602652160.00	655480768.00	688962816.00	686419968.00
	Medical device industries	1021396.94	823875.06	1401875.63	1509961.00	1614286.75	1363366.25
	per cent Medical Device	0.22	0.14	0.23	0.23	0.23	0.20
Exports	All Industries	21732.21	30900548.04	53086943.24	39716835.45	40452726.92	61230480.67
	Medical device industries	0.00	77621.45	73466.27	57729.51	145123.48	139292.81
	per cent Medical Device	0.00	0.25	0.14	0.15	0.36	0.23
Goods Sold in Same condition as purchased	All Industries	39923640.32	52262932.23	50612914.00	59606606.53	59041410.26	57290028.39
	Medical device industries	99055.51	76329.57	217268.95	261869.75	347614.56	261870.14
	per cent Medical Device	0.25	0.15	0.43	0.44	0.59	0.46

Source: Annual Survey of Industries (2011 -2016)

Table 4 Profile of Medical device Manufacturing Sector (2015-16)

Output (INR Crore)	No. of units	Per cent
<2	79.00	12.74
2-10	180.90	29.16
10-20	131.09	21.13
20-100	180.23	29.05
>100	49.10	7.92
Total	620.33	100.00

Source: Annual Survey of Industries (2015 -2016)

Table 5: Percentage of Medical and Non-Medical products

Industry Code NIC	Description	Medical	Medical	Non-medical	Non-medical	Others	Others	Total Output
30922	Manufacture of invalid carriages with or without motor	1145.43	100.00	0.00	0.00	0.00	0.00	1145.43
26600	Manufacture of irradiation, electro medical and electrotherapeutic equipment	157427.20	99.31	723.16	0.46	371.39	0.23	158521.70
32504	Manufacture of bone plates and screws, syringes, needles, catheters, cannula	157086.20	98.68	1571.27	0.99	530.59	0.33	159188.00
23104	Manufacture of laboratory or pharmaceutical glassware	70655.24	98.38	1146.25	1.60	17.79	0.02	71819.28
32502	Manufacture of laboratory apparatus	97755.35	97.15	1666.23	1.66	1203.28	1.20	100624.90
32503	Manufacture of medical, surgical, dental or veterinary furniture	57333.75	97.03	1624.42	2.75	128.63	0.22	59086.79
32501	Manufacture of dental fillings and cements	18700.96	92.05	1615.66	7.95	0.00	0.00	20316.62

21006	Manufacture of medical impregnated wadding, gauze, bandages, dressings, surgical gut string e	201520.70	89.17	23791.63	10.53	684.62	0.30	225996.90
32506	Manufacture of orthopedic and prosthetic devices	24084.58	87.70	3337.27	12.15	40.61	0.15	27462.46
32509	Manufacture of other medical and dental instruments n.e.c.	95102.10	87.32	13606.78	12.49	209.14	0.19	108918.00
32505	Manufacture of measuring instruments such as thermometers	4516.67	65.03	2338.10	33.66	90.89	1.31	6945.66
Total		885328.18	94.18	51420.77	5.47	3276.95	0.35	940025.73

Source: Annual Survey of Industries (2011 -2016)

Table 6 Percentages of Assembled and Marketed goods(AMG) in 2015-16

Industry Code (NIC)	Description	Total Output	AMG	per cent Share
32505	Manufacture of measuring instruments such as thermometers	20742.88	13520.38	65.18
26600	Manufacture of irradiation, electromedical and electrotherapeutic equipment	482703.40	187818.60	38.91
32509	Manufacture of other medical and dental instrumentsn.e.c.	132199.50	17778.15	13.45
32501	Manufacture of dental fillings and cements	23369.25	2753.75	11.78
32503	Manufacture of medical, surgical, dental or veterinary furniture	68099.02	7120.28	10.46
23104	Manufacture of laboratory or pharmaceutical glassware	82839.37	7930.22	9.57
32502	Manufacture of laboratory apparatus	114420.60	9306.83	8.13
30922	Manufacture of invalid carriages with or without motor	1231.39	72.08	5.85
32504	Manufacture of bone plates and screws, syringes, needles, catheters, cannula,	174414.70	9997.10	5.73
32506	Manufacture of orthopaedic and prosthetic devices	30126.58	1007.69	3.34
21006	Manufacture of medical impregnated wadding, gauze, bandages, dressings, surgical gut string e	233219.50	4565.03	1.96
Total		1363366.19	261870.09	19.21

Source: Annual Survey of Industries (2011 -2016)

Table 7:Indigenous& imported inputs (2015-16)

Industry Code	Description	Indigenous Inputs used	% indigenous Input	Imported Inputs used	% imported Inputs	Total
30922	Manufacture of invalid carriages with or without motor	279.08	36.91	477.03	63.09	756.10
32503	Manufacture of medical, surgical, dental or veterinary furniture	14065.36	54.50	11743.52	45.50	25808.88
32501	Manufacture of dental fillings and cements	3354.54	56.11	2624.29	43.89	5978.83
32509	Manufacture of other medical and dental instruments n.e.c.	27193.26	57.03	20491.40	42.97	47684.66
23104	Manufacture of laboratory or pharmaceutical glassware	14604.17	58.07	10546.92	41.93	25151.09
32504	Manufacture of bone plates and screws, syringes, needles, catheters, cannula	38009.25	65.58	19953.15	34.42	57962.40
21006	Manufacture of medical impregnated wadding, gauze, bandages, dressings, surgical gut string e	72087.15	69.72	31309.09	30.28	103396.20
32505	Manufacture of measuring instruments such as thermometers	2278.58	75.47	740.80	24.53	3019.37
26600	Manufacture of irradiation, electro medical and electrotherapeutic equipment	72278.21	82.03	15831.05	17.97	88109.26
32502	Manufacture of laboratory apparatus	30444.09	84.24	5697.03	15.76	36141.12
32506	Manufacture of orthopedic and prosthetic devices	9573.84	91.09	936.62	8.91	10510.45
Total		284167.52	70.25	120350.89	29.75	404518.37

Source: Annual Survey of Industries (2011 -2016)

Table 8 Top Twenty Products Manufactured in India by share in 2015-16

NPCMS	Category	Description	Output	%total
4815099	Implants	Retainers	331443.80	37.44
4814000	Instruments & Appliances	Sterilizers	77749.65	8.78
3694011	Consumables & Disposables	Disposable syringe, plastic	62082.10	7.01
4817100	Instruments & Appliances	Bone instruments	45811.21	5.17
3711206	Consumables & Disposables	Vials/ampoules, glass	31810.22	3.59
3529099	Instruments & Appliances	Other articles for medical or surgical purposes n.e.c	29754.08	3.36
3529012	Consumables & Disposables	Cotton wool (medicinal)	27935.61	3.16
3529005	Consumables & Disposables	Bandage including adhesive gauze bandage	27561.83	3.11
4815015	Electrical Devices	X ray tube	18771.30	2.12
3529041	Consumables & Disposables	Sterilized cotton buds	18441.23	2.08
4812100	Electrical Devices	Ultra sound scanner	15814.70	1.79
4818000	Instruments & Appliances	Medical, surgical, dental or veterinary furniture; barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements	15660.69	1.77
4811000	Electrical Devices	Apparatus based on the use of x-rays or of alpha, beta or gamma radiations	14709.26	1.66
3529014	Diagnostics	Different reagents and kits used for diagnostic purposes	14080.10	1.59
4481899	Instruments & Appliances	Dentists chairs	9826.43	1.11
2792299	Consumables & Disposables	Others (diaper stock, insulation, etc.); n.e.c	9228.82	1.04
3544003	Implants	Denture, prepared	9202.99	1.04
4299708	Consumables & Disposables	Needle, stainless steel excl. Sewing	8699.91	0.98
3719599	Diagnostics	Molecular sieves	8680.64	0.98
3529048	Electrical Devices	X-ray and rote film dryer	7819.58	0.88
Total			785084.15	88.68

Source: Annual Survey of Industries (2011 -2016)

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