Final Report

Survey of Medical Devices Clusters

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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ACKNOWLEDGEMENTS

Centre for Market Research & Social Development, New Delhi, wishes to express its sincere gratitude to Department of Pharmaceuticals, Government of India, for entrusting this work to us.

We are greatly indebted to all the respondents of the study for their kind cooperation and support extended towards this assignment. We are also thankful to state officials for providing us with the best support data and information required for the study.

We gratefully acknowledge the professional contributions of all the staff of Centre for Market Research & Social Development for their involvement in successful completion of the study.

February 2023

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CONTENTS

CHAPTER		PAGE
	EXECUTIVE SUMMARY	i - iv
I	BACKGROUND	1 - 13
II	STUDY OBJECTIVES, METHODOLOGY AND COVERAGE	14 - 16
III	GEOGRAPHICAL SPREAD OF MEDICAL DEVICES CLUSTERS	17 – 19
IV	ASSESSMENT OF INFRASTRUCTURE & LOGISTIC FRAMEWORK IN THE MEDICAL DEVICES CLUSTERS	20 – 23
V	DOMESTIC OUTPUT & EXPORTS OF MEDICAL DEVICES CLUSTERS	24 – 26
VI	OVERVIEW OF GOVERNMENT INTERVENTIONS UNDER VARIOUS SCHEMES	27 – 35
VII	CONCLUSION & RECOMMENDATIONS	36 – 37
ANNEXURE-1	LOCATIONS OF MEDICAL DEVICES CLUSTERS IN THE COUNTRY	38 – 40
ANNWXURE-2	LIST OF SURVEYED MEDICAL DEVICES MANUFACTURING UNITS	41 – 47
ANNEXURE-3	SURVEY QUESTIONNAIRES	48 – 63

EXECUTIVE SUMMARY

The Indian Government has identified medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthening the manufacturing ecosystem. Department of Pharmaceuticals intended to conduct “Survey of Medical Devices Clusters” with the objectives of

a. Evaluating contribution of medical devices clusters to overall production, supplies and exports;
b. Assessment of infrastructure and logistics framework and suggest improvements, and
c. Recommendations to boost efficiency and cost competitiveness of clusters

The broad scope of the “Survey of Medical Devices Clusters” are:

a. Diagnosis of Medical Devices Clusters of the Country w.r.t their geographical spread
b. Cluster-wise and aggregate analysis w.r.t.:
   (i) Assessment of common facilities viz., testing & prototyping infrastructure, warehousing infrastructure, accreditation labs etc.
   (ii) Size including contribution to domestic output including production as well as exports at product and aggregate level
   (iii) Overview of Government interventions under various Schemes of State Governments and Central Government
   (iv) Recommendations to promote cost competitiveness and boost infrastructure for each cluster

The study was carried out mainly based on both primary as well as secondary data. Apart from collecting cluster level data from the States/UTs, primary information was also collected through Key Informant Interviews. All the medical devices clusters were surveyed during the assignment. In order to get inputs from stakeholders, 10 Focus Group Discussions (FGD) were conducted at different clusters. Primary information was also collected through Key Informant Interviews. 70 medical devices industries were covered for the study. Other stakeholders (key informants) were selected through purposive sampling techniques. The data collection from various stakeholders was done during May to August 2022.

Major Survey Findings

1) The survey found that there are 21 medical devices clusters in the country spreading over 9 states. The highest number of 6 medical clusters are in Uttar Pradesh, followed by 4 each in Maharashtra and Haryana, 2 in Karnataka, and one each in Andhra Pradesh, Gujarat, Rajasthan, Tamil Nadu and Telangana.

2) Geographical region wise finding illustrates that there are 10 (48%) medical devices clusters in North & Central region, while 6 (28%) clusters are in West region and 5 (24%) clusters are in South region. There is no medical devices cluster in East and North-East regions of the country.

3) During the survey of 21 medical devices clusters, it was observed that there are 736 industries are in operation with an average of 35 units per cluster. There are some big medical devices clusters in Gurugram and Bhiwani in Haryana, Kanpur in Uttar Pradesh and Hyderabad in Telangana.

4) Out of these 736 medical devices industries in 21 clusters, 147 (20%) are micro industries, 229 (31.1%) are small industries, 284 (38.6%) are medium scale industries and 76 (10.3%) are large industries. Majority of the large scale medical devices industries are located in the cluster of Visakhapatnam, while some large scale industries are located in the clusters of Maharashtra.

5) During the survey of medical devices clusters an assessment was undertaken with regard to the availability of infrastructure and facilities in the medical devices clusters of the country. The study observed that testing & prototyping infrastructure, warehousing infrastructure, accreditation lab, regulatory awareness & facility center, and training centre are available in most of the medical devices clusters.

6) However, the study observed that Special Purpose Vehicle (SPV) and Common Logistics Centre are not available in majority of the medical devices clusters, which should be looked into to promote domestic manufacturing.

7) The survey findings illustrate that the annual domestic medical devices production by the industries of the 21 medical devices clusters in the country is approximately USD 3250 million. Apart from the domestic production, the annual export amount of

medical devices products from these clusters is about USD 2735 million. Thus, the total annual output of these 21 medical devices clusters is approximately USD 5985 million.

8) As per the survey, there are 126 export oriented medical devices industries in these 21 clusters. Major countries to where the exports of medical devices are done from these clusters are USA, Germany, China, France, Singapore and UAE.

9) The survey observed that the medical clusters have been benefitted under the MSE Cluster Development Programme (CDP) with regard to the development of infrastructure and common facilities in the clusters. The benefits received by the medical devices clusters under MSE-CDP are:
   1) Easy access to standard testing facilities
   2) Strengthening of the existing infrastructure facilities
   3) Getting the standard environment at a reduced cost
   4) Optimizing the available resources

10) The major recommendations to reduce production cost and develop infrastructure in the medical devices clusters are summarized and given below.
   - Transport facility to connect the international market
   - Aware the industries about Govt. Schemes
   - Low priced raw material should be available in Indian market

Recommendations

1) Boost research and development (R&D) through industry-academia collaboration: As envisioned in the advance paper to National Medical Devices Policy 2022, the Government is forging a new road for the accessibility of medical devices by placing the industry on accelerated growth. Boosting research and development (R&D) in medical devices sector is the need of the hour and effective academia-industry partnership is indispensable for it. Innovation lies at the heart of academia, and universities generate high-quality, intellectual property on a large scale. However, most of these innovations do not result in commercial translation. For optimal utilization of such innovations, the industry needs to join hands with the academia.

2) **Sufficient policy encouragement:** Sufficient policy encouragement and protection are required to attract increasing investment from private companies in medical devices sector. The Government is working to reduce its reliance on imports and make healthcare more accessible by building medical devices parks and medical device clusters. However, industry needs more than PLI schemes to encourage multinational medical device companies to manufacture in India to receive a 5-7 per cent incentive on earnings generated from those devices, as India still relies 70% on imports for medical devices.

3) **Strong funding mechanism:** A strong infrastructure is a pre-requisite for the expansion of the medical devices clusters. The medical devices clusters need to replace its structural backwardness and traditional technology with modern AI based capital-intensive methods. For strong infrastructure, growth and expansion of medical devices clusters, a strong funding mechanism is one of the most crucial things to be considered. This can be possible with government's support or in a public-private model, capital subsidies, tax exemptions in medical devices clusters. Common platforms shared by different innovation-centric companies such as shared raw material supplier base, testing services, shared infrastructure etc., could also help promote domestic manufacturing.

4) **Adopt collaborative approach:** With a futuristic and collaborative approach, the medical devices clusters can grow to its full potential. Collaboration among the industries and joint venture projects can help overcome various challenges. Seminars and events can be organized at regular intervals to bring the medical devices industries together.

CHAPTER-I
BACKGROUND

1.1 Indian Medical Devices Sector

The medical devices industry in India has been growing over the years, largely driven by proliferation of modern diagnostic and treatment solutions. In the last few years, changing lifestyles have further increased the human dependence on novel medical devices. With the ongoing exigency of the COVID-19 pandemic, the pressure is mounting to build the sector like never before. The time is ripe to transition into medical devices hub.

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of all medical conditions, diseases, illnesses, and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thereby helping achieve the key values enshrined in the National Health Policy (NHP) 2017 in terms of provision of good quality, affordable, and comprehensive healthcare to all citizens. The medical device is a multi-product sector, with the following broad classifications: (a) Electronics Equipment; (b) Implants; (c) Consumables and Disposables; (d) IVD reagents; and (e) Surgical Instruments.

The medical devices industry is a sunrise sector and has the potential of growing highest among all the sectors in the healthcare system. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. Major manufacturing of medical devices in the country is happening with respect to disposables such as catheters, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes, and implants such as cardiac stents, drug-eluting stents, intra-ocular lenses and orthopaedic implants.

The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies. The sector also requires continuous training of healthcare system providers to adapt to new technologies. Most of the high technology and innovative products originate from a well-developed

ecosystem and innovation cycle, which is yet to be fully developed in India. India depends on imports to an extent of 85% of its domestic requirements of medical devices.[1]

India is counted amongst the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China, and South Korea. The medical devices sector in India is still at a nascent stage. The Indian medical device market has a significant presence of multiple multi-national companies with about 80% of the sales generated from imported medical devices backed by multiple approvals, certification of accredited organizations and capacity to produce verified clinical trial record.[2]

The growth of medical device sector in India is primarily driven by growing and ageing population, increased per capita and disposable income, demand for healthcare infrastructure, rise in preventive testing and spread of healthcare services and insurance. In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector. Recently, the Indian medical devices sector's contribution has become even more prominent as India supported the global battle against COVID-19 pandemic through the production of medical devices & diagnostic kits, e.g., Ventilators, RT-PCR kits, IR Thermometers, PPE Kits & N-95 masks.

The COVID-19 pandemic has impacted medical equipment manufacturers. Moreover, the industry faces supply chain disruptions as well as several potential issues that include financial constraints and crises. This revelation highlights the dangers that stem from the dependence on imports because of the lack of domestic competitors in the game.

Despite the crisis, this opens new avenues of exploration. Prior to the development of medical devices and procedures, the use of these tools was extremely confined to medical facilities that treated many patients at once. With the COVID-19 protocols in place, these devices have become common in small medical institutions. More people are choosing home healthcare, resulting in an increase in demand for medical devices that can be used at home.

[1] Source: Chemical Industry Outlook, 2022
[2] Source: DoP's Approach paper on Draft National Medical Devices Policy 2022

Over the last few years, Indian medical devices industry has grown at a fast pace driven by the health care solutions for its large population. Despite promising growth, the state of the sector needs attention. While there exist some domestic capabilities to manufacture low end devices, majority of the market for high end devices is captured by the big global players like Johnson & Johnson, GE Healthcare and Philips Healthcare.

Several new factories were built due to the pandemic. For example, the Ministry of Health and Family Welfare (MoHFW) issued a report in December 2020 stating that prior to COVID-19, the average cost of each ventilator in March 2020 was 15 lakh rupees (approximately $21,000). However, due to the Indian ventilator industry taking up the production, the cost is 2–10 lakh rupees.

Medical devices manufacturers are interested in setting up a manufacturing facility in India due to the significant population and favourable regulatory climate. Medical device regulations were put in place in 2017, incorporating changes that are at par with global standards. Licenses for the importation, production, or sale, or licencing the use of medical devices were provided and risk-based regulation was introduced. By reducing regulatory requirements, this process has saved both time and money.

The Medical Device Rules (MDR) 2017 aims to bring all health products under the regulatory purview of the producers, importers, and suppliers. There are two different risk levels: low risk and medium risk.

Recently, the Government has formulated draft National Medical Device Policy which aims to facilitate an orderly growth of the medical device sector to meet the underlying objectives of accessibility, affordability, safety and quality, while ensuring focus on self-sustainability and innovation. Through this policy, the Department of Pharmaceuticals is driven to help the sector realize its full potential by creating a robust regulatory framework with feedback mechanisms, building an enabling ecosystem for medical device manufacturing within the country, focusing on innovation for high end technology, providing support in training and capacity building programs and promoting higher education to foster fresh talent and skilled resources in line with the industry requirements. Encouraging domestic production of medical devices is in consonance with the Government's 'Atmanirbhar Bharat Abhiyan' and 'Make in India' campaign.

1.2 Data on Medical Devices Sector

Around 65% of the manufacturers in India are domestic players operating in the consumables segment and catering to local consumption with limited exports. MNCs lead the high technology end of the Medical Devices market with extensive service networks.

The global medical devices sector has grown significantly in the last decade and is estimated to reach USD 433 billion by 2025, growing at a compound annual growth rate of 4.1% from 2020 to 2025. The market is dominated by United States of America (40% share), European market (25% share) and Japan (15% share) etc. Furthermore, the medical devices industry is also growing in the emerging markets. For e.g., Thailand's medical device market valued at USD 27 billion in 2019 is expected to grow by 8-10%, Brazil's current medical device market is worth approximately USD10.5 billion & is growing at a CAGR of 5.8%, and China's medical device sector currently valued at USD 96 billion is growing at a pace of more than 20% for several years.[3]

The per capita spend on medical devices in India is very low at USD 3, compared to global average of per capita consumption of USD 47 as well as the per capita consumption of developed nations like USA at USD 415 and Germany at US$ 313.[4]

The domestic players, who constitute around 65% of the medical device manufacturers in India, focus on low-cost low-technology devices such as consumables and disposables catering to local consumption with limited exports.

1.3 Export and Import of Medical Devices by India

India is one of the fastest growing markets in the global medical devices industry and is expected to grow at a CAGR of 15 per cent. Indian medical devices market stood at USD 11 billion in 2020**.** India is the 4th largest Asian medical devices market after Japan, China, and South Korea and among the top 20 global medical devices markets in the world. Currently, India is exporting ventilators, PPEs, diagnostic kits, sanitizers

[3] Source: India Brand Equity Foundation. Medical Devices Industry in India – Market Share, Reports, Growth & Scope
[4] Source: Deloitte Report on Medical Devices Making in India – A leap for Indian Healthcare

and surgical gloves (2/3 ply) etc. Exports and Imports of medical devices in last five financial years are given in the following segment.

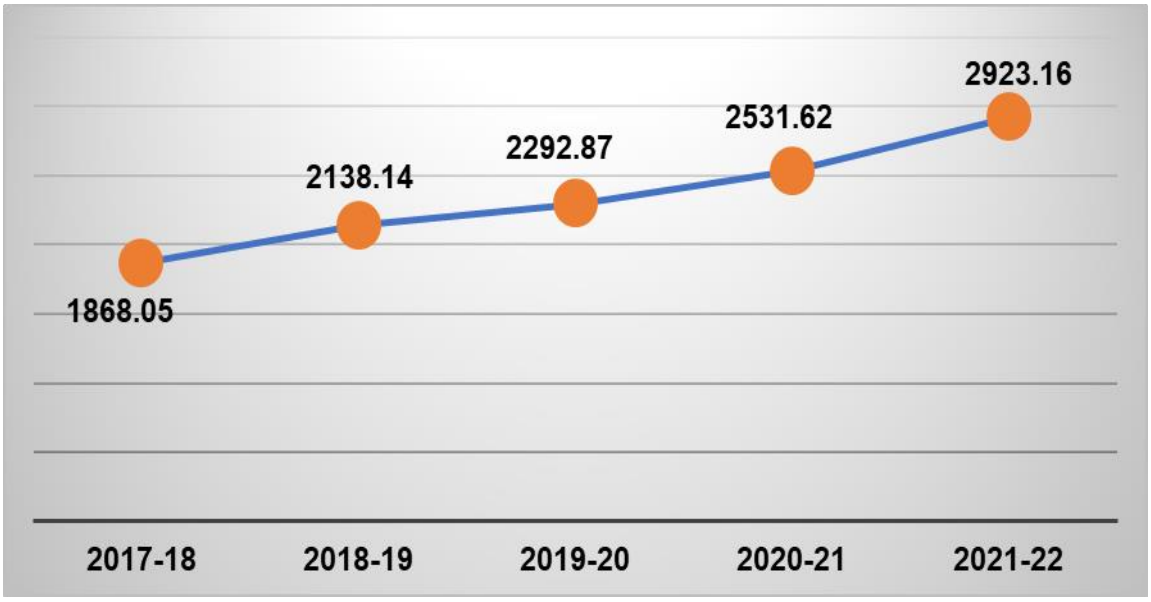
The EEPC data on exports of medical devices by India in last five financial years shows that the exports in FY 2017-18 was USD 1868.05 million, and it was increased by 13% to USD 2138.14 million in FY 2018-19. In FY 2019-20, it was increased by 7% to USD 2292.87 million, and it was increased by 10% to USD 2531.62 million in FY 2020-21, and increased by 15% to USD 2923.16 million in FY 2021-22.

Table-1.1: Exports of medical devices from India in last five financial years

Financial Year	*Values in USD million*
2017-18	1868.05
2018-19	2138.14
2019-20	2292.87
2020-21	2531.62
2021-22	2923.16

Source: EEPC, India

Chart-1.1: Exports of medical devices from India in last five financial years



(*Values in USD million)*

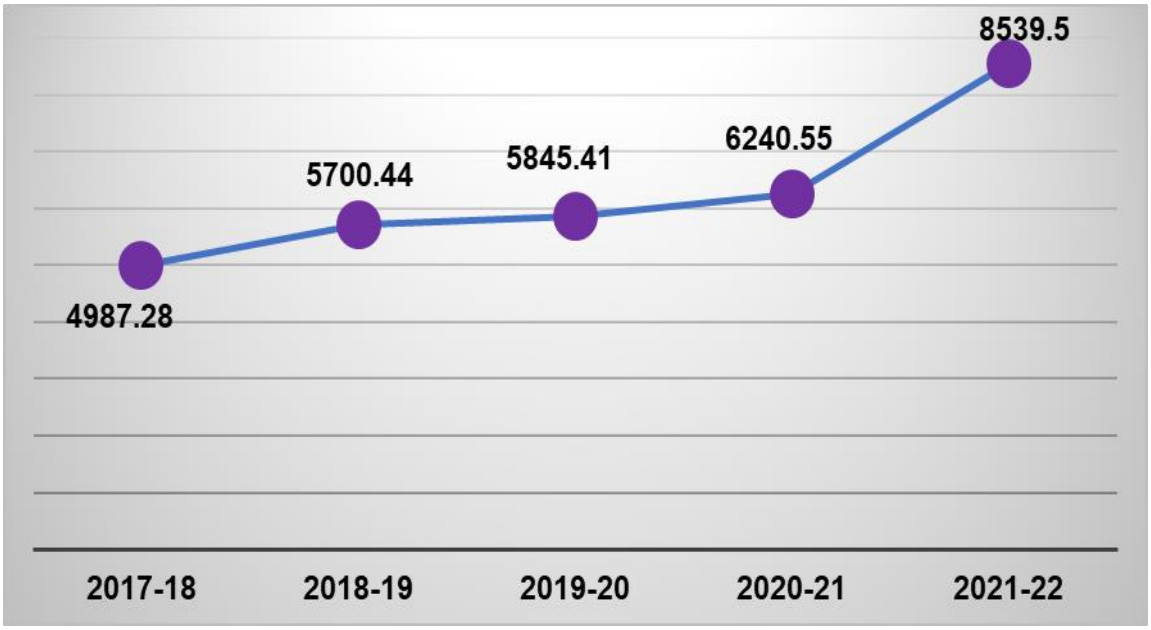
The EEPC data on imports of medical devices by India in last five financial years shows that the imports in FY 2017-18 was USD 4987.28 million, which was increased by 13% to USD 5700.44 million in FY 2018-19. In FY 2019-20, it was increased by 2% to USD 5845.41 million, while it was increased by 7% to USD 6240.55 million in FY 2020-21, and increased by 37% to USD 8539.50 million in FY 2021-22.

Table-1.2: Imports of medical devices by India in last three financial years

Financial Year	*Values in USD million*
2017-18	4987.28
2018-19	5700.44
2019-20	5845.41
2020-21	6240.55
2021-22	8539.50

Source: EEPC, India

Chart-1.2: Imports of medical devices by India in last five financial years



Source: EEPC, India (*Values in USD million)*

1.3.1 Export data of medical devices during last five years

Category wise EEPC data on exports of medical devices during last five years shows that about half of the exports were done in consumables & disposables, and about 40% exports were done in electronic equipments. Remaining about 10% exports were done in IVD reagent, implants and surgical equipments.

Table-1.3: Category wise export data of medical devices during last five years (2017-18, 2018-19, 2019-20, 2020-21 & 2021-22)

Sl. No.	Segment	Exports 2017-18	Exports 2018-19	Exports 2019-20	Exports 2020-21	Exports 2021-22
1	Consumables & Disposables	1012.39	1055.59	1082.53	1290.26	1378.48
2	Surgical Instruments	42.63	46.02	49.77	53.64	71.21
3	Electronic Equipment	696.39	887.83	998.87	984.73	1162.58
4	Implants	70.19	93.37	94.12	98.81	135.18
5	IVD Reagent	46.45	55.33	67.58	104.18	175.71
Total		**1868.05**	**2138.14**	**2138.14**	**2531.62**	**2923.16**

Source: EEPC, India *(values in USD million)*

Table-1.4: Category wise export share of medical devices during last five years (2017-18, 2018-19, 2019-20, 2020-21 & 2021-22)

Sl. No.	Segment	% share (1017-18)	% share (2018-19)	% share (2019-20)	% share (2020-21)	% share (2021-22)
1	Consumables & Disposables	54.2	49.4	47.2	51.0	47.2
2	Surgical Instruments	2.3	2.2	2.2	2.1	2.4
3	Electronic Equipment	37.3	41.5	43.6	38.9	39.8
4	Implants	3.8	4.4	4.1	3.9	4.6
5	IVD Reagent	2.5	2.6	3.0	4.1	6.0
Total		**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Source: EEPC, India

1.3.2 Import data of medical devices during last five years

Category wise EEPC data on imports of medical devices during last five years shows that majority of the imports were done in electronic equipments, and about 20% imports were done in consumables and disposables. Remaining about 20% imports were done in IVD reagent, implants and surgical equipments.

Table-1.5: Category wise import data of medical devices during last five years (2017-18, 2018-19, 2019-20, 2020-21 & 2021-22)

Sl. No.	Segment	Imports 2017-18	Imports 2018-19	Imports 2019-20	Imports 2020-21	Imports 2021-22
1	Electronic Equipment	3266.99	3676.74	3646.53	3568.64	5441.22
2	Surgical Instruments	136.58	190.18	180.1	103.62	169.02
3	Consumables & Disposables	792.8	966.1	1076.23	1470.77	1623.55
4	IVD Reagent	430.46	482.73	527.2	871.89	882.65
5	Implants	360.45	384.79	415.35	225.63	423.06
Total		**4987.28**	**5700.44**	**5845.41**	**6240.55**	**8539.50**

Source: EEPC, India *(values in USD million)*

Table-1.6: Category wise import share of medical devices during last five years (2017-18, 2018-19, 2019-20, 2020-21 & 2021-22)

Sl. No.	Segment	% share (1017-18)	% share (2018-19)	% share (2019-20)	% share (2020-21)	% share (2021-22)
1	Electronic Equipment	65.5	64.5	62.4	57.2	63.7
2	Surgical Instruments	2.7	3.3	3.1	1.7	2.0
3	Consumables & Disposables	15.9	16.9	18.4	23.6	19.0
4	IVD Reagent	8.6	8.5	9.0	14.0	10.3
5	Implants	7.2	6.8	7.1	3.6	5.0
Total		**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Source: EEPC, India

1.3.3 Export and Import data of different medical devices to top 10 countries in last two years

As per the EEPC data on major countries to where the exports and imports of medical devices are done are USA, Germany, China, France, Singapore and UAE. The EEPC data on export and import of different medical devices to and from top 10 countries in last two years are given in the following tables.

Table-1.7: Export and Import data in Consumables & Disposables (C/D)

	India's Export			India's Import			
Top 10 Exported Countries	2020-21	2021-22	Increase%	Top 10 Supplying countries	2020-21	2021-22	Increase%
USA	291.2	242.7	-0.17	USA	159.5	254.7	0.6
UAE	36.3	51	0.41	China	255.5	167.8	-0.34
Germany	41	33.3	-0.19	Malaysia	180.1	292	0.62
Brazil	41.3	59.5	0.44	Germany	46.8	51.4	0.1
China	30.7	31.9	0.04	Netherlands	29.7	118	2.98
Nigeria	29.6	33.3	0.13	Singapore	88.7	105.5	0.19
Sri Lanka	27.4	23.8	-0.13	Belgium	30.4	61.6	1.03
Nepal	21.2	33.4	0.58	Switzerland	46.3	60.3	0.3
France	21.5	26.1	0.21	France	52.4	69.6	0.33
Turkey	22.8	27.5	0.21	Japan	25.3	36.8	0.45

Source: EEPC, India *(values in USD million)*

Table-1.8: Export and Import data in Electronics Equipment (EL/EQ)

	India's Export			India's Import			
Top 10 Exported Countries	2020-21	2021-22	Increase%	Top 10 Supplying countries	2020-21	2021-22	Increase%
China	84.6	97.6	15%	USA	547.9	818.6	49%

USA	258.1	290.2	12%	China	768.4	1377	79%
Germany	81.7	81.1	-1%	Germany	493.7	593.7	20%
Singapore	64.2	73.6	15%	Singapore	367.4	532.9	45%
France	48.91	57.36	17%	Hong Kong	132.4	195.8	48%
Nepal	22.3	44.2	98%	UK	134.7	174.5	30%
Japan	20.7	26	26%	Netherlands	157.2	222	41%
Netherlands	14	40.4	189%	Japan	195.3	281.2	44%
Belgium	7	13.8	97%	Switzerland	123.4	151.7	23%
UAE	15.55	18.59	20%	South Korea	86.9	160.5	85%

Source: EEPC, India *(values in USD million)*

Table-1.9: Export and Import data in IVD Reagent (IVD)

	India's Export			India's Import			
Top 10 Exported Countries	2020-21	2021-22	Increase%	Top 10 Supplying countries	2020-21	2021-22	Increase%
USA	20.2	47.1	133%	USA	201.2	268.5	33%
UK	5.6	8.5	52%	UK	35.5	34.6	-3%
Lithuania	0.2	7.2	3500%	Netherlands	26.7	30.5	14%
Germany	2.7	4.8	80%	Singapore	42.3	43.3	2%
France	2.7	3.7	37%	Sweden	13.3	27.6	108%
Nigeria	0.9	6.2	597%	China	66.1	72.6	10%
Hong Kong	4.9	4.7	-4%	France	48.8	49.9	2%
Sweden	6.3	0.1	-98%	Hong Kong	26	36.6	41%
UAE	4.04	6.59	63%	South Korea	177.9	84.6	-52%
Ghana	8.2	2.6	-68%	Germany	85.8	73.4	-14%

Source: EEPC, India *(values in USD million)*

Table-1.10: Export and Import data in Implants							
	India's Export			India's Import			
Top 10 Exported Countries	2020-21	2021-22	Increase%	Top 10 Supplying countries	2020-21	2021-22	Increase%
USA	16.9	29.5	75%	USA	33.4	58.6	76%
Germany	5.5	5.0	-9%	China	7.1	8.8	24%
China	1.6	0.9	-40%	Germany	22.1	36.8	67%
Brazil	2.9	6.0	107%	Belgium	51.6	81.7	58%
Turkey	2.9	6.1	110%	Netherlands	12.7	23.9	88%
Belgium	4.2	0.6	-86%	Singapore	16.3	39.5	142%
Netherlands	6.1	9.8	61%	Switzerland	26.0	43.7	68%
Nepal	0.6	1.6	186%	Hong Kong	8.0	17.9	125%
France	0.2	0.5	104%	Japan	0.8	2.4	199%
UAE	1.3	1.9	44%	Ireland	12.1	28.8	137%

Source: EEPC, India *(values in USD million)*

Table-1.11: Export and Import data in Surgical Instruments (SI)							
	India's Export			India's Import			
Top 10 Exported Countries	2020-21	2021-22	Increase%	Top 10 Supplying countries	2020-21	2021-22	Increase%
China	11.6	13.2	14%	USA	42.1	64.3	53%
USA	13.6	22	62%	Germany	20.0	27.1	36%
Germany	3.0	3.2	7%	Belgium	0.8	1.2	61%
Nepal	1.3	1.8	39%	China	13.8	31.3	127%
Bangladesh	0.6	0.8	33%	Japan	0.4	0.9	123%
Spain	0.7	1.4	100%	Netherlands	2.3	3.3	43%
Turkey	0.7	1.0	43%	Hong Kong	2.7	2.7	1%
Belgium	0.4	0.7	75%	Singapore	3.0	8.0	166%
Mexico	0.3	0.4	33%	UK	1.3	2.0	53%
UK	0.6	0.7	3%	Vietnam	0.2	1.0	376%

Source: EEPC, India *(values in USD million)*

1.4 Recent Initiatives by the Government

Recognizing the importance of the sector, medical devices were included in the Make in India campaign launched and 100% FDI on the automatic route was allowed in Medical Devices in 2014. The Department of Pharmaceuticals has been allocated the responsibility for promotion of the medical devices. The initiatives taken in the recent past by the Department of Pharmaceuticals for the development of medical device sector are given below.[5]

1) In 2019, under the Scheme "Assistance to Medical Device industry for Common Facility Centre, financial assistance of Rs 25 crore was approved to Andhra Pradesh MedTech Zone (AMTZ) for a superconducting magnetic coils project which is under implementation.
2) In 2020, focused interventions to increase domestic manufacturing were introduced. The Production Linked Incentive PLI Scheme for Medical devices was introduced with an outlay of Rs. 3,420 crores to incentivize manufacturers in four target segments of high-end medical devices based on achieving investment and incremental production targets over a period of FY 2020-21 to FY 2027-28. The four target segments selected on the basis of domestic requirement with a view to build self-sufficiency are Cancer Care/ Radiotherapy medical devices, Radiology & Imaging Medical Devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices, Anaesthetics & Cardio-Respiratory Medical Devices including Catheters of Cardio Respiratory Category and Renal Care Medical Devices and All implants including Implantable Electronic Devices.
3) In addition, a scheme to support for financing of common facility projects in four medical devices parks was introduced in 2020 with an outlay of Rs. 400 crore wherein four States will be supported for creation of common facility projects which will be used by the industrial units to be set up in the medical device parks. These industrial parks are expected to be developed as manufacturing hubs for medical devices with associated testing, skilling and research facilities.
4) The Medical Devices Rules, 2017 notified by the Ministry of Health and Family Welfare under the Drugs and Cosmetics Act 1940, laid out the regulatory framework in terms of quality, safety and efficacy for medical devices. This expanded the regulatory oversight from 15 specified devices to the entire gamut of devices, categorized into four classes for regulation as per their risk categorisation.

[5] Source: DoP's Approach paper on National Medical Devices Policy 2022

5) The National Pharmaceutical Pricing Authority (NPPA) has stepped up price monitoring of essential medical devices and made interventions to cap margins on retail prices, where warranted in the case of some medical devices such as stents, oxygen concentrators and other Point of care devices.
6) To improve access, the Government has made available 250 types of surgical supplies in over 8800 stores or Jan Aushadhi Kendras at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana.
7) Health and Wellness Centres are being equipped with medical devices required for primary diagnostic services under Ayushman Bharat program.
8) The medical device sector has diversity of views and therefore to encourage a consensus-based approach for the larger good of the sector, a Standing Forum of Medical Device Industry Associations has been set up by the Department of Pharmaceuticals to provide a platform for discussion on various challenges being faced by the sector and arrive at well-rounded views.

1.5 Major medical devices clusters in India

Chennai, Bengaluru, Mumbai and Pune, being electronic hubs in India, are well equipped for manufacturing electro-medical devices and equipment. Gujarat is known for its orthopedic implant manufacturers. Presently, there are 21 medical devices clusters[6] in the country and majority of them are in Uttar Pradesh, Maharashtra and Haryana.

The medical devices clusters have “Medical Device Parks” developing around them. States have committed to set-up dedicated industrial parks where efficient domestic manufacturing at lower costs. The State Government of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh developing Medical Devices Parks to create a robust ecosystem for medical device manufacturing in the country.

The Indian Government has identified medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthening the manufacturing ecosystem. The Production Linked Incentive Scheme (PLI) Promoting Domestic Manufacturing of Medical Devices and Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) have been introduced to provide an impetus to India’s vision of becoming a global manufacturing hub for medical devices.

[6] Source: Survey conducted by CMRSD

CHAPTER-II
STUDY OBJECTIVES, METHODOLOGY AND COVERAGE

2.1 Study Objectives

The major objectives of the study are:

a. Evaluating contribution of Medical Devices clusters to overall production, supplies and exports

b. Assessment of infrastructure and logistics framework and suggest improvements

c. Provide recommendations to boost efficiency and cost competitiveness of clusters

The broad scope of the study are:

a. Diagnosis of Medical Devices Clusters of the Country w.r.t their geographical spread

b. Cluster-wise and aggregate analysis w.r.t.:

(i) Assessment of common facilities viz., testing & prototyping infrastructure, warehousing infrastructure, accreditation labs etc.

(ii) Size including contribution to domestic output including production as well as exports at product and aggregate level

(iii) Overview of Government interventions under various Schemes of State Governments and Central Government

(iv) Recommendations to promote cost competitiveness and boost infrastructure for each cluster

2.2 Approach & Methodology

The study was carried out mainly based on both primary as well as secondary data. However, more focus was given on in-depth analysis of the secondary data and primary sources was invariably used to validate the same. Both techniques were applied to obtain data / information in relation to the core areas of the study.

2.2.1 Secondary Study

Secondary data collection was a continuous process during the course of the study and data / information was collected from all the States and UTs of the country as well as

from publicly-available official sources. Emphasis was also given to collect data from articles / reports / research papers / policy documents on similar subjects and various records / data available of similar efforts undertaken by different government agencies in India in the nature of presentations, reports, brochures, photographs, articles, papers, write-ups, record of observations, project monitoring documents, etc, were analysed during the secondary study.

2.2.2 Primary Study

The questionnaires for different stakeholders are finalized after the desk review, and the questions were identified with respect to information requirements for the study. Various research techniques were applied to collect data / inputs from different States/UTs and different category of stakeholders. Focus group discussions, informal meetings and Key Informant Interviews (KII) were also conducted in the field besides canvassing the questionnaires.

(a) Field Visits

Apart from collecting cluster level data from the States/UTs, primary information was also collected through Key Informant Interviews. The interviews were conducted through face-to-face interviews. Visits / contacts were made to all medical devices clusters to collect the desired information. A semi-structured questionnaire was developed and inputs were solicited from different category of stakeholders. Total 70 medical devices industries from different clusters were also surveyed and the industries were pre-selected based on secondary research through purposive sampling techniques. Field work was conducted by visiting sample industries in selected clusters. Also, other stakeholders like Manufacturers Association, industrialists, and district & state officials of Industries Department were interacted for the purpose of the study.

(b) Focus Group Discussions

Primary information was also collected through Focus Group Discussions (FGD) covering 8-10 stakeholders. FGDs were conducted through discussion guidelines. Photographs were taken to support visual documentation of the initiatives The FGDs were conducted at different clusters across the country.

(c) Sample Size

The sample size of the study is as follows:

- All the medical devices clusters were surveyed.
- In order to get inputs from stakeholders, 10 Focus Group Discussions (FGD) were conducted at different clusters.
- Primary information was also collected through Key Informant Interviews. 70 medical devices industries were covered for the study.
- Other stakeholders (key informants) were selected through purposive sampling techniques.

Table-2.2: Sample Size for the Study

Sl. No.	Category	Sample Number
1	States & UTs	All
2	Medical Devices Clusters	17
3	Medical Devices Units	70
4	Other Stakeholders/ Key Informants	20
5	FGDs	10

2.3 Survey and data collection

The data collection from various stakeholders was done during May to August 2022. Data collection was conducted by adequate number of well-trained surveyors. The supervisors, data verifiers and other key study team members monitored the data collection procedure during the survey. All the data was checked and scrutinized by the supervisors and data verifiers. Following checks were conducted to gather and manage the quality of data.

2.4 Data management and analysis

The quality of data was ensured by imparting quality training to the study team members, surveyors and supervisors for the survey. Besides these, regular scrutiny of data checking was conducted to clean the database for the final analysis. Prior to data analysis, all relevant range and consistency checks were done. Finally, data was entered in SPSS 16.0 version and analyzed according to the analysis plan.

2.5 Study Limitations

Lack of reliable data and information available with key stakeholders on medical devices clusters has the impact on the findings and interpretation of the results of the present study.

CHAPTER-III
GEOGRAPHICAL SPREAD OF MEDICAL DEVICES CLUSTERS

3.1 State/UT wise spread of the medical devices clusters

The present survey found that there are 21 medical devices clusters in the country spreading over 9 states. The highest number of 6 medical clusters are in Uttar Pradesh, followed by 4 each in Maharashtra and Haryana, 2 in Karnataka, and one each in Andhra Pradesh, Gujarat, Rajasthan, Tamil Nadu and Telangana.

Out of total 21 medical clusters in the country, Uttar Pradesh has highest share with 29% clusters, followed by Maharashtra and Haryana with each having 19% clusters, 10% in Karnataka, and 5% each in Andhra Pradesh, Gujarat, Rajasthan, Tamil Nadu and Telangana.

State/UT wise number of medical devices clusters in the country is given in the following table.

Table-3.1: State/UT wise share of medical devices clusters in the country

Sl. No.	State/UT	Number of medical devices Clusters	Share of Medical Devices Clusters (%)
1	Uttar Pradesh	6	29
2	Maharashtra	4	19
3	Haryana	4	19
4	Karnataka	2	10
5	Andhra Pradesh	1	5
6	Gujarat	1	5
7	Rajasthan	1	5
8	Tamil Nadu	1	5
9	Telangana	1	5
	Total	**21**	**100**

Source: Field Survey by CMRSD

Geographical region wise finding illustrates that there are 10 (48%) medical devices clusters in North & Central region, while 6 (28%) clusters are in West region and 5 (24%) clusters are in South region. There is no medical devices cluster in East and North-East regions of the country.

Geographical region wise number of medical devices clusters in the country is given in the following table.

Table-3.2: Region wise share of medical devices clusters in the country

Sl. No.	Region	State/UT	Number of Clusters	Share of Clusters (%)
1	North & Central	Uttar Pradesh, Haryana, Punjab, Madhya Pradesh, Chhattisgarh, Delhi, Chandigarh	10	48
2	South	Telangana, Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Puducherry, Lakshadweep	5	24
3	West	Rajasthan , Gujarat, Goa, Maharashtra, Daman & Diu, Dadra & Nagar Haveli	6	28
4	East	Bihar, Orissa, Jharkhand, West Bengal, Andaman & Nicobar Islands	0	0
5	North East	Sikkim, Nagaland, Tripura, Arunachal Pradesh, Mizoram, Meghalaya, Manipur, Assam	0	0
Total			**21**	**100**

Source: Field Survey by CMRSD

3.2 State/UT wise location of the medical devices clusters

The following table gives the details of locations of medical devices clusters in the country.

Table-3.3: State/UT wise location of the medical devices clusters

Sl. No.	State/UT	Location of the medical devices clusters
1	Andhra Pradesh	Visakhapatnam
2	Gujarat	Lodhika
3	Haryana	Faridabad
4		Karnal
5		Bhiwani
6		Gurugram
7	Karnataka	Bengaluru
8		Mysuru
9	Maharashtra	Ambarnath, Pune
10		Satpur, Nashik
11		Sinnar, Nashik
12		Bhiwandi
13	Rajasthan	Jodhpur
14	Tamil Nadu	Chennai
15	Telangana	Hyderabad
16	Uttar Pradesh	Agra
17		Noida, GautamBuddha Nagar
18		Sahibabad, Ghaziabad
19		Kanpur
20		Lucknow
21		Meerut

Source: Field Survey by CMRSD

CHAPTER-IV
ASSESSMENT OF INFRASTRUCTURE & LOGISTIC FRAMEWORK IN THE MEDICAL DEVICES CLUSTERS

4.1 Size of the medical devices clusters

There are around 800 domestic Medical Devices manufacturers in India. During the present survey of 21 medical devices clusters, it was observed that there are 736 industries in operation with an average of 35 units per cluster. There are some big medical devices clusters in Gurugram and Bhiwani in Haryana, Kanpur in Uttar Pradesh and Hyderabad in Telangana.

Out of these 736 medical devices industries in 21 clusters, the survey found that 147 (20%) are micro industries, 229 (31.1%) are small industries, 284 (38.6%) are medium scale industries and 76 (10.3%) are large industries. Majority of the large scale medical devices industries are located in the cluster of Visakhapatnam, while some large scale industries are located in the clusters of Maharashtra.

Number of industries in different medical devices clusters and number of micro, small medium & large industries in each cluster are provided in the following tables.

Table-4.1: Size of units in medical devices clusters

Sl. No.	State/UT	Medical devices clusters	Micro	Small	Medium	Large	Total
1	Andhra Pradesh	Visakhapatnam	2	5	36	27	70
2	Guajrat	Lodhika	3	4	5	1	13
3	Haryana	Faridabad	4	6	3	1	14
4		Karnal	6	15	11	2	34
5		Bhiwani	8	18	25	2	53
6		Gurugram	25	55	102	8	190
7	Karnataka	Bengaluru	10	15	7	2	34

Table-4.1: Size of units in medical devices clusters							
Sl. No.	**State/UT**	**Medical devices clusters**	**Micro**	**Small**	**Medium**	**Large**	**Total**
8		Mysuru	4	6	3	0	13
9	Maharashtra	Ambarnath, Pune	8	10	12	15	45
10		Satpur, Nashik	3	3	6	4	16
11		Sinnar, Nashik	4	3	3	4	14
12		Biwandi	8	8	9	10	35
13	Rajasthan	Jodhpur	5	8	2	0	15
14	Tamil Nadu	Chennai	4	8	9	0	21
15	Telangana	Hyderabad	5	17	21	0	43
16	Uttar Pradesh	Agra	1	3	2	0	6
17		Noida, GautamBuddha Nagar	6	7	2	0	15
18		Sahibabad, Ghaziabad	13	2	1	0	16
19		Kanpur	20	25	5	0	50
20		Lucknow	6	3	13	0	22
21		Meerut	2	8	7	0	17
Total			**147**	**229**	**284**	**76**	**736**
			20.0%	**31.1%**	**38.6%**	**10.3%**	**100%**

Source: Field Survey by CMRSD

4.2 Availability of infrastructure & facilities in the medical devices clusters

Now, more and more hospitals are not only taking to automated systems for complete patient lifecycle management but also adopting software solutions such as Health Management Information System and Laboratory Information System providing for remote care. Therefore, the technological advancements in medical devices have catalyzed an overall improved treatment and care environment in the country.

The draft National Medical Devices Policy 2022 emphasises facilitating research and development and innovation with a focus on enhanced collaboration, global

partnerships, and joint ventures to bridge the gap between academic curriculum and industry requirements.

The plan is to ensure human resource development and introduce relevant curriculum at higher education level for enabling the clinician-engineering partnership along with skilling of various stakeholders comprising doctors, technicians, service engineers with a focus on the creation of high-end jobs with in-demand skill sets across the innovation value chain.

During the present survey of medical devices clusters, an assessment was undertaken with regard to the availability of infrastructure and facilities in the medical devices clusters of the country. The study observed that testing & prototyping infrastructure, warehousing infrastructure, accreditation lab, regulatory awareness & facility center, and training centre are available in most of the medical devices clusters.

The survey observed that the the units in the clusters manufacture different products in compliance with High-Quality Management standard and Good Manufacturing Practices (GMP). The units in the clusters have technically advanced machinery and equipment, which possess high production capacity. Most of the units carry out their productions and business operations in well organized and systematic manner. Most of the units have spacious warehouse and large storage capacity. The large units in the clusters have manufacturing units, product designing units, administrative units, warehouses, quality testing units and sales & marketing units to carry out their productions and business operations.

However, the study observed that Special Purpose Vehicle (SPV) and Common Logistics Centre are not available in majority of the medical devices clusters, which should be looked into to promote domestic manufacturing.

SPV is required in each cluster for the development of that cluster. SPV will work for development and sustainability of the cluster. Necessary directions should be provided by the government to set up special purpose vehicles (SPVs) for the development of the medical devices clusters in the country.

Secondly, there is the need of Common Logistics Centre in each cluster for organization and implementation of the complex business operations of the units in the clusters. Common Logistics Centres will support (i) the manufacturing units in providing logistics services, such as transportation, warehousing and forwarders, (ii) the logistics operations of units, such as the distribution operations, and (iii) the operations of the manufacturing units for whom logistics is a large part of their business".

CHAPTER-V
DOMESTIC OUTPUT AND EXPORTS OF MEDICAL DEVICES CLUSTERS

5.1 Market Size of Indian Medical Devices Industry

India is among the top 20 markets for medical devices worldwide. The medical devices sector in India comprises large multinationals and small and midsized companies.

The Government of India (GoI) has commenced various initiatives to strengthen the medical devices sector, with emphasis on research and development (R&D) and 100% FDI for medical devices to boost the market. FDI inflow in the medical and surgical appliances sector stood at US$ 2.35 billion between April 2000-December 2021. Between 2020 and 2025, diagnostic imaging is likely to expand at a CAGR of 13.5%.

The Medical Devices Virtual Expo 2021 showcased Indian products and enabled direct interaction between Indian suppliers and buyers/importers from participating countries. Also, 300 foreign buyers from the health care sector participated in this event.

5.2 Domestic output and exports of medical devices clusters

The survey findings illustrate that the annual domestic medical devices production by the industries of the 21 medical devices clusters in the country is roughly USD 3250 million. Apart from the domestic production, the annual export amount of medical devices products from these clusters is about USD 2735 million. Thus, the total annual output of these 21 medical devices clusters is approximately USD 5985 million.

As per the present survey, there are 126 export oriented medical devices industries in these 21 clusters. Major countries to where the exports of medical devices are done from these clusters are USA, Germany, China, France, Singapore and UAE.

The cluster wise annual domestic production, exports, and number of export oriented industries are given in the following table.

Table-5.1: Annual domestic production and exports of medical devices clusters

(Approx. Values in USD million)

Sl. No.	State/ UT	Medical devices clusters	Domestic Production	Exports	Number of Export Oriented Units in the cluster
1	Andhra Pradesh	Visakhapatnam	280	260	13
2	Gujarat	Lodhika	52	45	6
3	Haryana	Faridabad	56	35	3
4		Karnal	136	110	8
5		Bhiwani	212	195	11
6		Gurugram	660	580	11
7	Karnataka	Bengaluru	136	115	5
8		Mysuru	52	48	2
9	Maharashtra	Ambarnath, Pune	220	160	12
10		Satpur, Nashik	72	44	3
11		Sinnar, Nashik	68	46	3
12		Biwandi	140	110	8
13	Rajasthan	Jodhpur	30	10	2
14	Tamil Nadu	Chennai	84	81	9
15	Telangana	Hyderabad	172	165	6
16	Uttar Pradesh	Agra	24	20	3
17		Noida, GautamBuddha Nagar	60	47	3
18		Sahibabad, Ghaziabad	440	345	5
19		Kanpur	200	187	6
20		Lucknow	88	76	4
21		Meerut	68	56	3
Total			**3250**	**2735**	**126**

Source: Field Survey by CMRSD

During the survey of medical devices manufacturing units, most of the units did not disclose about their prodcucts. According to the information of some units, OT tables, OT lights, Calibrators, X-Ray Machines, Orthopaedic Implants, IVD Reagents, IVD Kits, Hospital Patient Furniture & Utility Furniture Products, Hospital Beds, Syringes, Needles, Gowns, MRI Machines, Cardiac Stents, etc. are the major medical devices/ products produced by them.

CHAPTER-VI
OVERVIEW OF GOVERNMENT INTERVENTIONS UNDER VARIOUS SCHEMES

6.1 Government Interventions under various schemes for development of Medical Devices Industry

The Government of India has recognized medical devices as a sunrise sector under the 'Make in India' campaign in 2014. Subsequent Union Budgets have announced several measures to encourage manufacturing, streamline regulatory approvals, and announced attractive fiscal incentives. To further promote the medical devices sector in the country with a focus on indigenization and reducing share of imports, the Government has implemented following key incentives and schemes: :

A) Scheme for Promotion of Medical Device Parks

The sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre" was a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was ₹ 100 crore for 2018-2020. The subscheme proposed to provide a one-time grant-in-aid of ₹ 25 crore or 70% of the project cost, whichever was less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The purpose of the grant was to render financial assistance for establishment of common facilities in any upcoming Medical Device Park promoted by a State Government/State Corporation. The DoP has supported the proposal of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the said sub-scheme.

Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" has been revised and renamed as ***"Promotion of Medical Device Parks***" which has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities/centre at one

place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country.

The total financial outlay of the scheme is ₹ 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under the Scheme, the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

A total number of 16 States submitted their proposals under the scheme. The Government has in-principally approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh, with the scheme being implemented by a State Implementing Agency. The States of Himachal Pradesh, Tamil Nadu, Uttar Pradesh and Madhya Pradesh have submitted their Detailed Project Reports (DPR). Final Approvals have been given to the States of TN, UP and MP and the DPR proposal of Himachal Pradesh, is under evaluation for final approval.

B) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices

The domestic medical devices industry faces challenges related to considerable cost of manufacturing disability, among other things, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of quality power, limited design capabilities and low investments on R&D and skill development. With a view to address these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a scheme called "Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices" has been approved by the Government of India on 20th March, 2020.

The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is ₹ 3,420 crore.

The identified products under this Scheme have been categorized into four Target Segments which is (i) “Cancer care/Radiotherapy medical devices, (ii) Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices (iii) Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices and (iv) All Implants including implantable electronic devices”.

In total, 42 applications were received in two rounds of application window spread across the four target segments of the Scheme. Out of which, 21 applications have been approved with a total Committed Investment of Rs. 1,059.33 Crore. The setting up of these plans will make the country self-reliant to a large extent in the specified target segments in the Medical Devices Sector.

C) Production Linked Incentive (PLI) scheme for Pharmaceuticals

To enhance India’s manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector, a scheme called “Production Linked Incentive Scheme for Pharmaceuticals” has been approved by the Government of India on 24th March, 2021. The guidelines of the scheme were issued on 1st June, 2021. The scheme covers In-vitro diagnostic devices amongst other pharmaceutical goods. Five (5) industry applicants have been selected under the scheme for Invitro diagnostic medical devices and the scheme provides for incentives based on their incremental sales for 6 years. The tenure of the scheme is from FY 2020-2021 to 2028-29.

Further, the challenges for the Sector are in terms of regulatory streamlining of the medical devices which is at a nascent stage, skilling of human resources and lack of technology for high end equipment and lack of appropriate infrastructure. Medical devices sector has seen significant activity in recent years with increase in demand, roll out of the regulatory timeline, introduction of PLI Schemes etc., all of which have contributed to a need to take on board a range of views on important policy issues. Medical devices sector had segmented participation from well-established Global MNCs (importing, manufacturing, exporting & investing in innovation, research & development), Indian firms and start-ups manufacturing, exporting & innovating a limited range of Medical Devices. The sector requires special co-ordination and

communication among Industry and Stakeholders because of its diversified nature, continuous innovation & variation.

D) Institutional Mechanisms for interaction with Industries

Besides, the regular interaction with the Industry representatives to redress the specific challenges, the following are the institutional mechanisms, adopted by DoP.

1. Standing Forum of Medical Devices Associations

A Standing Forum of medical device Industry associations has been set up on 25th August 2021 by the Department of Pharmaceuticals to provide a platform for discussion on various challenges being faced by the sector and arrive at well-rounded views The Department has constituted a Standing Forum of various Medical Device associations which deliberate on various issues with all the stakeholders including regulators and then the forum comes up with workable solutions after the consensus is built between various associations.

- Representatives from CII, AiMED, FICCI, USIBC, ADMI, AMTZ, MTAI, Advamed, PHDCCI, USISPF, AMCHAM, ASSOCHAM are part of this Standing Forum with DoP as facilitator
- The main objective of the Standing Forum is to deliberate upon issues pertaining to the sector and arrive at inputs from Industry for Policy and Program formulation, by DoP
- Tasks undertaken by the Standing Forum so far
- Drafting of Uniform Code for Medical Device Marketing Practices (UCMDMP), separate from the existing code for Drugs. The draft code is under stakeholder consultation.
- Consolidation of the views of the Industry on the "Streamlining of the Regulatory framework for Medical Devices". The recommendations received pertain to different regulators and are being processed.
- More tasks as and when identified will be assigned to the forum.

2. Interactions with the Industry and the Regulators

Medical Device sector has multiple regulators (CDSCO, NPPA, MoEF&CC, BIS, AERB etc) for different aspects of the medical devices. Hence, the Department from time to time, is holding regular meetings with industry and regulators to ascertain issues on short term and long term basis for redressal. In this regard, to address various issues concerning the industry and regulators, a regulatory roundtable was conducted by on 30.9.2021 to ascertain issues and address them in a timely manner.

3. Regulatory Roundtable during Annual Flagship event of the DoP

Regulatory Roundtable is also conducted annually, both for Pharmaceuticals and Medical Devices at the flagship event of the Department called India-Pharma and India-MedTech where there is a participation from other countries as well.

E) Public Procurement (Preference to Make in India) Order, 2017

The Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry issued the Order and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP issued its guidelines in May 2018 prescribing that domestically sourced components must contribute to 25-50 per cent of the cost of medical devices to qualify for public tenders, which would be subsequently increased in a phased manner to 25-75% over a period of time [27]. Also, Department vide Order dated 16.02.2021 & 25.03.2021 has notified 135 in-vitro diagnostic medical devices and 19 medical devices where there is sufficient local capacity and local competition available in the country, under Para 3(a) of PPO Order dated 16.09.2020 to enable procurement of the notified items only from the “Class-I local suppliers” The exercise is being resorted on regular basis, to update the details of Indian Manufacturers of Medical Devices with the the Central Procurement Agencies.

F) FDI in medical devices sector

In order to attract investments in this sector, the Government has allowed **100% foreign direct investments (FDI) in medical devices sector.**

G) National Medical Devices Promotion Council (NMDPC)

The National Medical Devices Promotion Council (NMDPC) under the aegis of DPIIT started functioning from 2020, Headed by Secretary, DPIIT. In total, there were 30 members including NITI Aayog Adviser, senior officials from health ministry, National Pharmaceutical Pricing Authority (NPPA), MSME, Department of Biotechnology and representations from various stakeholders including industry associations, health care industry and quality control institutions. Recognizing the need to redesign the NMDPC, to avoid duplication of work and bringing more efficiency in resolving the issues of Industry, the council is again reconstituted under the chairpersonship of Secretary Department of Pharmaceuticals (DoP).

The Council undertakes several activities including regulatory issues for ease of doing business, Public Procurement Order (Make in India) export related issues concerning the sector, by identifying the strengths of the Indian manufacturers.

H) National Medical Device Policy, 2022

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of medical conditions, diseases, illnesses, and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thereby helping achieve the key values in terms of provision of good quality, affordable, and comprehensive healthcare to all citizens.

To drive the growth of the sector, the Department of Pharmaceuticals is upcoming with National Medical Device Policy, 2022. The wider consultations with the stakeholders have been happened on the policy, and further action is being taken.

6.2 Government Interventions to strengthen the medical devices industry

The Government of India (GOI) has commenced various initiatives to strengthen the medical devices sector, with emphasis on research and development (R&D) and 100% FDI for medical devices to boost the market. Government interventions to strengthen the medical devices industry in last two years are given below.

- In the Union Budget 2022-23, Rs. 86,200 crores (US$ 11.3 billion) was allocated as a budget for the pharmaceutical and healthcare sector
- In November 2021, Indian Council of Medical Research (ICMR) collaborated with Indian Institutes of Technology (IITs) to establish 'ICMR at IITs' by setting up Centres of Excellence (CoE) for Make-in-India product development and commercialisation in the medical devices and diagnostics space. In October 2021, the government announced plan to draft a new drugs, cosmetics and medical devices bill to increase the acceptability of Indian medical devices in the global market.
- In October 2021, the government announced plan to draft a new drugs, cosmetics and medical devices bill to increase the acceptability of Indian medical devices in the global market.
- In October 2021, the government announced that 13 companies have been approved under the PLI scheme for medical devices, which are expected to boost domestic manufacturing in the country.
- The Government of India has recognised medical devices as a sunrise sector under the 'Make in India' campaign in 2014.
- In September 2021, the government sanctioned a proposal worth Rs. 5,000 crore (US$ 674.36 million) to build a medical devices park in Himachal Pradesh's industrial township, Nalagarh, in the Solan district.
- In September 2021, the government approved a medical devices park in Oragadam (Tamil Nadu) that is expected to attract an estimated investment of Rs. 3,500 crore (US$ 472.05 million) and offer direct and indirect employment to 10,000 people.
- In July 2021, the government announced to build medical park in Uttar Pradesh, which is expected to generate an estimated Rs. 500 crore (US$ 67.13 million) business in the state.

- To boost domestic manufacturing of medical devices and attract huge investments in India, the Department of Pharmaceuticals launched a PLI scheme for domestic manufacturing of medical devices, with a total outlay of funds worth Rs.3,420 crore (US$ 468.78 million) for the period FY21-FY28.
- In March 2021, the PLI Scheme for pharmaceuticals worth Rs. 15,000 crores (US$ 1.96 billion) was launched. This scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical and medical devices sectors and contribute to contribute to the availability of a wider range of affordable medicines for consumers.
- On March 25, 2021, the Department of Pharmaceuticals (DoP) released a revised notice on the Public Procurement Order (PPO), incorporating 19 medical devices in the revised guidelines of the PPO, which is expected to improve domestic medical devices manufacturing (and strengthen 'Make in India') and reduce import bills by Rs. 4,000 crore (US$ 538.62 million).
- In order to expedite the clearance of medical devices such as nebulisers, oxygen concentrators and oxygen canisters in April 2021, the government made it easier to import critical medical devices by easing the requirements for clearance under the Legal Metrology Act (Packaging Rules 2011).
- The government also approved applications for nine eligible projects that are expected to lead to a total committed investment of Rs. 729.63 crore (US$ 100.01 million) by the companies (e.g., Siemens Healthcare Private Limited, Allengers Medical Systems Limited (AMSL), Allengers OEM Private Limited (AOPL), Wipro GE Healthcare Private Limited, Nipro India Corporation Private Limited, Sahajanand Medical Technologies Private Limited, Innvolution Healthcare Private Limited, Integris Health Private Limited) and generate 2,300 jobs.

6.3 Benefits to Medical Devices Clusters under MSE-CDP

The survey observed that the medical clusters have been benefitted under the MSE Cluster Development Programme (CDP) with regard to the development of infrastructure and common facilities in the clusters. The benefits received by the medical devices clusters under MSE-CDP are:

1) Easy access to standard testing facilities
2) Strengthening of the existing infrastructure facilities
3) Getting the standard environment at a reduced cost
4) Optimizing the available resources

6.4 Expectations of the industries w.r.t. reduce production cost and development of infrastructure in the medical devices clusters

The expectations of the industries with regard to reduce production cost and develop infrastructure in the medical devices clusters are summarized and given below.

- Transport facility to connect the international market
- Aware the industries about Govt. Schemes
- Low priced raw material should be available in Indian market

CHAPTER-VII
CONCLUSION & RECOMMENDATIONS

Some of the essential factors determining the future potential and growth prospects of medical devices clusters need re-consideration and re-orientation. Policy intervention and measures can be successful only if they are guided by proper implementation. The following measures are necessary in order to re-structure the critical parameters of the medical devices clusters.

Recommendations

1) **Boost research and development (R&D) through industry-academia collaboration:** As envisioned in the advance paper to National Medical Devices Policy 2022, the Government is forging a new road for the accessibility of medical devices by placing the industry on accelerated growth. Boosting research and development (R&D) in medical devices sector is the need of the hour and effective academia-industry partnership is indispensable for it. Innovation lies at the heart of academia, and universities generate high-quality, intellectual property on a large scale. However, most of these innovations do not result in commercial translation. For optimal utilization of such innovations, the industry needs to join hands with the academia.

2) **Sufficient policy encouragement:** Sufficient policy encouragement and protection are required to attract increasing investment from private companies in in medical devices sector. The Government is working to reduce its reliance on imports and make healthcare more accessible by building medical devices parks and medical device clusters. However, industry needs more than PLI schemes to encourage multinational medical device companies to manufacture in India to receive a 5-7 per cent incentive on earnings generated from those devices, as India still relies 70% on imports for medical devices.

3) **Strong funding mechanism:** A strong infrastructure is a pre-requisite for the expansion of the medical devices clusters. The medical devices clusters need to replace its structural backwardness and traditional technology with modern AI

based capital-intensive methods. For strong infrastructure, growth and expansion of medical devices clusters, a strong funding mechanism is one of the most crucial things to be considered. This can be possible with government's support or in a public-private model, capital subsidies, tax exemptions in medical devices clusters. Common platforms shared by different innovation-centric companies such as shared raw material supplier base, testing services, shared infrastructure etc., could also help promote domestic manufacturing.

4) **Adopt collaborative approach:** With a futuristic and collaborative approach, the medical devices clusters can grow to its full potential. Collaboration among the industries and joint venture projects can help overcome various challenges. Seminars and events can be organized at regular intervals to bring the medical devices industries together.

ANNEXURE-1

LOCATIONS OF MEDICAL DEVICES CLUSTERS IN THE COUNTRY

Annexure-1: State/UT wise location of the medical devices clusters			
Sl. No.	**State/UT**	**Medical devices cluster**	**Location of the cluster**
1	Andhra Pradesh	Visakhapatnam	Visakhapatnam, Andhra Pradesh
2	Gujarat	Lodhika	Lodhika GIDC Village Metoda, Taluka, Lodhika, Gujarat
3	Haryana	Faridabad	SGM Nagar, New Industrial Town, Faridabad, Haryana
4		Karnal	HSIIDC, Industrial Estate, Karnal, Haryana
5		Bhiwani	Patel Nagar, Bhiwani, Haryana
6		Gurugram	Udyog Vihar, Sector 19, Gurugram, Haryana
7	Karnataka	Bengaluru	Export Promotion Industrial Park, Vijayanagar, EPIP Zone, Whitefield, Bengaluru, Karnataka
8		Mysuru	Wesley Rd, Mandi Mohalla, Mysuru, Karnataka
9	Maharashtra	Ambarnath, Pune	MIDC Anandnagar, Ambernath, Pune
10		Satpur, Nashik	Satpur MIDC, Nashik
11		Sinnar, Nashik	Malegaon Sinnar MIDC, Nashik
12		Bhiwandi	Kalyan-Bhiwandi Road, Bhiwandi
13	Rajathsan	Jodhpur	Jodhpur, Rajasthan
14	Tamil Nadu	Chennai	Kodungaiyur (East), Chennai, Tamil Nadu
15	Telangana	Hyderabad	Medtech Park, Hyderabad, Telangana
16	Uttar Pradesh	Agra	UPSIDC, Sikandra, Agra, Uttar

Annexure-1: State/UT wise location of the medical devices clusters			
Sl. No.	**State/UT**	**Medical devices cluster**	**Location of the cluster**
			Pradesh
17		Noida, GautamBuddha Nagar	Noida, Gautambudh Nagar, Uttar Pradesh
18		Sahibabad, Ghaziabad	Sahibabad, Ghaziabad, Uttar Pradesh
19		Kanpur	Kakadeo, Kanpur, Uttar Pradesh
20		Lucknow	Hazratganj, Lucknow, Uttar Pradesh
21		Meerut	Shastri Nagar, Meerut, Uttar Pradesh

ANNEXURE-2

LIST OF SURVEYED MEDICAL DEVICES MANUFACTURING UNITS

S.No	State	Cluster	Name of the unit/ company:	Address of the unit/ company:
1	Haryana	Faridabad	M/s Ramika Health Care Pvt. Ltd	S.C.F 156P Huda Market Sector - 37
2	Maharashtra	Kalyan Bhiwandi	Shree Balaji Surglcal Pvt Ltd	B - 3 Bhoomika Complat Behiend Rahul Kanta Village Puna Bhivandi
3	Haryana	Karnal	Kozmekare Pvt Ltd	359, Sec - 3 Extension, Karnal
4	Haryana	Jind	Apex Medivesion	9941639 Gau Shala Road Safidan
5	Haryana	Bhiwani	Shiv Surgical	Khemkan Ki Bagichi Near - Bansilal Park Azad Nager
6	Haryana	Bhiwani	Dev Industries	Plot No 127, Sec 21, Bhiwani - Rohtak Rd, Industrial Area, Vikas Nagar, Bhiwani
7	Haryana	Bhiwani	Technical India	Near Gas Godown, Behind Central School, Bhiwani
8	Haryana	Bhiwani	Hammertan Surgical Company	Kath Mandi, Bhiwani
9	Haryana	Bhiwani	Haspetech Industrial Corporlation	P.No - 84 Industrial Area Sec - 26 Bhiwani
10	Haryana	Bhiwani	Vansika Aguruedi Pvt. Ltd.	P.No - 132 Sector - 26 Industrial Area
11	Haryana	Bhiwani	Indotech Healthcare Sytem	Near Dog farm, Kaunt Road Bhiwani
12	Haryana	Bhiwani	Ravindra Ayurved	Front Poonia Market, Thana Road Bhiwani
13	Haryana	Bhiwani	Ankitech	P. No - 1 Dev Nagar Hansi Road Near Gupta Rark Bhiwani
14	Haryana	Karnal	Medox Pharmaceleticals	26, HS11DC Sector - 3 Karnal
15	Haryana	Bhiwani	Lanark Medicare	Dhani Chejaran,Patram Gate Bhiwani, Bhiwani

16	Haryana	Bhiwani	Vijaya Surgical	Halavad gate Jain Muni Ashram Bhiwani
17	Haryana	Karnal	JRS Oryk Pharma Pvt. Ltd.	217-218 HSIIDC Sector - 3 Karnal
18	Punjab	Dera Bassi (S.A.S Nager Mohali)	Allengers	Bhankaranpur Road Dera Bassi Mohali
19	Maharashtra	Nashik	Golden Grass health Care	Nice Area, Plot No.19/1, Ved Mandir, Trambakeshwar Rd, Matoshree Nagar, Nashik, Maharashtra 422002
20	Haryana	Bhiwani	Radhey Indueshries	P.No -1 Lajpat Nager Bhiwani
21	Haryana	Bhiwani	Nurve - Pharma Ceuticals	P.No - 186 Industrial Area Scetor - 26 Bhiwani
22	Haryana	Bhiwani	Feaspicare Surgical	Near Swaraj Traclor Agency Ultam Nager Bhiwani
23	Maharashtra	Nashik	Deep Techno System	Plot. 94, Addesh, Vanshree Colony, DGP Nager Nashik
24	Maharashtra	Ambarnath	Alltech Machines	Plot No. A - 49 MIDC Ind. Area Additional MIDC Anaad nager Ambarnath (EAST)
25	Maharashtra	Ambarnath	George Philips Medical Engg. Pvt.Ltd	B - 43 MIDC, Additonal Ambarnath (E)
26	Maharashtra	Ambarnath	Medimek Industeries	B-50, Additional M I D C, Anand Nagar, Ambarnath East, Ambarnath East, Mumbai, Maharashtra 421506
27	Maharashtra	Ambarnath	Entech Industries	Plot N. 33, Add Ambarnath Anand Nagar Ambarnath (E)
28	Maharashtra	Ambarnath	Meditek Engineers	W 13A Additionak MIDC Ambarnath
29	Maharashtra	Ambarnath	Sighaniya Tableting	275 Udyog Bhavan,Sonawala Road, Goregaon (E),Mumbai –

				400063, India.
30	Maharashtra	Ambarnath	Sasam Industries Private Limited.	B-133, MIDC Rd, Anand Nagar, Ambarnath, Maharashtra 421506
31	Maharashtra	Ambarnath	Alliance	A48 MIDC Ind Ambarnath
32	Maharashtra	Ambarnath	Prasad Bapat Owner	Star Medical System A/12-4, MIDC Anand Nagar
33	Himachal Pradesh	Baddi Dist-Solan (HP)	Multimedics Divice for life	Dic - Industriac Area Baddi (HP)
34	Himachal Pradesh	Baddi Dist-Solan (HP)	Allengers Global Health Care	# HPSI DC Industrial Area, Baddi
35	Telangana	Sangareddy	Promea Therapeutics	Plot M4, Medical Device Park, Sultanpur, Patancheruvu, Telangana 502319
36	Telangana	Sangareddy	Flexid Technopack	M3, Flexid Technopack Medical Devices Park, Sultanpur 8v) Ameenpur (m Sangareddy (d, Hyderabad, Telangana 502319
37	Telangana	Hydrebad	Renaud Bio Pvt Ltd	IDA Bollaram Road, Bollaram Industrial Area, Hyderabad, Telangana 502325
38	Telangana	Hydrebad	Majik Medical Solutions Pvt. Ltd	Plot No 55, ALEAP Industrial Estate, Pragathi Nagar, Hyderabad, Telangana 500090
39	Telangana	Sangareddy	Rees Medilife Pvt Ltd	Plot No: M30, Medical Devices Park, Sultanpur, Patancheruvu, Telangana 502319
40	Telangana	Hydrebad	SVP Techno Engineers Pvt Ltd	H8CC+55C, Hyderabad, Telangana 502319
41	Andhra Pradesh	Visakhapatnam	Nanoshel HealthCare Pvt. Ltd.	Hub B1, Ground Floor, Andhra Pradesh Medtech zone ltd, survey no 480/2, Nadupuru, Pedagantyada, mandal, Andhra Pradesh 530031

42	Andhra Pradesh	Visakhapatnam	Bharat Zeocat	D.No 50 53 11/10/5, Flat No 201, Revathi Vihar Tpt Colony,Near Nri Hospital,Seethammadh Ara, Vishakhapatnam AP 530013
43	Andhra Pradesh	Visakhapatnam	Inkoolu Design Private Limited	7-4-53/1 Amanchivari Street,Anakapalli, Vishakhapatnam AP 531001
44	Gujarat	Lodhika, Rajkot	Mehta Surgicare Pvt Ltd	Amrut Manthan House, opp bharat bakery, Sadar, Rajkot, Gujarat 360001
45	Gujarat	Lodhika, Rajkot	Nebula Orthosys	FF, Office – 3 “NEBULA”, Narmada Park, Soc.3, Amin Marg Main rd, Vidhyakunj Society, Rajkot, Gujarat 360005
46	Gujarat	Lodhika, Rajkot	Nebula Surgical Pvt Ltd	Narmada Park, 3, Main Road, Vidhyakunj Society, Rajkot, Gujarat 360001
47	Gujarat	Lodhika, Rajkot	Neo Surgical	Plot No. G/306, Almighty Gate, Road No. A/6 G.i.d.c. Metoda, Rajkot, Gujarat 360021
48	Gujarat	Lodhika, Rajkot	Sky Surgicals	Plot No. G-1950/2, Almighty Gate, G.I.D.C. Lodhika, Metoda, Gujarat 360021
49	Gujarat	Lodhika, Rajkot	Bombay Ortho India Pvt Ltd	Gate No. 3, G/551, Metoda, G. I. D. C., Lodhika, Kalawad Rd, Rajkot, Gujarat 360021
50	Gujarat	Lodhika, Rajkot	Genius Ortho Pvt Ltd	G-2019, Bh. Kishan Auto Parts,Phase-3, Kishan Gate No.3,G.I.D.C. Metoda,Dist. : Rajkot (Gujarat)
51	Karnataka	Bengaluru	Amaryllis Healthcare Private Limited	273/A, Bommasandra Industrial Area, Bengaluru, Karnataka 560099
52	Karnataka	Bengaluru	SMC Medical	Plot No. 53, Export Promotion

			Manufacturing Pvt Ltd	Industrial Park 4 Smc Medical Manufacturing, 54, Rd Number 4, Vijayanagar, EPIP Zone, Whitefield, Bengaluru, Karnataka 560066
53	Karnataka	Bengaluru	Bentley Healthcare Pvt. Ltd	#515E, 1st Main, 2nd Stage, Vijaynagar (Hampinagar), Bangalore - 560104
54	Karnataka	Bengaluru	Chirag Meditech Private Limited	2234, 9th Main, 'E' Block, Rajajinagar, 2nd Stage, Bangalore - 560 010
55	Karnataka	Bengaluru	Shree Lakshmi Venkateshwara Medical Instruments	12/6, S.M.S. Building, Hosur Rd, Madiwala, Bengaluru, Karnataka 560068
56	Karnataka	Bengaluru	Glastronix	21-E2, Phase II, Peenya Industrial Area, Near FFI, Bengaluru, Karnataka 560058
57	Tamilnadu	Chennai	Kody Medical Electronics Private Limited	Plot No.347, No.9, Kamaraj Nagar 12th E St, Kamaraj Nagar, Thiruvanmiyur, Chennai, Tamil Nadu 600041
58	Tamilnadu	Chennai	nice Neotech Medical Systems Private Limited	85, Krishna Ind. Estate, Porur Gardens Phase II, Krishna Industrial Estate, Porur, Chennai, Tamil Nadu 600095
59	Tamilnadu	Chennai	V. M. Meditech Pvt Ltd	921, 13th Main Rd, Anna Nagar West, Anna Nagar, Chennai, Tamil Nadu 600040
60	Tamilnadu	Chennai	Garuda Med Equipments	16, 23, 2nd Cross St, CIT Nagar West, CIT Nagar, Chennai, Tamil Nadu 600035
61	Tamilnadu	Chennai	Singexmedtech Private Limited	1st Floor, Poonamallee High Rd, Dr. Radhakrishnan Nagar, Arumbakkam, Chennai, Tamil

				Nadu 600106
62	Rajasthan	Jodhpur	Allengers Medical Systems Limited	Ist Floor, Above Saini Mobile Pushpa Niwas, Near Bombay Motor Circle, Jodhpur, Rajasthan 342001
63	Rajasthan	Jodhpur	Medisurge Therapeutics	9-10 Narsing Bhawan OPP. Shiv Mandir, Near gol building, 1st B Rd, Sardarpura, Jodhpur, Rajasthan 342003
64	Rajasthan	Jodhpur	Avtech Medical Systems	72PF+M2P, Govind bhawan in Side Redio Doctor ki pol M.G.H Road, Jodhpur, Rajasthan 342001
65	Rajasthan	Jodhpur	Elbee Medical Devices	71, Khasra No 428, Basni, Jodhpur, Rajasthan 342005
66	Uttar Pradesh	Gautambudh Nagar	Medisys Pvt.ltd. Company	A-113, A Block, Sector 63, Noida, Uttar Pradesh 201301
67	Uttar Pradesh	Gautambudh Nagar	Medico Electrodes Ibnternational Ltd.	12 Noida Special Economic Zone, Plot 142 A/11, Capgemini Rd, Phase-2, Noida, Uttar Pradesh 201305
68	Uttar Pradesh	Gautambudh Nagar	Manward Healthcare Products	K-002, SITE-c, UPSIDA, Surajpur Industrial Area, Greater Noida, Uttar Pradesh 201301
69	Uttar Pradesh	Gautambudh Nagar	Medical Devices India	Plot No. M, 5, Industrial Area, Surajpur Site V, Kasna, Uttar Pradesh 201306
70	Uttar Pradesh	Gautambudh Nagar	Vintage Medical System Pvt. Ltd.	Plot No. 9/10, Girdhapur Road, Chhapraula, Greater Noida, Uttar Pradesh 201009

ANNEXURE-3

SURVEY QUESTIONNAIRES

Government of India
Ministry of Chemicals & Fetilizers
Department of Pharmaceuticals

Survey of Medical Devices Clusters

This survey is being conducted by the Center for Market Research and Social Development as a part of the study to evaluate contribution of Medical Devices Clusters to overall production, supplies and exports, and assess the infrastructure and logistics framework. The data gathered will be used to provide appropriate suggestions to the Department. Your cooperation will help us gain valuable insights and provide recommendations that may benefit the sector in the future.

STATE SCHEDULE

1	**Particulars**		
1.1	State:		
1.2	Name of the Expert:		
1.3	Department:		
1.4	Designation:		
1.5	Address:		
1.6	Phone:	1.7	Mobile:
1.8	Email:		

2	**Medical Device Clusters and Units in the State**										
2.1	Please provide the details of Medical Device Clusters in your state.										
Sl. No.	Location	Number of Units	Name of the Units	Category (Organised/ Unorganised)	Size (Micro/ Small/ Medium/ Big)	No. of Q MS ISO 13485/fifth schedule certified unit	No. of Export Oriented Units	Major products of the units	Production Output of the cluster (in % to the total output of the state)	Details of supplies and exports by the cluster	Whether cluster area / land belongs and allotted by govern-ment

(Use separate Sheet)

4 Business & Government Support

4.1 What are the business services that the medical device industries locally avail in your state?

(Rating Scale: 1-Excellent 2-Very Good 3-Good 4-Satisfactory 5-Bad)

Particulars	Business services availed	Rating
Infrastructure		
Credit		
Marketing		
Technology / quality/ IT		
Specify, if any other……		

4.2 What State Government schemes / assistance/ interventions are available for the medical devices industries in your state?

1.

2.

3.

4.

4.3 What issues and challenges the medical devices industries face in availing these State Government schemes / assistance/ interventions?

4.4 In your opinion, how much these government schemes / assistance/ interventions have helped the medical device industries to boost their efficiency?

1-Significantly 2- Somewhat 3- Not at all

4.5 Please add recommendation or suggestion for improvement of medical device sector at POLICY level.

5	**Suggestions**	
5.1	What are the major gaps in various medical devices clusters in comparison to Role Model Clusters in the country?	
5.2	Suggestions to mitigate the above gaps.	
5.3	Please provide suggestions to boost efficiency of medical device sector at ENTERPRISE level.	
5.4	Please provide suggestions to promote cost competitiveness of medical device sector at ENTERPRISE level.	

Name of the Researcher **Signature** **Date**

Government of India
Ministry of Chemicals & Fetilizers
Department of Pharmaceuticals

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UNIT SCHEDULE

1	Particulars	Code
1.1	State:	
1.2	City:	
1.3	Location/ Address of the Medical Devices Cluster:	
1.4	Number of Medical Devices industries in this Cluster:	

Small	Medium	Big	Total

2	Unit/ Company Particulars		
2.1	Name of the unit/ company:		
2.2	Address of the unit/ company:		
2.3	Phone:	2.4	Mobile:
2.5	Email:		

3	Ownership and Company Details	
3.1	Type of ownership 1- Proprietorship 2- Partnership 3- Private Ltd. 4- Public Ltd. 5- Cooperative society 6- LLP 7- Any other (specify)……..	
3.2	Name of the Proprietor/Managing Director/Managing Partner:	
3.3	Is your unit registered with the Ministry of MSME? 1-Yes 2-No	
3.4	Is your unit registered with DIC? 1-Yes 2-No	
3.5	Are you a member of any Association? 1-Yes 2-No	
3.6	If Yes, please furnish details:	
3.7	Is your unit QMS ISO 13485/fifth schedule certified unit ? 1-Yes 2-No	

3.8	Is your unit an export-oriented unit (EOU)? 1-Yes 2-No	
3.9	Whether unit has Industry Academia linkage? 1-Yes 2-No	
3.10	If yes, specify, Name of Industry, Academia/University of medical device?	

4	**Size of the Unit**	
4.1	What is the average Annual Turn Over of the unit? Rs. in crore_____	
4.2	What is your average Turnover from local, regional markets and exports? (in % terms)	

Local market (in %)	Regional (in %)	Exports (in %)

4.3 Human resource of the firm

No. of Permanent Employees	No. of Temporary Employees	Total No. of Employees

4.4	What is the percentage of skilled manpower to the total human resources of the unit?	%

5	**Assessment of infrastructure & facilities** Rank: Excellent-1 Good-2 Average-3 Poor-4 Not having-5	
5.1	Testing & Prototyping infrastructure	
5.2	Warehousing infrastructure	
5.3	Accreditation labs	
5.4	Research & Development	
5.5	Other facilities	
5.6	Major common facilities and infrastructure that the unit does not have. 1. 2. 3. 4.	

5.7	Problems the unit faces due to lack of above common facilities.	
5.8	Suggestions to boost infrastructure of the unit and how it could help the unit in its business?	

6	**Production & Business**	
6.1	What are the main products of the unit? (Please rank the products 1, 2, 3, ……. on the no. of medical devices)	

1. Electronic Equipment	**2. Implants**	**3. Consumables & Disposables**	**4. In Vitro Diagnostics reagents**	**5. Surgical Instruments**
1. MRI Machines	1. Cardiac Stents	1. Syringes	1. IVD reagents	1.
2. CT Scanners	2. IOL	2. Needles	2. Calibrators	2.
3. X-Ray machines	3. Orthopaedic Implants	3. Catheters	3. IVD kits	3.
				4.

6.2	What are domestic raw materials required for production of medical devices in the cluster? Name of medical devices along with CDSCO classification.	
6.3	What are the raw materials imported for production of medical device in cluster ? if imported, from which custom point .Name of medical device along with CDSCO classification	
6.4	Do you export your products? 1-Yes 2-No	

6.5	If Yes, what are the products do you export? (Please rank the products 1, 2, 3, ……on no. of medical devices)	
6.6	What percentage of your total products do you export?	%

1. Electronic Equipment	**2. Implants**	**3. Consumables & Disposables**	**4. In Vitro Diagnostics reagents**	**5. Surgical Instruments**
1. MRI Machines	1. Cardiac Stents	1. Syringes	1. IVD reagents	1.
2. CT Scanners	2. IOL	2. Needles	2. Calibrators	2.
3. X-Ray machines	3. Orthopaedic Implants	3. Catheters	3. IVD kits	3.
				4.

7	**Government support**	
7.1	What Central Government schemes / assistance/ interventions are available for the industries of your sector? 1. 2. 3. 4.	
7.2	What State Government schemes / assistance/ interventions are available for the industries of your sector? 1. 2. 3. 4.	
7.3	Have you been supported under any Central or State government scheme/ intervention? 1-Yes 2-No	

7.4	If yes, please provide the following details. **Name of the scheme/ assistance/ support** | **Central Govt./ State Govt./ Any other** | **Department / Agency by which you have been supported** 1. | | | 2. | | | 3. | |	
7.5	Please add recommendation or suggestion for improvement of medical devices sector at POLICY level.	

8	**Suggestions**	
8.1	What are the gaps in your cluster in comparison to Role Model Clusters in this sector?	
8.2	Suggestions to mitigate the above gaps.	
8.3	Please provide suggestions to boost efficiency of medical device sector at ENTERPRISE level.	
8.4	Please provide suggestions to promote cost competitiveness of medical device sector at ENTERPRISE level.	

Name of the Researcher **Signature** **Date**

Government of India
Ministry of Chemicals & Fetilizers
Department of Pharmaceuticals

Survey of Medical Devices Clusters

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STAKEHOLDER SCHEDULE

1	**Particulars of the Expert/ Stakeholder/ Association Member**		
1.1	Name of the Stakeholder / Expert/ Association Member:		
1.2	Address:		
1.3	Phone:	1.4	Mobile:
1.5	Email:		
1.6	Years of engagement in this sector		

2	**Assessment of infrastructure & facilities the medical devices units have in the country** Rank: Excellent-1 Good-2 Average-3 Poor-4 Very poor-5	
2.1	Testing & Prototyping infrastructure	
2.2	Warehousing infrastructure	
2.3	Accreditation labs	
2.4	Research & Development	
2.5	Existing Quality management system i.e ISO 13485/fifth schedule in MDR 2017	
2.6	Any other facility	
2.7	Major common facilities and infrastructure that the units lack in this sector 1. 2. 3. 4.	
2.8	Problems the units face due to lack of above common facilities.	
2.9	Suggestions to boost infrastructure of the medical devices units.	

3 Business & Government Support

3.1 What are the business services that the medical device industries locally avail?

(Rating Scale: 1-Excellent 2-Very Good 3-Good 4-Satisfactory 5-Bad)

Particulars	Business services availed	Rating
Infrastructure		
Credit		
Marketing		
Technology / quality/ IT		
Specify, if any other……		

3.2 What Central Government schemes / assistance/ interventions are available for medical devices industries?

1.

2.

3.

4.

3.3 What State Government schemes / assistance/ interventions are available for medical devices industries?

1.

2.

3.

4.

3.4 What issues and challenges the medical devices industries face in availing the schemes / assistance/ interventions?

3.5 In your opinion, how much these government schemes / assistance/ interventions have helped the medical device industries to boost their efficiency?

1-Significantly 2- Somewhat 3- Not at all

3.6 Please add recommendation or suggestion for improvement of medical device sector at POLICY level.

4	**Suggestions**	
4.1	What are the major gaps in various medical devices clusters in comparison to Role Model Clusters in the country?	
4.2	Suggestions to mitigate the above gaps.	
4.3	Please provide suggestions to boost efficiency of medical device sector at ENTERPRISE level.	
4.4	Please provide suggestions to promote cost competitiveness of medical device sector at ENTERPRISE level.	

Name of the Researcher **Signature** **Date**

Government of India
Ministry of Chemicals & Fetilizers
Department of Pharmaceuticals

Survey of Medical Devices Clusters

This survey is being conducted by the Center for Market Research and Social Development as a part of the study to evaluate contribution of Medical Devices Clusters to overall production, supplies and exports, and assess the infrastructure and logistics framework. The data gathered will be used to provide appropriate suggestions to the Department. Your cooperation will help us gain valuable insights and provide recommendations that may benefit the sector in the future.

FGD GUIDELINE / QUESTIONS

<table>
<tr><th>1</th><th>Particulars</th><th>Code</th></tr>
<tr><td>1.1</td><td>State:</td><td></td></tr>
<tr><td>1.2</td><td>City:</td><td></td></tr>
<tr><td>1.3</td><td>Location/ Address of the Medical Devices Cluster:</td><td></td></tr>
<tr><td>1.4</td><td colspan="2">Number of Medical Devices industries in this Cluster:
<table>
<tr><th>Small</th><th>Medium</th><th>Big</th><th>Total</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>1.5</td><td colspan="2">Details of Participants</td></tr>
</table>

2	**Assessment of infrastructure & facilities**
2.1	Testing & Prototyping infrastructure: Warehousing infrastructure: Accreditation labs: Research & Development: Existing Quality management system (QMS) i.e ISO 13485/fifth schedule in MDR 2017 Other facilities:

2.2	What are the major common facilities and infrastructure that the units do not have in this cluster?
2.3	What type of problems the units of this cluster face due to lack of these facilities?
2.4	Suggestions to boost infrastructure and common facilities in this cluster and how it could help the units in their business?

3	**Production & Business**
3.1	What are the main products of the cluster? (Use extra sheet)
3.2	What are domestic raw materials required for production of medical device in the cluster? Name of medical devices along with CDSCO classification.
3.3	What are raw materials imported for production of medical device in cluster ? if so, from which custom point. Name of medical devices along with CDSCO classification.
3.4	What are the products of this cluster being exported?

3.5	What percentage of total products of this cluster are being exported?

4	**Government support**	
4.1	What Central Government schemes / assistance/ interventions are available for the industries of your sector? 1. 2. 3. 4.	
4.2	What State Government schemes / assistance/ interventions are available for the industries of your sector? 1. 2. 3. 4.	
4.3	Central or State government scheme/ intervention under which the industries of this cluster are benefitted and how?	
4.4	In the recent past, is there any change(s) in policy framework for the growth of this sector?	
4.5	Suggestions for improvement of medical devices sector at POLICY level.	

5	**SWOT Analysis of the Cluster**
	Strength, Weakness, Opportunities and Threats of the industries of this cluster today Strength: Weakness: Opportunities: Threats:

6	**Suggestions**	
6.1	What are the gaps in your cluster in comparison to Role Model Clusters in this sector?	
6.2	Suggestions to mitigate the above gaps.	
6.3	Suggestions to boost efficiency of medical device sector at ENTERPRISE level.	
6.4	Suggestions to promote cost competitiveness of medical device sector at ENTERPRISE level.	

Name of the Researcher **Signature** **Date**