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MEDICAL DEVICES
MANUFACTURING INDUSTRY IN INDIA
Market Structure, Import Intensity
and Regulatory Mechanisms

Pritam Datta
Indranil Mukhopadhyay
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March 2013

02

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Market Structure, Import Intensity and Regulatory Mechanisms

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[Abstract: India is one of the top twenty markets for medical devices in the world. Regulatory structures were virtually absent until some rudimentary control was initiated by Government of India in 2005. Experiences of OECD countries suggest that with increasing dependence on medical technology in health, costs of health care provisioning have gone up significantly. While India is planning to embark upon Universal Health Coverage mechanism regulation of imports, production and use of medical technologies would be one of the most challenging tasks before the government. This paper tries to analyze the supply side of the Indian medical devices industry in this conjuncture. The attempt is to study the trends and patterns of domestic production over the period 2004-05 to 2009-10. Similarly, trends of import and export have been studied for the period 2000-01 to 2011-12. The paper also attempts to review the existing regulatory mechanisms relevant for the medical device industry in India. Domestic production capacity has been analysed using unit records of the Annual Survey of Industry (ASI); while trends in import and export have been studied using India trade data provided by CMIE and Export Import Data by Department of Commerce, Government of India. The findings of the study shows that domestic production of medical devices is diverse in character, producing range of devices starting from the small accessories and disposables like needs and syringes to sophisticated X-Ray equipment. However, there is an overwhelming dominance of medical disposables in product mix, whereas high end equipment are generally imported.]

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Section-I

Introduction

Medical devices industry in India is very tiny by size as compared to registered manufacturing industry, though, India is one of the top twenty markets for medical devices in the world. Market for medical devices was around ₹13,000 crores in 2009-10. Regulatory structures were virtually absent until some rudimentary control was initiated by Government of India in 2005. Experiences of OECD countries suggest that with increasing dependence on medical technology in health, costs of health care provisioning have gone up significantly. Developing countries like India have much to gain from effective use of advanced medical technology but on the other hand inefficient and unregulated use of expensive medical devices may also cause medical expenditure inflation in the country. Effective regulation of medical devices industry is important at a juncture when India is planning to embark upon Universal Health Coverage mechanism regulation of imports, production and use of medical technologies would be one of the most challenging tasks before the government. In the context of India, on one hand with the increase in private providers of health services, use of high tech medical devices increasing; on the other hand most of domestic manufacturers produce at the low tech and disposable and supplies end of the market. Inflation in health expenditure because of over use of import intensive medical devices can act as a major barrier to access to health care in a country like India, where only a fifth of total health expenditure is public funded and more than ninety five per cent of private health expenditure is out of pocket expenditure. Whether diffusion of health technology will help in enhancing access to health care or only add fuel to inflation of medical expenses would critically depend on three basic factors, *viz.* domestic production capacity, market structure of the domestic production, import intensity and government regulation over the industry. There is a dearth of literature on these aspects of medical devices industry in recent years. This paper attempts to bridge this literature gap by analyzing the Indian medical devices manufacturing industry from supply side. Section-II describes the methodological issues, the data sources and variables used in the study. Size and market structure of the domestic manufacturing of medical devices industry in India is explained and analyzed in section-III. Trade intensity of Indian medical devices manufacturing industry is captured in Section-IV. We would like to compare the structure and pattern of domestic production, import and export in Section-V followed by discussion and conclusion in Section-VI.

Section-II

Methodology

Fundamental aim of this research piece is to analyze both domestic production and trade profile of the Indian medical devices industry in detail using unit level disaggregated figures from Annual Survey of Industries (CSO¹) and India Trade data (CMIE²). Using National Industrial Classification (NIC) one can identify the profile of domestic production for any particular industrial activity. For example if you want to know the domestic production profile of manufacture of pharmaceuticals, medicinal chemical and botanical products, we can pull the data for units fall under National Industrial Classification (NIC 2008) 2100 (four digit class). Similarly if we are interested in the study of tobacco industry we can pull data from unit level ASI for those units fall under class 1600 as per four digit NIC 2008 classifications. But manufacturing of medical devices is not clearly flagged in National Industrial Classification System. Even at the five digit level medical devices manufacturing industry is not clearly defined. For example, five digits subclass 26600 represents a set of sophisticated medical devices (e.g. CT scanner, MRI scanner) as well as a group of irradiation apparatus as per NIC 2008. Similarly subclass 32503 represents manufacture of medical, surgical, dental as well as veterinary furniture. This research paper defines manufacturing of medical devices industry as the sum of class 2660 (Manufacture of irradiation, electro medical and electro therapeutic equipment), 3250 (Manufacture of medical and dental instruments and supplies) excluding subclass 32507 (Manufacture of ophthalmic goods, eyeglasses, sunglasses, lenses ground to prescription, contact lenses, safety goggles etc.) and subclass 30922 (i.e. Manufacture of invalid carriages with or without motor). Detail description is given in *Table-1*. NIC 2008 and NIC 2004 systems have been harmonized for medical devices manufacturing sector for time series analysis for the period of 2004-05 to 2009-10. NIC 2004-NIC 2008 harmonization with item wise description is given in *Table-2*.

Indian trade data follow the Indian Trade Classification (Harmonization System) (ITC-HS) system. ITC-HS is a commodity classification system whereas, NIC is an activity classification system. Annual Survey of Industry follows another classification system called Annual Survey of Industry Commodity Classification (ASICC) system to classify commodity produced

¹ Central Statistical Organization.

² Centre for Monitoring Indian Economy.

Table-1
Medical Devices Manufacturing Industry as per NIC (2008) System

<i>NIC 2008 (4 digit)</i>	<i>Description</i>	<i>NIC 2008 (5 Digit)</i>	<i>Description</i>
2660	Manufacture of irradiation, electro-medical and electrotherapeutic equipment	26600	Manufacture of irradiation, electro-medical and electrotherapeutic equipment: -This class includes manufacture of electro-medical and electrotherapeutic apparatus, such as MRI scanner, CT scanner, medical ultrasound equipment, pacemakers, hearing aid, electrocardiographs etc. and irradiation apparatus. Irradiation can take the form of beta-rays, gamma-rays, X-rays, or other ionizing radiation
3092 (Partial)	Manufacture of bicycles and invalid carriages _Only invalid carriages	30922	Manufacture of invalid carriages with or without motor
3250 (excluding 32507)	Manufacture of medical and dental instruments and supplies	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
		32502	Manufacture of laboratory apparatus (laboratory ultrasonic cleaning machinery, laboratory sterilizers, laboratory type distilling apparatus, laboratory centrifuges etc.)
		32503	Manufacture of medical, surgical, dental or veterinary furniture such as operating tables, examination tables, dentists' chairs etc.
		32504	Manufacture of bone plates and screws, syringes, needles, catheters, cannulae, etc.
		32505	Manufacture of measuring instruments such as thermometers etc.
		32506	Manufacture of orthopedic and prosthetic devices
		32509	Manufacture of other medical and dental instruments n.e.c.

Source: National Industrial Classification (NIC2008), Ministry of Statistics and Programme Implementation (MOSPI).

Table-2
NIC 2008-2004 Concordance for Medical Devices Industry

<i>NIC 2008</i>	<i>Description NIC 2008</i>		<i>NIC 2004</i>	<i>Description NIC 2004</i>
2660	Manufacture of irradiation, electro-medical and electrotherapeutic equipment. This class includes manufacture of electro-medical and electrotherapeutic apparatus, such as MRI scanner, CT scanner, medical ultrasound equipment, pacemakers, hearing aid, electrocardiographs etc. and irradiation apparatus. Irradiation can take the form of beta-rays, gamma-rays, X-rays, or other ionizing radiation	<i>Medical Devices Manufacturing Industry</i>	3311	Manufacture of medical and surgical equipment and orthopedic appliances
3250 Excluding 32507	Manufacture of medical and dental instruments and supplies			
30922	Manufacture of invalid carriages with or without motor		35922	Manufacture of invalid carriages with or without motor

32507 includes "Manufacture of ophthalmic goods, eyeglasses, sunglasses, lenses ground to prescription, contact lenses, safety goggles etc."

or used as inputs. In this research paper we have disaggregated the domestic production profile up to ASICC level to get ultimate detailing over domestic production profile of medical devices as well as to compare trade figures comparable with this. On one hand ASICC has been identified against each NIC and on the other hand corresponding ITC(HS) has been identified. Item wise detail list of ASICC and ITC(HS) has been further classified into four major subgroups, *viz.*

- a) Furniture and other instruments (e.g. Dentists Chairs, Hospital Furniture etc.),
- b) Implants (e.g. Artificial Teeth, Artificial Joints etc),
- c) Medical Disposables (e.g. Syringes, Needles X-Ray Film & Plates etc.),
- d) Equipment (X-Ray Equipment, Dental Equipment etc.

Against each category or subgroup, domestic production has been compared with the trade profile. For example, this research piece by its unique method of product level concordance, directly compare how much equipment, implants etc. are produced domestically and in what extent it

has been imported from other countries. A brief concordance is given in Table-3. This paper uses value of ex-factory product instead of widely used

Table-3
ASICC–ITC(HS) Concordance Mapping Medical Devices
Manufacturing Industry

ASICC	ITC(HS)
1. Equipment	
33821,36503,36589,41487,42102,42169,4221 3,63483,71141,71142,71215,71242,71415,71 507,71571,72103,72245,73837,74011,75104, 75247,75254,75334,75338,76217,76317,7671 6,76723,76911,76921,76923,76926,76927,77 101,77102,77126,77187,77194,77205,77214, 77422,77443,77528,77534,77535,77551,7756 9,77732,77834,77936,77961,77969,78216,78 221,78238,78325,78922,78924,79119,79302, 79503,79512,79513,79515,79516,79521,7952 2,79526,79527,79531,79533,79534,79535,79 541,79543,79546,79548,79552,79554,79559, 81159,91114,91119,91135,91332,91344,9135 9,93113	30069100,90181100,90181210,90181290,901 81300,90181400,90181910,90181990,901819 20,90182000,90184100,90184900,90185010, 90185020,90185030,90185090,90189031,901 89032,90189033,90189041,90189042,901890 43,90189044,90189091,90189092,90189093, 90189094,90189095,90189096,90189097,901 89098,90191010,90191020,90191090,901920 10,90192090,90200000,90211000,90221200, 90221300,90221410,90221420,90221490,902 21900,90222100,90222900,90223000,902290 10,90229020,90229030,90251920,90251990, 90258010,90258020,90258030,90258090,902 59000,90261010,90261020,90261090,902620 00,90268010,90268090,90269000,90272000, 90275010,90275020,90275030,90275090,902 78010,90278020,90278030,90278040,902780 90,90279010,90279020,90279090
2. Medical Disposables	
29189,31149,31718,32506,33702,33712,3371 3,33789,33989,35199,38301,38319,41405,41 463,41531,41999,42103,42112,42604,42606, 42644,42649,42719,42905,42941,51243,7113 4,71403,71407,71408,73604,74046,74154,74 177,75311,77964,78328,78411,78939,79523, 79537,79544,79545,82405,82406,91101,9110 3,91104,91105,91108,91112,91117,91159,91 312,91313,91343,94186,94189,99211	30051010,30051020,30051090,30059010,300 59020,30059030,30059040,30059050,300590 60,30059070,30059090,30062000,30063000, 30064000,90183100,90183210,90183220,901 83230,90183290
3. Implants	
33718,36505,36507,71307,79504,79517	90183910,90183920,90183930,90183990,902 12100,90212900,90213100,90213900,902140 10,90214090,90215000,90219010,90219090
4. Minor Instruments, Accessories & Furniture	
41427,41461,42989,71306,71338,71429,7153 1,71533,73228,73231,74042,74095,75325,76 603,76907,77117,77231,77452,77455,77722, 78152,78179,78211,78307,78332,79507,7951 8,79524,79547,82419,91549	94021010,94029010,94029020,94029090,300 65000,90189012,90189019,90189021,901890 22,90189023,90189024,90189025,90189029, 90229040,90229090,90230010,90230090,902 51110,90251910,90189011

gross value added (GVA) to measure value of output at product level (ASICC) for two important reasons, *viz.*

- a) At ASICC level, it is difficult to calculate all components of GVA. ASI unit level data is given as firm as final sampling unit. So at product level calculation other components (e.g. value of input) of GVA can't be calculated for those firms producing multiple products. Given the structure of data it is not possible to identify input used for each product produced by any multiproduct firms. So this study prefers to use value of ex-factory output instead of GVA to analyze domestic production profile of medical devices manufacturing industry in India.
- b) Gross Value Added by any firms includes value of products (and by products) as well as income from services, electricity sold out etc. So GVA can be taken as output at industry level or firm level comparison. But the main aim of this research paper is to know what kind of medical devices are produced domestically in India and what kind of devices India export or import. So for our purpose product level detailing is needed, where ex-factory value is more applicable than GVA.

This paper uses some other variables namely number of factories, gross fixed capital, number of people engaged estimated from Annual Survey of Industries, to depict the basic picture of the medical devices manufacturing industry in India. Trade figures are extracted from CMIE India Trade Database. This paper also explores 'Export-Import Database', Ministry of Commerce, Government of India as the alternative source of trade data.

Section-III

Structure of Indian Medical Devices Manufacturing Industry

Indian medical devices manufacturing industry is a tiny part of total registered manufacturing industry. There were around 356 registered manufacturing units producing medical devices of the value of outputs of ₹312 crores in 2009-10. Among all registered manufacturing factories only 0.19 per cent factories are engaged in production of medical devices. It is clear from *Table-4*, that there are only few units manufacturing medical devices compared to the growing manufacturing sector in India. Value of fixed capital in medical devices as percentage of value of fixed capital of total registered manufacturing is declining over time. Fixed capital in

Table-4
Production of Medical Devices in India: Some Basic Characteristics

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
Number of Factories						
Medical Devices	310	339	326	362	377	301
Total Manufacturing Sector (Reg.)	136353	140160	144710	146385	155321	158877
Medical Devices as Percentage of Total Manufacturing Sector (Reg.)	0.23%	0.24%	0.23%	0.25%	0.24%	0.19%
Number of Workers Employed						
Medical Devices	280910	201245	252000	277000	301000	377770
Total Manufacturing Sector (Registered)	128700000	148800000	183000000	212700000	248600000	273300000
Medical Devices as percentage of Total Manufacturing Sector (Reg.)	0.22%	0.14%	0.14%	0.13%	0.12%	0.14%
Value of Output						
Medical Devices	14987	16909	17608	20842	17914	18975
Total Manufacturing Sector (Reg.)	6600089	7137887	7881577	8200718	8776980	9171050
Medical Devices as Percentage of Total Manufacturing Sector (Reg.)	0.23%	0.24%	0.22%	0.25%	0.20%	0.21%

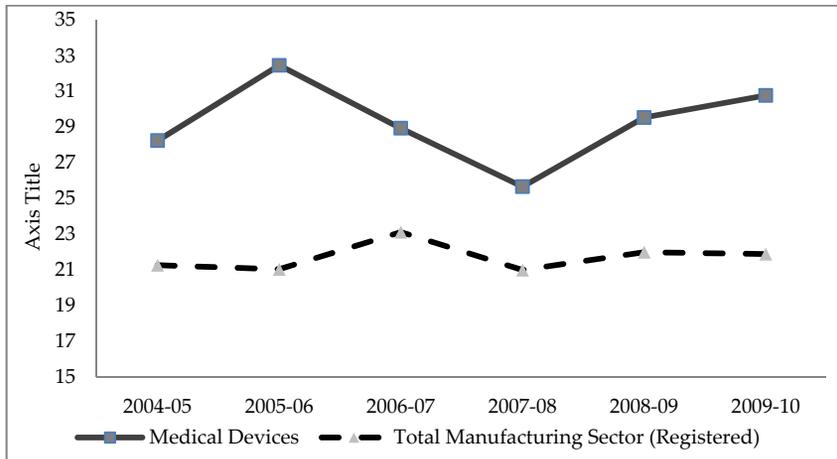
Source: ASI Panel Data, Unit Level.

medical devices as percentage of fixed capital of total registered manufacturing sector went down steadily from 0.23 per cent in 2004-05 to only 0.09 per cent in 2009-10.

Indian medical devices manufacturing industry engages around 0.37 million workers which is around 0.14 per cent of total manufacturing sector workforce. Share of skilled labour in work force is better in Indian medical devices manufacturing industry as compared to the total registered manufacturing sector. In registered manufacturing sector share of skilled

labour in total work force is 21 per cent in 2009-10 whereas in medical devices manufacturing industry it is around 31 per cent. (Figure-1)

Figure-1
Share of Skilled Labour in Work Force

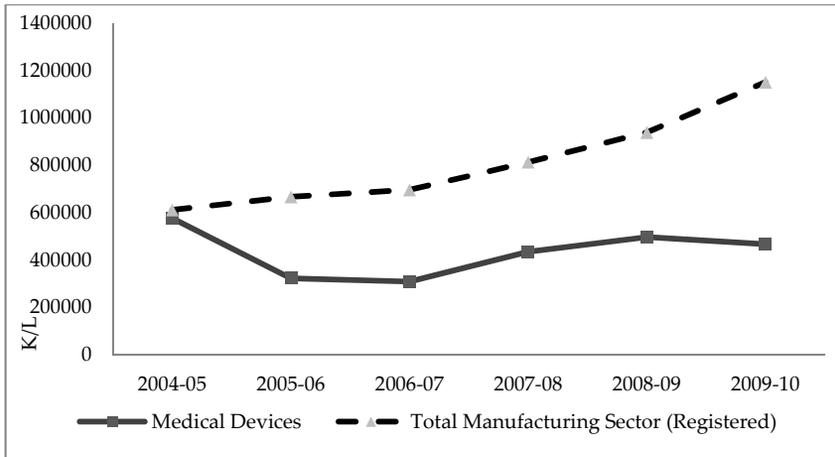


Source: ASI Panel data, various years.

Figure-2 explains the capital intensity of the Indian medical devices industry. Capital intensity in Indian medical devices industry and total registered manufacturing sector were at similar level in 2004-05 but the gap increased over time. While capital intensity of the manufacturing sector is increasing steadily, in case of medical devices industry there was a decline between 2004-05 and 2006-07. Since then there is some increment in capital labour ratio. From our discussion it is not difficult to visualize the macro scenario of medical devices manufacturing industry in India. It is not only small and negligible in size in terms of output and employment contribution but also a pre modern in nature both in terms of, low capital per labour (capital intensity) and high share of less skilled labour in the workforce, though the intensity of skilled workforce is higher in medical devices industry. The picture will become clearer when we analyse the composition of product basket produced in Indian medical devices industry.

Medical device industry is a multi-product industry. The industrial unit which produces some medical devices may also produce products which are not of medical use. Under the same NIC code, for instance 32501, dental instruments, artificial tooth are produced along with acrylic materials which may not be used as medical devices. Overall of the total value of the products covered under the ten NIC industries medical devices is 55 per

Figure-2
Capital Labour Ratio (Capital Intensity) of Medical Devices and
Total Registered Manufacturing Sector



Source: ASI Panel data, various years.

cent (Table-5). NIC 32501, which largely cater to manufacturing of dental filling and instruments have only 27 per cent of total value of product produced which can be categorised as medical devices. NIC 26600 which caters to manufacturing of electro-medical and electro-therapeutic goods produces 65 per cent of products which are of non-medical use. Three NIC industries, namely 32502 (98%), 32503 (97%) and 32504 (89%) produce only medical devices and the remaining are by-products in the form of metal scrap etc.

There can be couple of explanations for the above phenomenon. Many of the products produced in the units engaged in the production of medical devices may be of other use. For instance, furniture produced for medical use, like beds may also be for non-medical uses. The unit that produces syringe for medical use may also produce syringes for veterinary uses. At times, an unit may be mainly producing medical devices but have other by-products which are used otherwise. The other issue is of erroneous classification. The products which are not of medical use, may be clubbed with medical devices, due to unclear definitions. A further breakup of data into exact products would definitely throw more light on the question, but may be safely commented here that while the former depicts the complexity of medical devices industry and hence may be unavoidable, the later should be addressed to get greater clarity on data.

Table-5
Medical and Other Profile of Indian Medical Devices Industry: Year

NIC 2008	Description of Industry	Share in Total Value of Product & By- Products Produced		Total Value of Product and (₹Lakh) by Products produced
		Medical Devices	Other Product	
26600	Manufacture of irradiation, electro-medical and electro-therapeutic equipment	35	65	188240
30922	Manufacture of invalid carriages with or without motor	45	55	8707
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	27	73	17025
32502	Manufacture of laboratory apparatus (laboratory ultrasonic cleaning machinery, laboratory sterilizers, laboratory type distilling apparatus, laboratory centrifuges etc.)	98	2	3770
32503	Manufacture of medical, surgical, dental or veterinary furniture such as operating tables, examination tables, dentists' chairs etc.	97	3	18133
32504	Manufacture of bone plates and screws, syringes, needles, catheters, cannulae, etc.	89	11	69562
32505	Manufacture of measuring instruments such as thermometers etc.	29	71	45770
32506	Manufacture of orthopedic and prosthetic devices	59	41	21718
32509	Manufacture of other medical and dental instruments n.e.c.	73	27	124547
	ALL Medical Devices Manufacturing Industry	55	45	497472

Source: ASI, Panel data, unit records.

Section-IV

International Trade on Medical Devices

Import constitutes a substantial part of the medical device market in India. Market for medical device was around ₹13,000 crores during 2009-10, of which almost seventy per cent is imported. Currently 1.14 per cent of global import of medical devices takes place in India, which in turn constitutes less than 0.6 per cent of total imports of India for the year 2012. Similarly, its export constitutes less than 0.5 per cent of total exports of 2012. In the year 2012, total value of imports of medical devices was ₹13,520 crores and export was ₹6,362 crores and thus the total volume of trade is ₹19,882 crores. There is a steady decline in the share of both imports and exports in total trade. In fact, as percentage of import of manufacturing products, there is a constant decline in share of medical devices. During 2002 this was close to three per cent (2.87%). There was continuous decline in share since then and in 2008 the share reached the nadir of 1.57 per cent, only to recover marginally during the subsequent periods (*Figure-3*).

Figure-3
India's Share in Global Import of Medical Devices: 1995-2011



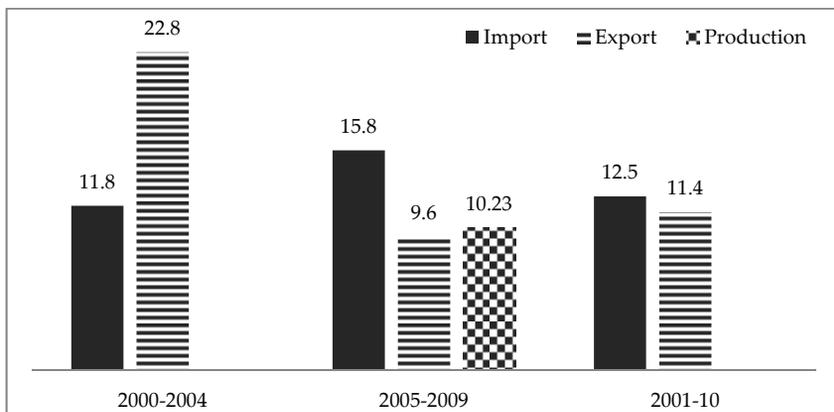
Source: UNCTAD Statistical Dataset, accessed on 10.04.13: http://unctadstat.unctad.org/ReportFolders/reportFolders.aspx?sCS_referer=&sCS_ChosenLang=en

After liberalization of trade during early 1990s, when import tariffs on medical devices were significantly cut, India's share in medical device import grew steadily. During 1980s the prevailing rate of tariff on medical devices were around 40-60 per cent, though the 'life saving' medical devices

were imported duty free (Mahal 2009). During late 1990s tariffs were reduced to 25 per cent and subsequently to 12.5 per cent in 2003-04. Though the initial reduction in import duty provided impetus in increasing share in imports, the 2003-04 reduction has not succeeded in addressing the decline that had started in 2001. The existing custom duty on medical devices is a uniform rate of five per cent with countervailing duty of four per cent and with complete exemption from special additional duty (Union Budget 2010-11). The rapid decline in India's share in developing countries import of medical devices since 2001 can be due to couple of reasons: it may be the case that import in some other developing countries have increased or growth in India's import of medical devices have gone down.

During the period of 2001 to 2010, both import and export of medical devices have grown at more than ten per cent rate, at constant prices. Import has grown at 12.5 per cent rate whereas export has grown at 11.4 during this period. As depicted in *Figure-4*, exports grew at a rate of 22.8 per cent during 2000-2004. However, during 2005-09, export growth slipped to 9.6 per cent. In contrast, import growth rate improved during 2005-09 compared to the previous period. During 2005 to 2009 domestic production has increased at 10.2 per cent per annum at constant prices, a rate comparable to export growth.

Figure-4
Growth Rates of Production, Export and Import of Medical Devices
(Constant Prices)



Source: India Trades data and ASI unit records for various years.

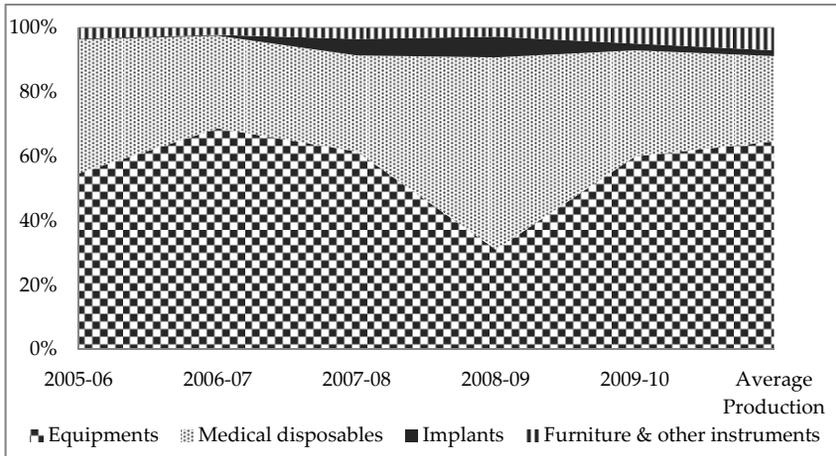
Section-V

Structure and Patterns of Production and Trade of Medical Devices in India

The definition of medical devices ranges from MRI scanning machine to needles, products of various size, intensity of capital requirements, degree of value added. They also vary in their usage, for diagnostic purposes, surgical purposes, prevention and cure of diseases and conditions and others are implants. Given the widely varying uses of devices, an attempt was made to categorize medical devices into four major categories- namely major equipment; medical disposables; implants and minor equipment, accessories and furniture. Major equipment include all the devices like the ECG, USG, MRI Scanner and other electro-diagnostic devices, major surgical instruments etc. There are 78 items listed in the trade data and 34 items as per the ASICC of domestic production data which can be categorized into major equipment. Disposables include devices which are mainly used for limited number of times and disposed of- these include syringes, needles, dental cements, X-ray films, adhesive tapes etc. As per ASI data there are 26 disposable items produced and according to India Trades data there are 18 disposables traded. Medical implants are medical devices that are used to replace a missing biological structure or support or enhance a damaged one. The range of implants include artificial tooth, heart valve to orthopaedic implants etc. There are only six items produced domestically and some 13 items traded. Furniture and other instruments, which do not come in direct use in treatment but are essential ancillary instruments for hospital industry, constitute a substantial part of medical device production in India. There are 15 items produced in India and 19 items traded ranging from clinical thermometer, BP instruments, and stethoscope to hospital beds and dentist chair etc.

On an average, equipment forms almost two-third (64.7%) of total value of domestic production, whereas disposables form 26.5 per cent of total value. Implants form less than 2 per cent of total value and minor instruments and furniture constitute around seven per cent. In 2008-09 medical disposables constituted 60 per cent of total production, share of equipment was 31 per cent. The share of equipment increased to 60 per cent in 2009-10 and consequently share of disposables came down to a third. The other important observation that comes out of *Figure-5* is that implants form a small part of the production.

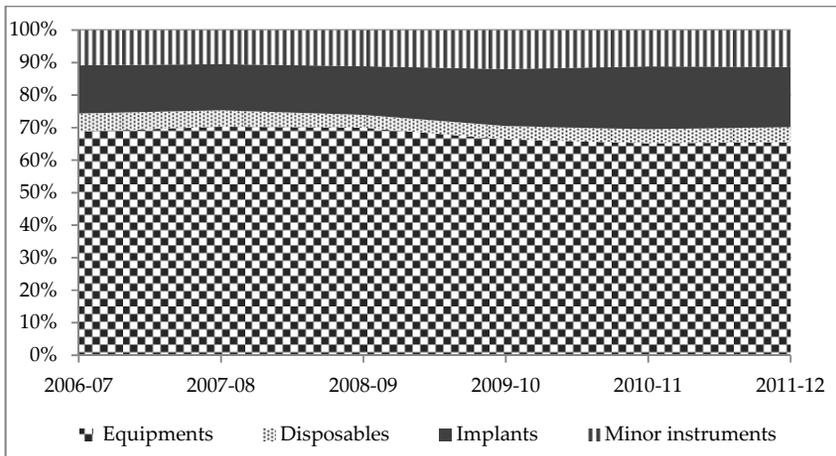
Figure-5
Domestic Production: Broad Categories



Source: ASI, unit records.

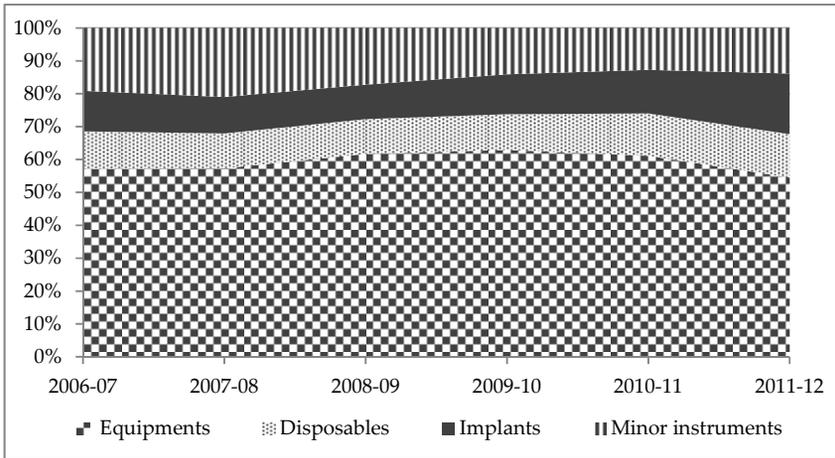
Structure of trade varies widely from the domestic production. Though equipment constitutes more than 80 per cent of total import and export, some variations can be clearly observed. Medical disposables constitute around 15 per cent of total exports, whereas less than 10 per cent of imports are on account of disposables (*Figure-6a & -6b*). Higher proportion of exports

Figure-6a
Share of Major Categories of Import



Source: India Trades.

Figure-6b
Share of Major Categories of Exports



Source: India Trades.

of disposables corresponds to our earlier finding that these goods constitute a major part of domestic production also. Medical implants form a very tiny part of exports, but its share in imports has increased significantly between 2000 and 2012. However, a comparison of trade and domestic production suggest that disposables have higher share in domestic production and export and much lesser proportion in imports. Disposables are often less technology intensive and remain at the lower part of the value chain. Implants, on the other hand form a tiny part of domestic production but its share in import is much higher, implying that a larger part of domestic demand for implants are met through import. The category of major equipment is also not uniform and capture wide gamut of products with varying intensity of use of technology. We need to look at further break ups of production, exports and imports of specific products to get a better picture of medical devices industry.

Main Products: Domestic Production and International Trade

It is important for our study to identify the main products in domestic production, exports and imports to understand the nature of medical devices used. For the domestic production market we have used the ASICC five-digit code, which is the most detail account of commodity description available for analysis of domestic production, to identify the top twenty commodities produced domestically for 2004-05 to 2009-10. We have taken the average value of the products for this period and these top twenty

products constitute 90 per cent of total value of output of the industry. Almost 48 per cent of total value of output is produced under the category “medical/bio-medical/lab machines which are not elsewhere classified”. This shows the limitation of ASI data, in not being able to provide adequate details. Different forms of syringes form more than fourteen per cent of the value of total product. Other important category includes different instruments and disposables related to X-ray (11.6%). Among the furniture operating tables (2.8%) and dentists’ chair appear prominently (1.02%). Among the major medical devices only ECG machines figures in the top twenty products. So predominance of disposables, minor equipment and equipment and products related to radiology emerge clearly from the *Table-6*.

Table-6
Top Twenty Products in Domestic Production Market and their Share in Value Output

<i>ASICC</i>	<i>Category</i>	<i>Description</i>	<i>Value share</i>
79559	Equipment	Medical/bio-medical/lab. Machines N.E.C	47.50
79537	Disposable	Syringe	6.06
79525	Equipment	Optic set for stereo microscope	4.87
42606	Disposable	Disposable syringe plastic	4.87
77194	Equipment	X-ray equipment	4.61
79524	Furniture and minor instrument	Operation & examination tables	2.80
38301	Disposable	Film X-Ray unexposed in roll	2.75
79544	Disposable	Health care products	2.42
38319	Disposable	X-Ray film & plates N.E.C	2.34
79527	Equipment	Pharmaceutical machine. others	1.92
79545	Disposable	Needle surgical	1.42
38302	Disposable	Film X-Ray unexposed in sheet	1.22
79516	Furniture and minor instrument	H IV testing kits	1.12
74154	Disposable	Needle	1.07
79507	Furniture and minor instrument	Dentists chairs	1.02
79533	Equipment	Sterilizers	0.83
91359	Disposable	Laboratory wares & components N.E.C	0.82
79523	Disposable	Needle holder surgical	0.82
79512	Equipment	E.C.G. machine	0.77
38304	Disposable	Film X-Ray unexposed -others	0.72

Source: ASI unit records.

From the 8-digit ITC-HS, we have identified top ten commodities in terms of import and export values for the years 2006-07 to 2009-10 (*Table-7*). Top twenty constitute three quarter of total exports and 72 per cent of total

imports. X-ray machines and other devices related to radiotherapy constitute a fourth of the total value of exports- there are four such commodities figuring in top twenty. Disposables dominate the list of exports. Out of twenty items eight fall into the category of disposables— catheters, cannulae, syringes, adhesive bandages, needles etc. Other important exports include surgical tools and demonstration materials. This trend is consistent with the domestic production, which is also dominated by X-ray and radiology related devices on one hand and disposables on the other. The analysis of domestic production data and the export data shows that the domestic production industry is characterized by the dominance of products which are less technology intensive. The only high-end medical equipment is related to radio-logical equipment including X-Ray machines. The spread and popularity of X-Ray machines as diagnostic devices dating back since 1980s, the domestic production capacity has also grown over the years.

Table-7
Top Twenty Exports and Imports of Medical Devices:
Average Share between 2006-07 and 2009-10

<i>Import</i>			<i>Export</i>		
<i>ITC_HS</i>	<i>Commodity</i>	<i>Share</i>	<i>ITC_HS</i>	<i>Commodity</i>	<i>Share</i>
90279090	Other parts & accessories for physical and chemical analysis	7.62	90221490	Other X-ray machines for medical uses	12.6
90278090	Exposure meters	6.97	90181990	Other electro-diagnostic apprts	9.1
90272000	Chromatographs & electrophoresis instrmnt	5.95	90223000	X-ray tubes	6.7
90181990	Other elctro-diagnostc apparatus	5.13	90229090	Others parts & accessories related to radiotherapy	5.7
90229090	Others Parts & accessories related to radiotherapy	4.84	90183990	Catheters and others	5.2
90183990	Catheters and others	4.45	90183930	Cannulae	5.1
90185090	Ophthalmic surgical instrument & appliances	3.95	90261010	Flow meters (gas)	3.1
90181300	Magnetic resonance imaging apparatus	3.65	90181290	Other electro-diagnostic apparatus	2.9
90181290	Other ultra-sonic scanning apparatus	3.45	90269000	Parts & accessories of instrments / apparatus for measuring /	2.6

<i>Import</i>			<i>Export</i>		
<i>ITC_HS</i>	<i>Commodity</i>	<i>Share</i>	<i>ITC_HS</i>	<i>Commodity</i>	<i>Share</i>
				checking flow of gas / liquids etc	
90221200	Computed tomography apparatus	2.95	90230090	Other demonstration aids	2.5
90213900	Other artificial joints	2.78	30059040	Bandages without adhesive layer	2.2
90189019	Other diagnostics instruments	2.45	90183100	Syringes, w/n with needles	2.1
90221490	Other X-ray machines for medical uses	2.36	30059090	Other dressing articles n.e.s.	2.1
90219090	Others	2.29	90189029	Other surgical tools	1.9
90269000	Parts & accessories of checking flow of gas/ liquids etc	2.02	90183210	Suture needles	1.9
90213100	Artificial joints	1.93	90189032	Blood transfusion apparatus including plastic container / bags	1.8
90183920	Cardiac catheters	1.87	90189022	Surgical knives, scissors & blade	1.8
90262000	Pressure gauge and other instruments & apparatus for measuring/checking pressure	1.75	90262000	Pressure gauge and other instruments & apparatus for measuring/checking pressure	1.8
90275090	Others	1.72	90268090	Other instruments & apparatus for measuring,checking or automatically controlling the flow,dpth,prsr etc	1.6
90261010	Flow meters (gas)	1.64	90189019	Other diagnostics instruments	1.5
90223000	X-ray tubes	1.52	90279090	Other parts & accessories for physical and chemical analysis	1.5

Source: CMIE, India Trade.

Three major patterns emerge from the analysis of top imports. The first thing is medical equipment dominate the list and as expected the high end electro-diagnostic devices like the magnetic resonance imaging apparatus (MRI), Ultra-sonic scanning machines, computed tomography apparatus and other electro-diagnostic apparatus figure prominently in the list. The other thing is some of the major imports are actually part of larger

equipment used as inputs. For instance, exposure meters, chromatographs, flow meters and other diagnostic instruments. These point out that assembling and re-exports may be major trends in domestic production which need to be looked at. The other trend that emerges is that implants in the form of artificial joints are being imported in India to fill in the void in production of these articles. Our analysis of domestic production sector also suggests that implants form very small part of the domestic production and whatever being produced are in the form of artificial teeth and some prosthetic parts.

Imported Inputs in Domestic Production:

Imported inputs constitute a significant part of the domestic production of medical devices. Almost 44 per cent of the total value of inputs used is imported inputs. Some of the imported inputs are also medical devices. Among the top twenty imported inputs medical devices are three- thus indicating that devices are being assembled in India. There are more than 80 imported inputs which constitute 90 to 100 per cent of the total value of inputs used for a specific product (*Table-8*).

Table-8
Top Twenty Imported and Indigenous Inputs Used
in the Production of Medical Devices

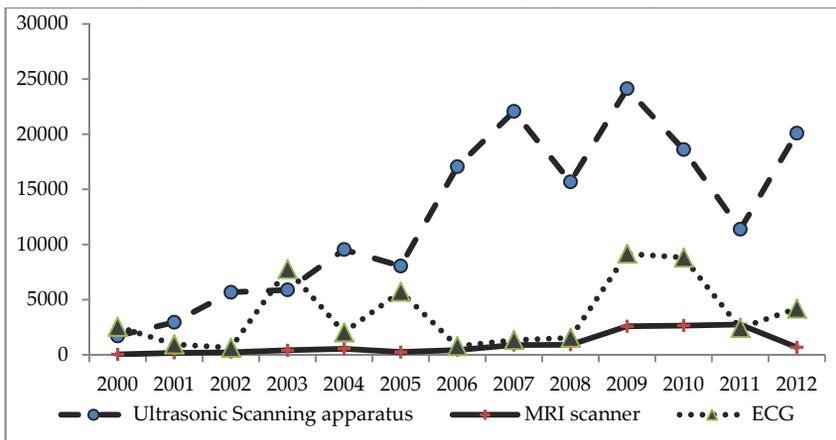
<i>Indigenous Inputs</i>		<i>Imported Inputs</i>			
99201	Other Basic Items (Indigeneous)	99221	Other Items Imported		
99908	Packing Items	38301	Film X-Ray Unexposed in Roll	Yes	
42941	Plastic Granules	78234	L. C. D.		
99905	Electricity Purchased	78328	Monitor (Computer Display)		
99906	Petrol Diesel Oil Lubricants	78152	Sensors		
64221	Fibre Polypropylene	78211	Cable T V Equipment		
41477	Rubber Processed	91359	Laboratory Wares & Components N.E.C		
79533	Sterilizers	79559	Medical/Bio-Medical/Lab. Machines N.E.C	Yes	
31908	Polymers-Others	79545	Needle Surgical	Yes	
32457	Propylene	78221	DIODES		
79559	Medical/Bio-Medical/Lab. Machines N.E.C	Yes	77904	Resistance /Resistor	
71401	Bars Rods Stainless Steel	78939	Electronic Components & Parts N.E.C		

<i>Indigenous Inputs</i>		<i>Imported Inputs</i>	
32599	Organic Chemicals N.E.C	77404	Anodes - Others
41523	Rubber Lined Goods	41487	Moulded Goods Rubber
78939	Electronic Components & Parts N.E.C	64221	Fibre Polypropylene
74147	Monometal	74055	Cover Crank Cases
41407	Dipped Goods Rubber	41427	Cables Inner & Outer Rubber
77415	Cable Jelly Filled	71306	Drill Pipe Of Iron
71429	Stainless Steel & Its Products N.E.C	74161	Non Ferrous Metal
72235	Nuts Bolts Washer & Screw Copper /Brass	71425	Wires/Coil/Circle Stainless Steel
71204	Rods Bars Bright Steel	78336	Printer All Kinds

Imports of Diagnostic Equipment:

India is a major importer of diagnostic equipment like Magnetic Image Resonance (MRI), Ultra-sound machines (USGs), X-Ray machines, full body scanners etc. Over the last decade significant number of USG machines, MRI scanners have been imported. For instance, 0.15 million Ultrasonic Scanning apparatus of the value of ₹2,916 crores have been imported into India between 2001 and 2011 (Figure-7). Similarly some 12,500 MRI scanning machines of value of ₹2,626 crores have been imported during the same period. The meteoric rise of diagnostic centers in the context of complete

Figure-7
Import of Some Electro-Diagnostic Equipment (quantity)



Source: India Trade data, various years.

vacuum of regulatory apparatus has led to this kind of trends. This also indicate increasing dependence on electro-diagnostic methods in medical care which might result in increasing cost of treatment, a phenomenon widely prevalent in developed countries such as in US or other OECD countries.

Section-VI

Discussion and Conclusion

Medical device industry is multi-product industry, producing wide range of products, with varied degree of capital intensity and multipurpose use. though it constitutes a very small population in comparison with total manufacturing sector, in public health its importance is significant. Manufacturing and trade in medical devices is also growing quite steadily over the period of analysis. Double digit growth rates in real term indicates its growing importance in health care. Its requirement for skilled workforce is high compared to the overall manufacturing industry. This also corroborates to the observation that capital- labour ratio is declining, thus larger share going towards wages.

When we compare the domestic production data with the trade data a definite pattern of the industry clearly emerges. The domestic industry produces those segments, which are relatively less technology intensive, thus we see the presence of disposables figuring prominently. The most advanced part of the domestic production is the segment catering to radio-diagnostic equipment. The same pattern is also found in export sector. Other high end electro diagnostic equipment, like the MRI, CT Scan, USG are generally imported. But import also consists of parts and accessories of larger equipment. This may be a pointer towards the emerging area of assembling and re-export, though this couldn't be confirmed with existing data sources.

Household survey data shows that a vast majority of Indians do not have access to medical devices, and private sector hospitals are using medical devices in major way (Mahal 2009). Proactive role of government in ensuring access to medical technologies is definitely the most effective vehicle, but regulation could also play a complementary role in ensuring quality and access. The regulatory structure of medical devices in India is nascent to say the list. Central Drugs Standard Control Organisation (CDSCO) is the main regulatory body in India. The list of medical devices

under regulation is not detailed and hence leaves out many of the devices. The other issue is that many medical devices are regulated as part of the Drugs and Cosmetics Act. The recent attempts to introduce a comprehensive regulation involving both Ministry of Health and Family Welfare and Department of Science and Technology (DST), has not taken off yet. One major step ensuring implementation of better regulatory framework would be to have clearer definition of the industry and better data. As it is evident from the ASI data, the current method of identifying medical devices industry is inadequate. A much more detailed product classification is the need of the hour. Implementation of National Product Classification for Manufacturing Sector (NPC(MS)), which complies with international standard classifications could facilitate this process.

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About the ISID

The Institute for Studies in Industrial Development (ISID), successor to the Corporate Studies Group (CSG), is a national-level policy research organization in the public domain and is affiliated to the Indian Council of Social Science Research (ICSSR). Developing on the initial strength of studying India's industrial regulations, ISID has gained varied expertise in the analysis of the issues thrown up by the changing policy environment. The Institute's research and academic activities are organized under the following broad thematic areas: *Industrialization; Corporate Sector; Trade, Investment and Technology; Regulatory Mechanism; Employment; Public Health; Media Studies; and Other Issues.*

ISID has developed databases on various aspects of the Indian economy, particularly concerning industry and the corporate sector. It has created On-line Indexes of 203 Indian Social Science Journals (OLI) and 18 daily English Newspapers. More than one million scanned images of Press Clippings on diverse social science subjects are available online to scholars and researchers. These databases have been widely acclaimed as valuable sources of information for researchers studying India's socio-economic development.

About the PHFI

The Public Health Foundation of India (PHFI) is a public private initiative that has collaboratively evolved through consultations with multiple constituencies including Indian and international academia, state and central governments, multi & bi-lateral agencies and civil society groups. PHFI is a response to redress the limited institutional capacity in India for strengthening training, research and policy development in the area of Public Health.

Structured as an independent foundation, PHFI adopts a broad, integrative approach to public health, tailoring its endeavours to Indian conditions and bearing relevance to countries facing similar challenges and concerns. The PHFI focuses on broad dimensions of public health that encompass promotive, preventive and therapeutic services, many of which are frequently lost sight of in policy planning as well as in popular understanding.

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