REPORT NO.

138

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

ONE HUNDRED THIRTY EIGHTH REPORT

ON

"MEDICAL DEVICES: REGULATION & CONTROL"
PERTAINING TO
DEPARTMENT OF HEALTH &FAMILY WELFARE

(Presented to the Chairman, Rajya Sabha on 12th September, 2022)
(Forwarded to the Speaker, Lok Sabha on 12th September, 2022)

(Presented to the Rajya Sabha on 8th December, 2022)
(Laid on the Table of Lok Sabha on 8th December, 2022)

Rajya Sabha Secretariat, New Delhi
September, 2022/Asvina, 1944 (SAKA)

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CONTENTS

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(2021-22)

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RAJYA SABHA

1. Dr. Anil Agrawal
2. Dr. L. Hanumanthaiah
3. *Vacant*
4. *Vacant*
5. Dr. Santanu Sen
6. Shri A. D. Singh
7. Dr. Kanimozhi NVN Somu
8. *Vacant*
9. *Vacant*

LOK SABHA

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28. Dr. Mahesh Sharma
29. Dr. Krishna Pal Singh Yadav
30. Dr. Lorho S. Pfoze

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1. Shri Mahesh Tiwari — Joint Secretary
2. Shri Shashi Bhushan — Director
3. Shri Bhupendra Bhaskar — Additional Director
4. Shri Praveen Kumar — Deputy Secretary
5. Shrimati Harshita Shankar — Deputy Secretary
6. Shri Rajesh Kumar Sharma — Assistant Committee Officer
7. Ms. Monika Garbyal — Assistant Committee Officer

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this One-Hundred Thirty Eighth Report on the Medical Devices: Regulation and Control.

2. The primary objective behind identifying the subject – "Medical Devices: Regulation and Control" by the Committee is to assess recent developments in the medical device industry, the regulatory structure, measures which can be taken to improve the manufacturing scenario in the country, steps needed to improve promotion and production of medical devices in the country.

3. The Committee took the subject "Medical Devices: Regulation and Control" on 14th December, 2016 and held first meeting on the subject on 28th December, 2016 by hearing the views of the Ministry of Health and Family Welfare. The consideration remained inconclusive due to other impending works with the Committee. In the meanwhile the Ministry of Health & Family Welfare notified the Medical Device Rules, 2017 under the provisions of the Drugs and Cosmetics Act, 1940. The Committee decided to issue a Press Release on the subject in January 2018 to elicit feedback from the concerned stakeholders and general public. In response thereto, 24 memoranda were received. The Committee continued actively deliberating on the subject post-covid, to understand the recent developments on the subject and the immense importance of the medical devices industry in the recent times. The Committee again heard the views of Department of Health and Family Welfare on 1st December, 2021. Following this, during the course of its deliberations on the subject, the Committee held several meetings with other Government Departments, private organizations, industry bodies like FICCI, CII and also sought written view of various stakeholders. Accordingly, the Committee, deliberated on the subject during the course of 5 meetings. The meetings of the Committee were held on 1, December, 2021, 12th, 13th and 30th May, 2022.

4. During the finalization of its Report, the Committee relied upon the following documents/ papers:-

(i) Background Note on "Medical Devices: Regulation and Control" received from Department of Health and Family Welfare;

(ii) Background Note on "Medical Devices: Regulation and Control" received from Department of Pharmaceuticals;

(iii) Oral Evidences tendered by Secretaries, Department of Health and Family Welfare and Department of Pharmaceuticals;

(iv) Oral evidences tendered by stakeholders and their written submissions;

(v) Written submissions of various Organizations/Associations;

(vi) Response of the Department of Health and Family Welfare on the issues raised in memoranda received by the Committee;

(vii) Replies to the questionnaires received from the Department of Health and Family Welfare;

(viii) Written submissions of various State Governments; and

(ix) Other relevant documents pertaining to the subject.

5. The Report is divided into four chapters, viz: - (i) Chapter 1 deals with introduction to the subject, definition and classification of Medical Devices in India, (ii) Chapter 2 focuses on regulation on medical devices industry and quality control measures (iii) Chapter 3 deals with manufacturing, promotion, production and pricing and (iv) Chapter 4 enlists the views of Ministry and other stakeholders.

6. The Committee, in its meeting held on 8th August, 2022, considered the draft Report and adopted the same.

7. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report and also reproduced at the end of the Report at 'Observations/Recommendations -at a Glance' .

8. On behalf of the Committee and on my own behalf, I extend special thanks to Secretaries and officers of the (i) Department of Health and Family Welfare (ii) Department of Pharmaceuticals for their useful inputs on the subject. I also acknowledge the contribution of the stakeholders for their deep insight and useful suggestions during the course of interactions. I further extend special appreciation to the officers of the Committee Section for their useful efforts in assimilating all relevant information and enabling the Committee in producing this quality Report.

New Delhi
8th August, 2022
Sravana , 1944 (Saka)

PROF. RAM GOPAL YADAV
Chairman, Department-related
Parliamentary Standing Committee on
Health and Family Welfare

ACRONYMS

ABDM	Ayushman Bharat Digital Mission
AMTZ	Andhra Pradesh Medtech Zone Ltd.
ASSOCHAM	Associated Chambers of Commerce and Industry of India
AERB	Atomic Energy Regulatory Board
ASTM	American Society for Testing and Materials
AIMeD	Association of Indian Medical Device Industry
AIIMS	All India Institute of Medical Sciences
ADMI	Association of Diagnostics Manufacturers of India
BIS	Bureau of Indian Standards
BCD	Basic Customs Duty
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organisation
CII	Confederation of Indian Industry
CSIR	Council of Scientific and Industrial Research
D&CA	Drugs and Cosmetics Act
DCGI	Drugs Controller General of India
DPR	Detailed Project Reports
DRPSC	Department Related Parliamentary Standing Committee
DoP	Department of Pharmaceuticals
DPIIT	Department for Promotion of Industry and Internal Trade
DPCO	Drugs (Prices Control) Order
DRDO	Defense Research and Development Organisation
ETP	Effluent Treatment Plant
EPC	Export Promotion Council
FDI	Foreign Direct Investment
FICCI	Federation of Indian Chambers of Commerce and Industry
GST	Goods and Services Tax
ICMED	Indian Certification of Medical Devices
ICMR	Indian Council of Medical Research
IEC	International Electrotechemical Commission
IISC	Indian Institute of Science
IIT	Indian Institute of Technology
ISO	International Standards Organisation
IVD	In-vitro Diagnostics
INI	Institutes of National Importance
MoH&FW	Ministry of Health and Family Welfare
MTAI	Medical Technology Association of India
MvPI	Materiovigilance Programme of India
MDR	Medical Device Rules
MoCA	Ministry of Consumer Affairs
MoEF&CC	Ministry of Environment, Forest and Climate Change
MNC	Multi National Company

NABL	National Accreditation Board for Testing and Calibration Laboratories
NABCB	National Accreditation Board for Certification Bodies
NIPER	National Institute of Pharmaceutical Education and Research
NITI	National Institution for Transforming India
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
PLI	Production Linked Incentive
QCBS	Quality-cum-Cost Based Selection
QCI	Quality Council of India
RCVRDL	Resource Centre for Virus Research; Diagnostic Laboratories
RDTL	Regional Drugs Testing Laboratory
R&D	Research and Development
SAD	Special Additional Duty
SLA	State Licensing Authorities
SIA	State Implementing Agency
SME	Small and Medium Enterprises
SSC	Scheme Steering Committee
TMR	Trade Margin Rationalisation
US-FDA	United States- Food and Drug Administration
WHO-GMP	World Health Organisation- Good Manufacturing Practices

CHAPTER - I

INTRODUCTION

1.1 Vaccines, drugs and medical devices are the three vital pillars of the modern healthcare industry. Like vaccines and drugs, medical devices play a key role in screening, monitoring, diagnosing, treating patients and also in restoring patients to normal lives. With technological advancements in recent decades, medical devices have become an essential and integral constituent of the healthcare sector and proved fundamental in providing quality health care across each stage of the healthcare continuum. In India, the Medical Devices sector forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry. Owing to the recent spurt in demand, improvements in regulation and government support, the Indian Medical Device industry is on a high growth trajectory having evolved significantly in the last decade.

1.2 High-end technology and innovative products originate from a well-developed eco-system and innovation cycle, which is yet to be fully developed in India. In 2014, taking note of the need to address these issues, "Medical Device Industry" has been recognized as a key industry under the 'Make in India' initiative and accorded the status of "Sunshine Sector" of 'Make in India' initiative.

A. Medical Devices: Definition and Classification

1.3 The Ministry of Health and Family Welfare submitted to the Committee that presently the medical devices are regulated as "drugs" under Drugs and Cosmetics Act, 1940. To have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Ministry notified Medical Device Rules, 2017 under the provisions of the Drugs and Cosmetics Act, 1940. As per the Medical Device Rules 2017 notified by Ministry of Health and Family Welfare and effective from 1st January, 2018, "Medical Device" means:-

a) *substances used for in-vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i)(of Drugs and Cosmetics Act, 1940),*
b) *substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii) (of Drugs and Cosmetics Act, 1940),*
c) *Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act.*

1.4 On 11th February, 2020, the Ministry of Health and Family Welfare issued a notification giving a new definition of medical devices, the new definition is:-

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

a) *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*
b) *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
c) *investigation, replacement or modification or support of the anatomy or of a physiological process;*
d) *supporting or sustaining life;*
e) *disinfection of medical devices; and*
f) *Control of conception.*

1.5 Medical Devices Rules, 2017 has introduced risk based classification of medical devices. The classification of medical devices is as follows:-

Risk Criteria	**Risk Class**
Low	Class A
Low Moderate	Class B
Moderate High	Class C
High Risk	Class D

1.6 Under the said rules, import of all classes of Medical Devices as well as manufacturing of Class C & D Medical Devices are regulated by CDSCO(Central Drugs Standard Control Organisation), while manufacturing of Class A & B Medical devices is regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments. However, sale and distribution of all classes of Medical Devices are regulated by the SLAs.

1.7 In India the Medical devices are segregated into five major segments:

- Consumables & Disposables which includes needles and syringes, etc
- Diagnostic Imaging which includes MRI, X-Ray, Ultrasounds, etc
- Dental Products which includes dentures, braces, etc
- Orthopaedics & Prosthetics which includes knee implants, artificial joints
- Patient Aids which includes hearing aids and pacemakers, etc

1.8 The medical devices industry in India is mainly governed by Ministry of Health and Family Welfare (through CDSCO) for regulatory framework and Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers) for promotion, production and manufacturing. For other

aspects of the industry like pricing, availability of raw materials, standardization, consumer affairs etc, following government bodies/departments also regulate the industry:-

- National Pharmaceutical Pricing Authority- for pricing control;
- Ministry of Environment, Forest and Climate Change- for environment clearances;
- Department of Telecommunications;
- Department of Consumer Affairs - for labeling requirements;
- Department of Revenue- for taxation and other related issues;
- Department of Heavy Industries - for establishment of industries and factories;
- Department of Animal husbandry- for raw materials like proteins;
- Department for Promotion of Industry and Internal Trade;
- Bureau of Indian Standards- for standardization of devices;
- Quality Council of India- for quality aspects; and
- Atomic Energy Regulatory Board.

B. Market Scenario of Medical Devices in the Country

1.9 Over the last decades, India has become a global leader in development of pharmaceuticals and biotechnology so much so that the country is now known as the "Pharmacy" of the world. The recent Covid-19 pandemic saw India's pharma and biotech prowess as it developed and manufactured two vaccines (Covaxin and Covishield with former being indigenously developed and manufactured) at large scale for the local population and promoted vaccine diplomacy by exporting the vaccines to different countries under the "Vaccine Maitri" initiative. However, the same cannot be said about medical device industry in the country.

1.10 The current market size of the medical devices sector in India is estimated to be USD 11 billion and its share in the global medical device market is estimated to be 1.5%. India is the 4th largest market for medical devices in Asia after Japan, China and South Korea and is amongst the top 20 markets in the world. Today, the medical devices industry in India consists of large multinational companies as well as small and medium enterprises (SMEs) growing at an unprecedented scale. The medical device sector has been growing steadily at a CAGR (Compounded Annual Growth Rate) of 15% over the last 3 years. Now with 100% FDI (Foreign Direct Investment) being allowed under the automatic route for both Brownfield and Greenfield setups, the medical device sector is expected to grow at higher rate.

1.11 Medical Devices industry has a lot of potential in India. In the recent years the medical device industry has grown tremendously but still remains under-penetrated with a large gap between demand and supply. Almost 80% (by value) of the domestic requirements are met by imports. In India disposables and consumables make up the major portion of products manufactured, therefore, to meet the medical devices' needs of the population, expensive medical devices are imported.

C. Impact of Covid-19 on the Medical Device Industry

1.12 The Committee observes that Covid-19 pandemic wrecked havoc on the world for almost two years and still lingers as a looming threat. The pandemic caused great human and financial loss and severely affected almost all the sectors of the economy. The Healthcare system of India like of other countries was put to severe test and the healthcare resources were stretched to their limits. Like other segments of the healthcare system, the Medical devices industry had to work overtime to meet the surge in demands of medical equipments and devices. During the first wave of pandemic, owing to its sudden nature, the country faced severe shortages of medical equipments like testing kits, PPE (Personal Protective Equipment) kits, masks, sanitisers, and other related critical items as domestic and international supply chains got disrupted leading to almost stoppage of imports. The situation was compounded by poor domestic manufacturing capacity.

1.13 The Committee further notes that amidst the prevailing pandemic situation the domestic manufactures saw opportunity in adversity and ramped up their production capacities to meet the sudden surge in the demand of medical equipments like PPE Kits, masks, sanitisers etc. The Government supported the local manufactures and start-ups were provided/extended soft loans and other incentives. The assured procurement and predictable demand encouraged Indian manufacturers to step forward and serve the country in crisis. Within months of the Covid-19 pandemic India went from importing PPE kits, masks, testing kits to not only self-reliant but the country also exported these devices to other countries. However, the current situation is that India still remains largely an import dependent nation w.r.t medical devices, but the very least the pandemic has done to the industry is that it has brought the industry to the limelight and gradually with government attending to the industry with improvements in regulation, manufacturing facilities, incentives, India in all probability would be a major player in global medical devices industry.

1.14 The Department Related Parliamentary Standing Committee on Health and Family Welfare (DRPSC-H&FW) has taken up the subject - "Medical Devices: Regulatory and Control" to address range of issues plaguing the industry today *viz*. existing regulatory framework, manufacturing, promotion, quality and pricing aspects, standardisation of devices, availability of raw materials etc. The Committee's objective in undertaking this subject for study is to recommend the Government to make concerted efforts for transforming India as a "self-reliant" country in Medical Device sector and thus provide a competitive edge to the sector so as to increase the market share, thereby making India a major exporter of medical devices and their spare parts in the global market as also to make it a Medical Devices Repairs Hub for the world.

CHAPTER- II

REGULATORY FRAMEWORK: STANDARDS & QUALITY CONTROL

2.1 In India, prior to notification of Medical Device Rules in 2017 there were no specific medical device regulations and devices were regulated under the Drugs and Cosmetics Act, 1940. The definition of "drugs" under the Drugs and Cosmetics Act, 1940 (D&CA, 1940) was amended in November, 1982 to include such medical devices as may be notified by the Government from time-to-time. Post notification these devices would then be governed by the DCA's regulatory framework. Interestingly, to this day, to be recognised as a medical device, a device must first be notified as a "drug" under DCA and thereafter be governed by the regulatory framework meant for drugs. In 2005 the Health Ministry notified the requirements and guidelines to be followed for obtaining permission to import or manufacture new drugs and for conducting clinical trial. In the same year the Ministry of Health & Family Welfare notified 10 sterile devices: Cardiac Stents; Drug-Eluting Stents; Catheters; Intra Ocular Lenses; I.V. Cannulae; Bone Cement; Heart Valves; Scalp Vein Set; Orthopaedic Implants; Internal Prosthetic replacements. Thus till 2005, only 12 medical devices in India were recognised. In January, 2017, the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare notified the Medical Device Rules, 2017 (MDR, 2017). In 2020, the Ministry expanded the definition of "drugs" in Section 3(b), the new definition covered almost all the medical devices including softwares, digital wearables etc.

A. Medical Device Rules, 2017

2.2 In India the primary legislation regulating manufacturing, authorization, import, export and sale of medical devices is the Medical Device Rules, 2017 (MDR-2017). The Medical Device Rules are a set of rules framed under the Drugs and Cosmetics Act, 1940 (D&C Act). The D&C Act (including the MDR) is enforced by the CDSCO at the central level and the SLAs at the state level. In 2020, the Ministry expanded the definition of "Medical Devices" which almost brings all medical devices under the ambit of regulation.

2.3 Responding to a query, whether MoH&FW/CDSCO is in the process of bringing separate law for regulation of Medical Devices in the country, the Ministry submitted that it intends to bring Drugs, Medical Devices and Cosmetics Bill which will contain separate provisions for Medical Devices. A committee has been constituted to draft the new Drugs, Medical Devices and Cosmetics Bill. It further submitted that appropriate action will be taken after review of the draft bill. The bill is meant for regulation of Drugs, Medical Devices and Cosmetics with separate provisions for Medical Devices. Currently all Medical Devices, be it an implant or an MRI machine are classified as “drugs” under the Drugs and Cosmetics Act, 1940.

2.4 Medical Technology Association of India (MTaI) in its Memorandum to the Committee submitted that – Drugs, which are chemical entities, are drastically different from Medical Devices which are technology solutions for diagnosis and treatment for various diseases. The technology is so varied that it can be radiation based technology or and electronic based technology. Unlike Pharmaceutical products, the product life cycle of some of the Medical

Devices is very short. Based on the scientific and technical parameters, there is a need for a separate Medical Device Act for regulation of medical devices.

2.5 In reply to this submission by MTaI, the MoH&FW apprised the Committee that Medical Device Rules (MDR) 2017 under the Drugs and Cosmetics Act, 1940 includes comprehensive regulatory provisions to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the notified medical devices in the country as per risk based classification. These rules have already been implemented from 01, January 2018. Prior to grant of Import or Manufacturing licence along with schedule V compliance various quality, effectiveness, performance parameters are checked and inspected thoroughly as per requirements of Medical Device Rules, 2017. Further, for import or manufacture of medical device which does not have predicate device (Investigational New Medical Devices), the permission is granted after completion of clinical investigation i.e. trial on human being for proving safety, effectiveness and performance.

2.6 The Central Licensing Authority (CDSCO) issue the permission to initiate/ conduct a clinical investigation including pilot or pivotal clinical study, after evaluation of preclinical data which include biocompatibility data and animal trials data. The data generated during clinical investigation is evaluated by CDSCO in consultation with the Subject Expert Committee in the relevant therapeutic areas and if the data is found satisfactory to prove that the device is safe, effective and performs as per intended use, the authority shall grant the permission to manufacture or import the Investigational Medical Devices. Subsequent to approval of a new Medical Device (Investigational Medical Device), the applicant is required to closely monitor the device for their clinical safety. The applicant is required to submit Periodic Safety Update Reports (PSURs) to CDSCO. Globally medical devices are regulated by the Drug and Device Regulatory Authority under the Health ministry. During the meeting of Secretaries held in NITI Aayog on 03.07.2018 there was no consensus on separate legislation on medical devices. Therefore, Government preferred to continue the same as it related to patient safety.

2.7 The Committee notes that Drugs and Cosmetics Act lacks offences and penalties for malpractices like manufacturing of sub-standard devices, fake USFDA/CE certifications. The D&C Act does contain a penal provision for the manufacture of sub-standard drugs but does not penalize the manufacturers of sub standard medical devices (although medical devices are legally defined in terms of drugs) because the legally binding standards which are recognised in the Act pertain only to drugs. Therefore, due to lack of penal provisions for Medical Devices in the said Act, the manufacturers of sub-standard medical devices move scot free. The scope of Medical Devices Rules, 2017 is restricted to only those medical devices which are notified by the Government from time to time as 'drugs'. The Committee appreciates the initiatives of the Ministry to change the definition of Medical Devices in 2020 to make it more inclusive and thus include almost all medical devices for regulation. However, the Committee feels that the definition of "Medical Devices" be such that any product which falls under the definition is automatically eligible for regulation.

2.8 The Committee notes that in the recent years the Medical Devices has become a vast industry. Improvements in economy, life-expectancy, rise in income levels and overall rise in awareness about health coupled with surge in communicable and non-communicable

diseases have been some of the key drivers behind growth of the industry. This has necessitated better regulation and control of the industry. The Committee believes that there is a need for a well-researched, organised and inclusive legal architecture for regulating activities of manufacturing units, medical institutions, laboratories, clinical trials having well defined responsibility, roles and accountability for all the stakeholders of the industry.

2.9 The Committee, while welcoming, the initiative of the Ministry to set up a panel to make the new Drugs, Medical Devices and Cosmetics Bill with separate provisions for Medical Devices strongly recommends that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should appreciate the potential of the Medical Device industry and formulate a separate legilsation for Medical Devices.

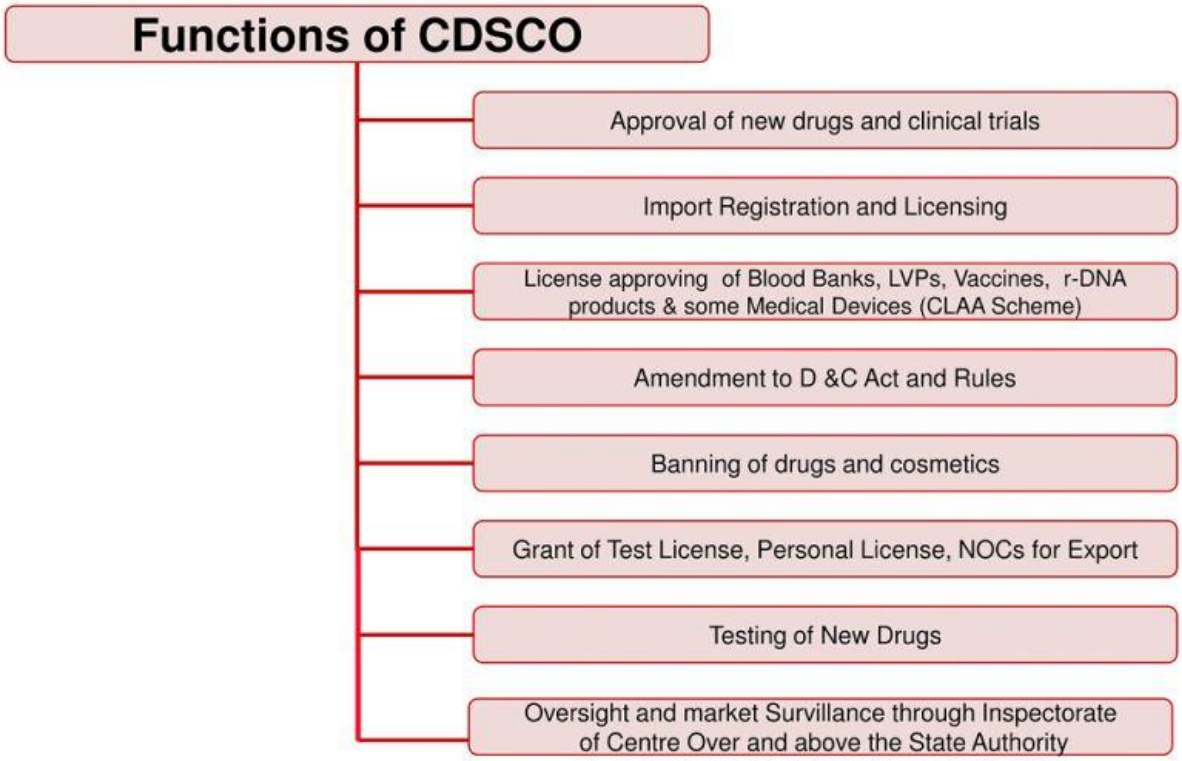
2.10 The Committee believes that the new legislation on Medical Devices should have the provisions to transform the medical devices industry and bring about a Medical Device Revolution in the country. The Committee further recommends that instead of the panel the Government should come up with a 'National Commission on Medical Devices' to examine all aspects of the Industry in detail and bring forth a comprehensive law supported by a holistic policy and institutional infrastructure for the purpose. The Committee further recommends that this Commission should study the aspect of centralizing the Medical Device licensing with the Central regulator so as to make the approval process easy. The Ministry should also focus on guaranteeing transparency by designing this legislation so that the citizens/ experts get a right to participate in decision making. The legal provisions should be such that citizens/experts can participate in the regulatory process & register their objections. The blueprint for the new legislation must also include a 10-15 year roadmap with a clear policy plan & targets. The Committee strongly believes that with a 15 year roadmap with annual targets for the Medical Device industry, India would emerge as the world's biggest centre for manufacture & service of Medical Devices and thus also a leader in medical tourism.

B. Central Drugs Standard Control Organization (CDSCO)

2.11 The Central Drugs Standard Control Organization (CDSCO) comes under the Ministry of Health and Family Welfare (MoH&FW) as the national regulating authority for medical devices and pharmaceuticals in India. The CDSCO works to regulate and monitor the health standards of pharmaceuticals and medical devices, specifically their safety, efficacy, and quality levels. The standards to which devices are held are outlined under the Drugs and Cosmetics (D&C) Act, 1940 Act. The Central Drugs Standard Control Organization (CDSCO) headed by the Drugs Controller General of India (DCGI) is primarily responsible for coordinating the activities of the State Drugs Licensing Authorities (SLAs), formulating policies, and ensuring uniform implementation of the DCA and MDR throughout India.

2.12 As per the information submitted by the Ministry of Health and Family Welfare, the import of all classes of Medical Devices as well as manufacture of Class C &D Medical Devices are regulated by CDSCO, while manufacture of Class A & B Medical Devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments. However, sale and distribution of all classes of Medical Devices are regulated by the SLAs. In case of new Medical Devices, the safety, efficacy and performance data are evaluated by CDSCO in

consultation with the Subject Expert Committee in the relevant therapeutic areas. According to the website of the CDSCO, the functions of CDSCO are:-



2.13 The Committee observes that the functions of CDSCO primarily focus on the regulation of drugs as the regulatory body was originally set up to regulate Pharma and other related segments. The MDR 2017 mandated the CDSCO to regulate the Medical Devices segment as well. However, the existing structure and expertise (which is more pharma centric) of the workforce in CDSCO is falling short in effectively regulating the medical devices industry.

2.14 The Committee recommends that the new legislation should set up a new set of regulator at different levels for regulating the Medical Devices industry. Unlike the present structure, the proposed regulator should license the manufacturing of all classes of medical devices i.e. Class A, B, C, and D. This would help harmonise the regulation process throughout the country as it would do away with different regulating procedures employed by different States. This step would greatly help the manufacturers and will reduce the time required to start a manufacturing unit thereby facilitating ease of doing business. The Committee also recommends that to undertake the regulation for all Classes of medical devices throughout the country, the proposed regulator should be adequately staffed with workforce which is technically skilled and is well-versed with the functioning of medical devices industry. The Committee recommends the Ministry to work in synergy with State Governments and impart the necessary skills to the local medical device officers and also devise a mechanism to regularly designate State Medical personnel as Medical Device/ Medical Device Testing Officers so that the mandate of the legislation can be implemented effectively. The Committee believes that with industry growing by leaps & bounds, the

government should not afford regulation of medical devices by pharma experts and its time that at ground level the medical device regulations are dispensed with by qualified and well-trained Medical Device Officers to give a fillip to the Medical Device industry in the country.

2.15 The Committee recommends the Ministry of Health and Family Welfare to allow the new regulator to involve institutions like IISC, CSIR, DRDO and network of IITs to test medical devices for safety and efficacy. The Committee is of the firm view that these institutes have high-tech labs and thus can be used to test medical devices for their electronic, electromagnetic, biochemical-run aspects. The Committee further recommends that additional investments should be made to raise the standards of these labs as per the requirements.

2.16 Presently, in India primarily the following regulatory authorities have jurisdiction over medical devices in India: -

- The Central Drugs Standard Control Organisation (CDSCO)
- State Drug Licensing Authorities (also referred to as the state licensing authorities or SLAs).
- National Pharmaceutical Pricing Authority (NPPA).
- Department of Pharmaceuticals (DoP)

2.17 Apart from the above-mentioned bodies, for different aspects, the medical devices industry is also regulated by bodies like Ministry of Environment, Forest and Climate Change (MoEF&CC), Atomic Energy Regulatory Board (AERB), Bureau of Indian Standards (BIS), Ministry of Consumer Affairs (MoCA) etc.

2.18 The Committee notes that multiplicity of regulations exists at the component level from different departments/ ministries. The Committee recommends that CDSCO which operates a single window clearing platform for application of license for manufacturing, export, import shall also integrate all these bodies involved in the regulation of medical devices. A single window clearance for all the department/ ministries would significantly boost investment in R&D in the field of medical devices and would also reduce the time required for obtaining approvals from different departments/ ministries. The Ministry must incorporate such an all-encompassing "single window clearing/approval system" in the proposed new separate Act for the regulation of Medical Devices.

2.19 The Orthopaedic Implant Manufacturers Association in its submission apprised the Committee that all products standards are not yet available. The association further stated that most of raw materials and testing standard in world are based on ASTM (American Society for Testing and Materials) standard. Hence, ISO and another International standard like ASTM should be allowed to be used.

2.20 Replying to a query regarding standards of Medical Devices in the country the Ministry of Health and Family Welfare submitted to the Committee that as per the Rule 7 of Medical Devices Rules, 2017, the medical devices shall conform to the standards laid down by the Bureau of Indian Standards (BIS) – India's national standards body – or those notified by Ministry of Health and Family Welfare. In the absence of such standards, the device should conform to standards laid down by the International Standards Organisation ("ISO") or the

International Electrotechemical Commission ("IEC"). If ISO or IEC standards are also not available, the device may conform to the validated manufacturer's standards.

2.21 The Committee opines that while setting the standards and benchmark of medical devices the foremost factor which should be considered is "health", the standards devised must prioritise health and wellness. In this regard, the Committee believes that BIS should focus on harmonising the Indian standards with world-class and globally accepted quality standards. Adapting Indian standards as per global standards would also help Indian medical device manufacturers in global market as it would make them more competitive and acceptable, which in turn would transform India into a net exporter of medical devices, spare parts and services. The Committee, therefore, recommends BIS to periodically update Indian Standards to corresponding global medical device standards as complying with Indian standards is affordable for local manufactures in comparison to global standards.

2.22 The Committee further recommends that BIS should encourage manufacturers to demonstrate/adhere to conformance to essential principles of the medical device concerned, as this would reorganise Indian products achieve greater international acceptance. This will engineer a shift towards increase in India's global share in the medical devices sector.

2.23 Replying to the issue of quality standards and the number of Medical Device testing laboratories established so far, the Ministry in its written reply has informed that the Government has designated the following 5 Medical Device Testing Laboratories so far:

- The National Institute of Biologicals, Noida.
- The Central Drugs Testing laboratory, Chennai.
- The Central Drugs Laboratory, Kolkata
- The Regional Drugs Testing Laboratory (RDTL), Guwahati
- The Central Drugs Testing Laboratory, Mumbai

2.24 The Ministry further informed that the laboratories having NABL certifications which were willing to function for performance evaluation or testing of medical devices would be designated across the country under Medical Device Rules 2017, which will also take care of regional parity. In addition, to carry out Test or Evaluation of a medical device on behalf of manufacturer, CDSCO may issue Certificate of registration to Medical Device testing Laboratory in Form MD-40 under Medical Devices Rules, 2017.

2.25 As per the submission by the Government of National Capital Territory of Delhi, as on 10.12.2021, a total number of 18 certified Medical Device Testing Laboratories have been approved by CDSCO, Govt. of India under the provision of Medical Devices Rules, 2017 across the country to carry out test or evaluation of Medical Devices on behalf of Manufacturers.

2.26 The state of Kerala in its submission to the Committee pointed out that manufacturers have to send their medical devices to Tamil Nadu and Karnataka for conducting Biocompatibility Tests as per ISO 10993 standards. Manufacturers of electrically operated devices including the operation theatre tables, OT lights etc. need to send those products to Maharashtra or Delhi for IEC Testing. Similarly, there is lack of sterilization centres in the State.

2.27 The Committee notes that the country has only 18 certified Medical Device Testing Laboratories that have been approved by CDSCO and that is grossly insufficient keeping

in view the size of the country. The Committee is of the considered opinion that having adequate common infrastructure including accredited laboratories in different regions of the country for standard testing would significantly encourage local manufacturers to get their products tested for standards and such measures undertaken would also help in reducing the cost of production which ultimately will improve the availability and affordability of medical devices in the domestic market.

2.28 The Committee finds that there is a dire need for developing a robust IT enabled feedback driven post market surveillance system for Medical Devices to evaluate the efficiency of specific Medical Devices. A medical device registry, particularly for implants should also be made to ensure traceability of patient who has received the implant in order to assess the performance of the implant and ascertain upto what extent the implant has made the life of the patient comfortable and also to seek feedback of functional capacity of medical devices. Such measures would ensure that patients get access to good quality and approved medical devices.

C. Quality Control

2.29 Quality Council of India (QCI) was established as a National body for Accreditation through a Cabinet decision in 1996. Accordingly, QCI was set up through a PPP model as an independent autonomous organization with the support of Government of India and the Indian Industry represented by the three premier industry associations, (i) Associated Chambers of Commerce and Industry of India (ASSOCHAM), (ii) Confederation of Indian Industry (CII) and (iii) Federation of Indian Chambers of Commerce and Industry (FICCI). QCI is a non-profit organization registered under the Societies Registration Act XXI of 1860. The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry was designated as the nodal point for all matters connected with quality and QCI.

2.30 QCI has been established to create a mechanism for independent third-party assessment of products, services and processes. It plays a pivotal role at the national level in propagating, adoption and adherence to quality standards in all important spheres of activities including education, healthcare, environment protection, governance, social sectors, infrastructure sector and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.

2.31 The Quality Council of India, in its submission, apprised the Committee that globally, the international standard ISO 13485:2016 is used by the regulators, industry, accreditation & conformity bodies to ensure that medical device manufacturers have implemented quality management systems and they consistently met customer and applicable regulatory requirements. In India too, the relevant stakeholders such as CDSCO/ DCGI (Drugs Controller General of India) -the regulator, NABCB- the Accreditation Body, the Medical Devices Industry and the Certification Bodies apply this standard for ensuring quality systems in the medical devices sector, apart from product-specific standards. In line with the international best practices, the Medical Device Rules, 2017 prescribes NABCB accreditation for certification bodies for performing audits of medical devices manufacturers and NABL accreditation for testing laboratories for testing of medical devices.

2.32 Various international certifications for medical devices such as CE Mark, US FDA approval etc are being recognized and accepted by CDSCO/DCGI while registration and

granting approvals to medical devices manufacturers for selling their medical devices in the Indian market. However, the reciprocal treatment may not be available in foreign countries for the medical devices manufactured in India. The buyers of medical devices in India, especially in the private sector, many a times prescribe international certifications while procuring medical devices instead of relying on Indian standards and certifications. In 2021, the Ministry of Commerce and Industry announced the launch of the "Indian Certification of Medical Devices (ICMED-13485) Plus" voluntary certification scheme established by QCI with AIMED (Association of Indian Medical Device Industry). This is the first scheme around the world wherein quality management and product certification standards were integrated with regulatory requirements. ICMED-13485 along with the compliance requirements mentioned in ISO-13485 has additional essential and regulatory requirements.

2.33 The Committee is of the considered view that quality and affordability are two vital factors regarding medical devices. Indian Medical Devices Industry presently lacks research ecosystem and infrastructure for manufacturing of high tech, advanced medical devices (Class C&D) and Indian Medical Devices Industry doesn't have facilities to produce such medical devices comparable to global standards. Here, the Committee appreciates QCI for filling up the vacuum in quality certification space by extending the option of Indian Certification of Medical Devices (ICMED) 13485. The Committee believes that QCI can play a pivotal role in establishing norms of quality and ensuring that Indian manufactured products have competitive product advantage, *vis-à-vis*, the international standards in terms of quality. The Committee, therefore, recommends the Ministry to introduce standards and certification process (particularly for Class C&D products) comparable to global standards. The Ministry, along with compulsory compliance to Quality Management System as per schedule 5 of the MDR, 2017, should also allow cognizance to 3rd party assurance schemes like ICMED 13485.

2.34 In response to the query of mandatory requirement of USFDA, CE or other international certification, the Ministry has stated that since, Medical devices rules has already specified procedure to grant a licence for manufacture or import or sale of medical devices therefore further need of any certification process may not be required. Further BIS has stated that where India Standards are not available, gap analysis is under progress with the procurement agencies of Government of India, for formulation of Indian Standards as per norms.

2.35 Further, regarding the measures being taken to ensure certification of all medical devices under BIS, the Ministry has informed that BIS are having specifications for various medical devices and medical equipments and some of the commonly used devices like MRI, PET, Ultrasound, Dialysis Machines are presently not covered under the BIS. The BIS has been requested vide letter dated 01.03.2018 and 26.04.2018 by CDSCO to develop standards for all medical devices and medical equipments for which ISO standards are already available and list of commonly used equipments was also forwarded.

2.36 The Committee further recommends that till such time the Indian Medical Device Industry come up with comparable standards and certification process, the Ministry should extend financial support to the local manufacturers in capacity building for compliance to USFDA/CE regulations considering that USFDA and CE certification processes are costly affairs. The Government support would facilitate local manufacturers to gain access to US and European markets thereby boosting exports.

CHAPTER- III

MANUFACTURING, PRODUCTION, PROMOTION& PRICING

3.1 Department of Pharmaceuticals, in its submission, to the Committee highlighted that Medical Device industry is a continuously growing sector and this sector has one of the highest potential for growth among all the sectors in the healthcare market. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. Major manufacturing of medical devices in the country relates 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 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 80% by value of its domestic requirements of medical devices.

3.2 As per the Department of Pharmaceuticals, following schemes are being implemented in the country for the promotion of manufacturing of medical devices:-

a. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:

3.3 The Department apprised the Committee that the domestic medical devices industry faces challenges related to considerable cost of manufacturing, 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 20thMarch, 2020.

3.4 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 is 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 Rs. 3,420 crore. The four Target Segments of medical devices are-

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

iv. All Implants including implantable electronic devices

3.5 The Scheme is being implemented through a Project Management Agency (PMA). An Empowered Committee under the chairmanship of CEO, NITI Aayog oversees various issues under the scheme from time to time. 21 applications have been approved with a total committed Investment of Rs.1059 Crore and expected incentive utilisation of Rs 2,541 crore. The next round of applications will be considered with suitable amendment in the guidelines, if approved.

3.6 The Committee has found that the Medical Device Industry is facing following challenges:

- Inadequacy of indigenous research and development (R&D) in high end technology including lack of adequate funding;
- Non-availability of adequate, trained and qualified manpower in high end/cutting edge technology with entrepreneurial skills;
- Failure to undertake research in academic institutions in cutting edge technologies and establishing clear pathways for translation from lab to manufacturing facilities;
- Non-availability of adequate finances at concessional rates and other fiscal incentives as compared with countries like Ireland;
- Higher cost of development of indigenous technology and failure to ensure transfer of technology from other countries to set up manufacturing facilities in the country.
- Industry has been introduced to digitalization methods such as artificial intelligence and robotics. These have modernized the whole process, making things easier, faster, and more efficient. However, the same technological advancements have paved the way for the cyber security threat.

3.7 **The Committee is of the considered view that in order to encourage indigenous manufacturing, the Government should provide incentives or encourage preferential purchase for domestically manufactured products in Government procurement. In this regard, the Department should ensure that in all public procurement, the preference must be given to Indian manufactured medical devices having domestic content of at least 50%. Given the size of Government's (both Central and State) purchase, the Preferential Purchase Agreement would have a significant pull for a number of medical devices companies to manufacture medical devices in India. Also, the PLI scheme should be broad based and all the medical devices should be covered under the scheme.**

3.8 **The Committee notes that most of the high-end technology and innovative products originate from a well-developed ecosystem and innovation cycle. The Committee is pained to note that despite boasting of several IT hubs like Bengaluru, Pune, Hyderabad, Delhi-NCR the desired ecosystem for manufacturing of highly advanced medical devices is yet to be fully developed in the country. The Committee, therefore, recommends prioritizing and developing a robust funding mechanism to nurture an ecosystem for innovation for medical devices industry. In this regard, the Committee recommends the Department of Pharmaceuticals to have a dedicated corpus to fund start-ups and Small & Medium**

Enterprises (SMEs) undertaking research projects that aim for improving quality, efficiency of existing devices and other healthcare outcomes.

3.9 In response to a question regarding the institutes conducting Research & Development in high end medical device technology, the Committee had been informed that as of now the following 13 institutions/organizations were conducting Research and development in high end medical device technology:

1. Defence Research and Development Organization (DRDO)
2. Indian Institute of Technology (IIT), Delhi
3. Indian Council for Medical Research (ICMR)
4. HLL, Chennai
5. Indian Institute of Technology (IIT), Chennai
6. Indian Institute of Technology (IIT), Mumbai
7. Christian Medical College, Vellore
8. Veterinary Medical College, Chennai
9. PSG Institute of Medical Science and Research, Coimbatore
10. Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram
11. Society for Applied Microwave Electronics Engineering and Research, Mumbai
12. Jawaharlal Nehru Centre for Advance Scientific Research (JNCASR), Bengaluru
13. IISC, Bangalore

3.10 To invigorate the culture of research and development in medical devices in institutions like IITs, NITs and other academic institutions the Committee recommends the Department to start Research Linked Incentive (RLI) Scheme in Line with PLI scheme. The Department should facilitate academia- industry partnership for undertaking research projects on industry challenges and incentivize the successful outcomes.

3.11 The Committee had been informed that for making India a dominant global player in the Medical Device Industry, seven National Institutes of Pharmaceutical Education and Research (NIPERs), have been set up in various parts of the country as Institutes of National Importance, to nurture and promote quality and excellence in the pharmaceutical education & research. NIPER at Ahmedabad, in addition to other courses, is running MS Pharma (Medical Devices) and PhD courses in medical devices. The Department also intends to set up a national center of excellence in medical devices at NIPER Ahmedabad. NIPERs at Mohali, Hyderabad and Guwahati have started courses in M. Tech. (Medical Devices). NIPER, Kolkata has also started course from this Academic year.

3.12 **The Committee realizes that biomedical engineers are integral to develop ecosystem for research in medical devices in India. These engineers are trained in the principles of physics and mathematical computation for the development of safe and effective medical devices that best fit the needs of medical providers and patients. However, biomedical engineers generally do not interface directly with patients to the same extent as physicians; therefore, biomedical engineers may not fully understand the specific needs of patients in the same way that medical professionals and manufacturers do. The Committee, therefore,**

strongly recommends the Department to facilitate regular interactions of biomedical engineers with leading physicians and manufacturers and thus encourage them to undertake research on medical devices. Furthermore, the Committee recommends expediting setting up centers of excellence in medical devices at all the National Institutes of Pharmaceutical Education and Research (NIPERs). The courses may commence in these centers of excellence to train and educate biomedical engineers on ongoing challenges faced by medical device industry.

3.13 The Committee also recommends that the Government should arrange to provide international exposures to domestic manufactures and to their products.

b. Scheme for Promotion of Medical Device Parks:

3.14 The sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre" is a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was Rs. 100 crore for 2018-2020. The sub-scheme provides a one-time grant-in-aid of Rs. 25 crore or 70% of the project cost, whichever is 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 is to render financial assistance for establishment of common facilities in any upcoming Medical Device Park promoted by a State Government/State Corporation. The Department has approved the proposal for creation of Common Facility for superconducting magnetic coils testing & research facility of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the said sub-scheme.

3.15 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 Rs. 400 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025.

3.16 Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States, financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to Rs 100 crore. A Medical Device Park project selected under the Scheme will be implemented by a State Implementing Agency (SIA). The proposals under the scheme are to be approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals (DoP). A Project Management Agency (PMA) will assist DoP for effective implementation of the Scheme.

3.17 The Department apprised the Committee that 16 States submitted their proposals under the scheme. The Department gave in-principle approval to the proposal from Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh. Thereafter, based on the evaluation of the Detailed Project Reports (DPRs) of the said 4 States, the SSC gave the final approval to 4 States

viz Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh. The expected date of completion of the Parks is January, 2024. As per scheme guidelines, first tranche of grant-in-aid of Rs. 30 crore each has been released to the four States in the 4th Quarter of Financial year 2021-22.

3.18 The Committee commends the Department for launching Scheme for Promotion of Medical Device Parks in India. The Committee believes that India has huge growth potential in manufacturing of medical devices. Well-coordinated inter-ministerial and inter-governmental (central and state) strategies aimed at offering manufacturers competitive advantage in manufacturing in India will result in importers finding it more profitable to manufacture in India than to import it. The Committee believes that logistical support in shared manufacturing facilities like Medtech parks would significantly reduce capital expenditure of manufacturers and thus giving a boost to manufacturing in India.

3.19 The Committee recommends following steps for improving the efficiency and overall facilities of Medtech Parks in India:-

i. **The Mediparks should have NABL (National Accreditation Board for Testing and Calibration Laboratories) approved medical device testing laboratories to reduce time required in manufacturing a product;**
ii. **Each park should have dedicated office for skilled and unskilled labor force. This said office should maintain a registry of registered workers so as to maintain the continuous availability of workforce;**
iii. **To control pollution, each Medipark should have Effluent Treatment Plant (ETP);**
iv. **Availability of subsidized power and water ;and**
v. **For promoting the Indian medical device market, Mediparks should organize- "Medical Device Exhibitions" and workshops.**

3.20 The Committee further recommends that some of the Mediparks should focus on manufacturing medical device components and thus make the country self reliant on spare parts with provision for extending necessary services. This can further strengthen into India emerging as hotspot for medical devices spare parts and hub for medical devices repairing and service centres for other countries. Thus Medical Devices industry would have added advantage of huge employment generation capacity.

3.21 As per the information furnished by the Department of Pharmaceuticals, the import and export data of medical devices over the past two financial years is as under:-

(in USD million)

Import		**Export**	
2020-21	2021-22	2020-21	2021-22
6240.55	8539.5	2532.16	2923.16

A. **Export Data (USD million)**

(in USD million)

Si.No.	Segment	FY 2020-21	FY2021-22	Growth%
1.	Consumables &Disposables	1290.43	1378.48	7%
2.	Electronic Equipments	985.09	1162.58	18%
3.	Implants	98.81	135.18	37%
4.	IVD Reagent	104.19	175.71	69%
5.	Surgical Instrument	53.64	71.21	33%
	Total	2532.16	2923.16	15%

B. **Import Data (USD million)**

(in USD million)

Si.No.	Segment	FY 2020-21	FY2021-22	Growth%
1.	Consumables &Disposables	1471	1623.55	10%
2.	Electronic Equipments	3569	5441.22	52%
3.	Implants	225.6	423.06	88%
4.	IVD Reagent	871.9	882.65	1%
5.	Surgical Instrument	169.02	169.02	63%
	Total	6241	8539.5	37%

3.22 The Committee observes that India imported medical devices worth USD 8.5 billion in 2021-22 and the corresponding export figure for 2021-22 was only 2.9 billion. The Committee is of the firm view that three segments viz. electronic equipments, implants and surgical instruments account for the highest imports in the medical devices sector. These segments include highly important and widely used high-end technology devices such as CT Scanners, MRI, Ultrasound & X-Ray machines, knee and hip implants, dental fixtures, Cancer diagnostics and other sophisticated surgical instruments. The Committee observes that manufacturing of high-end technology devices would require evolved medical devices sector having a robust Research and Development infrastructure and trained workforce, therefore, the Government must strive towards improving R&D infrastructure in the country.

3.23 The Committee recommends that to realise the goal of making India a USD 50 billion market by 2025, all the three pillars of the medical devices sector viz. Government, Industry and Academia should work in synergy on a common vision and roadmap. With the ultimate goal of becoming "self-reliant" the focus should be on increasing the manufacturing capacity by having a simplified yet effective regulatory regime and liberal taxation system. The Government must also focus and invest in R&D in premier technological institutions like IITs; stress must also be laid on skill development to have a trained and qualified workforce for the sector. The Committee strongly feels that Industries must also take a lead in R&D and the leading manufacturers and manufacturers' associations should establish convergence and collaboration between the Industry and academia.

3.24 The Committee believes that indigenous manufacturing can only be fostered if there is local availability of raw materials and critical components; the 80% dependency on imported products is primarily due to the lack of (i) high end technology and (ii) poor availability of raw materials. The Committee, therefore, recommends that the Government must incentivize such institutes, start-ups, manufacturing units which are engaged in manufacturing of raw materials and spare parts locally. Academic institutions like IITs, AIIMS & IISCs and research bodies like CSIR who have the technical know-how and the technology required should be allowed and encouraged to produce certain raw materials like antibodies, synthetic antigens, proteins etc. Additionally, the Committee recommends that PLI scheme should be expanded to cover raw material and component manufacturing as well so that India can become a hub for raw material for the world.

3.25 Regarding rationalization of Duty Structure to encourage companies to manufacture in India, the Ministry has informed that the rate of Basic Customs Duty (BCD) on certain specified medical devices was increased from 5% to 7.5%. Simultaneously, the exemption from Special Additional Duty (SAD) on these medical devices was withdrawn, and they now attract 4% SAD.

3.26 Market in developing countries like India is generally price sensitive, this result in strong emergence for refurbished medical devices, such medical devices are cheaper and save out of pocket expenditure of the patients to a large extent. Therefore, till the domestic medical device manufacturing industry does not achieve the maturation state, the refurbished Medical Devices be allowed in the country but with certain conditions ensuring the safety of the medical device on the patient.

3.27 The Committee feels that the Medical Devices segments in which India is 80% dependent upon imports are the highly capital intensive, having long gestation period and requiring more R&D segment. Simultaneously, the devices are essential for the people as they are mostly the diagnostic devices which help one detect any disease. If such detections are early, the chances of their control would also be more. The Committee, therefore, recommends that the Government must chalk out specific strategy for import of refurbished diagnostic devices to increase the penetration of such devices in each district of the country, till such devices are not manufactured at low cost domestically. The Committee also recommends that domestic manufacturers should be supported in installation of manufacturing plants in collaboration with international players, thus promoting production of high quality medical devices at low cost. The Committee also recommends that the safety parameters of the incoming medical devices should be ensured so that only those medical devices which qualify the set parameters of safety and quality enter the Indian market. Sub-standard and obsolete medical devices shall not be allowed to enter the Indian market.

3.28 The Committee observed following factors that affect Indian domestic manufacturers and recommends certain additional measures for boosting manufacturing and exports and improve ease of doing business which inter-alia include:-

i. **Reviewing import duty structure- Lower import duty makes it cheaper to import than manufacture in India. Lower import duty on imported devices coupled with**

12% GST on locally manufactured products discourages manufacturing in India. Moreover, 18% GST on sanitizer and IVD equipments is regressive and should be reduced to 12%.

ii. **US/UK manufacturers design medical products like implants on bone structures of Caucasian people, such products are not ideal for Indian population, however, due to deficiency of Indian designs, surgeons recommend such products to the patients. In this regard, the Department shall reward/ incentivize products that carry Design India Certificate issued by Department for Promotion of Industry and Internal Trade (DPIIT). Incentivizing products built on Indian design would boost innovation in India.**

iii. **Due to lack of local availability, machinery for setting up manufacturing plants is imported from countries like China, till the time India is capable of producing such machinery on its own, the Government should reduce excise duty on importing of machinery to set up plants. High excise duty on raw materials and parts of devices adds to the cost of production and this encourages import of finished products.**

iv. **Considering the potential of growth in the medical device industry, the Committee strongly recommends that there is urgent need to have a separate EPC for promotion of exports in the medical devices sector.**

3.29 The Secretary, Department of Pharmaceuticals apprised the Committee that to promote 'Make in India' products for the public procurement, the Department has come out with the Medical Device Policy. The draft has already been circulated for inter-Departmental consultation.

3.30 The Committee commends the Department for preparing the Draft Medical Device Policy 2022 that proposes regulations to ease patent processes, create ecosystem for R&D, skilling the regulatory workforce, streamline regulatory clearances, and establish 'Centres of Excellence'. The, Committee, however expresses its concern over absence of provisions regarding data security of patients in the proposed policy. With the Government's push for health records digitization under Ayushman Bharat Digital Mission (ABDM), the Committee understands that there is an urgent need to regulate digital devices likes "wearables (smart watches)" to protect health data of people. Therefore, considering huge data generation, the Committee recommends the Department to include stringent data protection norms in the Draft Medical Device Policy, 2022.

3.31 The Committee further recommends that the government should come up with an enabling environment for the growth of the industry in multiple ways *viz.* manufacturing, import, capacity building, spare parts and a centre for repairs of medical devices thus bringing forth a medical device revolution in the country. The policies should contain supportive and continuous tax structure for encouraging international players to set up industries in India thus reducing the cost of the medical devices.

Regulation of Pricing by the National Pharmaceutical Pricing Authority (NPPA)

3.32 The mandate of the NPPA is to implement and enforce the provisions of the Drugs (Prices Control) Order (DPCO), 2013 in accordance with the powers delegated to it and to monitor the availability of drugs, identify shortages, if any, and to take remedial steps.

3.33 **Scheduled Medical Devices:** There are 4 Medical Devices (Cardiac stents, drug eluting stents, condoms and intra uterine devices) that have been included in the National List of Essential Medicines and hence they are in Schedule-I of the DPCO, 2013. The Ceiling Prices are notified for these 4 Scheduled Medical Devices by NPPA.

3.34 **Non - Scheduled Medical Devices:** Under Para 19 of DPCO, 2013, NPPA fixed the ceiling price for Knee Implants vide notification dated 16.08.2017. During the Surge of Covid-19 in May – June 2021, 6 COVID essential medical devices, namely, Oxygen Concentrators, Pulse Oximeters, BP Monitoring Machine, Glucometer, Digital Thermometer and Nebuliser were brought under price regulation.

3.35 Apart from the above, the remaining medical devices are also non-scheduled Medical Devices under the DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955. Under Para 20 of the DPCO, 2013, NPPA monitors the Maximum Retail Prices of all non-scheduled medical devices and ensure that no manufacturer increases the maximum retail price of any medical device more than ten percent of maximum retail prices during preceding twelve months. Where the increase is beyond ten percent of maximum retail price, the overcharged amounts are recovered as per the provisions of DPCO, 2013.

3.36 **Collection of Price related information from non-scheduled Medical Devices**: NPPA vide OM dated 16th February 2021 sought price related information from the manufacturers/importers of all the notified 24 categories of non-scheduled Medical Devices in order to monitor the MRPs under Para 20 of the DPCO, 2013 to ensure that no manufacturers/importers increased the MRP more than 10% in preceding twelve months.

3.37 Department for Promotion of Industry and Internal Trade (DPIIT), issued Public Procurement (Preference to Make in India) Order (PPO), 2017 dated 15.06.2017 (revised on 16.09.2020). In order to facilitate the implementation of the PPO, 2017, DPIIT *vide* D.O. dated 14.08.2017 identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO 2017 relating to goods & services related to Pharmaceuticals Sector. Based on the above, DoP issued guidelines dated 16.02.2021 for implementation of the Order. DoP vide Order dated 16.02.2021 and 25.03.2021 further notified 135 & 19 medical devices respectively 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 these medical devices only from the "Class-I local suppliers".

3.38 The Committee notes that there are only 4 Medical Devices (Cardiac stents, drug eluting stents, condoms and intra uterine devices) that have been included in the National List of Essential Medicines. The Ceiling Prices are notified for these 4 Scheduled Medical Devices by National Pharmaceutical Pricing Authority (NPPA). Apart from the above, the remaining medical devices come under non-scheduled Medical Devices under the DPCO,

2013. The Committee has learnt that NPPA monitors the Maximum Retail Prices of all non-scheduled medical devices and ensures that no manufacturer increases the maximum retail price of any medical device more than ten percent of maximum retail prices during preceding twelve months. The Committee believes that allowing a maximum increase of 10% may result in serious jump in prices in a span of few years. The Committee, therefore, strongly recommends that instead of this 'same size fits all' approach; the Department like risk-based classification of devices should create separate baskets for medical devices for pricing depending upon their cost, availability, need and affordability by the patients. The devices which are required for critical care to the patients should ideally be categorized under "Scheduled Medical Devices" and be listed under National List of Essential Medicines.

3.39 Additionally, the pricing of medical devices should also take into consideration the cost of the manufacturing and the value the medical device adds to the patient experience and ease it brings to the physician. The Committee, therefore, recommends the Department to strike a balance between providing affordable healthcare and providing quality healthcare. As mere providing healthcare services without considering how a product can best deliver desired outcomes for sustainable period goes against the basic policy and principles of the welfare State. In this regard, the Committee welcomes the Government's decision to move from L1 (lowest price) procurement method to Quality-cum-Cost Based Selection (QCBS), thus incorporating the element of quality in public procurement.

3.40 The Committee further believes that quality comes from innovation and in medtech sector, more than completely new inventions, incremental innovations to add features and improve accuracy & efficiency of the existing devices is the norm, so much so that more than 60% of the innovation is incremental innovation. A lot of effort and cost go into R&D, designing, testing, approvals and marketing before innovative products are provided to the needy persons. The Committee is of the opinion that till the time the desired synergy between Government policies, initiatives, academic institutes and Medtech industry is established to create an ecosystem for innovation and R&D in India, so that cost of production of innovative products comes down, the Government shall continue with steps like price exemptions, value based procurement and subsidy support to the domestic manufacturers. The Committee is of the opinion that the measures so undertaken would result in boost of demand generation as good quality products would be available at affordable prices.

3.41 The Committee has been given to understand that besides the factors like availability of technology and raw materials, the phenomenon of inflation in medical devices is due to unfair trade practices by certain entities. The Committee lists following measures to provide a level playing field to the domestic medical device manufacturers and curb the artificial inflation in the prices of medical devices:-

i. **Certain MNCs (Multi National Companies) avoid printing of MRP on each unit of product, so that the buyer (large distributors and hospitals) can list such a price to derive high profits, resulting in unnecessary surge in prices of medical devices. The DoP, in co-ordination with Ministry of Finance, must ensure strict adherence to the**

compliance of the rule which necessarily mandates the printing of MRP on each product. The Department through the Ministry concerned should instruct the Port officials to check each medical device consignment for compliance of the said rule, so that the issue can be addressed at the origin.

ii. **Some manufacturers indulge in manufacturing of low-cost but substandard products that wholly disturbs the market for genuine manufacturers who comply with all the regulations and standards. The Committee, therefore, strongly recommends for strict surveillance over entry of sub-standard Medical device into Indian Market so as to avoid hazardous impact on patient's health.**

3.42 Regarding the initiatives of the Government to reduce trade margin rationalization, the Ministry has informed that NPPA has suggested that in case of medical devices, the trade margins upto maximum of 30% is within acceptable norms. In this regard, DoP was also requested to consider fixing trade margin upto maximum 30% and the issue of trade margin rationalization is under active examination of Department of Pharmaceuticals.

3.43 The Committee recommends the Department to effectively implement the "Trade Margin Rationalization" policy to address the issue of arbitrary pricing by importers. Considering the number of supply chain in a vast country like India, the Department needs to have consultation with all the stakeholders in the industry. The Committee believes that thorough consultation with all the stakeholders would help the Department in arriving at a justified trade margin by which not only the interests of consumers, suppliers and manufacturers would be taken care of but also the problem of irrational pricing would be resolved. Effective implementation of "Trade Margin Rationalisation" (TMR) would result in lower out-of-pocket expenditure which ensures that families are not pushed below the poverty line due to the medical expenses.

3.44 Regarding the manpower upscaling for medical devices sector, the Secretary, Department of Pharmaceuticals apprised the Committee about the initiatives taken by the Department which would supply skilled work force across the innovation value chain e.g. scientists, regulators, health experts, managers, technicians, etc. She also informed that 20 courses have been started relating to biotechnology engineering across the country. The National Institutes of Pharmaceuticals Education and Research is being run by the Department of Pharmaceuticals to impart training for different roles in medical device sector. She further informed that draft National Medical Device Policy, 2022 has been prepared to set up National Institutes of MedTech Education and Research (NIMERs) on the lines of NIPERs, as Institutes of National Importance (INIs) and to leverage the Skill India Mission platform for development of skill sets in medical device sector.

3.45 The Committee appreciates the initiative of the Department of Pharmaceuticals in upscaling of manpower for the sector, however, feels that considering the potential of growth of the medical device sector, there is an urgent need to prepare a mammoth skilled manpower at various levels, hence more steps should be taken on priority.

CHAPTER- IV

VIEWS OF THE GOVERNMENT & OTHER STAKEHOLDERS

4.1 During the course of its deliberations on the subject, the Committee held several meetings with Ministry of Health and Family Welfare, other Government Departments, private organizations, industry bodies like FICCI, CII etc.

A. Oral Evidence by Ministry of Health & Family Welfare

4.2 The Committee in its meeting held on 01st December, 2021 heard the views of Ministry of Health and Family Welfare. The Joint-Secretary, gave a presentation on the subject during the course of his presentation he apprised the Committee that medical device industry was regulated by Drugs and Cosmetics Act, 1940 which was a Central Act and aim to ensure safety, efficacy and quality of not only drugs but also medical devices and cosmetics. There are four types of medical devices viz. medical equipments, medical implants, medical disposables and medical furniture. At present 37 medical devices are notified. Difference between drugs and devices is that while the former is based on chemistry and biochemistry, the latter one is based on engineering.

4.3 Medical Devices Rules, 2017 (MDR-2017) became effective from 1st January, 2018. These rules regulated Medical Devices and IVDs (In-vitro diagnostics). According to these rules the devices are classified into Class-A, Class-B, Class-C and Class-D. Class A and B of devices are low/moderate-risk devices and C and D are of high-risk devices. Further State Licensing Authorities are responsible for regulating of manufacturing of Class A&B devices and regulation of C&D devices is done by Central Regulating Authority. MDR 2017 also govern clinical investigation, the standard of medical devices, perpetual validity of licenses, registration and regulation of notified bodies, online submission, processing and approval of applications, quality management system and timelines for approval.

4.4 All manufacturers and importers of non-regulated Medical Devices should register with CDSCO. Initially such registrations are on a voluntary basis up to 18 months. After submission of information by the applicant on the SUGAM portal registration number is generated, this is required to be printed on label by the manufacturer or importer. Registration process of Class A&B devices must be completed in 30 months (18 months for voluntary registration and 12 months for mandatory registration) and for the Class C&D devices this period is of 42 months (18 months for voluntary registration and 24 months for mandatory registration). 5 Central Medical Device Testing Laboratories have been notified for statutory testing and 19 Medical Device Testing Laboratories are registered by the CDSCO for TEST or Evaluation of a medical device on behalf of the manufacturer.

4.5 Materiovigilance Programme of India (MvPI), intended to ensure the safety of devices which was launched in 2015 at the Indian Pharmacopoeia Commission, Ghaziabad. Under MvPI, 124 Medical Devices Adverse Events Monitoring Centres have been identified in the country to report the events on a voluntary basis. Presently there is a need to create 754 posts for separate vertical of medical devices comprising 449 posts for regulatory officials and 305 for laboratory officials.

B. **Oral Evidence by Department of Pharmaceuticals**

4.6 The Department of Pharmaceuticals (DoP) is a key department concerning Medical Devices industry. The Mandate of the department is to work on industry issues relating to promotion, production and manufacture; and the department through NPPA (National Pharmaceutical Pricing Authority) also aims to regulate prices of medical devices in the country. Continuing its deliberations on the subject the Committee heard the views of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on 30th May, 2022. The Secretary made a brief presentation before the Committee, during the course of her presentation she apprised the Committee that 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.

4.7 India depends on imports to an extent of 80% by value of its domestic requirements of medical devices. The Department runs a scheme called "Production Linked Incentive" scheme for promoting domestic manufacturing of medical devices, under the scheme, financial incentive is given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India. There are four types of Medical Devices covered under the scheme, namely (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.

4.8 There is another scheme called "Scheme for Promotion of Medical Device Parks", this scheme was started with objective of giving financial assistance to State Governments for supporting specific infrastructure in medical device parks. The total financial outlay of the scheme is Rs. 400 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. The Department gave in-principle approval to the proposal from Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh. The first instalment of Rs. 30 crore each has been released to the four States in the 4th Quarter of Financial year 2021-22.

4.9 The NPPA takes various steps to control price of medical devices which are categorized as Scheduled Medical Devices and Non-Scheduled Medical Devices. NPPA monitors the maximum retail prices of all non-scheduled medical devices and ensure that no manufacturer increase the maximum retail price of any medical device more than 10% of maximum retail prices during preceding 12 months; Jan Aushadhi Kendras aims to improve access of medical products, apart from generic drugs, the Government has made available 250 types of surgical items in over 8700 stores of Jan Aushadhi Kendras at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana; National Institutes of Pharmaceuticals Education and Research is being run by the DoP to impart training for different roles in medical device sector.

4.10 The Department of Pharmaceuticals is entrusted with the responsibility of policy, planning, development and regulation of Pharmaceuticals Industries as detailed below:-

1. Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
2. Medical Devices - Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
3. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector.
4. Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
5. Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
6. Promotion of public – private – partnership in pharmaceutical related areas.
7. International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
8. Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
9. Technical support for dealing with national hazards in pharmaceutical sector.
10. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
11. All matters relating to National Institutes for Pharmacy Education and Research.
12. Planning, development and control of, and assistance to, all industries dealt with by the Department.
13. Bengal Chemicals and Pharmaceuticals Limited.
14. Hindustan Antibiotics Limited.
15. Indian Drugs and Pharmaceuticals Limited.
16. Karnataka Antibiotics and Pharmaceuticals Limited.
17. Rajasthan Drugs and Pharmaceuticals Limited.

4.11 The Committee feels that the mandate of the Department of Pharmaceuticals is very much related to the health sector like drugs & medical devices, their production, development, control, promotion, education, training & research. Hence, the Committee strongly feels that, for better coordination, the Department should be brought alongwith Department of Health and Family Welfare under the Ministry of Health & Family Welfare from the Ministry of Chemicals & Fertilizers by amending the Government of India (Allocation of Business) Rules, 1961.

C. Oral Evidence by Other Stakeholders

4.12 To understand the industry view on the subject, the Committee during the course of its deliberations heard several experts from the industry. On 12th May, 2022, the Committee heard the views of leading industry organization Confederation of Indian Industries (CII) and Orthopaedic Implant Manufacturers Association (OIMA) which is the largest group of the medical device manufacturers regulated and certified by CDSCO. CII's National Medical Technology Forum (NMTF) has membership covering all MedTech - implantables, consumables, In-vitro Diagnostics (IVD) and equipment. On 13th May, 2022, the Committee

heard the views of Association of Indian Medical Device Industry (AiMeD), New Delhi and leading industry body Federation of Indian Chambers of Commerce and Industry (FICCI).

4.13 The Committee in its meeting held on 30th May, 2022 heard the views of Association of Diagnostics Manufacturers of India. Association of Diagnostic Manufacturers of India (ADMI) is an organization of IVD (in-vitro diagnostic) manufacturers in India.

i. Confederation of Indian Industries (CII)

4.14 The Committee heard the views of CII- NMTF (National Medical Technology Forum) on 12th May, 2022. The Chairman, CII NMTF gave a presentation to the Committee on the subject and during the course of his presentation he apprised the Committee that Medical Device Rules (MDR) 2017 (under the aegis of Drugs and Cosmetics (D&C) Act) is the prime medical device regulation. There is an urgent need of its alignment with the best regulatory practices globally and establishing a level playing field for manufacturers, importers and distributors so that flexibility to cope up with ever changing landscape of medical technology innovations is achieved. There is need of decriminalizing the provisions of current Act and exemption from Legal Metrology, Quality Control Orders etc. In public procurement of medical devices in India, there are three essential criteria: (a) Conformance to applicable standards (IS/ISO/IEC); (ii) Regulatory Approval (CDSCO (Central Drugs Standard Control Organisation), MoHFW, and (iii) Product Technical Specifications

4.15 The Government must regulate import of refurbished equipment and refurbishing in India. Production Linked Incentive (PLI) scheme should be opened for all medical devices categories. Inverted duty structure needs to be corrected especially for medical devices that are manufactured in India. There is need for schemes to support medical device manufacturing infrastructure beyond PLI. They also suggested the need for recognition to incremental innovation, differential pricing, Value Based Procurement / Health Economics Driven Reimbursement Models, export incentivization and making Indian manufacturers globally competitive.

ii. Orthopedic Implants Manufacturing Association (OIMA)

4.16 The Committee heard the views of the Secretary, OIMA (Othopaedic Implant Manufacturers Association) on 12th May, 2022. He in his submission to the Committee stated that in India around 70-80 per cent of the companies were CDSCO (Central Drugs Standard Control Organisation) approved. The indigenous manufacturing industry have been adversely affected by reduced import duties and were facing tough times competing with imported products. He apprised the Committee that even though Covid-19 had an adverse impact on the medical devices industry but the loan provided by the Government helped the industry survive through the pandemic. There was shortage of raw material during the pandemic and there was a need of design and regulatory framework to cope up with future emergencies. Regarding quality control and standards of medical devices in line with best international practices, he suggested that CDSCO should harmonize standards with the standards of international companies, but obtaining international certification like CE (Conformitè Europëenne) and USFDA (United States' Food and Drug Administration) has increasingly become costly thus, the industry needs Government intervention in this regard. Another representative of OIMA apprised the Committee that in orthopaedic implants two raw materials i.e. stainless steel and titanium are

extensively used but owing to absence of indigenous manufacturers of these two, the industry is dependent on expensive imports.

iii. Association of Indian Medical Device Industry (AiMeD)

4.17 The Committee heard the views of Forum Coordinator of Association of Indian Medical Device Industry (AiMeD), New Delhi on 13th May, 2022. He in his presentation apprised the Committee that the industry is mostly dependent on imports and there is need for separate act on medical devices. They stated that rules and regulations must clearly define roles and responsibilities of regulating bodies. They further sought supportive polices like predictive tariff policy, restrictions on second hand imports, preferential public procurement to significantly boost domestic manufacturing of medical devices.

4.18 In 1989 the medical devices were classified as drugs and in 2017 Medical Device rules were notified; certain section of the Drugs and Cosmetics Act like Section 17 (on misbranded drugs), Section 17A (adulterated drugs), Section 34 (offences of companies) are needed to be made "not applicable" or they should be amended. Patient safety must be ensured without affecting investment and Small and Medium Enterprises (SMEs). He also suggested that all manufacturers and importers should be registered and manufacturers of Class-A non-sterile should be allowed self-certification.

4.19 They proposed that the Government must aim towards building a pool of competent auditors, medical device officers and manufacturers along with a comprehensive infrastructure of NABL accredited testing labs, regulatory controls need to be split, shared and delegated between the Center, State and Conformity Assessment Bodies. They stated that overpriced imported medical devices are severely affecting India's manufacturing growth.

4.20 The Association of Indian Medical Devices Industry in their further communication stated that in medical devices India is dependent on imports to the tune of 80% and the imports crossed Rs. 63,000 crores in 2021-22 and the estimated market is of Rs. 1,60,000 crores. The Association emphasized upon the creation of separate Department for Medical Devices. They stated that there should be a separate law, separate rules and a separate regulatory authority to make India as one of the top 5 manufacturing hubs for Medical Devices. They further mentioned that the Department of Pharmaceuticals and the Ministry of Chemicals and Fertilizers had limited understanding and expertise of the medical devices industry and therefore limited output to show in terms of results and outcomes. Accordingly, they suggested that the administrative department of Medical Devices should ideally be with Ministry of Health and Family Welfare which is the key stakeholder of the industry. According to them the CDSCO, a regulator being asked to make policies for medical devices was not appropriate.

4.21 The Association also proposed that although ensuring the patient safety was the foremost objective of the law but any lapse in the manufacturing must not be made a criminal offence as it might lead to manufacturers leaving the field due to fear of being prosecuted. They suggested that criminality should be only for those manufacturers who do not take proper license for manufacturing and enter the industry illegally. They said that there was a need to do market surveillance and monitor adverse events to enable needful systematic action to prevent recurrence of such incidences for enabling greater patient safety.

iv. Federation of Indian Chambers of Commerce and Industry (FICCI)

4.22 Thereafter, on 13th May, 2022, the Committee heard the views of FICCI, the FICCI representative in his presentation apprised the Committee that India constitutes 1.6% of total global market and almost 86% of the Indian medical device industry is import dependent; right policy decisions can help India grow by at least 12 times of the present market size; medical device industry is capital intensive and has long gestation period and requires continuous induction of new technologies. India lacks well developed ecosystem and innovation cycle for medical device industry to flourish.

4.23 They informed that working on Demand Generation, Policy Predictability and Ease of Doing Business can make India a hub for med-tech in the next two decades (by 2047). India currently has only 1.3 hospital beds/1000 population and thus additional 3 million beds are required. India only has 0.65 physicians per 1000 people and the WHO standard is 1 per 1,000 people. Similarly 1.54 million doctors and 2.4 million nurses would be required to meet the growing demand. 60% of India's health infrastructure is concentrated in the large cities across the country. There is need to skill, upskill and reskill healthcare professionals and those in manufacturing of medical devices as well. Trade Margin Rationalisation from first point of sale also needs attention along with standardized, streamlined and digitized implementation of PCPNDT (Pre-Conception and Pre-Natal Diagnostic Techniques) Act.

4.24 They also proposed that the Government must develop a process for defining and rewarding incremental innovation and breakthrough innovation. Implementation of Medical Device Rules 2017 should be harmonized with global practices. There is need to have single window clearance system and interface between ministries dealing with medical device rules 2017 and to develop and operationlise more medical device parks and lend support to ancillary industry.

v. Association of Diagnostics Manufacturers of India (ADMI)

4.25 The Committee in its deliberations on the subjects held a meeting on 30th May, 2022. In this meeting the Committee heard the views of the President of Association of Diagnostic Manufacturers of India (ADMI). In her presentation, the President of ADMI apprised the Committee that in-vitro Diagnostics or IVD is a niche industry within the Healthcare sector. It is a subset of the Medical Devices industry and it was estimated to be worth US$ 1.8 billion in 2020, the industry is estimated to reach US $ 5 billion by 2027. The IVD Medical Devices encompasses diagnostics tests performed outside the body of the patient, in pathology laboratories, hospitals and blood banks. IVD industry has two major components in reagents and instruments, currently the demand for both the components is largely met by imports.

4.26 To meet the sudden rise in demand in view of Covid-19, the number of local manufacturers in IVD industry increased from 60 in 2019 to 180 post Covid. The IVD industry should continue to be regulated under the purview of the MDR 2017 and the CDSCO. She proposed that the government should avoid the burden of over-regulation on the IVD industry and foster ease of doing business; the government should facilitate ecosystem for innovation and incentivize investment in R&D and policies for local availability of critical raw materials that are currently being imported at reasonable prices should be formulated. She further stated that the

import duty on all components and spare parts should be reduced; clinical samples from labs and hospitals for all types of diseases and infections should be provided to the industry; and the government must aim towards integration of industry and academia for boosting innovation.

4.27 The Committee, during its deliberations on the subject observed issues in the functioning of current regulation and the Committee, therefore, strongly recommends incorporating suitable provisions in the new Bill so as to overcome the shortcomings in MDR. As per MDR-2017, sale and testing of Class A/B/C/D medical devices along with IVD (In-vitro diagnostics) is vested with the State Governments, however, the Drug Testing Laboratories are not notified and Medical Device Testing Officers of State are not designated regularly by the CDSCO thus causing inordinate delay in granting approvals. Presently, there is neither a provision in the online portal for referring the licensed manufacturing unit (for Class A devices) for audit by the notified body nor there is any feedback mechanism in the CDSCO portal to refer the technically deficient audit reports which are prepared by notified bodies. Further, there is no mechanism for registering complaints regarding functioning of CDSCO portal. The Committee also found that there is non-adherence of timelines for audit and report as per MDR-2017 by the notified bodies.

4.28 The Committee feels that for a strong regulator it needs to be supported with required expertise from the backgrounds of Medical, Biomedical Engineering, Product Development and Marketing. The Committee further recommends that there is utmost requirement of training programmes for regulatory officials (both central and State level) as well as for industry persons for effective implementation of the rules and regulations. The Committee feels that developing skilled and trained manpower possessing technical know-how of the medical devices is essential for smooth implementation of the regulations. This could be done through long-term, short-term and crash courses on medical device manufacturing and quality control in institutes like IITs, NITs and medical colleges for new regulatory officers. The Ministry of Skill Development may also be requested to formulate courses related to medical devices, manufacturing, use and maintenance. There is a need for devising a mechanism to pre-empt exigencies and provision for "emergency use authorization" of medical devices in case of emergencies. The Ministry should also lower high fee charged by notified medical devices testing laboratories like NIB particularly for Class C&D devices. The Committee observes that there is lack of co-ordination between academic institutions and industrial requirements. The Committee recommends that the innovators and scientists at research institutions should be made aware of the required standards and regulations, otherwise it's difficult to commercialize their innovation/creation.

4.29 Another major issue that hampers R&D and delays operations in IVD (in-vitro diagnostic) industry is the non-availability of bio specimens required for the preparation of QC (Quality Check) panels for testing manufactured products. Such panels are also required for testing the working of new /improved projects. In this regard, the Ministry must devise a mechanism so that such specimens and related data are shared by labs and hospitals with the IVD manufactures.

4.30 Taking into account the potential growth and independent development of Indian Medical Devices in the country, the Committee recommends that the separate Act on

medical devices should have rules and regulations with clearly defined roles and responsibilities of regulating bodies; supportive polices like predictive tariff policy, refurbished imports to enable spread of unavailable medical devices at a low cost for deeper penetration in the smaller cities and rural areas and preferential public procurement to boost domestic manufacturing. The Committee has already recommended for a single window clearance system. The Committee further recommends that interface between ministries dealing with Medical Device Rules, 2017 should be organised to carve out Road Maps for growth and development of Medical Device Industry in the country. The Committee is of the considered view that development of more number of medical device parks in differential space would operationlise linkage along with lending support to ancillary industry that can proliferate the Medical Device Industry in the country.

4.31 The Committee further recommends the Ministry to expedite the process of formulating the new separate legislation having adequate provisions to give Medical Devices industry in the country a kick start for pacing up with global market.

4.32 The Committee expresses concern over the fact that the highly technical medical devices industry, having no synergy with the Ministry of Chemicals & Fertilizers is being promoted by them instead of Ministry of Health and Family Welfare. The Committee, therefore, recommends that since the Ministry of Health and Family Welfare is the key stakeholder and the medical devices' being very diverse in range with respect to technology and material sciences, inter-ministry co-ordination is required between various departments, which should be done by the Ministry of Health and Family Welfare only. The Committee, accordingly, recommends that to nurture the nascent medical devices industry, the government should consider creation of a separate Department of Medical Devices for playing the role of a policy maker, facilitator as well as regulator. The Committee recommends that the new Department of Medical Devices can co-ordinate with the Ministries connected with the industry to perform the following key functions:-

i. **Catalyze Growth of the Indian Medical Device Sector;**
ii. **Define Priority Devices to fight Priority Diseases in consultation with national and international bodies;**
iii. **Implement Strategy to Shift India's Import Dependency from around 80% to less than 30% in next 5 years for Priority Devices and Next 10 years for all Devices;**
iv. **Facilitate Creation and Development of clusters for Medical Devices;**
v. **Facilitate Creation of Laboratories and service centers under PPP;**
vi. **Facilitate Skill Development of Personnel in the field of manufacturing, sales, service and regulations of medical devices;**
vii. **Create a forum for close cooperation between user, developers, manufacturers and academia;**
viii. **Create and manage a Special Purpose Vehicle Fund for long gestation R&D projects under Made by India and Make for India projects for enterprises.**

4.33 The Committee is given to understand that in medical devices India is dependent on imports to the tune of 80% and the imports crossed Rs. 63,000 crores in 2021-22 and the estimated market is of Rs. 1,60,000 crores. The Committee, therefore, recommends a

separate simple, implementable regulation for Medical Devices to encourage 'Make in India' of Medical Devices to deal with the 80% import dependence. The Quality Management System (QMS) and Quality Assurance of the medical devices should be ensured to prevent zero defectives from reaching the market and for consistent performance.

4.34 The Committee feels that the law to regulate Medical Devices need to have provision for risk proportionate regulatory controls and for risk proportionate penal system and provide clarity of exemptions or diluted regulatory requirements for very Low Risk Non Sterile Surgical Instruments and other non measuring Non Sterile Medical Devices. The Committee feels that in the new legislation regulatory controls need to be shared between Centre, State and Conformity Assessment Notified Bodies in Law. There should be no duplication of State and Central Government regulations. There needs to be accountability fixed on State Regulator to the Central Licensing Authority (or a National Regulator) to ensure harmonious enforcement. As regards the quality certification of the medical devices, the Committee feels that following the international practices, voluntary certification system for indigenous medical devices should also be promoted to a large extent for their better acceptability in the world market.

4.35 Chairman and Managing Director of Shalby Multi-Specialty Hospitals in his submission apprised the Committee that most of 90% companies which are into medical device manufacturing in India are having turnover within the range of INR 5 to 50 crores turnover and only 10% of the manufacturing companies are in the range of INR 50 to 500 crores turnover. He further said that the need is to have proper standards operating protocol for manufacturers, licensing, product quality, design verification, validation and testing certificate. The strategy should be to conduct clinical studies, biocompatibility studies, post market surveillance, pre-testing studies for implants/ equipments etc. This will enable the medical devices including implants to have a very high quality and safety standards to provide good healthcare. Furthermore, he gave following inputs regarding Orthopaedic implants:-

a. Create Private Bone Banks- Hugely dependent on Tata memorial and imported synthetic bone graft.
b. Regulate implant manufacture- Various type of quality, alloys of implants without any Biocompatibility studies products are sold, thus leading to poor patient and clinical outcome.
c. Support and adapt product registry for orthopaedic implant usage as mandatory for better tracking of patients and implants success/ failure outcome.
d. Currently, failure of products is an economic offence as a rare case; however need to make it as a criminal offence.

4.36 The Committee appreciates the views of Chairman and Managing Director of Shalby Multi-Specialty Hospitals and the need for bone banks for grafting. The Committee recommends the MoH&FW to consider creating "Bone Banks" to facilitate its easy availability. The Committee also recommends that the "Biocompatibility studies" should be made mandatory so as to prevent poor quality products from entering the market and failure of implants that end up being life-threatening should have stringent penalty to discourage such faulty products.

4.37 The Department related Parliamentary Standing Committee on Health and Family Welfare also went on a visit to Union Territories of Jammu & Kashmir and Chandigarh from 6th to 9th September, 2021 in connection with the examination of the subject Medical Devices: Regulation & Control. The Committee had a firsthand account of the present status of medical device industry in the respective UTs/States; steps taken by local governments to boost promotion and facilitate setting up of medical devices manufacturing facilities etc.

4.38 During its study visit the Committee was apprised of the status of Medical Devices Industry in the UTs of Jammu & Kashmir and the States of Punjab and Haryana.

Jammu and Kashmir

4.39 At present 11 Medical Device Industry exist in the UT of Jammu & Kashmir and there are no testing laboratories in the UT. Setting up of Medical Device Parks with common utilities and incentivizing domestic manufacturers are two key steps to strengthen the Medical Device Industry in the UT of J&K. Non-availability of raw materials, high input and transportation cost and lack of skilled labor resource are major challenges identified by UT administration for the medical device industry.

4.40 Regulatory mechanism to monitor quality of Medical Devices manufactured in India needs to be strengthened. Random Sampling of such products is the only option to ensure availability of Quality Medical Devices. As far as import of Medical Devices is concerned, the same can be monitored through a strict regulatory surveillance to be put in place at the site of import (Ports, Airlines, other intercepts). For the regulation of medical devices, a system of 'Third Party Conformity Assessment and Certification" can be an effective tool to secure fast track regulatory clearances in respect of Medical Device Units.

4.41 At present, the presence of CDSCO is very thin across the country. The Government of India should expand its size as per size of population & industry. Zone wise special trainings for Medical Device Officers/ Medical Device Testing Officers can be organized by National Drug Authority on routine basis so that technical expertise of officers gets enhanced. Regular Capacity Building Programmes / Skill Enhancement Workshops can also help the regulators to perform their legitimate duties in a better and pragmatic manner.

Haryana

4.42 The Government of Haryana stated that high cost of land and electricity in the State are major challenges in the Medical Device industry. To enhance the quality and cost-effectiveness, the Cluster Labs may be established, along with the subsidy of testing of equipments to the individual entrepreneurs. According to them, the States must be given administration autonomy regarding category C &D devices and States must be involved in the licensing procedure as drugs fall in the concurrent list. A representative from State FDA may be made part of the inspection/ audit, carried out by the notified body; so that uniformity of the inspection procedure may be ascertained. State Officers are proposed to be included for inspection of C&D category medical devices. Also, State Officers/ members must be part of CDSCO to make its operations more effective.

4.43 The Notified Bodies have very high fee for audit and for grant of license. Audit fee must be fixed at low prices by the Government so as to encourage indigenous industries. The Government of India must establish dedicated R&D wings in teaching institutes e.g. Medical Colleges, Pharmacy Colleges, Bio-medical engineering Colleges, etc along with in large manufacturing units to encourage research in high end Medical Device technology. To promote "Make in India" the Government must give incentives, subsidies, tax rebates and other benefits to the manufacturers and entrepreneurs. Also, industrial park shall be developed in areas having good logistics and sufficient skilled manpower, along with ease of accessibility. Materiovigilance Programme (MvPI) may be extended to medical devices to ensure the safety of medical devices in the country.

Chandigarh

4.44 The Chandigarh administration suggested that a representative from State FDA may be made part of the inspection/ audit, carried out by the notified body, so that uniformity of the inspection procedure may be ascertained. State Officers are proposed to be included for inspection of C&D category medical devices. Also, State Officers/ members must be part of CDSCO to make its operations more effective. Materiovigilance Programme (MvPI) may be extended to medical devices to ensure the safety of medical devices in the country.

4.45 Apart from this, the Committee sought written comments from various States/ UTs on the subject "Medical Device: Regulation and Control". The Committee received detailed responses from several States. Views of the State Governments on the subject are listed below:

1. Assam

4.46 Presently the State of Assam has only one licensed manufacturing facility for class-B Medical Devices. The Medical Device segment has good market potential in the State. Due to effective monitoring, surveillance and co-ordination with all the stake holders no shortage has been reported in medical devices during pandemic.

2. Delhi

4.47 Presently there are 44 Medical Device Manufacturing units in the Union Territory of Delhi. Most of these industries are involved in manufacturing of medical devices falling under Class A&B.

4.48 Medical Device officers appointed by the State Government are not getting opportunity for site inspection in case of application for manufacturing of Class A&B Medical Devices. Also, there is utmost requirement of training programmes both for regulatory official as well as for industry personnels for effective implementation of Medical Devices Rules, 2017. Since the Medical Device industry is largely technology based and is increasingly becoming more tech-centric, the need is to have regulators who are highly skilled and have sound technology knowledge.

4.49 Out of the 18 certified Medical Device Testing Laboratories approved by CDSCO, 05 are located in Delhi. The Delhi Government has suggested that every medical device approved for manufacture, sale, distribution or import should bear a unique device identification mark/number. Indian products which qualify as L1 are generally of sub-standard quality and thus are not preferred by doctors as most of them are life saving equipments also Indian Standards are not available for product standardization certification in case of many products. Due to the pandemic Covid-19, several new manufacturers started production in the country resulting in manifold increase in the production of medical devices. This has not only eased out the availability of these medical devices but has also made their availability at affordable price to the general public.

3. **Gujarat**

4.50 The Gujarat Government stated that due to current dual licensing procedure in Medical Devices Rules 2017, MSME manufacturer from the state are having difficulties in getting license from central licensing authority. As per the MDR -2017 manufacturing license premises for class A & B medical devices is audited by the notified body. Due to limited number of notified bodies in the State and less staff many times new manufacturers experience delay in audit. It is recommended to carry out audit by state drug authority for class A& B medical device.

4. Himachal Pradesh

4.51 The Himachal Government has suggested that the lack of regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices etc. are affecting the medical devices industry in the State. Experts and device manufacturers are demanding to bring a separate Medical Devices Act, to regulate the medical devices industry in India. Presently, India does not have any legal provisions to compensate patients facing health problems due to implants or the use of faulty medical devices. Under the law, companies are liable to pay compensation only when something goes wrong during a clinical trial. The State's upcoming Medical Devices Park project is located in Nalagarh. The project cost for the Medical Devices Park is around Rs 350 Cr. and the expected investment for Medical Devices Park is Rs 5000 Cr. with expected gainful employment of 10,000 persons. The State intends to be a leader in the medical device industry in next 5 years.

5. Jharkhand

4.52 The Jharkhand Government has stated that currently, a very few medical device industries are situated in Jharkhand which manufactured the limited categories of medical Devices. Therefore, the current demand and supply side dynamics provide a significant opportunity and rationale for manufacturing medical devices in the State. Medical Device Rules 2017 (MDR) at some instances provide incomplete and inconsistent information. For example, if we compare clinical investigation and clinical performance evaluation mentioned in the MDR, while talking about clinical performance evaluation, the rules seldom mentions the plan as a clinical investigation plan instead of the clinical performance evaluation plan; the reporting of suspected unexpected serious adverse reaction is mentioned for clinical investigation, but it is not

mentioned for clinical performance evaluation; similarly clinical performance evaluation section does not talk about the compensation to the patient in case of death or injury which the clinical investigation section talks about.

4.53 The Government should incentivize manufacturing in this emerging sector and specifically in early stages of creating the manufacturing ecosystem. Also, Quality certifications that are globally recognised are critical for indigenously manufactured medical devices to compete with products from other countries. This requires domestic manufacturers to align their product quality and processes to global standards. To encourage indigenous manufacturing, the Government could provide a price preference for incentives for domestically manufactured products. As healthcare is increasingly being financed by public and private insurance any preference in reimbursement for indigenously manufactured products would be a key demand-side driver for manufacturing in India.

4.54 The State Government suggested that human resource availability for both manufacturing and Research & Development in medical devices should be improved. The need is to promote research, innovation and India specific products for the innovation and manufacturing needs to be aligned to generate domestic demand. Creating an ecosystem with research institutions, technology parks, incubators is key for the development of industry in the State. In the State, the level of indigenous manufacturing is high for consumables and implants. However, within this segment too, there is still dependence on imports for mid to high tech products. Several factors relating to the policy' framework and tax structure lead to high dependence on imports these include inverted duty structure favouring imports of finished goods over raw materials, limited access to technology, intellectual property right protection and, size and scale of indigenous manufacturers. In the current state indigenous manufacturing is limited to products in the lower end of technology value chain, and driven by the consumables and implants segment. Jharkhand does not have the existing base of the medical device industries. Therefore, it is difficult to compete with the more developed state. Hence, the Government of India needs to give special attention and support to the state of Jharkhand to develop favorable ecosystem support, to established the indigenous 'Quality Certification' authority in State and also some exemption in PLI scheme.

6. Kerala

4.55 The State Government apprised the Committee that presently, there are 15 manufacturing firms licensed for the manufacture of Class A & B category of medical devices, and 05 manufacturing firms licensed for the manufacture of Class C &D medical devices in Kerala State. Total turnover of medical devices & in-vitro diagnostic devices industry in the state is approximately 800 Crore. CDSCO has stopped issuing WHO-GMP (Good Manufacturing Practices) certification after the implementation of Medical Devices Rules (MDR) 2017. The reasons for not issuing the certificate are not mentioned in the manufacturing licence issued. Hence all manufacturers have to explain the reasons for not having GMP certificates, to every overseas customers. As per MDR 2017, even though the manufacturing licence is perpetually valid for five years, the validity is not mentioned in the license, which creates confusion to overseas customers.

4.56 The State Government suggested that provisions for fast tracking of applications, in case of emergency situations needs to be considered. Standards are mandated for finished medical devices but, not always required for raw materials. The challenges faced by the medical devices industry in the State are- lack of availability of manufacturers of indigenous raw materials, electronics parts in the State, delay in licensing of Class C and D products from CDSCO, Delhi & South Zone, Chennai, fee charged for many applications are very high which ranges in lakhs (Rs. 50,000- Rs. 500000) which is a burden for small enterpreneurs/startups to develop their products.

7. Meghalaya

4.57 The manufacturing status of Medical Devices industry in the state is Nil. The market potential in the state is huge. With the increase in consumption there are marginal opportunities to facilitate contribution to the economy. A development trajectory is needed to cope with future emergencies by reviewing and assessing the current regulatory system for Medical Devices and regulatory capacity building in cooperation with the national regulatory authority.

8. Odisha

4.58 The Odisha Government apprised the Committee that there are very few medical device manufacturing industries or units in the State. Presently, there are around 25 manufacturers in the State. One of the main reasons for the very low number of Medical Device Manufacturing units is non-availability of any electronics components manufacturing units. The State of Orissa has excellent growth opportunities for Medical Equipment industries as it shares a common border with states of southern, central as well as eastern parts of India. Odisha is a power surplus State and provides electricity to nearby States. Odisha is drained by 11 major rivers and their tributaries provide ample water supply. The State has demanded to set up an office of CDSCO in the state of Odisha to help entrepreneurs understand the requirement of starting a new venture in Medical Device. Laboratories should also be set up in the State with necessary accreditations for testing of medical equipment.

4.59 Classification based on risk assessment is not present with the BIS standards. Besides, BIS standards are not available for many critical medical devices. In view of this, international certification for procurement becomes necessary. The students passing out of technical institutes should be industry ready to meet the basic requirement of the field/place of work, they should be well versed with electrical and electronics components: their use, application and common variants available in the market. In order to achieve this in the State of Odisha, Bachelors/ Master / Diploma courses maybe opened in prestigious Govt. Technical institutes such as IIT-Bhubaneswar, NIT- Rourkela where Bio-Medical engineering courses can be merged with medical colleges/ institutions for hands on experience.

9. Punjab

4.60 Total number of existing medical devices manufacturing units in the State is 12. Licensing of only Class-A & B Medical Devices is being done by State Licensing Authority.

However, inspection for grant of medical devices of Class C and D category are being carried out by Drugs Regulators of CDSCO (GOI). It is suggested that inspection of Class A & B (which includes Surgical Dressing, Disinfectants & Syringes etc.) may be done by State Drugs Regulators instead of 3rd party audit. There is need to strengthen the medical device testing facilities at State level.

10. Tamil Nadu

4.61 The TN Government has stated that every here are around 100 Medical devices/ IVD manufacturing units in the State. The Drugs Testing Laboratories of the State have not been notified by the Union Government and the Medical Device Testing Officers of the State have not been designated by the Union Government to analyse & issue of Test reports of Medical Devices. In Medical Devices Rules 2017, no provision has been made in the online portal to refer cases of audit of manufacturing units to the notified body for audit. Also, the reports of the notified bodies are not technically sound and the remarks are incomplete as per Medical Devices Rules 2017. There is no provision in the portal to refer back such deficient audit reports to the notified bodies for clarification. There is no uniform procedure for the issue of manufacturing approvals for Class A/B and Class C/D Medical Devices. There is no timeline for Class C/D as that of Class A/B. There is huge difference in Fee structure between Class A/B and Class C/D.

4.62 High end and sophisticated Medical equipment need to have standards comparable with USFDA and European CE certification, till such time the Country could come up with comparable standards and certification process. Non-availability of proven technology, dependence on import of raw materials and its high cost, limitation on infrastructure facilities in manufacturing and marketing, lack of proper regulatory mechanism for ensuring the quality, non - availability of BIS for Medical devices in line with international standards and finance are some of the major challenges in the growth of manufacturing of medical devices in the State.

4.63 The Committee endorses the views of some of the State Governments for Zone wise special trainings for Medical Device Officers. Trainings for Medical Device Testing Officers can be organized by National Drug Authority on routine basis so that technical expertise of officers gets enhanced. The Committee feels that Capacity Building Programmes/ Skill Enhancement Workshops will also help the regulators to perform their legitimate duties in a better and pragmatic manner.

4.64 The Committee feels that Materiovigilance Programme (MvPI) may be extended to medical devices to ensure the safety of medical devices in the country and uniformity of the inspection procedure may be ascertained. The Committee also recommends that lower rates of audit fee by the Government would also encourage indigenous manufacturers.

Conclusion

4.65 The recent surge in demand and improvement in manufacturing scenario of medical devices coupled with robust regulatory regime addressing the challenges being faced by the indigenous manufacturers, importers, exporters and more importantly patients provides great opportunity to Indian medical device industry to establish itself as a major player in the global medical devices market.

4.66 The Committee, in this report has extensively examined the subject and identified key concern areas and challenges that are yet to be resolved. The Committee believes that separate legislation exclusively for the Medical Devices and bringing the Department of Pharmaceuticals (DoP) under the Ministry of Health and Family Welfare would really help solve some of the major challenges being faced by the medical device manufacturers.

4.67 The Committee notes that the Covid-19 pandemic has highlighted the need to support indigenous manufacturers of Medical Devices. The pandemic laid bare various issues like insufficient infrastructure and fund for research and development, lack of public funding for research, dearth of skilled manpower, lack of synergy between Central-State regulatory authorities, inappropriate regulations for medical devices, lack of global-level quality standards etc plaguing the medical device industry in India. With the immense potential for the medical devices industry anticipated, the Ministry should focus on resolving the challenges and develop a detailed "Roadmap with Practical and Actionable Strategy".

RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE

IMPACT OF COVID-19 ON THE MEDICAL DEVICE INDUSTRY

The Committee observes that Covid-19 pandemic wrecked havoc on the world for almost two years and still lingers as a looming threat. The pandemic caused great human and financial loss and severely affected almost all the sectors of the economy. The Healthcare system of India like of other countries was put to severe test and the healthcare resources were stretched to their limits. Like other segments of the healthcare system, the Medical devices industry had to work overtime to meet the surge in demands of medical equipments and devices. During the first wave of pandemic, owing to its sudden nature, the country faced severe shortages of medical equipments like testing kits, PPE (Personal Protective Equipment) kits, masks, sanitisers, and other related critical items as domestic and international supply chains got disrupted leading to almost stoppage of imports. The situation was compounded by poor domestic manufacturing capacity.

(Para 1.12)

The Committee further notes that amidst the prevailing pandemic situation the domestic manufactures saw opportunity in adversity and ramped up their production capacities to meet the sudden surge in the demand of medical equipments like PPE Kits, masks, sanitisers etc. The Government supported the local manufactures and start-ups were provided/extended soft loans and other incentives. The assured procurement and predictable demand encouraged Indian manufacturers to step forward and serve the country in crisis. Within months of the Covid-19 pandemic India went from importing PPE kits, masks, testing kits to not only self-reliant but the country also exported these devices to other countries. However, the current situation is that India still remains largely an import dependent nation w.r.t medical devices, but the very least the pandemic has done to the industry is that it has brought the industry to the limelight and gradually with government attending to the industry with improvements in regulation, manufacturing facilities, incentives, India in all probability would be a major player in global medical devices industry.

(Para 1.13)

REGULATORY FRAMEWORK: STANDARDS & QUALITY CONTROL

The Committee notes that Drugs and Cosmetics Act lacks offences and penalties for malpractices like manufacturing of sub-standard devices, fake USFDA/CE certifications. The D&C Act does contain a penal provision for the manufacture of sub-standard drugs but does not penalize the manufacturers of sub standard medical devices (although medical devices are legally defined in terms of drugs) because the legally binding standards which are recognised in the Act pertain only to drugs. Therefore, due to lack of penal provisions for Medical Devices in the said Act, the manufacturers of sub-standard medical devices move scot free. The scope of Medical Devices Rules, 2017 is restricted to only those medical devices which are notified by the Government from time to time as 'drugs'. The Committee appreciates the initiatives of the Ministry to change the definition of Medical Devices in

2020 to make it more inclusive and thus include almost all medical devices for regulation. However, the Committee feels that the definition of "Medical Devices" be such that any product which falls under the definition is automatically eligible for regulation.

(Para 2.7)

The Committee notes that in the recent years the Medical Devices has become a vast industry. Improvements in economy, life-expectancy, rise in income levels and overall rise in awareness about health coupled with surge in communicable and non-communicable diseases have been some of the key drivers behind growth of the industry. This has necessitated better regulation and control of the industry. The Committee believes that there is a need for a well-researched, organised and inclusive legal architecture for regulating activities of manufacturing units, medical institutions, laboratories, clinical trials having well defined responsibility, roles and accountability for all the stakeholders of the industry.

(Para 2.8)

The Committee, while welcoming, the initiative of the Ministry to set up a panel to make the new Drugs, Medical Devices and Cosmetics Bill with separate provisions for Medical Devices strongly recommends that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should appreciate the potential of the Medical Device industry and formulate a separate legilsation for Medical Devices.

(Para 2.9)

The Committee believes that the new legislation on Medical Devices should have the provisions to transform the medical devices industry and bring about a Medical Device Revolution in the country. The Committee further recommends that instead of the panel the Government should come up with a 'National Commission on Medical Devices' to examine all aspects of the Industry in detail and bring forth a comprehensive law supported by a holistic policy and institutional infrastructure for the purpose. The Committee further recommends that this Commission should study the aspect of centralizing the Medical Device licensing with the Central regulator so as to make the approval process easy. The Ministry should also focus on guaranteeing transparency by designing this legislation so that the citizens/ experts get a right to participate in decision making. The legal provisions should be such that citizens/experts can participate in the regulatory process & register their objections. The blueprint for the new legislation must also include a 10-15 year roadmap with a clear policy plan & targets. The Committee strongly believes that with a 15 year roadmap with annual targets for the Medical Device industry, India would emerge as the world's biggest centre for manufacture & service of Medical Devices and thus also a leader in medical tourism.

(Para 2.10)

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

The Committee observes that the functions of CDSCO primarily focus on the regulation of drugs as the regulatory body was originally set up to regulate Pharma and other related segments. The MDR 2017 mandated the CDSCO to regulate the Medical Devices segment as well. However, the existing structure and expertise (which is more pharma centric) of the workforce in CDSCO is falling short in effectively regulating the medical devices industry.

(Para 2.13)

The Committee recommends that the new legislation should set up a new set of regulator at different levels for regulating the Medical Devices industry. Unlike the present structure, the proposed regulator should license the manufacturing of all classes of medical devices i.e. Class A, B, C, and D. This would help harmonise the regulation process throughout the country as it would do away with different regulating procedures employed by different States. This step would greatly help the manufacturers and will reduce the time required to start a manufacturing unit thereby facilitating ease of doing business. The Committee also recommends that to undertake the regulation for all Classes of medical devices throughout the country, the proposed regulator should be adequately staffed with workforce which is technically skilled and is well-versed with the functioning of medical devices industry. The Committee recommends the Ministry to work in synergy with State Governments and impart the necessary skills to the local medical device officers and also devise a mechanism to regularly designate State Medical personnel as Medical Device/ Medical Device Testing Officers so that the mandate of the legislation can be implemented effectively. The Committee believes that with industry growing by leaps & bounds, the government should not afford regulation of medical devices by pharma experts and its time that at ground level the medical device regulations are dispensed with by qualified and well-trained Medical Device Officers to give a fillip to the Medical Device industry in the country.

(Para 2.14)

The Committee recommends the Ministry of Health and Family Welfare to allow the new regulator to involve institutions like IISC, CSIR, DRDO and network of IITs to test medical devices for safety and efficacy. The Committee is of the firm view that these institutes have high-tech labs and thus can be used to test medical devices for their electronic, electromagnetic, biochemical-run aspects. The Committee further recommends that additional investments should be made to raise the standards of these labs as per the requirements.

(Para 2.15)

The Committee notes that multiplicity of regulations exists at the component level from different departments/ ministries. The Committee recommends that CDSCO which

operates a single window clearing platform for application of license for manufacturing, export, import shall also integrate all these bodies involved in the regulation of medical devices. A single window clearance for all the department/ ministries would significantly boost investment in R&D in the field of medical devices and would also reduce the time required for obtaining approvals from different departments/ ministries. The Ministry must incorporate such an all-encompassing "single window clearing/approval system" in the proposed new separate Act for the regulation of Medical Devices.

(Para 2.18)

The Committee opines that while setting the standards and benchmark of medical devices the foremost factor which should be considered is "health", the standards devised must prioritise health and wellness. In this regard, the Committee believes that BIS should focus on harmonising the Indian standards with world-class and globally accepted quality standards. Adapting Indian standards as per global standards would also help Indian medical device manufacturers in global market as it would make them more competitive and acceptable, which in turn would transform India into a net exporter of medical devices, spare parts and services. The Committee, therefore, recommends BIS to periodically update Indian Standards to corresponding global medical device standards as complying with Indian standards is affordable for local manufactures in comparison to global standards.

(Para 2.21)

The Committee further recommends that BIS should encourage manufacturers to demonstrate/adhere to conformance to essential principles of the medical device concerned, as this would reorganise Indian products achieve greater international acceptance. This will engineer a shift towards increase in India's global share in the medical devices sector.

(Para 2.22)

The Committee notes that the country has only 18 certified Medical Device Testing Laboratories that have been approved by CDSCO and that is grossly insufficient keeping in view the size of the country. The Committee is of the considered opinion that having adequate common infrastructure including accredited laboratories in different regions of the country for standard testing would significantly encourage local manufacturers to get their products tested for standards and such measures undertaken would also help in reducing the cost of production which ultimately will improve the availability and affordability of medical devices in the domestic market.

(Para 2.27)

The Committee finds that there is a dire need for developing a robust IT enabled feedback driven post market surveillance system for Medical Devices to evaluate the efficiency of specific Medical Devices. A medical device registry, particularly for implants should also be made to ensure traceability of patient who has received the implant in order

to assess the performance of the implant and ascertain upto what extent the implant has made the life of the patient comfortable and also to seek feedback of functional capacity of medical devices. Such measures would ensure that patients get access to good quality and approved medical devices.

(Para 2.28)

QUALITY CONTROL

The Committee is of the considered view that quality and affordability are two vital factors regarding medical devices. Indian Medical Devices Industry presently lacks research ecosystem and infrastructure for manufacturing of high tech, advanced medical devices (Class C&D) and Indian Medical Devices Industry doesn't have facilities to produce such medical devices comparable to global standards. Here, the Committee appreciates QCI for filling up the vacuum in quality certification space by extending the option of Indian Certification of Medical Devices (ICMED) 13485. The Committee believes that QCI can play a pivotal role in establishing norms of quality and ensuring that Indian manufactured products have competitive product advantage, *vis-à-vis*, the international standards in terms of quality. The Committee, therefore, recommends the Ministry to introduce standards and certification process (particularly for Class C&D products) comparable to global standards. The Ministry, along with compulsory compliance to Quality Management System as per schedule 5 of the MDR, 2017, should also allow cognizance to 3rd party assurance schemes like ICMED 13485.

(Para 2.33)

The Committee further recommends that till such time the Indian Medical Device Industry come up with comparable standards and certification process, the Ministry should extend financial support to the local manufacturers in capacity building for compliance to USFDA/CE regulations considering that USFDA and CE certification processes are costly affairs. The Government support would facilitate local manufacturers to gain access to US and European markets thereby boosting exports.

(Para 2.36)

MANUFACTURING, PRODUCTION, PROMOTION& PRICING

The Committee is of the considered view that in order to encourage indigenous manufacturing, the Government should provide incentives or encourage preferential purchase for domestically manufactured products in Government procurement. In this regard, the Department should ensure that in all public procurement, the preference must be given to Indian manufactured medical devices having domestic content of at least 50%. Given the size of Government's (both Central and State) purchase, the Preferential Purchase Agreement would have a significant pull for a number of medical devices companies to manufacture medical devices in India. Also, the PLI scheme should be broad based and all the medical devices should be covered under the scheme.

(Para 3.7)

The Committee notes that most of the high-end technology and innovative products originate from a well-developed ecosystem and innovation cycle. The Committee is pained to note that despite boasting of several IT hubs like Bengaluru, Pune, Hyderabad, Delhi-NCR the desired ecosystem for manufacturing of highly advanced medical devices is yet to be fully developed in the country. The Committee, therefore, recommends prioritizing and developing a robust funding mechanism to nurture an ecosystem for innovation for medical devices industry. In this regard, the Committee recommends the Department of Pharmaceuticals to have a dedicated corpus to fund start-ups and Small & Medium Enterprises (SMEs) undertaking research projects that aim for improving quality, efficiency of existing devices and other healthcare outcomes.

(Para 3.8)

To invigorate the culture of research and development in medical devices in institutions like IITs, NITs and other academic institutions the Committee recommends the Department to start Research Linked Incentive (RLI) Scheme in Line with PLI scheme. The Department should facilitate academia- industry partnership for undertaking research projects on industry challenges and incentivize the successful outcomes.

(Para 3.10)

The Committee realizes that biomedical engineers are integral to develop ecosystem for research in medical devices in India. These engineers are trained in the principles of physics and mathematical computation for the development of safe and effective medical devices that best fit the needs of medical providers and patients. However, biomedical engineers generally do not interface directly with patients to the same extent as physicians; therefore, biomedical engineers may not fully understand the specific needs of patients in the same way that medical professionals and manufacturers do. The Committee, therefore, strongly recommends the Department to facilitate regular interactions of biomedical engineers with leading physicians and manufacturers and thus encourage them to undertake research on medical devices. Furthermore, the Committee recommends expediting setting up centers of excellence in medical devices at all the National Institutes of Pharmaceutical Education and Research (NIPERs). The courses may commence in these centers of excellence to train and educate biomedical engineers on ongoing challenges faced by medical device industry.

(Para 3.12)

The Committee also recommends that the Government should arrange to provide international exposures to domestic manufactures and to their products.

(Para 3.13)

SCHEME FOR PROMOTION OF MEDICAL DEVICE PARKS

The Committee commends the Department for launching Scheme for Promotion of Medical Device Parks in India. The Committee believes that India has huge growth potential in manufacturing of medical devices. Well-coordinated inter-ministerial and inter-governmental (central and state) strategies aimed at offering manufacturers competitive advantage in manufacturing in India will result in importers finding it more

profitable to manufacture in India than to import it. The Committee believes that logistical support in shared manufacturing facilities like Medtech parks would significantly reduce capital expenditure of manufacturers and thus giving a boost to manufacturing in India.

(Para 3.18)

The Committee recommends following steps for improving the efficiency and overall facilities of Medtech Parks in India:-

vi. **The Mediparks should have NABL (National Accreditation Board for Testing and Calibration Laboratories) approved medical device testing laboratories to reduce time required in manufacturing a product;**

vii. **Each park should have dedicated office for skilled and unskilled labor force. This said office should maintain a registry of registered workers so as to maintain the continuous availability of workforce;**

viii. **To control pollution, each Medipark should have Effluent Treatment Plant (ETP);**

ix. **Availability of subsidized power and water ;and**

x. **For promoting the Indian medical device market, Mediparks should organize- "Medical Device Exhibitions" and workshops.**

(Para 3.19)

The Committee further recommends that some of the Mediparks should focus on manufacturing medical device components and thus make the country self reliant on spare parts with provision for extending necessary services. This can further strengthen into India emerging as hotspot for medical devices spare parts and hub for medical devices repairing and service centres for other countries. Thus Medical Devices industry would have added advantage of huge employment generation capacity.

(Para 3.20)

The Committee observes that India imported medical devices worth USD 8.5 billion in 2021-22 and the corresponding export figure for 2021-22 was only 2.9 billion. The Committee is of the firm view that three segments viz. electronic equipments, implants and surgical instruments account for the highest imports in the medical devices sector. These segments include highly important and widely used high-end technology devices such as CT Scanners, MRI, Ultrasound & X-Ray machines, knee and hip implants, dental fixtures, Cancer diagnostics and other sophisticated surgical instruments. The Committee observes that manufacturing of high-end technology devices would require evolved medical devices sector having a robust Research and Development infrastructure and trained workforce, therefore, the Government must strive towards improving R&D infrastructure in the country.

(Para 3.22)

The Committee recommends that to realise the goal of making India a USD 50 billion market by 2025, all the three pillars of the medical devices sector viz. Government, Industry and Academia should work in synergy on a common vision and roadmap. With

the ultimate goal of becoming "self-reliant" the focus should be on increasing the manufacturing capacity by having a simplified yet effective regulatory regime and liberal taxation system. The Government must also focus and invest in R&D in premier technological institutions like IITs; stress must also be laid on skill development to have a trained and qualified workforce for the sector. The Committee strongly feels that Industries must also take a lead in R&D and the leading manufacturers and manufacturers' associations should establish convergence and collaboration between the Industry and academia.

(Para 3.23)

The Committee believes that indigenous manufacturing can only be fostered if there is local availability of raw materials and critical components; the 80% dependency on imported products is primarily due to the lack of (i) high end technology and (ii) poor availability of raw materials. The Committee, therefore, recommends that the Government must incentivize such institutes, start-ups, manufacturing units which are engaged in manufacturing of raw materials and spare parts locally. Academic institutions like IITs, AIIMS & IISCs and research bodies like CSIR who have the technical know-how and the technology required should be allowed and encouraged to produce certain raw materials like antibodies, synthetic antigens, proteins etc. Additionally, the Committee recommends that PLI scheme should be expanded to cover raw material and component manufacturing as well so that India can become a hub for raw material for the world.

(Para 3.24)

The Committee feels that the Medical Devices segments in which India is 80% dependent upon imports are the highly capital intensive, having long gestation period and requiring more R&D segment. Simultaneously, the devices are essential for the people as they are mostly the diagnostic devices which help one detect any disease. If such detections are early, the chances of their control would also be more. The Committee, therefore, recommends that the Government must chalk out specific strategy for import of refurbished diagnostic devices to increase the penetration of such devices in each district of the country, till such devices are not manufactured at low cost domestically. The Committee also recommends that domestic manufacturers should be supported in installation of manufacturing plants in collaboration with international players, thus promoting production of high quality medical devices at low cost. The Committee also recommends that the safety parameters of the incoming medical devices should be ensured so that only those medical devices which qualify the set parameters of safety and quality enter the Indian market. Sub-standard and obsolete medical devices shall not be allowed to enter the Indian market.

(Para 3.27)

The Committee observed following factors that affect Indian domestic manufacturers and recommends certain additional measures for boosting manufacturing and exports and improve ease of doing business which inter-alia include:-

i. **Reviewing import duty structure- Lower import duty makes it cheaper to import than manufacture in India. Lower import duty on imported devices coupled with**

12% GST on locally manufactured products discourages manufacturing in India. Moreover, 18% GST on sanitizer and IVD equipments is regressive and should be reduced to 12%.

ii. **US/UK manufacturers design medical products like implants on bone structures of Caucasian people, such products are not ideal for Indian population, however, due to deficiency of Indian designs, surgeons recommend such products to the patients. In this regard, the Department shall reward/ incentivize products that carry Design India Certificate issued by Department for Promotion of Industry and Internal Trade (DPIIT). Incentivizing products built on Indian design would boost innovation in India.**

iii. **Due to lack of local availability, machinery for setting up manufacturing plants is imported from countries like China, till the time India is capable of producing such machinery on its own, the Government should reduce excise duty on importing of machinery to set up plants. High excise duty on raw materials and parts of devices adds to the cost of production and this encourages import of finished products.**

iv. **Considering the potential of growth in the medical device industry, the Committee strongly recommends that there is urgent need to have a separate EPC for promotion of exports in the medical devices sector.**

(Para 3.28)

The Committee commends the Department for preparing the Draft Medical Device Policy 2022 that proposes regulations to ease patent processes, create ecosystem for R&D, skilling the regulatory workforce, streamline regulatory clearances, and establish 'Centres of Excellence'. The, Committee, however expresses its concern over absence of provisions regarding data security of patients in the proposed policy. With the Government's push for health records digitization under Ayushman Bharat Digital Mission (ABDM), the Committee understands that there is an urgent need to regulate digital devices likes "wearables (smart watches)" to protect health data of people. Therefore, considering huge data generation, the Committee recommends the Department to include stringent data protection norms in the Draft Medical Device Policy, 2022.

(Para 3.30)

The Committee further recommends that the government should come up with an enabling environment for the growth of the industry in multiple ways *viz*. manufacturing, import, capacity building, spare parts and a centre for repairs of medical devices thus bringing forth a medical device revolution in the country. The policies should contain supportive and continuous tax structure for encouraging international players to set up industries in India thus reducing the cost of the medical devices.

(Para 3.31)

REGULATION OF PRICING BY THE NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

The Committee notes that there are only 4 Medical Devices (Cardiac stents, drug eluting stents, condoms and intra uterine devices) that have been included in the National

List of Essential Medicines. The Ceiling Prices are notified for these 4 Scheduled Medical Devices by National Pharmaceutical Pricing Authority (NPPA). Apart from the above, the remaining medical devices come under non-scheduled Medical Devices under the DPCO, 2013. The Committee has learnt that NPPA monitors the Maximum Retail Prices of all non-scheduled medical devices and ensures that no manufacturer increases the maximum retail price of any medical device more than ten percent of maximum retail prices during preceding twelve months. The Committee believes that allowing a maximum increase of 10% may result in serious jump in prices in a span of few years. The Committee, therefore, strongly recommends that instead of this 'same size fits all' approach; the Department like risk-based classification of devices should create separate baskets for medical devices for pricing depending upon their cost, availability, need and affordability by the patients. The devices which are required for critical care to the patients should ideally be categorized under "Scheduled Medical Devices" and be listed under National List of Essential Medicines.

(Para 3.38)

Additionally, the pricing of medical devices should also take into consideration the cost of the manufacturing and the value the medical device adds to the patient experience and ease it brings to the physician. The Committee, therefore, recommends the Department to strike a balance between providing affordable healthcare and providing quality healthcare. As mere providing healthcare services without considering how a product can best deliver desired outcomes for sustainable period goes against the basic policy and principles of the welfare State. In this regard, the Committee welcomes the Government's decision to move from L1 (lowest price) procurement method to Quality-cum-Cost Based Selection (QCBS), thus incorporating the element of quality in public procurement.

(Para 3.39)

The Committee further believes that quality comes from innovation and in medtech sector, more than completely new inventions, incremental innovations to add features and improve accuracy & efficiency of the existing devices is the norm, so much so that more than 60% of the innovation is incremental innovation. A lot of effort and cost go into R&D, designing, testing, approvals and marketing before innovative products are provided to the needy persons. The Committee is of the opinion that till the time the desired synergy between Government policies, initiatives, academic institutes and Medtech industry is established to create an ecosystem for innovation and R&D in India, so that cost of production of innovative products comes down, the Government shall continue with steps like price exemptions, value based procurement and subsidy support to the domestic manufacturers. The Committee is of the opinion that the measures so undertaken would result in boost of demand generation as good quality products would be available at affordable prices.

(Para 3.40)

The Committee has been given to understand that besides the factors like availability of technology and raw materials, the phenomenon of inflation in medical devices is due to unfair trade practices by certain entities. The Committee lists following measures to provide a level playing field to the domestic medical device manufacturers and curb the artificial inflation in the prices of medical devices:-

i. **Certain MNCs (Multi National Companies) avoid printing of MRP on each unit of product, so that the buyer (large distributors and hospitals) can list such a price to derive high profits, resulting in unnecessary surge in prices of medical devices. The DoP, in co-ordination with Ministry of Finance, must ensure strict adherence to the compliance of the rule which necessarily mandates the printing of MRP on each product. The Department through the Ministry concerned should instruct the Port officials to check each medical device consignment for compliance of the said rule, so that the issue can be addressed at the origin.**

ii. **Some manufacturers indulge in manufacturing of low-cost but substandard products that wholly disturbs the market for genuine manufacturers who comply with all the regulations and standards. The Committee, therefore, strongly recommends for strict surveillance over entry of sub-standard Medical device into Indian Market so as to avoid hazardous impact on patient's health.**

(Para 3.41)

The Committee recommends the Department to effectively implement the "Trade Margin Rationalization" policy to address the issue of arbitrary pricing by importers. Considering the number of supply chain in a vast country like India, the Department needs to have consultation with all the stakeholders in the industry. The Committee believes that thorough consultation with all the stakeholders would help the Department in arriving at a justified trade margin by which not only the interests of consumers, suppliers and manufacturers would be taken care of but also the problem of irrational pricing would be resolved. Effective implementation of "Trade Margin Rationalisation" (TMR) would result in lower out-of-pocket expenditure which ensures that families are not pushed below the poverty line due to the medical expenses.

(Para 3.43)

The Committee appreciates the initiative of the Department of Pharmaceuticals in upscaling of manpower for the sector, however, feels that considering the potential of growth of the medical device sector, there is an urgent need to prepare a mammoth skilled manpower at various levels, hence more steps should be taken on priority.

(Para 3.45)

VIEWS OF THE GOVERNMENT & OTHER STAKEHOLDERS

The Committee feels that the mandate of the Department of Pharmaceuticals is very much related to the health sector like drugs & medical devices, their production, development, control, promotion, education, training & research. Hence, the Committee strongly feels that, for better coordination, the Department should be brought alongwith Department of Health and Family Welfare under the Ministry of Health & Family Welfare from the Ministry of Chemicals & Fertilizers by amending the Government of India (Allocation of Business) Rules, 1961.

(Para 4.11)

The Committee, during its deliberations on the subject observed issues in the functioning of current regulation and the Committee, therefore, strongly recommends incorporating suitable provisions in the new Bill so as to overcome the shortcomings in MDR. As per MDR-2017, sale and testing of Class A/B/C/D medical devices along with IVD (In-vitro diagnostics) is vested with the State Governments, however, the Drug Testing Laboratories are not notified and Medical Device Testing Officers of State are not designated regularly by the CDSCO thus causing inordinate delay in granting approvals. Presently, there is neither a provision in the online portal for referring the licensed manufacturing unit (for Class A devices) for audit by the notified body nor there is any feedback mechanism in the CDSCO portal to refer the technically deficient audit reports which are prepared by notified bodies. Further, there is no mechanism for registering complaints regarding functioning of CDSCO portal. The Committee also found that there is non-adherence of timelines for audit and report as per MDR-2017 by the notified bodies.

(Para 4.27)

The Committee feels that for a strong regulator it needs to be supported with required expertise from the backgrounds of Medical, Biomedical Engineering, Product Development and Marketing. The Committee further recommends that there is utmost requirement of training programmes for regulatory officials (both central and State level) as well as for industry persons for effective implementation of the rules and regulations. The Committee feels that developing skilled and trained manpower possessing technical know-how of the medical devices is essential for smooth implementation of the regulations. This could be done through long-term, short-term and crash courses on medical device manufacturing and quality control in institutes like IITs, NITs and medical colleges for new regulatory officers. The Ministry of Skill Development may also be requested to formulate courses related to medical devices, manufacturing, use and maintenance. There is a need for devising a mechanism to pre-empt exigencies and provision for "emergency use authorization" of medical devices in case of emergencies. The Ministry should also lower high fee charged by notified medical devices testing laboratories like NIB particularly for Class C&D devices. The Committee observes that there is lack of co-ordination between academic institutions and industrial requirements. The Committee recommends that the innovators and scientists at research institutions should be made aware of the required standards and regulations, otherwise it's difficult to commercialize their innovation/creation.

(Para 4.28)

Another major issue that hampers R&D and delays operations in IVD (in-vitro diagnostic) industry is the non-availability of bio specimens required for the preparation of QC (Quality Check) panels for testing manufactured products. Such panels are also required for testing the working of new /improved projects. In this regard, the Ministry must devise a mechanism so that such specimens and related data are shared by labs and hospitals with the IVD manufactures.

(Para 4.29)

Taking into account the potential growth and independent development of Indian Medical Devices in the country, the Committee recommends that the separate Act on medical devices should have rules and regulations with clearly defined roles and responsibilities of regulating bodies; supportive polices like predictive tariff policy, refurbished imports to enable spread of unavailable medical devices at a low cost for deeper penetration in the smaller cities and rural areas and preferential public procurement to boost domestic manufacturing. The Committee has already recommended for a single window clearance system. The Committee further recommends that interface between ministries dealing with Medical Device Rules, 2017 should be organised to carve out Road Maps for growth and development of Medical Device Industry in the country. The Committee is of the considered view that development of more number of medical device parks in differential space would operationlise linkage along with lending support to ancillary industry that can proliferate the Medical Device Industry in the country.

(Para 4.30)

The Committee further recommends the Ministry to expedite the process of formulating the new separate legislation having adequate provisions to give Medical Devices industry in the country a kick start for pacing up with global market.

(Para 4.31)

The Committee expresses concern over the fact that the highly technical medical devices industry, having no synergy with the Ministry of Chemicals & Fertilizers is being promoted by them instead of Ministry of Health and Family Welfare. The Committee, therefore, recommends that since the Ministry of Health and Family Welfare is the key stakeholder and the medical devices' being very diverse in range with respect to technology and material sciences, inter-ministry co-ordination is required between various departments, which should be done by the Ministry of Health and Family Welfare only. The Committee, accordingly, recommends that to nurture the nascent medical devices industry, the government should consider creation of a separate Department of Medical Devices for playing the role of a policy maker, facilitator as well as regulator. The Committee recommends that the new Department of Medical Devices can co-ordinate with the Ministries connected with the industry to perform the following key functions:-

i. **Catalyze Growth of the Indian Medical Device Sector;**
ii. **Define Priority Devices to fight Priority Diseases in consultation with national and international bodies;**
iii. **Implement Strategy to Shift India's Import Dependency from around 80% to less than 30% in next 5 years for Priority Devices and Next 10 years for all Devices;**
iv. **Facilitate Creation and Development of clusters for Medical Devices;**
v. **Facilitate Creation of Laboratories and service centers under PPP;**
vi. **Facilitate Skill Development of Personnel in the field of manufacturing, sales, service and regulations of medical devices;**
vii. **Create a forum for close cooperation between user, developers, manufacturers and academia;**

viii. Create and manage a Special Purpose Vehicle Fund for long gestation R&D projects under Made by India and Make for India projects for enterprises.

(Para 4.32)

The Committee is given to understand that in medical devices India is dependent on imports to the tune of 80% and the imports crossed Rs. 63,000 crores in 2021-22 and the estimated market is of Rs. 1,60,000 crores. The Committee, therefore, recommends a separate simple, implementable regulation for Medical Devices to encourage 'Make in India' of Medical Devices to deal with the 80% import dependence. The Quality Management System (QMS) and Quality Assurance of the medical devices should be ensured to prevent zero defectives from reaching the market and for consistent performance.

(Para 4.33)

The Committee feels that the law to regulate Medical Devices need to have provision for risk proportionate regulatory controls and for risk proportionate penal system and provide clarity of exemptions or diluted regulatory requirements for very Low Risk Non Sterile Surgical Instruments and other non measuring Non Sterile Medical Devices. The Committee feels that in the new legislation regulatory controls need to be shared between Centre, State and Conformity Assessment Notified Bodies in Law. There should be no duplication of State and Central Government regulations. There needs to be accountability fixed on State Regulator to the Central Licensing Authority (or a National Regulator) to ensure harmonious enforcement. As regards the quality certification of the medical devices, the Committee feels that following the international practices, voluntary certification system for indigenous medical devices should also be promoted to a large extent for their better acceptability in the world market.

(Para 4.34)

The Committee appreciates the views of Chairman and Managing Director of Shalby Multi-Specialty Hospitals and the need for bone banks for grafting. The Committee recommends the MoH&FW to consider creating "Bone Banks" to facilitate its easy availability. The Committee also recommends that the "Biocompatibility studies" should be made mandatory so as to prevent poor quality products from entering the market and failure of implants that end up being life-threatening should have stringent penalty to discourage such faulty products.

(Para 4.36)

The Committee endorses the views of some of the State Governments for Zone wise special trainings for Medical Device Officers. Trainings for Medical Device Testing Officers can be organized by National Drug Authority on routine basis so that technical

expertise of officers gets enhanced. The Committee feels that Capacity Building Programmes/ Skill Enhancement Workshops will also help the regulators to perform their legitimate duties in a better and pragmatic manner.

(Para 4.63)

The Committee feels that Materiovigilance Programme (MvPI) may be extended to medical devices to ensure the safety of medical devices in the country and uniformity of the inspection procedure may be ascertained. The Committee also recommends that lower rates of audit fee by the Government would also encourage indigenous manufacturers.

(Para 4.64)

The Committee, in this report has extensively examined the subject and identified key concern areas and challenges that are yet to be resolved. The Committee believes that separate legislation exclusively for the Medical Devices and bringing the Department of Pharmaceuticals (DoP) under the Ministry of Health and Family Welfare would really help solve some of the major challenges being faced by the medical device manufacturers.

(Para 4.66)

The Committee notes that the Covid-19 pandemic has highlighted the need to support indigenous manufacturers of Medical Devices. The pandemic laid bare various issues like insufficient infrastructure and fund for research and development, lack of public funding for research, dearth of skilled manpower, lack of synergy between Central-State regulatory authorities, inappropriate regulations for medical devices, lack of global-level quality standards etc plaguing the medical device industry in India. With the immense potential for the medical devices industry anticipated, the Ministry should focus on resolving the challenges and develop a detailed "Roadmap with Practical and Actionable Strategy".

(Para 4.67)

MINUTES

III

THIRD MEETING

The Committee met at 3.00 p.m. on Wednesday, the 14th December, 2016 in Room No '139', First Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - **Chairman**

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Dr. Vikas Mahatme
4. Shri Ashok Siddharth
5. Shri Gopal Narayan Singh
6. Shri K. Somaprasad
7. Dr. C.P. Thakur

LOK SABHA

8. Shri Thangso Baite
9. Dr. Ratna De (Nag)
10. Dr. Sanjay Jaiswal
11. Shri Arjunlal Meena
12. Shri Chirag Paswan
13. Shri C. R. Patil
14. Shri M.K. Raghavan
15. Dr. Manoj Rajoria
16. Shri R.K. Singh (Arrah)
17. Shri Bharat Singh
18. Shri Kanwar Singh Tanwar
19. Shrimati Rita Tarai

SECRETARIAT

1. Shri P.P.K. Ramacharyulu — Additional Secretary
2. Smt. Arpana Mendiratta — Director
3. Shri Rakesh Naithani — Joint Director
4. Shri Dinesh Singh — Joint Director
5. Smt. Harshita Shankar — Assistant Director
6. Shri Pratap Shenoy — Committee Officer

I. OPENING REMARKS

2. The Chairman, at the outset, welcomed the Members of the Committee and apprised them of the agenda of the meeting, ***.

II. ***

3. ***

III. Future course of action

4. During the course of the meeting, the Committee expressed concern about the exorbitant cost of stents and took note of the fact that stents are manufactured at a low cost but sold at a very high cost in the Indian Market. The Committee felt that in absence of any control and regulation of medical devices including stents, the patients are dependent on imported stents which sharply escalate the health expenses of helpless patients. In view of this, the Committee felt that there was a need to strengthen regulation of medical devices and hence decided to take up the subject "Medical Devices: Regulation and Control" for detailed examination. In this connection, the Committee decided to have evidence of the Health Secretary in its next meeting. The Committee also discussed the issue of access of quality medicines at affordable prices to the people and felt that promotion of the use of generic drugs would substantially reduce drug costs and increase drug availability. The Committee, therefore, also decided to take up the subject of "Promotion of the use of generic medicines" for detailed examination.

5. ***

6. The Committee then adjourned at 4.20 p.m.

** Pertains to other matter*

IV

FOURTH MEETING

The Committee met at 3.00 p.m. on Wednesday, the 28th December, 2016 in Committee Room 'B', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - **Chairman**

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Shri Rajkumar Dhoot
4. Dr. Vikas Mahatme
5. Shri Jairam Ramesh
6. Shri Ashok Siddharth
7. Shri Gopal Narayan Singh
8. Shri K. Somaprasad

LOK SABHA

9. Dr. Ratna De (Nag)
10. Dr.(Smt.) Heena Vijay Gavit
11. Dr. Sanjay Jaiswal
12. Dr. K. Kamaraj
13. Shri J. Jayasingh Thiyagaraj Natterjee
14. Shri C. R. Patil
15. Dr. Manoj Rajoria
16. Dr. Shrikant Eknath Shinde
17. Shri R.K. Singh (Arrah)
18. Shri Bharat Singh
19. Shri Kanwar Singh Tanwar
20. Shrimati Rita Tarai

SECRETARIAT

1. Smt. Arpana Mendiratta — Director
2. Shri Rakesh Naithani — Joint Director
3. Shri Dinesh Singh — Joint Director
4. Smt. Harshita Shankar — Assistant Director

WITNESSES

DEPARTMENT OF HEALTH AND FAMILY WELFARE

1.	Sh. C. K. Mishra	Secretary
2.	Sh. K. L. Sharma	Joint Secretary
3.	Sh. Arun Singhal	Joint Secretary
4.	Sh. G. N. Singh	Drugs Controller General of India DCG (I)
5.	Dr. Eshwara Reddy	Joint Drugs Controller (India)

A. OPENING REMARKS

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, i.e., to hear the views of the Secretary of the Department of Health and Family Welfare on the subject- 'Medical Devices: Regulation & Control.'

B. ORAL EVIDENCE OF HEALTH SECRETARY

3. The Secretary, Department of Health and Family Welfare then gave a brief background of the medical devices industry in the country, present regulatory system, the challenges faced and the initiatives taken by the Department for better regulation and control. He highlighted that the medical devices industry was worth Rs. 40,000 crore. He admitted that currently there was no proper framework for regulation of medical devices and lack of certification hampers growth of medical devices industry in the country. He also informed that quality, safety and performance aspects of medical devices is under Ministry of Health and Family Welfare and promotion, production & manufacture of medical devices is under Department of Pharmaceuticals. Only 15 groups of devices have been notified by the Ministry of Health and Family Welfare presently and there was a need to increase this basket of devices. He further stated that as of now, medical devices were notified as drugs under the Drugs and Cosmetics Act, 1940, however, since devices were different from drugs, the Department was working towards distinguishing between drugs and devices which need distinct testing and treatment and hence there was a need to have a separate vertical structure within the Central Drugs Standard Control Organisation (CDSCO) to regulate medical devices and the Ministry was working on it.

4. Thereafter, an official from the Department made a power-point presentation on the subject. He *inter-alia* covered the following points during the course of the presentation:- (i) import of devices;(ii) approval and clinical trials of new devices which is regulated under CDSCO while manufacturing, sale and distribution is governed by State Licensing Authority (SLA); (iii) certification of medical devices as followed in the country; (iv) Good Manufacturing Practice (GMP) requirements for drugs and Quality Management System (QMS) requirements for devices; (v) distinction between clinical trials (drugs) and clinical investigation (Medical devices); (vi) recent changes in Drugs and Cosmetics (D&C) rules for medical devices like replacement of Schedule M III of Drugs and Cosmetics Rules by a new Quality Management System i.e. ISO 13485, etc; (vii) proposing separate medical devices rules with the objective of increasing the number of devices to be regulated, certification of medical devices and to have a transparent and objective process to attract investment and industry growth; (viii) steps being taken for notification of final Rules in Gazette by January, 2017; (ix) classification of medical

devices and risk criteria for classification based on intended use of devices as well as international classification of devices; (x) approval process by Central Licensing Authority through online central portal for import, manufacturing and sale of medical devices; (xi) clinical investigation of drugs and devices and review by Central Licensing Authority (CLA), etc.

5. Thereafter, Members sought clarifications from the Secretary regarding nodal Ministry for controlling and regulating medical devices; revision of import duty structure; licensing of new age medicines and technologies for treating various diseases; need for standardization of medical devices; relooking at the classification between drugs and devices; use of imported machinery lying idle for the poor; category of stents and pacemakers; pricing of stents; certification of stents; need for prior permission for X-ray machines/radiation based technologies before selling / buying; exercising control over doctors/hospitals on commission received for using highly priced devices/stents; need for Indian certification for manufacturing devices instead of requirement of foreign certification like Conformite' *Europe'enne* (CE) marking and United States Food and Drug Administration(USFDA); reviewing exemption list and category of devices w.r.t. import/export; reviewing manufacturers' validation, etc. The Chairman, then, directed the Secretariat to forward a questionnaire on the subject to the Ministry for their written replies and also asked the Health Secretary to furnish replies to the queries raised in the meeting which remained unanswered within a week.

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee then adjourned at 4.33 p.m.

II

SECOND MEETING

The Committee met at 3.00 p.m. on Wednesday, the 1st December, 2021 in Committee Room-A, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

RAJYA SABHA

2. Shri AK. Antony
3. Dr. L. Hanumanthaiah
4. Shri Jugalsinh Lokhandwala
5. Shri Suresh Prabhu
6. Dr. Kanimozhi NVN Somu
7. Dr. Subramanian Swamy
8. Shrimati Sampatiya Uikey

LOK SABHA

9. Shrimati Mangal Suresh Angadi
10. Shri Maddila Gurumoorthy
11. Dr. Chandra Sen Jadon
12. Dr. Amol Ramsing Kolhe
13. Dr. Sanghmitra Maurya
14. Shri Arjunlal Meena
15. Dr. Pritam Gopinath Munde
16. Shri K. Navaskani
17. Adv. Adoor Prakash
18. Dr. Rajdeep Roy
19. Dr. DNV Senthilkumar. S
20. Shri Anurag Sharma
21. Dr. Mahesh Sharma
22. Dr. Krishna Pal Singh Yadav

SECRETARIAT

1. Shri J. Sundriyal - Joint Secretary
2. Shri V.S.P. Singh - Director
3. Shri Bhupendra Bhaskar - Additional Director
4. Smt. Harshita Shankar - Under Secretary

WITNESSES

Department of Health and Family Welfare

1. Shri Rajesh Bhushan, Secretary (Health)
2. Shri Vikas Sheel, Additional Secretary
3. Dr. Mandeep K. Bhandari, Joint Secretary
4. Dr. V.G. Somani, DCG(I), CDSCO
5. Shri Rajiv Wadhawan, Director
6. Shri Pardeep Dahiya, Drugs Inspector, CDSCO

2. ***

2.1 He also informed that after the consideration and adoption of reports, the Committee would be hearing the views of the Secretary, Department of Health and Family Welfare on the subject "Medical Devices: Regulation and Control".

3. ***

3.1 ***

4. The Chairman thereafter informed the members that the Committee is presently considering the subject - Medical Devices: Regulation and Control. The Committee felt that a favourable regulatory climate and better infrastructure are fundamental in incentivising the medical device industry to set up their manufacturing facilities in the States and the support of the States Government is crucial in the effective implementation of the medical device policies. For a comprehensive and critical examination of the subject, the Committee, therefore, decided that it should seek the comments/views of the State/UT Governments on the subject.

Oral Evidence of the Secretary, Department of Health and Family Welfare on Medical Devices: Regulation and Control:

5. ***

6. The Secretary in his deposition to the Committee gave a brief about the medical device industry in the country which is essentially governed by three bodies- Ministry of Health and Family Welfare oversees the regulatory aspects, Department of Pharmaceuticals is responsible for production, promotion and manufacturing and National Pharmaceutical Pricing Authority (NPPA) tasked with the implementation of provisions and monitoring of availability of drugs.

6.1 The Joint Secretary, Ministry of Health and Family Welfare, then, gave a presentation on the subject and inter-alia highlighted the following key points:

i. Medical device industry is regulated by Drugs and Cosmetics Act, 1940 which is a Central Act and aims to ensure safety, efficacy and quality of not only drugs but also medical devices and cosmetics;

** Pertains to other matter*

ii. There are four types of medical devices viz. medical equipments, medical implants, medical disposables and medical furniture; At present 37 medical devices are notified; Differences between drugs and devices; while the former is based on chemistry and biochemistry, the latter one is based on engineering;

iii. Medical Devices Rules, 2017 became effective from 1st January, 2018. These rules regulated Medical Devices and IVDs (In-vitro diagnostics). According to these rules the devices are classified into Class-A, Class-B, Class -C and Class -D. Class A and B are devices are low/moderate-risk devices and C and D are high-risk devices. Further State Licensing Authorities are responsible for regulating of manufacturing of Class A&B devices and regulation of C&D devices is done by Central Regulating Authority;

iv. Medical Devices Rules, 2017 also govern clinical investigation, the standard of medical devices, perpetual validity of licenses, registration and regulation of notified bodies, online submission, processing and approval of applications, quality management system and timelines for approval;

v. All manufacturers and importers of non-regulated Medical Devices should register with CDSCO, initially, such registrations are on a voluntary basis up to 18 months. After submission of information by the applicant on the SUGAM portal registration number is generated, which shall be printed on label by the manufacturer or importer;

vi. Registration process of Class A&B devices must be completed in 30 months (18 months for voluntary registration and 12 months for mandatory registration) and for the Class C&D devices this period is of 42 months (18 months for voluntary registration and 24 months for mandatory registration);

vii. 5 Central Medical Device Testing Laboratories are notified for statutory testing and 19 Medical Device Testing Laboratories are registered by the CDSCO for TEST or Evaluation of a medical device on behalf of the manufacturer;

viii. Materiovigilance programme of India (MvPI), intended to ensure the safety of devices was launched in 2015 at the Indian Pharmacopoeia Commission, Ghaziabad. Under MvPI, 124 Medical Devices Adverse Events Monitoring Centres have been identified in the country to report the events on a voluntary basis;

ix. Presently there is a need to create 754 posts for separate vertical of medical devices comprising 449 posts for regulatory officials and 305 for laboratory officials;

x. Medical Devices sector has the highest growth potential amongst all the sectors in the healthcare market;

xi. India depends on imports to an extent of more than 70%.

6.2 Thereafter, the Chairman and the members of the Committee raised certain issues/queries on the regulation and control of medical devices which are as follows:-

i. Need for a separate legislative framework for regulating medical devices as these continue to be regulated as drugs in India under the Drugs and Cosmetics Act, 1940;

ii. Ambiguity in the law and rules regarding the regulation of the medical devices by the Central and State governments;

iii. Clarity on the purpose behind the controlling and regulation of the medical device industry;

iv. Including devices of Dental care, hearing and vision aids in the rules for regulation of medical devices;

v. Standardization of materials used in the manufacturing of medical devices;

vi. Importance of effectiveness of medical devices along with safety features;

vii. Effective implementation of regulating laws so that they serve the intended purpose;

viii. Control over the manufacturers or the distributors of drugs to regulate their prices; disparity in pricing of implants and other devices in the government and private hospitals;

ix. Provisions in regulation for promoting indigenous manufacturing, innovation and export;

x. Inclusion of medical software, devices used in physiotherapy, occupational therapy along with laboratory reagents under the category of medical devices;

xi. Laws to deter overstocking of medical devices and regulation of online selling of medical devices;

xii. Laws and rules for the regulation of medical devices should cover entire paraphernalia of medical implants encompass along with devices used for prosthetics, orthotics, stents, coils etc;

xiii. Bringing more devices under the category of "Notified Medical Devices",

xiv. Licensing of Class A&B medical devices would be effective from 2022 and for C&D devices the licensing would be effective from 2023, hence the system put in place till these licensing regulations become effective;

xv. Effective disposal of medical devices; and

xvi. Creation of posts to increase manpower for the better regulation of the medical device industry.

6.3 After that, the Chairman pointed out that, of late, there has been a tendency of the Ministry to pick and choose queries raised by members for answering as per their convenience thereby avoiding the important questions. The Chairman asked the officials to furnish replies to all the questions/queries raised by the members.

6.4 The Secretary, the Department of Health and Family Welfare, thereafter, responded to some of the queries of the Chairman and the members as enumerated below:

i. On the issue of separate legislative framework for regulating medical devices, the Secretary, DoH&FW informed the committee that it is a global practice to not to have an independent Act but to have separate chapters for the regulation of Drugs, Devices and Cosmetics in the same act;

ii. Regarding making the laws comprehensive for the Medical Device, the Department has already undertaken the exercise of comprehensive amendment of the Drugs and Cosmetics Act;

iii. On creation of posts in the Department for appropriate deployment the Department had already pursued the matter with the Ministry of Finance and

iv. The need for more experts bioengineers in the medical devices' vertical structure in the central regulator's office;

6.5 The Chairman then directed the Department to send written replies to the queries raised by the Members within a week's time. ***.

7. A verbatim record of the proceedings of the meeting was kept.

8. The Committee then adjourned at 4:17 p.m.

** Pertains to other matter*

IX

NINTH MEETING

The Committee met at 3.00 p.m. on Thursday, the 12th May, 2022 in Committee Room-4, Parliament House Annexe Extension Building, New Delhi.

MEMBERS PRESENT

1. **Prof. Ram Gopal Yadav - Chairman**

RAJYA SABHA

2. Dr. Anil Agrawal
3. Dr. L. Hanumanthaiah
4. Shri Suresh Prabhu
5. Shri A.D. Singh

LOK SABHA

6. Shri Maddila Gurumoorthy
7. Dr. Pritam Gopinath Munde
8. Dr. Sujay Radhakrishna Vikhe Patil
9. Dr. Rajdeep Roy
10. Dr. Mahesh Sharma
11. Dr. Krishna Pal Singh Yadav
12. Dr. Lorho S. Pfoze

SECRETARIAT

1. Shri Mahesh Tiwari — Joint Secretary
2. Shri Bhupendra Bhaskar — Additional Director
3. Shri Praveen Kumar — Deputy Secretary

WITNESSES:

A. Representatives of CII National Medical Technology Forum (NMTF)

i. Mr Himanshu Baid, Chairman -CII NMTF
ii. Mr Vibhav Garg, Director-Health Economics & Govt Affairs
iii. Ms. Elizabeth Jose, Deputy Director, NMTF
iv. Mr. Deepak Sharma, Executive Officer, NMTF

B. Representatives of Othopaedic Implant Manufacturers Association (OIMA), Mumbai

i. Mr. Hemkumar Patel, Secretary-Mumbai

ii. Mr. Anuj Dureja

2. At the outset, the Chairman welcomed the Members of the Committee and apprised the Members that the Committee would be hearing the views of two organizations, namely, (i) Confederation of Indian Industries- National Medical Technology Forum (CII-NMTF), New Delhi and (ii) Orthopaedic Implant Manufacturers Association (OIMA), Mumbai on the subject, "Medical Device: Regulation and Control".

3. The Committee first heard the views of Chairman, CII NMTF who *inter-alia* highlighted the following points:

i. CII NMTF membership covers all MedTech - implantables, consumables, IVD and equipment;
ii. Medical Device Rules (MDR) 2017 (under the aegis of Drugs and Cosmetics (D&C) Act) is the prime medical device regulation;
iii. Need of alignment with the best Regulatory Affairs practices globally;
iv. Establishing a level playing field for manufacturers; importers or distributors;
v. Flexibility to cope up with ever changing landscape of medical technology innovations;
vi. Need of decriminalizing the provisions of current act;
vii. Exemption from Legal Metrology, Quality Control Orders etc;
viii. In public procurement of medical devices in India, there are three essential criteria: (a) Conformance to applicable standards (IS/ISO/IEC); (ii) Regulatory Approval (CDSCO (Central Drugs Standard Control Organisation), MoHFW), and (iii) Product Technical Specifications; Third party certification beyond regulatory approvals are redundant**;**
ix. Regulating Import of Refurbished Equipment and refurbishing in India;
x. (Production Linked Incentive (PLI) scheme should be opened for all medical devices categories ;
xi. Inverted duty structure to be corrected especially for medical devices that are manufactured in India;
xii. Need for Schemes to support medical device manufacturing infrastructure beyond PLI;
xiii. Need for Scheme for Promotion of manufacturing of Electronic Components and Semiconductors (SPECS);
xiv. Recognition to Incremental Innovation; Differential Pricing;
xv. Need of Value Based Procurement / Health Economics Driven Reimbursement Models;
xvi. Need for export incentivization and making Indian Manufacturers Globally Competitive;
xvii. Multiple regulators for med tech industry hampers ease of doing business

4. The Committee then heard the views of the Secretary, OIMA (Othopaedic Implant Manufacturers Association) who stated that in India around 70-80 per cent of the companies were CDSCO (Central Drugs Standard Control Organisation) approved. The indigenous manufacturing industry have been adversely affected by reduced import duties and were facing tough times competing with imported products. He apprised the Committee that even though Covid-19 had an adverse impact on the medical devices industry but the loan provided by the Government helped the industry survive through the pandemic. There was shortage of raw material during the pandemic and there was a need of design and regulatory framework to cope up with future emergencies. Regarding quality control and standards of medical devices in line

with best international practices, he suggested that CDSCO should harmonize standards with the standards of international companies, but obtaining international certification like CE (Conformitè Europëenne) and USFDA (United States' Food and Drug Administration) has increasingly become costly thus, the industry needed Government intervention in this regard.

5. Another representative of OIMA apprised the Committee that in orthopedic implants two raw materials i.e. stainless steel and titanium are extensively used but owing to absence of indigenous manufacturers of these two, the industry is dependent on expensive imports.

6. Thereafter, the members raised certain queries which are as follows:-

a. Whether digitalisation has improved the systems for approval to start a business; need for single-window approval system;
b. Steps required to balance the trade issues in medical device industry; import-export imbalance;
c. How can the new legislation be made beneficial to both industry and the patients?;
d. Self regulatory measures required to be taken by industry to regulate pricing of medical devices; measures taken to ensure quality of devices while keeping prices in control;
e. In India CDSCO approved medical devices should be given the same value *vis-à-vis* CE and USFDA approved devices;
f. Quality Council of India (QCI) can play an active role in ensuring quality of medical devices manufactured in India;
g. Need to promote research in product used in biodegradable implants; industry should also invest in research and development of medical device industry ;
h. Promoting manufacturing of devices and implants which are designed specifically for Indians considering their bone structure and other parameters;
i. Boosting domestic manufacturing to boost exports and employment;
j. Educating officials about medical industry, its working, structure, international standards for better regulation and quality control;
k. Steps required to sustain the Covid induced spurt in domestic manufacturing of medical equipments and devices; and
l. The ultimate and unanimous goal of all the stakeholders of the industry should be that the patients must get quality treatment at affordable prices.

7. Thereafter, Director Health Economics & Govt Affairs of CII answered few of the queries raised by the Members; he submitted that medical device being an innovation-driven industry needed 'Innovate in India' as much as 'Make in India' for the medical devices. He apprised the Committee that reason behind sudden increase in manufacturing of devices/ equipments during Covid was a definite demand for such devices/ equipments in the market and from the Government of India. He stated that assured and predictable demand boosts investment and thus manufacturing and supply.

8. The Chairman then asked the witnesses to submit a written response to the queries raised by the Members within seven days.

9. A verbatim record of the proceedings of the meeting was kept.

10. The Committee then adjourned at 4.41 p.m to meet again at 11.00 am on 13th May, 2022.

RECORD OF DISCUSSION

The Committee met at 11.00 a.m. on Friday, the 13th May, 2022 in Committee Room-D, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. **Prof. Ram Gopal Yadav - Chairman**

RAJYA SABHA

2. Dr. Anil Agrawal
3. Shri A.D. Singh

LOK SABHA

4. Shri Maddila Gurumoorthy
5. Dr. Rajdeep Roy
6. Dr. DNV Senthilkumar S.
7. Dr. Mahesh Sharma
8. Dr. Krishna Pal Singh Yadav
9. Dr. Lorho S. Pfoze

SECRETARIAT

1. Shri Bhupendra Bhaskar — Additional Director
2. Shri Praveen Kumar — Deputy Secretary

A. Representatives of Association of Indian Medical Device Industry (AiMeD), New Delhi

i. Mr. Rajiv Nath, Forum Coordinator

ii. Mr. P.K. Sharma, Technical Officer

B. Representatives of Federation of Indian Chambers of Commerce and Industry

i. Mr. Praveen Kumar Mittal, Senior Director, Federation of Indian Chambers of Commerce and Industry

ii. Mr. Arnab Basumallik, Business Unit Head- Critical Care &Vascular, Edwards Lifesciences (India) Pvt Ltd

iii. Mr. Sudhakar Mairpadi, Director- Regulatory and Govt Affairs (Health care, Personal health) India and Indian subcontinent, Philips India Limited.

iv. Mr. Ravi Valia, General Manager-Govt Affairs, Market Access and CSR, B Braun Medical (India) Pvt. Ltd

v. Mr. Gaurav Verma, Director - RA & GA, Becton Dickinson India Pvt. Ltd.

2. At the outset, the Chairman welcomed the Members of the Committee and apprised the Members that the Committee would be hearing the views of two organizations, namely, (i) Association of Indian Medical Device Industry (AiMeD), New Delhi and (ii) Federation of Indian Chambers of Commerce and Industry (FICCI) on the subject, "Medical Device: Regulation and Control".

3. The Committee first heard the views of Forum Coordinator, AiMED who inter-alia highlighted the following points:

i. The industry is 80-85% dependent on imports;
ii. Introduction of separate act on medical devices; rules and regulations must clearly define roles and responsibilities regulating bodies;
iii. Supportive polices like predictive tariff Policy, restrictions on second hand imports, preferential public procurement can significantly boost domestic manufacturing;
iv. In 1989 the medical devices were classified as drugs and in 2017 Medical Device rules were notified;
v. Certain section of the Drugs and Cosmetics Act like Section 17 (on misbranded drugs), Section 17A (adulterated drugs), Section 34 (offences of companies) are needed to be made
"not applicable" or they should be amended;
vi. Patient safety must be ensured without affecting investment and Small and Medium Enterprises (SMEs);
vii. All manufacturers and importers should be registered and manufacturers of of Class-A non-sterile should be allowed self-certification;\
viii. Build a pool of competent auditors, medical device officers and manufacturers along with a comprehensive infrastructure of NABL accredited testing labs;
ix. Regulatory controls need to be split, shared and delegated between the Center, State and Conformity Assessment Bodies; and
x. Overpriced imported medical devices are severely affecting India's manufacturing growth.

4. The Committee then heard the views of United Head of FICCI, his presentation to the Committee included following major points:-

i. India constitutes 1.6% of total global market and almost 86% of the Indian medical device industry is import dependent;
ii. Right policy decisions can help India grow by at least 12 times of the present market size;
iii. Medical device industry is capital intensive; has long gestation period and requires continuous induction of new technologies;
iv. India lacks well developed ecosystem and innovation cycle for medical device industry to flourish;
v. Working on Demand Generation, Policy Predictability and Ease of Doing Business can make India a hub for med-tech in the next two decades (by 2047);
vi. India currently has only 1.3 hospital beds/1000 population and thus additional 3 million beds are required; India only has 0.65 physicians per 1000 people and the WHO standard is 1 per 1,000 people;
vii. Similarly 1.54 million doctors and 2.4 million nurses would be required to meet the growing demand;

viii. 60% of India's health infrastructure is concentrated in the large cities across the country;
ix. Need to skill, upskill and reskill healthcare professionals and those in manufacturing of medical devices as well;
x. Trade Margin Rationalisation from first point of sale;
xi. Standardized, streamlined and digitized implementation of PCPNDT (Pre-Conception and Pre-Natal Diagnostic Techniques)Act;
xii. Developing a process for defining and rewarding incremental innovation and breakthrough innovation;
xiii. Implementation of Medical Device Rules 2017 harmonized with global practices;
xiv. Need to have single window clearance system and interface between ministries dealing with medical device rules 2017;
xv. Need to develop and operationlise more medical device parks and lend support to ancillary industry; and
xvi. Encourage export-oriented industries by facilitating smooth approvals and providing technical and fiscal assistance.

5. Thereafter, the members raised certain queries which are as follows:-

i. Need for price capping in medical device industry;
ii. Requirement for a separate legislation for the regulation of medical device industry;
iii. Indigenous manufacturing of medical devices would boost exports;
iv. Regulating self-certification of medical devices;
v. Need for Government and industry led support in improving the Research and Development;
vi. Establishing medical device parks in various States;
vii. Need for public manufacturing of medical devices which are used in large scale;
viii. Providing capital to the industry at reduced interest rates;
ix. Reduction of import duty is adversely impacting domestic manufacturers; \
x. Need to identify and control unscrupulous elements who create artificial inflation;
xi. Need to address wide variation in prices of medical devices available in the market;
xii. Research-linked incentive scheme on the lines of Production Linked Incentive (PLI) scheme;
xiii. Harmonisation of Medical Device Rules (2007) with the global best practice;
xiv. Single window clearance system to obtain various clearances for the operationalization of medical device industries; and
xv. Health Budget should be at least 5% of the GDP.

6. The stakeholders then answered few of the queries, regarding need for industry support for research; the business Unit Head of FICCI replied that the industry is doing fantastically in terms of research and innovation. Regarding price regulation, he said that the country needed to focus on Health Technology Assessment (HTA). In this assessment there are methodologies which see the health benefit along with the cost. Regarding regulation of medical devices, the forum co-ordinator of Association of Indian Medical Device Industry (AiMeD) submitted that there was a need for separate department for medical devices and the legislation, regulation and promotion, manufacturing should be dealt by the same department. He recommended self-

certification for the non-sterile low risk medical devices. He also highlighted the issue of fake certification and usage of wrong labeling on the devices by certain manufacturers.

7. The Chairman then asked the witnesses to submit a written response to the queries raised by the Members within seven days.

8. A verbatim record of the proceedings of the meeting was kept.

9. The Committee then adjourned at 12.49 p.m.

X

TENTH MEETING

The Committee met at 3.00 p.m. on Tuesday, the 30th May, 2022 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. **Prof. Ram Gopal Yadav - Chairman**

RAJYA SABHA

2. Dr. L. Hanumanthaiah
3. Shri Suresh Prabhu
4. Dr. Kanimozhi NVN Somu

LOK SABHA

5. Shri Maddila Gurumoorthy
6. Dr. Chandra Sen Jadon
7. Dr. Sanghamitra Maurya
8. Shrimati Pratima Mondal
9. Dr. Pritam Gopinath Munde
10. Shri K. Navaskani
11. Dr. Sujay Radhakrishna Vikhepatil
12. Adv. Adoor Prakash
13. Dr. DNV Senthilkumar S.
14. Dr. Mahesh Sharma
15. Dr. Krishna Pal Singh Yadav
16. Dr. Lorho S. Pfoze

SECRETARIAT

1. Shri Mahesh Tiwari	Joint Secretary
2. Shri Shashi Bhushan	Director
3. Shri Bhupendra Bhaskar	Additional Director
4. Shri Praveen Kumar	Deputy Secretary
5. Smt. Harshita Shankar	Deputy Secretary

WITNESSES

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

1. Ms. S. Aparna, Secretary, Department of Pharmaceuticals
2. Shri Kamlesh Kumar Pant, Chairman, National Pharmaceuticals Pricing Authority
3. Dr. N. Yuvaraj, Joint Secretary, Department of Pharmaceuticals

4. Shri Rajneesh Tingal, Joint Secretary, Department of Pharmaceuticals
5. Smt. Vinod Kotwal, Member Secretary, National Pharmaceuticals Pricing Authority

Ministry of Health and Family Welfare

1. Dr. Mandeep Kumar Bhandari, Joint Secretary
2. Dr. V. G. Somani, Drugs Controller General of India (DCGI)

Association of Diagnostics Manufacturers of India (ADMI)

1. Ms. Veena Kohli, President
2. Shri Jatin Mahajan

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them the agenda of the meeting i.e. examination of the subject "Medical Devices: Regulation and Control" and to hear the views of stakeholders like the Department of Pharmaceuticals and Association of Diagnostics Manufacturers of India.

3. The Committee first heard the views of the Secretary, Department of Pharmaceuticals who gave a brief introduction on the subject explaining the mandate of the Department of Pharmaceuticals. The submission to the Committee included following points:-

i. Medical Device industry has the highest potential for growth among all the sectors in the healthcare market;
ii. 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;
iii. The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies;
iv. Need for a well-developed ecosystem and innovation cycle in India;
v. India depends on imports to an extent of 80% by value of its domestic requirements of medical devices;
vi. The current market size of the medical devices sector in India is estimated to be $11 billion and its share in the global medical device market is estimated to be 1.5%.
vii. Audit/Inspection is done by Notified body accredited by National Accreditation Board for Certification Bodies (NABCB) for class A and class B (low and moderate risk).
viii. Tests and evaluations of medical devices are carried out by Medical Device Testing Laboratory (MDTL) with 5 MDTL notified for statutory testing and 24 MDTL registered on behalf of manufacturer.

4. The Joint Secretary, Department of Pharmaceuticals explained the schemes/initiatives being implemented by the Department:-

i. A scheme called “Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices” was approved by the Government of India on 20th March, 2020. 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.

ii. The Scheme is applicable only to the Greenfield projects with total financial outlay of the scheme being Rs. 3,420 crore. The Scheme is being implemented through a Project Management Agency (PMA).

iii. A Scheme for Promotion of Medical Device Parks was started with the objective of giving financial assistance to State Governments for supporting specific infrastructure in medical device parks.

iv. The scheme "Assistance to Medical Device Industry for Common Facility Centre" has been revised and renamed as "Promotion of Medical Device Parks" and the total financial outlay of the scheme is Rs. 400 crore. So far, 16 States/UTs have submitted their proposals in which the proposals of 4 States namely, Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh have been approved.

v. Production Linked Incentive (PLI) Scheme for Pharmaceuticals **c**overs In-vitro diagnostic medical devices amongst other pharmaceutical goods. Five (5) industry applicants have been selected under the scheme for In-vitro diagnostic medical devices and the scheme provides for incentives based on their incremental sales for 6 years.

vi. A draft National Medical Device Policy, 2022 has been prepared in consultation with the medical device industry.

vii. The Standing Forum of Medical Devices Associations has provided inputs to the Department based on consensus approach between the industry associations.

viii. The sector requires special co-ordination and communication among Industry and Department since the regulators of medical devices are spread across different Departments like MoHFW, D/o Consumer Affairs, Indian Council of Medical Research, Atomic Energy Regulatory Board, Bureau of Indian Standards etc.

ix. Medical Device Sector is one of the attractive sectors for Foreign Direct Investment (FDI) in India. Up to 100% foreign direct investment is allowed under automatic route in Medical Device sector without Government approval. India has recorded significant growth in FDI inflow in Medical Device sector in the recent past, however, the inflow in 2020-21 was low due to impact of Covid-19.

5. The Committee was also apprised by the Department of Pharmaceuticals about the mandate of the National Pharmaceuticals Pricing Authority (NPPA) to implement and enforce the provisions of the Drugs (Prices Control) Order, 2013 and to monitor the availability of drugs, identify shortages, if any, and to take remedial steps. The Secretary further informed the Committee about the steps taken by the NPPA to control price of medical devices which are categorized as Scheduled Medical Devices and Non-Scheduled Medical Devices. NPPA monitors the maximum retail prices of all non-scheduled medical devices and ensures that no manufacturer increases the maximum retail price of any medical device more than 10% of maximum retail prices during preceding 12 months. If any manufacturer increases the price beyond 10% of maximum retail price, the overcharged amounts are recovered as per the provision of Drugs (Price Control) Order, 2013.

6. The Secretary, Department of Pharmaceuticals further informed the Committee about the Jan Aushadhi Kendras which aims to improve access of medical products, apart from generic drugs. The Government has made available 250 types of surgical items in over 8700 stores of Jan

Aushadhi Kendras at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana.

7. The Secretary apprised the Committee about the initiatives taken by the Department for up scaling of manpower for medical devices sector which would supply skilled work force across the innovation value chain e.g. scientists, regulators, health experts, managers, technicians, etc. She also informed that 20 courses have been started related to biotechnology engineering across the country. The National Institutes of Pharmaceuticals Education and Research is being run by the Department of Pharmaceuticals to impart training for different roles in medical device sector. She further informed that draft National Medical Device Policy, 2022 has been prepared to set up National Institutes of MedTech Education and Research (NIMERs) on the lines of NIPERs, as Institutes of National Importance (INIs) and to leverage the Skill India Mission platform for development of skill sets in medical device sector.

8. Thereafter, the Members raised certain queries which are as follows:-

i. Mechanism being adopted to find out the volume and value of products that are consumed, at the same time.
ii. Steps to be taken to regulate the prices of stents all over the country.
iii. Overpricing of oxygen concentrators during the COVID-19 times as also the exorbitant prices of the devices used for the prosthesis, orthopedics and stents in the cardiac department.
iv. Measures being taken to develop and promote medical tourism in India.
v. Identification/ development of Key Performance Indicators to assist the quality and performance of medical devices and to enable manufacturers to sell their devices to doctors and hospitals instead of patients directly.
vi. Need to create a framework to facilitate direct link between the medical device manufacturers and patients while protecting the health data of the patients.
vii. Steps being taken regarding Central Drug Standard Control Organisations (CDSCO) approved devices.
viii. The scheme for promotion of medical device parts and its selection criteria.
ix. Control of Central Government on price fixation of pharmaceuticals and medical equipments.
x. Proposal to manufacture Computed Tomography (CT) scan machine and the Magnetic Resonance Imaging (MRI) machine in medical devices parks of four States.
xi. Regulatory control on the import of medical devices.
xii. Status on availability of all medicines and steps taken by the Government to ensure availability of regularly-used medicines in 8,700 Jan Aushadhi Kendras.
xiii. Inclusion of hip implants in non-scheduled medical devices to reduce its price for the benefit of large section of population.
xiv. Availability and price control of life supporting drugs, especially in organ transplantation.
xv. Formulation of a policy on various diseases in which patients require drugs for a longer period of time.
xvi. Regulation of import of cochlear implant from U.S.A along with removal of import duty.

(The witnesses then withdrew)

9. Thereafter, the Committee heard the views of the President of ADMI. She informed the Committee on the following points :-

- It is estimated that the Indian IVD market size will exceed the US$ 5.0 Bn mark by the year 2027 while growing at a rate of 20% per annum with the help of these parameters (i) Increasing awareness, affordability and demand for quality healthcare (ii) Rapidly rising burden of chronic and lifestyle related diseases like Diabetes mellitus, cardiac disorders etc. (iii) Spurt in communicable infections like Dengue, Chikungunya, Typhoid etc., resulting in a significant increase in the number of IVD tests being conducted in the country; (iv) In order to meet the increased work load and to maintain the quality turnaround times, the market is rapidly moving towards automation. This in turn, is giving an impetus to the growth of the industry; (v) Increase in adoption of healthcare insurance; (vi) Growth of the medical tourism industry in India.
- Overlapping and duplication with respect to the labelling requirements under the Legal Metrology Act and eight additional requirements under the Multiple Drug Resistant (MDR) for labelling of In vitro diagnostics (IVDs) and two extra requirements of the Legal Metrology Act, and these two extra ones are the display of MRP on the box label of the product and also that the consumer details should be displayed which is the phone number and the E-mail ID.
- Covid-19 assisted to democratize molecular diagnostics within a year and the share of the segment dramatically soared from 4% in 2019 to 54% in 2020.
- Entry of several players into *in-vitro* diagnostics from the adjacent segments like Pharma, *in-vivo* Medical Devices, Life Sciences etc.
- India therefore contributed 10% to the new tests developed in the world for the detection of Covid-19 during the years 2020 and 2021.
- The regulatory framework for *in-vitro* Diagnostics (IVD) Medical Devices was elucidated and implemented very recently, in January 2018 in the form of the Medical Devices Rules (MDR), 2017.
- The IVD industry requires the listed Guidance Documents from the CDSCO, to guide and hand-hold the industry in understanding and implementing the MDR Rules comprehensively and uniformly.
- The aim of the Vision @2047 of Indian IVD industry is to catalyse Research & Development and Innovation in the IVD Sector, in order to be amongst the top 5 geographies in the global market with 10% share by 2047, to reduce import dependence and ensure a self-reliance quotient of 80% in the IVD sector by 2047 with SMART milestones and to achieve continued backward integration in manufacturing through industry-academia collaborations.

10. A verbatim record of the proceedings of the meeting was kept.

11. The Committee then adjourned at 1.05 p.m.

XV

FIFTEENTH MEETING

The Committee met at 3.00 p.m. on Monday, the 8th August, 2022 in Committee Room-A, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav - Chairman

RAJYA SABHA

2. Dr. Santanu Sen
3. Shri A. D. Singh

LOK SABHA

4. Dr. Chandra Sen Jadon
5. Dr. Sanghmitra Maurya
6. Dr. Pritam Gopinath Munde
7. Shri K. Navaskani
8. Dr. Sujay Radhakrishna Vikhe Patil
9. Shri Haji Fazlur Rehman
10. Dr. Rajdeep Roy
11. Dr. DNV Senthilkumar S.
12. Shri Anurag Sharma
13. Dr. Mahesh Sharma
14. Dr. Krishna Pal Singh Yadav
15. Dr. Lorho S. Pfoze

SECRETARIAT

1. Shri Shashi Bhushan	Director
2. Shri Bhupendra Bhaskar	Additional Director
3. Shri Praveen Kumar	Deputy Secretary
4. Smt. Harshita Shankar	Deputy Secretary

2. At the outset, the Chairman welcomed the Members of the Committee and informed that the meeting has been convened to consider and adopt *** draft 138th Report on the subject "Medical Devices: Regulations and Control".

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* *Pertains to other matter*

3. The Committee, thereafter, took up for consideration the draft *** and 138th Reports of the Committee. The Chairman informed the Committee that *** and 49 observations/recommendations were there in the draft 138th Report. He invited views/suggestions/modifications, if any, from the Members in the draft reports. During the brief deliberation, some Members highlighted the issues involved in implementation of GST on medical devices manufactured in India. The members suggested that the GST rate on medical devices should be reduced to benefit the patients. However, while deciding the GST on medical devices, cost of manufacturing and GST rates on parts and components required in manufacturing of medical devices should also be considered. After a brief discussion, the Committee adopted both reports with some modifications.

4. The Committee, thereafter, decided that the aforementioned two Reports may be presented to the Rajya Sabha and simultaneously laid on the Table of the Lok Sabha on Wednesday, the 10th August, 2022. The Committee authorized its Chairman Prof. Ram Gopal Yadav, MP, Rajya Sabha and in his absence Dr. Anil Agrawal, MP, Rajya Sabha and in the absence of both members, Dr. Kanimozhi NVN Somu to present the Reports in Rajya Sabha. The Committee also authorized Dr. Rajdeep Roy, MP, Lok Sabha and in his absence Dr. Sanghamitra Maurya MP, Lok Sabha to lay the Reports on the Table of the Lok Sabha.

5. The Committee further decided that in case the Parliament gets adjourned sine die, the reports would be presented to the Hon'ble Chairman, Rajya Sabha during the inter- session period.

6. The Committee then adjourned at 3:18 p.m.

** Pertains to other matter*