REPORT NO.

146

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

ONE HUNDRED FORTY SIXTH REPORT

ON

ACTION TAKEN BY GOVERNMENT ON THE RECOMMENDATIONS/OBSERVATIONS CONTAINED IN THE 138TH REPORT ON THE "MEDICAL DEVICES: REGULATIONS AND CONTROL"

(Presented to the Rajya Sabha on 4th August, 2023)
(Laid on the Table of Lok Sabha on 4th August, 2023)

Rajya Sabha Secretariat, New Delhi
August, 2023/ Sravana, 1945 (Saka)

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* appended at the circulation stage.

COMPOSITION OF THE COMMITTEE
(2022-23)

1. **Shri Bhubaneswar Kalita - Chairman**

RAJYA SABHA

2. Dr. Anil Agrawal
3. Shri Sanjeev Arora
4. Dr. L. Hanumanthaiah
5. Shri Shambhu Sharan Patel
6. Shri Imran Pratapgarhi
7. Shri B. Parthasaradhi Reddy
8. Shri S. Selvaganabathy
9. Dr. Santanu Sen
10. Shri A. D. Singh

LOK SABHA

11. Shrimati Mangal Suresh Angadi
12. Ms. Bhavana Gawali (Patil)
13. Shri Maddila Gurumoorthy
14. Ms. Ramya Haridas
15. Shri K. Navas Kani
16. Dr. Amol Ramsing Kolhe
17. Shri C. Lalrosanga
18. Dr. Sanghmitra Maurya
19. Shri Arjunlal Meena
20. Shrimati Pratima Mondal
21. Dr. Pritam Gopinath Rao Munde
22. Dr. Lorho S. Pfoze
23. Adv. Adoor Prakash
24. Shri Haji Fazlur Rehman
25. Dr. Rajdeep Roy
26. Dr. DNV Senthilkumar S.
27. Dr. Jadon Chandra Sen
28. Shri Anurag Sharma
29. Dr. Mahesh Sharma
30. Dr. Sujay Radhakrishna Vikhepatil
31. Dr. Krishna Pal Singh Yadav

SECRETARIAT

1. Shri Sumant Narain — Joint Secretary
2. Shri Shashi Bhushan — Director
3. Shri Rajendra Tiwari — Director

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 Forty Sixth Report of the Committee on Action Taken by the Government on the Recommendations/ Observations contained in the 138th Report on Medical Devices: Regulations and Control pertaining to Department of Health & Family Welfare

2. The One Hundred Thirty Eighth Report of the Department-related Parliamentary Standing Committee on Health and Family Welfare was presented to Rajya Sabha and laid on the Table of Lok Sabha on 8th December, 2022. The Action Taken Notes of the Government on the recommendations contained in the Report was received from the Departments in April, 2023.

3. The Committee made a total of 49 recommendations in the 138th Report, out of which 9 recommendations have been accepted by the Ministry and has been categorized under Chapter-I. There are 26 recommendations, which the Committee does not desire to pursue in view of the Ministry's replies that have been categorized under Chapter-II. There are 11 recommendations/ observations, in respect of which replies of the Ministry have not been accepted by the Committee and the Committee has made further recommendations thereon and have been categorized under Chapter-III while 3 recommendations/observations in respect of which final replies of the Ministry have not been received, have been categorized under Chapter- IV.

4. The Committee, in its meeting held on the 31st July, 2023 considered the Draft Report and adopted the same.

New Delhi
31st July, 2023
Sravana 9, 1945 (Saka)

BHUBANESWAR KALITA
Chairman,
Department-related Parliamentary Standing Committee on Health and Family Welfare

ACRONYMS

ABDM	Ayushman Bharat Digital Mission
AERB	Atomic Energy Regulatory Board
AIIMS	All India Institute of Medical Sciences
ADC	Ana log to Digital Convertor
BIS	Bureau of Indian Standards
CDSCO	Central Drugs Standard Control Organisation
CSIR	Council of Scientific and Industrial Research
CE	Conformities European
COE	Centre of Excellence
D&CA	Drugs and Cosmetics Act
DCC	Drugs Consultative Committee
DoP	Department of Pharmaceuticals
DPIIT	Department For Promotion OF Industry and Trades
DPCO	Drugs (Prices Control) Order
DRDO	Defence Research and Development Organisation
DGHS	Director General Health Services
EFC	Expenditure Finance Committee
ETP	Effluent Treatment Plant
EPC	Export Promotion Council
GST	Goods and Services Tax
GSR	General Statutory Rules
HR	Human Resources
HIV	human immunodeficiency virus
HCV	hepatitis C virus
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
IPC	Indian Pharmacopoeia Commission
MoH&FW	Ministry of Health and Family Welfare
MvPI	Materiovigilance Programme of India
MDR	Medical Device Rules
MDO	Medical Device Officer
MD	Medical Device
MRP	Maximum Retail Price
MNC	Multi National Companies
MDMC	Medical Devices Adverse Event Monitoring Centres
NABL	National Accreditation Board for Testing and Calibration Laboratories
NITs	National Institute of Technology
NIB	National Institute Of Biological
NIPER	National Institute of Pharmaceutical Education and Research
NIMER	National Institute of Medical Devices Education and Research
NPPA	National Pharmaceutical Pricing Authority
NLEM	National List of Essential Medicines
NOC	No Objection Certificate
PMDA	Pharmaceuticals and Medical Devices Agency

PRIP	Promotion of Research and Innovation in Pharmaceutical
PLI	Production Linked Incentive
PPO	Public Procurement Order
QCBS	Quality-cum –Cost Based Selection
QC	Quality Check
QMS	Quality Management System
QCI	Quality Council Of India
R&D	Research and Development
RLI	Research Linked Incentive
SLA	State Licensing Authority
SMEs	Small & Medium Enterprises
TGA	Thermo gravimetric Analysis
TMR	Trade Margin Rationalisation
USFDA	U.S Food and Drugs Administration
UK	United Kingdom
US	United State

REPORT

The Report of the Committee deals with the Action Taken by the Government on the Recommendations/ Observations contained in the 138th Report on Medical Devices: Regulations and Control pertaining to Department of Health & Family Welfare, Ministry of Health & Family Welfare.

2. Action Taken Notes have been received from the Department of Health & Family Welfare in respect of the recommendations contained in the Report. They have been categorized as follows:

Chapter–I:

Recommendations/Observations which have been accepted by the Government:

Paragraph Nos: 2.15, 2.18, 2.36, 3.12, 3.24, 3.27, 3.45, 4.28 and 4.63.

TOTAL- 9

Chapter–II:

Recommendations/Observations which the Committee does not desire to pursue in view of the Government's replies:

Paragraph Nos: 2.7, 2.8, 2.10, 2.14, 2.21, 2.22, 2.27, 2.28, 3.7, 3.8, 3.13, 3.20, 3.22, 3.23, 3.28, 3.30, 3.38, 3.39, 4.11, 4.30, 4.31, 4.33, 4.36, 4.64, 4.66 and 4.67.

TOTAL- 26

Chapter –III:

Recommendations/Observations in respect of which replies of the Government have not been accepted by the Committee:

Paragraph Nos: 2.9, 2.13, 2.33, 3.10, 3.18, 3.19, 3.41, 3.43, 4.27, 4.32 and 4.34.

TOTAL- 11

Chapter –IV:

Recommendations/Observations in respect of which final replies of the Government are still awaited:

Paragraph Nos: 3.31, 3.40, and 4.29.

TOTAL- 3

3. The details of the ATNs are discussed in various Chapters in the succeeding part of the Report.

CHAPTER-1

RECOMMENDATIONS/OBSERVATIONS WHICH HAVE BEEN ACCEPTED BY THE MINISTRY

1.1 INVOLVEMENT OF HIGH-TECH INSTITUTIONS TO TEST MEDICAL DEVICES

Recommendation/Observation

1.1.1 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 of 138th Report)

Action Taken

1.1.2 The recommendation of Honorable Committee to involve the institutions like CSIR, DRDO, IISC, IITs for testing of medical devices is noted.

1.1.3 There is already a provision under Medical Devices Rules (MDR) 2017, that the laboratory of various institutions may get registered with CDSCO for testing of Medical Devices on behalf of manufacturers. CDSCO has reached out to various institutions for registering testing laboratory on CDSCO website under MDR 2017.

1.1.4 Further, there is provision in rule 19 of Medical Devices Rules (MDR) 2017 that, the Central Government may notify/designate any laboratory for the purpose of testing and evaluation of Medical Devices. The laboratories of institution like IISC, CSIR, DRDO and network of IITs will be utilized for the purpose based on their competence & willingness. Presently, CDSCO is already utilizing the laboratories of ICMR for testing and validation purpose.

1.2 SINGLE WINDOW CLEARANCE/APPROVAL

Recommendation/Observation

1.2.1 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 of ibid)

Action Taken

1.2.2 CDSCO is receiving all applications for grant of Import License/ manufacturing license and for other approvals through www.cdscomdonline.gov.in in a single window. If there is any requirement, like NOCs from other allied department viz; AERB, etc, then the firm can submit the NOC in the checklist at a single place and document received are reviewed as per the requirement of MDR 2017 without further referring to other department, in order to comply the timelines as per MDR and to avoid further delay for getting the approvals.

1.3 FINANCIAL SUPPORT TO THE LOCAL MANFACTURERS IN CAPACITY BUILDING

Recommendation/Observation

1.3.1 The Committee further recommends that till such time the Indian Medical Device Industry comes 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 *ibid*)

Action Taken

1.3.2 Licenses are granted by regulatory authorities at central and state level after satisfactory compliance of regulations as per global practice in line with stringent regulations of Medical Devices in the countries like USA, Japan, Canada, Australia is carried out by the regulatory agencies like USFDA, PMDA-Japan, Health Canada and TGA Australia through licensing system. The conformity assessment is carried out by the officials as per regulations.

1.3.3 Further, recently, Separate Export Promotion Council for Medical Devices have been notified under the Department of Pharmaceuticals and all efforts will be taken with the help of this new EPC to facilitate Indian Manufacturers for boosting the exports.

1.3.4 Recommendation of the Committee to provide support for Capacity Building of Local Manufacturer has been noted.

1.4 CENTERS OF EXCELLENCE IN MEDICAL DEVICES AT NIPERs

Recommendation/Observation

1.4.1 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 *ibid*)

Action Taken

1.4.2 As informed by DoP, the department has moved the proposal for establishing 7 Institutes of National Importance (INIs) called National Institute for Medical Devices Education and Research (NIMERs) on the lines of NIPERs. The proposal awaits formal approval. This will address the needs for qualified HR for the medical devices industry in the coming years.

1.4.3 Meanwhile, M.Tech (MD) course has been started in four NIPERs to train and educate biomedical engineers on ongoing challenges faced by medical device industry. Process has been initiated to develop Medical Device Testing facilities in all the NIPERs, for addressing the testing needs of the medical devices industries.

1.4.4 DoP has proposed a scheme - Promotion of Research and Innovation in Pharmaceutical Sector (PRIP) scheme – for establishment of CoEs at NIPERs and incentivizing research projects, related to pharma and Medtech sector. The Scheme awaits appraisal by the EFC.

1.5 PLI SCHEME FOR RAW MATERIAL AND COMPONENT MANUFACTURING UNITS

Recommendation/Observation

1.5.1 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 *ibid*)

Action Taken

1.5.2 As informed by CSIR, they have welcomed suggestions of the committee regarding incentivization of institutes, start-ups, manufacturing units which are engaged in manufacturing of raw materials and spare parts locally and allowing and encouraging academic institutions like IITs, AIIMS & IISCs and research bodies like CSIR to produce certain raw materials like antibodies, synthetic antigens, proteins etc. besides extending PLI scheme to cover raw material and component manufacturing as well, so that India can become a hub for raw material for the world. It is

submitted that CSIR is working in the area of antibodies, synthetic antigens and proteins. Streptokinase and Hepatitis B vaccine are some of the examples of these developments which are in the market.

1.5.3 As informed by DoP, the recommendation of the committee for encouraging the academic institutions to produce certain raw materials like antibodies, synthetic antigens, proteins has been noted.

1.5.4 Present PLI Scheme for Medical Devices also covers certain key components which constitute major part of finished medical devices such as Rotating Anode Tube, Stationary Anode Tube, MRI Magnet, Flat Panel Detector and similar components and has a distinct HS code for itself, as eligible products under the scheme.

1.6 IMPORT OF REFURBISHED MEDICAL DEVICES WITH SAFETY PARAMETERS

Recommendation/Observation

1.6.1 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 *ibid*)

Action Taken

1.6.2 The suggestion has been noted. Director General Health Services (DGHS) technical wing of MoHFW is working with Ministry of Environment, Forests and Climate Change in this regard.

1.7 SKILLED MANPOWER FOR MEDICAL DEVICE INDUSTRY

Recommendation/Observation

1.7.1 The Committee appreciates the initiative of the Department of Pharmaceuticals in up scaling 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 *ibid*)

Action Taken

1.7.2 As informed by DoP, the department has moved the proposal for establishing 7 Institutes of National Importance (INIs) called National Institutes for Medical Devices Education and Research (NIMERs) on the lines of NIPERs. The proposal awaits formal approval. This will address the needs for qualified HR for the medical devices industry in the coming years.

1.7.3 Meanwhile, M.Tech (MD) course has been started in four NIPERs to train and educate biomedical engineers on ongoing challenges faced by medical device industry.

1.8 INNOVATION AND TRAINING

Recommendation/Observation

1.8.1 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 *ibid*)

Action Taken

1.8.2 Observations/Recommendations of the Committee have been noted for further appropriate action in consultation with the stakeholders.

1.8.3 Government is continuously engaged in strengthening Central Drugs Standards Control Organization (CDSCO) as a regulator in terms of man power to strengthen the medical device regulation in the Country. In this regard, CDSCO has recruited manpower from various engineering fields (recruitment rules provide for manpower for Medical Devices regulation to be sourced, inter alia, from Bio-Medical engineering, Chemical engineering, Bio-Technology or Electrical engineering, Electronics, Instrumentation engineering, Polymer engineering, Computer science fields) in order to strengthen and effectively regulate the medical devices sector.

1.8.4 Further, various subject expert committees have already been constituted for review/ deliberation for the approval of new medical devices, which include medical practitioners, who actually use or conduct Clinical investigation on medical devices. For various in-vitro

diagnostics, the product development and evaluation scientists are part of Subject Expert Committees for evaluation.

1.8.5 CDSCO has conducted various training programs region wise to cover all the states, central regulators and other stake holders including importers and manufacturers across India for implementation of Medical Devices Rules, 2017 and operation of Online System/Portal for Medical Devices.

1.8.6 The details of training programmes on Medical Devices are attached as Annexure-1.

1.8.7 The suggestion for 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 is noted for further action.

1.8.8 The provision for giving approvals in emergency situation is not barred/ prohibited under MDR 2017 & provisions of MDR can be used to give marketing authorization in emergency situations.

1.8.9 With respect to lowering of fees charged by testing laboratories for Class C&D medical devices by NIB - the matter has been taken up with NIB for rationalization of fees.

1.8.10 As informed by DoP, the department has moved the proposal for establishing 7 Institutes of National Importance (INIs) called National Institutes for Medical Devices Education and Research (NIMERs) on the lines of NIPERs. The proposal awaits formal approval. This will address the needs for qualified HR for the medical devices industry in the coming years. Meanwhile, M.Tech (MD) course has been started in four NIPERs to train and educate biomedical engineers on ongoing challenges faced by medical device industry.

1.8.11 The proposed R&D Policy of DoP, strives to address various issues of R&D and Innovation in pharma and medtech sector, including the Industry Academic linkages. Industry Associations will be involved in creating awareness of Standards and Regulations of MedTech Sector to the Innovators and Scientists at Research Institutions.

1.9 CAPACITY BUILDING PROGRAMME

Recommendation/Observation

1.9.1 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 *ibid*)

Action Taken

1.9.2 Training programme for strengthening State/ Central Regulators are conducted from time to time. Inclusion of Medical Device Testing Officers in such trainings will also be considered in future trainings.

1.9.3 The details of training on Medical Device Regulation is as Annexure-1.

CHAPTER-II

RECOMMENDATIONS/OBSERVATIONS ON WHICH THE COMMITTEE DOES NOT DESIRE TO PURSUE IN VIEW OF THE MINISTRY'S REPLIES

2.1 SEPARATE REGULATION FOR MEDICAL DEVICES

Recommendation/Observation

2.1.1 The Committee notes that Drugs and Cosmetics Act lacks the provision of 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 substandard 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 of 138th Report)

Action Taken

2.1.2 MOH&FW vide notification vide S.O. 648 (E) dated 11.02.2020 has exhaustively defined medical devices at par with the global definition. Further, as regard regulation of all medical devices falling under definition, it is submitted that all such medical devices are under regulation in a phase wise manner by virtue of notification GSR 102(E) dated 11.02.2020 and S.O. 648(E) dated 11.02.2020. Category A and B Medical Devices have already come under licensing regime w.e.f. 01.10.2022, whereas Category C & D Medical Devices shall come under licensing regime w.e.f. 01.10.2023, though these are presently under compulsory registration regime.

2.1.3 In respect of all the Medical Devices which have been notified as drugs under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 all the penal provisions applicable to drugs are applicable to Medical Devices as well.

2.1.4 However, it is to inform that the Ministry has already initiated the process of drafting and preparing a new Bill "The Drugs, Medical Devices & Cosmetics Bill 2022" in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, sale, distribution and clinical investigation, has been proposed with specific penal provisions for various contraventions of quality and safety, and provisions of the medical device chapter.

2.1.5 The proposed bill includes more stringent penal provision i.e., the bill proposes to enhance the period of imprisonment between 1-10 years which may extend to life imprisonment and amount of fine up to Rs. 15 lakhs for any contravention of provisions of the bill.

2.1.6 The proposed bill, which establishes a distinct definition for medical devices, prohibits the manufacture, import, sale or distribution of medical devices that are not in conformity with the prescribed standards of quality, safety, and performance.

2.2 WELL-RESEARCHED, ORGANISED AND INCLUSIVE LEGAL ARCHITECTURE FOR MEDICAL DEVICES

Recommendation/Observation

2.2.1 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 ibid*)

Action Taken

2.2.2 Ministry is in process of drafting and preparing a new Bill "The Drugs, Medical Devices & Cosmetics Bill 2022" in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, Central/State medical device testing centres, sale, distribution and clinical investigation has been proposed.

2.3 COMPREHENSIVE LAW SUPPORTED BY INSTITUTIONAL INFRASTRUCTURE FOR MEDICAL DEVICE INDUSTRY

Recommendation/Observation

2.3.1 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 *ibid*)

Action Taken

2.3.2 The Ministry of Health and Family Welfare has proposed a new Drugs, Medical Devices and Cosmetics Bill, 2022 which is a comprehensive legislation to ensure that the medical products including medical devices sold in Country are safe and effective, and conform to prescribed quality standards.

2.3.3 The proposed bill has a distinct definition for medical devices. The Bill also proposes to constitute a separate Medical Devices Technical Advisory Board to advise the government on technical matters pertaining to medical devices, which shall include officials from the various Government Departments and experts nominated by the government from the field of medical devices industry.

2.3.4 Although no National Commission on medical device has been set-up, the said new Drugs, Medical Devices and Cosmetics Bill, 2022 has been prepared after exhaustive consultation with the stakeholders including manufacture associations, State/Central Regulators, Experts, and Consumer Associations etc. It is to bring a comprehensive Law striking balance to have provisions for ensuring the quality, safety, performance of medical products without hindrance to the growth of the medical device sector/industry.

2.3.5 The proposed bill contains detailed provisions for clinical investigations, definitions of clinical investigation, clinical performance evaluation for in-vitro diagnostics, investigational and predicate medical devices, apart from detailed comprehensive chapter on medical devices. This is to make the regulatory ecosystem of medical devices more predictable and robust, thereby contributing to innovation research and development, in the sector of medical devices and overall growth of the medical devices industry. This will naturally give boost to domestic manufacturing of medical devices as well as attract huge investments in India in healthcare sector.

2.4 REGULATIONS TO BOOST MEDICAL DEVICE INDUSTRY

Recommendation/Observation

2.4.1 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 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 *ibid*)

Action Taken

2.4.2 The Ministry of Health and Family Welfare has proposed a new Drugs, Medical Devices and Cosmetics Bill, 2022 which is a comprehensive legislation to ensure that the medical products including medical devices sold in Country are safe and effective, and conform to prescribed quality standards.

2.4.3 The proposed bill has a distinct definition for medical devices. The Bill also proposes to constitute a separate Medical Devices Technical Advisory Board to advise the government on technical matters pertaining to medical devices, which shall include officials from the various Government Departments and experts nominated by the government from the field of medical devices industry.

2.4.4 The Medical Devices Rules (MDR), 2017 are in line with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices, which will foster Make in India also.

2.4.5 Currently, as per MDR 2017 Medical Devices are classified into into four classes (A, B, C and D) as per the risk of the intended use and purpose.

According, import of all classes of Medical Devices as well as manufacture of Class C&D (High Risk) Medical Devices are regulated by CDSCO, while manufacture of Class A&B (Low Risk) Medical devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments.

2.4.6 The online system for accepting the applications for grant of manufacturing license, import licence, free sale certificate, market standing certificate, non- conviction certificate, is functional. This has digitised & streamlined the regulatory submission procedures and expedited licensing process for ease of doing business.

2.4.7 Government is continuously engaged in strengthening CDSCO in terms of man power and infrastructure to strengthen the medical device regulation in the country.

2.4.8 In this regard, CDSCO has recruited manpower from various engineering fields (recruitment rules provide for manpower for Medical Devices regulation to be sourced, inter alia, from Bio-Medical engineering, Chemical engineering, Bio-Technology or Electrical engineering, Electronics, Instrumentation engineering, Polymer engineering, Computer science fields) in order to strengthen and effectively regulate the medical devices sector.

2.4.9 Presently there are 23 Drugs Inspectors (Medical Devices), 236 Medical Device Officers (MDO) and 03 ADC (Medical Devices) working in CDSCO. Further, recently the Government has created additional 219 posts at various levels to strengthen CDSCO in medical device regulations.

2.4.10 Further, in order to increase skills, knowledge of central/ state regulators, various training programmes are being conducted. Moreover, a mechanism to regularly designate State Medical personnel as Medical Device Testing Officers so that the mandate of the legislation can be implemented effectively; is already in place.

2.5 BENCHMARKS AND STANDARDS OF MEDICAL DEVICES

Recommendation/Observation

2.5.1 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 prioritize health and wellness. In this regard, the Committee believes that BIS should focus on harmonizing 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 *ibid*)

Action Taken

2.5.2 As informed by BIS, under Medical Equipment and Hospital Planning department, BIS has published 620 Indian Standards harmonized with International Standards (ISO or IEC). BIS harmonizes Indian Standards with International Standards, taking into consideration the interest of the country, where ever feasible.

2.6 ADHERENCE TO INDIAN STANDARDS OF MEDICAL DEVICES.

Recommendation/Observation

2.6.1 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 *ibid*)

Action Taken

2.6.2 As informed by BIS, it has published Indian Standard IS 23485 covering the essential principles for safety and performance of medical devices.

2.7 LOW COST MEDICAL DEVICE TESTING LABORATORIES

Recommendation/Observation

2.7.1 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 *ibid*)

Action Taken

2.7.2 Currently, 6 Central Medical device testing laboratories are notified by Government of India for carrying out test and evaluation of various medical devices, and 26 medical device laboratories are registered by CDSCO to carry out testing on behalf of device manufacturers for various medical devices. All these laboratories are NABL accredited.

2.7.3 Further, CDSCO engages with BIS, QCI and ICMR to provide the list of their Laboratories who are involved in testing of Medical Devices and in test/ evaluation of specified In-vitro Diagnostics Reagents/ kits, Analyzers, Instruments and Software in order to increase the number of medical device testing laboratories across the country. This will significantly encourage the local manufacturers to get their products tested and ultimately will improve the availability and affordability of medical devices in the domestic market.

2.7.4. This is a dynamic process. Further, the laboratories which are NABL accredited and having adequate infrastructure for testing of medical device/ IVDs may also apply to CDSCO for registration.

2.7.5 As informed by BIS, it has its own 08 laboratories spread across the country which are carrying out testing of samples under conformity assessment schemes being operated by BIS. In addition, BIS also recognizes outside laboratories from public and private sector under its laboratory recognition scheme (BIS LRS2020) for testing samples meant for the purpose of conformity assessment schemes being operated by BIS. As on date 293 such laboratories have been recognized.

2.7.6 List of Indian standards pertaining to medical devices and laboratories having test facilities for carrying out testing of these Indian standards is attached at Annexure-2. The IS wise list of laboratories available for testing products is also available at www.lims.bis.gov.in

2.8 IT ENABLED POST MARKET SURVEILLANCE SYSTEM FOR MEDICAL DEVICES

Recommendation/Observation

2.8.1 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 up to 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 *ibid*)

Action Taken

2.8.2 Observations/ Recommendations of the Honourable Committee have been noted.

2.8.3 Materio-vigilance Programme of India (MvPI) was approved by the Govt. of India on 10.02.2015. The Programme was formally launched at IPC, Ghaziabad on 6.07.2015 to ensure the safety of medical devices in the country.

2.8.4 293 Medical Devices Adverse Event Monitoring Centres (MDMCs) have been identified and recognized across the country and more are in pipeline. MDMCs report adverse events associated with the use of Medical Devices. The adverse reactions/ Serious Adverse events related to medical device are regularly analysed by the concerned technical committee.

2.9 PREFERENTIAL PURCHASE OF DOMESTIC PRODUCTS

Recommendation/Observation

2.9.1 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 *ibid*)

Action Taken

2.9.2 As informed by DoP, vide OM dated 16.02.2021 guidelines have been issued for implementing the provisions of Public Procurement Order, 2017 with respect to procurement of goods & services in Medical Devices. As per these Guidelines, preference is given by the Central Procurement agencies, to Class-I local supplier of Medical Devices, where local content is more than or equal to 50%.

2.9.3 Further, pursuant to the DPIIT's Public Procurement (Preference to Make in India) Order (PPO), 2017 dated 16.09.2020, DoP has also 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.

2.9.4 Further, a list of 340 medical devices, where claims of local manufacturing have been received, were shared with Central Procurement Agencies.
The PLI scheme for Medical Devices is being implemented with the objective to boost domestic manufacturing capacity of the Medical Devices, under four segments, whose import dependency is considerably high, with a budget outlay of Rs.3,420 Cr for incentivizing the manufacturing for a period of five years. A note on the status of implementation of PLI scheme and the list of medical devices covered thereon are given in Annexure-3.

2.10 ROBUST FUNDING MECHANISM FOR INNOVATION FOR MEDICAL DEVICES INDUSTRY

Recommendation/Observation

2.10.1 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 ibid)

Action Taken

2.10.2 As informed by DoP, they are taking action for bringing out a Policy to catalyze Research & Development and Innovation in Pharma-MedTech Sector with an objective to create an ecosystem for innovation. This policy awaits approval of the Cabinet.

2.11 INTERNATIONAL EXPOSURES TO DOMESTIC MANUFACTURES

Recommendation/Observation

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

(Para – 3.13 *ibid*)

Action Taken

2.11.2 As informed by DOP, after the operationalization of the separate Export Promotion Council for Medical Devices, same will be undertaken by this council.

2.12 DEVELOPMENT OF MEDICAL DEVICE PARKS

Recommendation/Observation

2.12.1 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 *ibid*)

Action Taken

2.12.2 As informed by DoP, the suggestions have been noted and the same has been conveyed to the four States given in principle approval (Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh) and inputs in this regard will again be shared with the four States developing the medical device parks.

2.13 POLICY TO CATALYZE RESEARCH & DEVELOPMENT AND INNOVATION

Recommendation/Observation

2.13.1 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 *ibid*)

Action Taken

2.13.2 As informed by DoP, they have initiated action for bringing out a Policy to catalyze Research & Development and Innovation in Pharma- MedTech Sector with an objective to create an ecosystem for innovation. The policy awaits approval of the Cabinet.

2.14 *CONVERGENCE AND COLLABORATION BETWEEN THE INDUSTRY AND ACADEMIA*

Recommendation/Observation

2.14.1 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 *ibid*)

Action Taken

2.14.2 As informed by DoP, they have initiated action for bringing out a policy to catalyze Research & Development and Innovation in Pharma- MedTech Sector with an objective to create an ecosystem for innovation. The policy awaits approval of the Cabinet.

2.14.3 Collaboration between the Industry and academia like IITs will be achieved by Inter-Departmental R&D Council proposed to be set up, for which draft Cabinet note has been circulated.

2.15 PROMOTION OF LOCAL MANFACTURERS

Recommendation/Observation

2.15.1 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 *ibid*)

Action Taken

2.15.2 As informed by DoP, most of the medical devices fall in standard rate of import tariff and an additional Health Cess on full import value is charged on many of the medical devices. Any further increase in import tariff will impact the procurement budgets of the Central Government and the State Governments. Hence a holistic view is required for tariff increase.

2.15.3 Further, GST rate slab is also decided keeping in mind that the manufacturer is able to set off the GST credit which accumulates at the time of purchase of inputs and services. Further, GST rate slabs are not decided by the Central Government alone but by the GST Council which is a federal body for taking all decisions on GST. Requests relating to GST rate slab will be forwarded to GST Council for consideration.

2.15.4 Excise duty is no more levied after the introduction of GST. Specific instance/ example is required for it to be shared with GST Council.

2.15.5 As informed by the Department of Pharmaceuticals, the Department of Commerce has conveyed the approval for setting up of a separate Export Promotion Council for Medical Devices under the administrative charge of the D/o Pharmaceuticals. Its formation is under process.

2.16 INCLUSION OF STRINGENT DATA PROTECTION NORMS IN THE DRAFT MEDICAL DEVICE POLICY, 2022

Recommendation/Observation

2.16.1 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 *ibid*)

Action Taken

2.16.2 As informed by DoP, personal data protection is being dealt with by MeitY and recently, a bill is proposed by MeitY on the personal data protection. Department of Pharmaceuticals will work with the medical devices manufacturers and healthcare facilities in this regard.

2.17 PRICING MECHANISM FOR MEDICAL DEVICES

Recommendation/Observation

2.17.1 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 *ibid*)

Action Taken

2.17.2 It is to inform that Medical Devices by definition have been notified as Drugs under Section 3(b)(iv) of the Drugs and Cosmetic Act,1940 (Notification dated 11th February, 2020) w.e.f. April 2020. Accordingly, NPPA issued Order dated 31.03.2020 notifying that all Medical Devices shall be governed under the provisions of the DPCO, 2013 w.e.f. April, 2020. Hence, Medical Devices which are included in the NLEM, 2015 are treated as

scheduled drugs for their regulations. Other than these, all medical devices are treated as non-scheduled drugs for their monitoring of prices under Para 20 of DPCO, 2013.

2.17.3 In respect of non-scheduled drugs, a manufacturer is at liberty to fix its Maximum Retail Price (MRP) but cannot increase the same by more than 10% of what was prevalent during the preceding 12 months. The extent of price change depends upon the decision made by the manufacturer while taking note of market dynamics, demand-supply situation, relative profitability, ease of entry, access to technology, etc. The interplay of these factors may ensure that there is no unbridled increase in prices and the effective increase in prices are lower than the maximum permissible level of 10% every year.

2.18 BALANCE BETWEEN PRODUCTION COST AND PRICING

Recommendation/Observation

2.18.1 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 *ibid*)

Action Taken

2.18.2 As informed by NPPA, as per National Pharmaceutical Pricing Policy, 2012, DoP has shifted from cost-based pricing to market-based pricing method. Other observations of the committee have been noted.

2.19 BRINGING DEPARTMENT OF PHARMACEUTICALS UNDER THE MINISTRY OF HEALTH & FAMILY WELFARE

Recommendation/Observation

2.19.1 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 along with the 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 *ibid*)

Action Taken

2.19.2 The suggestion has been noted.

2.20 ROADMAP FOR GROWTH OF MEDICAL DEVICE INDUSTRY

Recommendation/Observation

2.20.1 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 *ibid*)

Action Taken

2.20.2 Ministry has initiated the process of drafting and preparing a new Bill **"The Drugs, Medical Devices & Cosmetics Bill 2022"** in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, sale, distribution and clinical investigation, has been proposed with specific penal provisions for various contraventions of quality and safety, and provisions of the medical device chapter.

2.20.3 The Department of Pharmaceuticals is working on a National Medical Device Policy with the aim to provide a road map for promotion of medical device industry. Focussed interventions, as suggested such as single window clearance system for all regulators of the medical devices, promotion of more MD clusters, etc will be taken up as per the Policy.

2.21 LEGISLATION TO BOOST MEDICAL DEVICE INDUSTRY

Recommendation/Observation

2.21.1 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 *ibid*)

Action Taken

2.21.2 Ministry has already initiated the process of drafting and preparing a new Bill "The Drugs, Medical Devices & Cosmetics Bill 2022" in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, sale, distribution and clinical investigation, has been proposed with specific penal provisions for various contraventions of quality and safety, and provisions of the medical device regulation.

2.22 QUALITY MANAGEMENT AND QUALITY ASSURANCE SYSTEM FOR MEDICAL DEVICES

Recommendation/Observation

2.22.1 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 *ibid*)

Action Taken

2.22.2 The MDR, 2017 were enacted in consultation with the associations and stakeholder and implemented from 01.01.2018. These rules are harmonised in line with International practices, to facilitate speedy disposal while ensuring quality, safety and performance. These rules cover Import/ manufacturing/ sale and distribution/ Clinical Investigation etc. The manufacturer has to comply with all requirements laid down in Fifth Schedule for Quality Management System and the standards as per MDR, 2017 to ensure quality of the Medical Devices.

2.22.3 Existing regulatory framework will definitely help to ensure the quality and increase the exportability of the licensed product. Such licensed products under MDR, 2017, will be accepted not only in India but any part of the globe, thereby promoting the export ecosystem.

2.23 CREATION OF BONE BANKS

Recommendation/Observation

2.23.1 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 *ibid*)

Action Taken

2.23.2 It is pertinent to mention that Biocompatibility is already mandatory for implantable medical devices under MDR 2017.

2.23.3 Creation of “Bone Banks” may be considered by appropriate institution/ entities after consultation with stakeholders. However, such activities are usually not a part of regulation.

2.24 SAFETY AUDIT OF MEDICAL DEVICES

Recommendation/Observation

2.24.1 The Committee feels that Materiovigilance Programme of India (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 *ibid*)

Action Taken

2.24.2 Materiovigilance Programme of India (MvPI) was approved by the Govt. of India on 10.02.2015. The Programme was formally launched at Indian Pharmacopoeia Commission, Ghaziabad on 06.07.2015 to ensure the safety of medical devices in the country, is already implemented.

2.24.3 Materiovigilance Program of India is already being strengthened by MoHFW, in order to ascertain the safety of medical devices which are commercially available in the market. Further, the MDR 2017 describes requirements of quality management system & product characteristics, conformity assessment in stepwise manner – which is used for inspection by all for ensuring uniformity in inspection.

2.24.4 The application fee for grant of manufacturing license (for Class A/B/C/D) is prescribed in Second schedule of MDR, 2017. The fees were decided after consultation of stakeholders. The recommendations of the Committee have been noted.

2.25 EXCLUSIVE LEGISLATION FOR MEDICAL DEVICES

Recommendation/Observation

2.25.1 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 *ibid*)

Action Taken

2.25.2 Ministry has already initiated the process of drafting and preparing a new Bill **"The Drugs, Medical Devices & Cosmetics Bill 2022"** in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, sale, distribution and clinical investigation, has been proposed with specific penal provisions for various contraventions of quality and safety, and provisions of the medical device regulation. It is a comprehensive legislation to ensure that the medical products including medical devices sold in Country are safe and effective, and conform to prescribed quality standards.

2.25.3 The proposed bill has a distinct definition for medical devices. The Bill also proposes to constitute a separate Medical Devices Technical Advisory Board to advise the government

on technical matters pertaining to medical devices, which shall include officials from the various Government Departments and experts nominated by the government from the field of medical devices industry.

2.25.4 It is to bring a comprehensive Law striking balance to have provisions for ensuring the quality, safety, performance of medical products without hindrance to the growth of the medical device sector/industry.

2.25.5 The proposed bill contains detailed provisions for clinical investigations, definitions of clinical investigation, clinical performance evaluation for in-vitro diagnostics, investigational and predicate medical devices, apart from detailed comprehensive chapter on medical devices. This is to make the regulatory ecosystem of medical devices more predictable and robust, thereby contributing to innovation research and development, in the sector of medical devices and overall growth of the medical devices industry. This will naturally give boost to domestic manufacturing of medical devices as well as attract huge investments in India in healthcare sector

2.25.6 Recommendations of the Committee have been noted.

2.26 COMPREHENSIVE ROADMAP WITH PRACTICAL AND ACTIONABLE STRATEGY

Recommendation/Observation

2.26.1 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 *ibid*)

Action Taken

2.26.2 Recommendations of the Committee have been noted. Ministry is in process of drafting and preparing a new Bill “The Drugs, Medical Devices & Cosmetics Bill 2022” in which a separate chapter for comprehensive regulation of medical devices for import, manufacture, Central/State medical device testing centres, sale, distribution and clinical investigation has been proposed to ensure safety, quality and performance without hindrance to growth of the sector.

2.26.3 As informed by DoP, they are working on a National Medical Device Policy with the aim to provide a road map for promotion of medical device industry. Focussed interventions on promotion of more MD clusters, R&D promotional interventions, etc will be taken up as per the Policy.

CHAPTER- III

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE MINISTRY HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

3.1 CREATION OF DEPARTMENT OF MEDICAL DEVICES UNDER MINISTRY OF HEALTH AND FAMILY WELFARE.

Recommendation/Observation

3.1.1 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 legislation for Medical Devices.

(Para - 2.9 of 138th Report)

Action Taken

3.1.2 Appreciating the potential of the Medical Device industry, Ministry has prepared and proposed a new Bill "The Drugs, Medical Devices & Cosmetics Bill 2022". Although the proposed Bill "The Drugs, Medical Devices & Cosmetics Bill, 2022'' is combined bill for regulation of drugs, cosmetics and medical devices, it is proposed to have separate chapter for regulation of medical devices for import, manufacture, sale, distribution, Central/State medical device testing centres and clinical investigation.

3.1.3 The Bill also proposes to constitute a separate Medical Devices Technical Advisory Board to advise the government on technical matters pertaining to medical devices, which shall include officials from the various Government Departments and experts nominated by the government from the field of medical devices industry.

3.2 SEPARATE REGULATORY INFRASTRUCTURE FOR MEDICAL DEVICES

Recommendation/Observation

3.2.1 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 *ibid*)

Action Taken

3.2.2 Government is continuously engaged in strengthening Central Drugs Standards Control Organization (CDSCO) in terms of manpower and infrastructure to strengthen the medical device regulation in the Country.

3.2.3 In this regard, CDSCO has recruited manpower from various engineering fields (recruitment rules provide for manpower for Medical Devices regulation to be sourced, inter

alia, from Bio-Medical engineering, Chemical engineering, Bio-Technology or Electrical engineering, Electronics, Instrumentation engineering, Polymer engineering, Computer science fields) in order to strengthen and effectively regulate the medical devices sector.

3.2.4 Presently there are 23 Drugs Inspectors (Medical Devices), 236 Medical Device Officers (MDO) and 03 ADC (Medical Devices) working in CDSCO. Further, recently the Government has created additional 219 posts at various levels to strengthen CDSCO in medical device regulations.

3.3 STRINGENT STANDARDS AND CERTIFICATION PROCESS FOR CLASS C & D PRODUCTS

Recommendation/Observation

3.3.1 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 *ibid*)

Action Taken

3.3.2 Rule 7 of the Medical Devices Rules, 2017 provides the product standards for medical device: (1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time. (2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards. (3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

3.3.3 Further, the Quality Management System as per schedule V of the MDR, 2017, and essential principles for safety and performance are required to be complied with by the manufacturers of Medical Devices.

3.3.4 The scheme for ensuring the quality, safety and performance of medical devices, as per the Medical Devices Rules, is through grant of licenses, which is also a mechanism harmonized with and adopted by many regulatory authorities globally. The regulator is responsible to ensuring the above through compliance with the QMS and product standards as mandated in the Rules.

3.4 PROMOTION OF RESEARCH AND INNOVATION IN PHARMACEUTICAL SECTOR (PRIP) SCHEME

Recommendation/Observation

3.4.1 To invigorate the culture of research and development in medical devices in the Institutions like IITs, NITs and other academic institutions the Committee recommend 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 *ibid*)

Action Taken

3.4.2 As informed by DoP. a scheme - Promotion of Research and Innovation in Pharmaceutical Sector (PRIP) – for establishment of Centres of Excellence (CoEs) at National Institutes of Pharmaceutical Education and Research (NIPERs) and incentivizing research projects, related to pharma and Medtech sector has been proposed. The Scheme awaits appraisal by the EFC.

3.5 SCHEME FOR PROMOTION OF MEDICAL DEVICE PARKS IN INDIA

Recommendation/Observation

3.5.1 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 *ibid*)

Action Taken

3.5.2 DoP has informed that the suggestions are noted

3.6 FACILITIES IN MED TECH PARKS

Recommendation/Observation

3.6.1 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 labour 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);

ix. Availability of subsidized power and water; and
iv. For promoting the Indian medical device market, Mediparks should organize-"Medical Device Exhibitions" and workshops.

(Para - 3.19 *ibid*)

Action Taken

3.6.2 As informed by DoP, the suggestions of the Committee for promotional activities by the four medical device parks, ETP and dedicated offices for HR will be shared with States.

3.6.3 Further, DoP is proposing a scheme to increase the number of NABL approved Medical Devices Testing Labs in the Country and the scheme awaits in-principle approval of the Department of Expenditure (DoE). Post approval, actions will be initiated to bring out a schematic intervention

3.7 STRICT COMPLIANCE OF EXISTING LAWS/REGULATIONS BY MANFACTURES

Recommendation/Observation

3.7.1 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 patients' health.

(Para – 3.41 *ibid*)

Action Taken

3.7.2 As informed by DoP, as per Para 24&25 of DPCO, 2013, it is mandatory for every manufacturer to display MRP on the label of the container of formulation and the minimum pack thereof. Same is being monitored scrupulously.

3.7.3 Licenses are issued only after satisfactory compliance of regulatory requirements and unlicensed manufacturers are not allowed to sell their products in market. Moreover, post market surveillance is in practice by regulatory authorities both at Center and State levels by means of routine inspections, sampling, and surveys. A comprehensive Materiovigilance Programme has also been put in place by DoHFW for the same.

3.8 IMPLEMENTATION OF TRADE MARGIN REGULARISATION POLICY

Recommendation/Observation

3.8.1 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 *ibid*)

Action Taken

3.8.2 As informed by DoP, the Issue of Trade Margin is under active consideration of the Department in consultation with the stakeholders.

3.9 SHORTCOMINGS IN MEDICAL DEVICE TESTING SYSTEM

Recommendation/Observation

3.9.1 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 *ibid*)

Action Taken

3.9.2 Observation/Recommendations of the Committee have been noted.

3.9.3 Further, as per the existing provisions under MDR 2017 the medical device testing laboratories and medical device testing officers are being notified by the Central Government and State Governments.

3.9.4 On the basis of request of stakeholders & as per international practices, MoHFW has published GSR 754(E) dated 30.09.2022, to exempt Class A (Non Sterile and Non Measuring) from audit. This initiative taken by MoHFW will rationalise regulation & also ensure ease of doing business.

3.9.5 Even in case of the class A (Sterile and measuring) medical device, the audit prior to issue the manufacturing license is not required. The license is granted by the concerned State Licensing Authority after the review of the documents. The audit may be carried out within 4 months from the date of issue of the manufacturing license, without interruption of manufacturing and supply of the products. Currently the licensing authority are informing to Notified Body through email. However, the mechanism for considering online applications is under active consideration.

3.9.6 As per MDR 2017, in case of Class B medical devices, prior to grant of the license, audit is compulsory. As the Licensing authority for Class B is the concerned State Licensing Authority, if there are any non-conformities as per the report, then there is a provision on online licensing portal and Notified bodies have to submit audit report on portal. This is the feedback mechanism.

3.9.7 IT help desk email id has been provided to stakeholders – to register complaints regarding functioning of portal.

3.9.8 Further, with respect to non-adherence of timelines for audit and report as per MDR 2017, by the notified bodies, CDSCO has convened several meetings with the notified bodies to stress on the time lines and also to augment their infrastructure.

3.10 INTER-MINISTRY CO-ORDINATION FOR PROMOTION OF MEDICAL DEVICE INDUSTRY

Recommendation/Observation

3.10.1 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 *ibid*)

Action Taken

3.10.2 Observation/Recommendations of the Committee have been noted.

3.10.3 The regulatory body namely Central Drugs Standards Control Organization has a vertical on Medical Devices with 23 Drugs Inspectors (Medical Devices), 236 Medical Device Officers (MDO) and 03 ADC (Medical Devices) working in CDSCO. Further, recently the Government has created additional 219 dedicated posts at various levels to strengthen CDSCO in medical device regulations.

3.10.4 DoP has also suggested that there may not be any need for creation of a separate Department for medical devices, however the medical device division can be strengthened with more manpower to address the growing needs of the sector.

3.10.5 It is also informed that the DoP has taken various initiatives for the last 7 years for the Medical Devices sector and same is given in Annexure-4.

3.11 CERTIFICATION SYSTEM FOR INDIGENOUS MEDICAL DEVICES

Recommendation/Observation

3.11.1 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 *ibid*)

Action Taken

3.11.2 The present Medical Devices Rules, 2017 have risk based classification and the same is also included in the proposed Bill. The regulatory controls are carried out on the basis of risk based approach. If a device is declared to be defective the root cause analysis is to be carried out by the manufacturers and, accordingly, the manufacturer has to initiate the corrective and preventive action.

3.11.3 In this regard, CDSCO has followed International practices and based on request of stakeholders and associations MOHFW has already published a notification vide GSR 777(E) dated 14.10.2022 wherein Class A (Non Sterile and Non measuring) devices are exempted from Chapter IV,V, VII, VIII and XI of MDR 2017.

3.11.4 The duties of Central Licensing Authority, State Licensing Authority and Notified Bodies are clearly defined under Medical Devices Rules 2017.

3.11.5 There is a mechanism in the Act and Rules for uniform implementation through Drugs Consultative Committee (DCC). Further, the Central Licensing Authority is convening meetings on regular basis with State Licensing Authorities for the deliberation of various issues raised by State Licensing Authorities. The issues are deliberated and decision is taken to harmonize the enforcement across the country.

3.11.6 Rule 7 of the Medical Devices Rules, 2017 provides the product standards for medical device:

(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time. (2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards. (3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

3.11.7 Further, the Quality Management System as per schedule V of the MDR, 2017, and essential principles for safety and performance are required to be complied with by the manufacturers of Medical Devices.

3.11.8 The scheme for ensuring the quality, safety and performance of medical devices, as per the Medical Devices Rules, is through grant of licenses, which is also a mechanism harmonized with and adopted by many regulatory authorities globally. The regulator is responsible to ensuring the above through compliance with the QMS and product standards as mandated in the Rules.

3.11.9 Voluntary certification, in addition to the license, is the choice of the manufacturer.

CHAPTER- IV

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH FINAL REPLIES OF THE MINISTRY HAVE NOT BEEN RECEIVED

4.1 MEDICAL DEVICE POLICY

Recommendation/Observation

4.1.1 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 of 138th Report)

Action Taken

4.1.2 As information by DoP, the Department is working on a National Medical Device Policy with the aim to provide a road map for promotion of medical device industry. Focused interventions, as suggested, will be taken up as per the Policy.

4.2 R&D AND INNOVATION

Recommendation/Observation

4.2.1 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 *ibid*)

Action Taken

4.2.2 As informed by NPPA/DoP, Para 32 of DPCO, 2013 provides exemptions to domestic manufacturers to promote innovation. Other observations of the committee have been noted.

4.3 NON-AVAILABILITY OF BIO-SPECIMENS FOR QC PANELS

Recommendation/Observation

4.3.1 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 *ibid*)

Action Taken

4.3.2 Following panels are available at National Institute of Biologicals (NIB) to the indigenous IVD manufacturers on request to strengthen the QC of their products:

1. HIV
2. HBSAg
3. HCV
4. SYPHILIS
5. VTMs (COVID positive and negative)

NIB is making efforts to make panels for more infections available in future.

RECOMMENDATIONS/OBSERVATIONS - AT A GLANCE

CHAPTER-III

RECOMMENDATIONS/OBSERVATIONS IN RESPECT OF WHICH REPLIES OF THE MINISTRY HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

The Committee welcomes the proposal of Government to constitute a separate Medical Devices Technical Advisory Board to advise the Government on technical matters pertaining to medical devices. However, the Committee feels that though both are the medicals products but the medical devices are not pharmaceuticals. To bring a world class regulatory frame work, give boost to medical device industry and minimise the dependency on imports, a separate Department and separate legislation is required. Accordingly, the Committee again recommends that instead of bringing a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should formulate a separate legislation for Medical Devices and create a new Department namely- Department of Medical Devices under Ministry of Health and Family Welfare.

(Para 3.1.4)

The Committee has observed that in the recent years indigenous medical industry is growing fast and to match with the pace existing Drug Inspectors (Medical Devices) and Medical Device Officers working under CDSCO would not be able to cater the needs of the industry. Therefore, a separate regulatory infrastructure for medical devices with dedicated work force instead of adjoining with the CDSCO would serve the purpose better.

(Para 3.2.5)

The Committee is of the considered view that to compete with global standards of medical devices, quality control and quality assurance in conformity with international standards play a major role. Accordingly, the Committee re-iterates that in the suggested Medical Devices Bill, there should be stringent standards and certification process, particularly for Class C & D products.

(Para 3.3.5)

The Committee appreciates Government move for envisaging the Promotion of Research and Innovation in Pharmaceutical Sector (PRIP) Scheme for establishment of Centres of Excellence (CoEs) and further recommends that DoP must approach EFC for immediate appraisal of the Scheme for final approval by the Government.

(Para 3.4.3)

The Committee once again recommends that Government may expeditiously provide logistic support for shared manufacturing facilities like Medtech Parks to reduce the capital expenditure of manufactures, which will give a boost to indigenous manufacturing of medical devices.

(Para 3.5.3)

The Committee hopes that to improve the efficiency and overall facilities of Mediparks, expeditious action on its suggestions would be taken by the Government. Necessary approval of Department of Expenditure in this regard may also be expedited.

(Para 3.6.4)

The Committee notes that despite provisions for regulatory mechanism and its regular monitoring and surveillance, violations of norms are still being done by some manufacturers. Accordingly, the Committee recommends that the Government must ensure that the strict compliance of different provisions of existing laws/regulations are done by each and every manufacturer and penalty provisions are invoked.

(Para 3.7.4)

The Committee appreciates Government's move in this direction and recommends that DoP must ensure expeditious implementation of Trade Margin Regularisation Policy.

(Para 3.8.3)

The Committee recommends that action may be initiated at the earliest.

(Para 3.9.9)

The Committee appreciates the steps taken by the Government for strengthening of CSCO, however it feels that since the Ministry of Health and Family Welfare is the key stakeholder of medical devices, the inter-ministry co-ordination for promotion of the industry should be done by the Ministry of Health and Family Welfare only.

(Para 3.10.6)

The Committee recommends that Government may ensure that there are adequate provisions in the New Medical Devices Policy for risk proportionate regulatory controls, accountability mechanism, stringent action on violation of norms and risk proportionate penal system.

(Para 3.11.10)

Annexure-1

List of Trainings conducted on Medical Devices Rules, 2017

This office has conducted training program regional wise to cover all the state, central regulators and other stakeholders including importers and manufacturers in India for implementation of e-Governance and Medical Devices Rules 2017.

S.No	Training details	Training period
1.	CDAC training on MD Online portal	19/02/2018
2.	CDAC training on MD Online portal – SLA, Delhi	17/03/2018
3.	National Workshop on regulatory compliances for innovations dated 10/12/2018 at ICGEB	10/12/2018
4.	Workshop on e-Governance initiatives of CDSCO, Jaipur	27/04/2018
5.	Workshop on e-Governance initiatives of CDSCO, Gurgaon	11/01/2020
6.	Workshop on e-Governance initiatives of CDSCO, Mumbai	01/02/2020
7.	Training of new Drugs Inspectors (Medical Devices)	03/02/2020 to 04/05/2020
8.	Workshop on e-Governance initiatives of CDSCO, Ahmedabad	08/02/2020
9.	Workshop on e-Governance initiatives of CDSCO, Bangalore	22/02/2020
10.	Industry awareness workshop on "MDR 17 – Regulation of Medical Devices" , New Delhi	29/02/2020
11.	Workshop on e-Governance initiatives of CDSCO, Hyderabad	29/02/2020
12.	Workshop on e-Governance initiatives of CDSCO, Kolkata	07/03/2020
13.	Workshop on e-Governance initiatives of CDSCO, Chennai	14/03/2020
14.	Workshop on e-Governance initiatives of CDSCO, Chandigarh	21/03/2020

Annexure-2

S. No.	IS No.	Product Name	Labs with facility for Medical device	BIS recognized OSL under BIS LRS/ OSL with test facility as per IS and OSL code
	IS 3390:1988	Sphygmomanometers, mercurial (Second Revision)	CL –P WROL – P	-
	IS 7652:1988	Specification for Sphygmomanometer, Aneroid Type (First Revision)	CL –C WROL – P	-
	IS 4148 : 1989	Surgical Rub'ber Gloves	CL – C SROL – C NROL – C	Atmy Analytical Labs Pvt Ltd (8167506) Central Institute of Plastic Engg. & Tech.(CIPET)(5102634) Centre for Bio-Polymer Science & Technology(CBPST) (6137634) Indian Rubber Manufacturers Research Association, (7119305) Intertek India Pvt Ltd (8166336) Shriram Institute For Industrial Research (8102006) Sleen India Biz Venture Private Limited (9139736) Trustin Analytical Solutions PvtLimted(6139136)
	IS 3319: 1995/ ISO 7740:198	Surgical Blades	CL – P SROL – P WROL – P	-
	IS 13422:1992	Disposable Surgical Rubber Gloves	BNBOL – C CL – P WROL – P SROL – C	Central Institute of Plastic Engg. & Tech.(CIPET) (5102634) Choksi Laboratories Ltd (8136916) Intertek India Pvt Ltd (8166336) Trustin Analytical Solutions PvtLimted(6139136)
	IS 8521 (Part 1) : 1977	Specification for industrial safety face shields Part 1 with plastics visor	CL - C	Central Institute of Plastic Engg. & Tech.(CIPET) (5102634) Sleen India Biz Venture Private Limited(9139736)
	IS 9473:2002	(Respiratory Protective devices – Filtering half masks to protect against particles)	CL- P	Alpha Test House (8162006) Defence Research & Development Establishment (8144304) Defence Research & Development Establishment (DRDE) (8144304) Intertek India Pvt Ltd (8166336) SGS India Private limited (6162436)

				Sleen India Biz Venture Pvt. Ltd. (9139736) TUV Rheinland (India) Pvt. Ltd. (6167206) Viridian Testing Laboratories LLP (6169806)
	IS 15354 : PART 1 : 2018	Single-Use Rubber Examination Gloves)	CL –P SROL – C	1. Central Institute of Plastic Engg. & Tech.(CIPET)(5102634) 2. Intertek India Pvt Ltd (8166336) 3. Sleen India Biz Venture Private Limited (9139736)
	IS 13422:1992	Disposable Surgical Rubber Gloves	BNBOL – C CL – P SROL – C WROL – P	Central Institute of Plastic Engg. & Tech.(CIPET) (5102634) Choksi Laboratories Ltd (8136916) Intertek India Pvt Ltd (8166336) Trustin Analytical Solutions PvtLimted(6139136)
	IS 5983 : 1980	Specification for eye – Protectors	CL – P	-
	IS 17334:2019	Medical Textiles-Surgical gowns and surgical drapes-Specification		The South India Textile Research Association (6165234) Viridian Testing Laboratories LLP (6169806) Intertek India Pvt Ltd (8166336) TUV Rheinland (India) Pvt Ltd (6167206)
	IS 16289:2014	medical textile-surgical face mask	CL – N	Defence Research & Development Establishment (8144304) Defence Research & Development Establishment(DRDE) (8144304) Eurofins Product Testing India Pvt Ltd (6166036) Intertek India Pvt Ltd(8166336) Viridian Testing Laboratories LLP (6169806) Sleen India Biz Venture Private Limited (9139736) Spectro Analytical Labs Limited (8167836) The South India Textile ResearchAssociation (6165234) TUV Rheinland (India) Pvt Ltd (6167206)
	IS 17423 :2020	Medical Textiles-Coveralls	CL –C EROL – C SROL – C	Central Institute of Plastic Engg. & Tech.(CIPET) (5102634) Eurofins Product Testing India Pvt Ltd (6166036) Institute of Nuclear Medicine & Allied Sciences (8144904) Institute of Nuclear Medicine & Allied

				Sciences (8144904) Intertek India Pvt Ltd(8166336) Northern India Textile Research Association (8163504) Sleen India Biz Venture Private Limited(9139736) Spectro Analytical Labs Limited (8167836) Textile Committee (6150704) Textile Laboratory (7149904) Textile Laboratory (7149904) Textile Laboratory, (Ministry of Textiles) (6150704) The South India Textile Research Association (6165234) Viridian Testing Laboratories LLP (6169806)
	IS 13450:2018 P:1	Medical electric equipment-Pt-1:general requirement for basic safety and essential performance		Bharat Test House Pvt Ltd (9137826)
	IS 13450:2018 P:2 Sec:25	Medical Electrical Equipment-Electro cardiograph		AA Electromagnetic Test laboratory Pvt Ltd (8165826)

BIS has published following Standards for Medical Devices as on today.

S.no.	Category	**No of published Standards**
1.	Surgical Instruments	116
2.	Orthopaedic Instruments, Implants And Accessories	127
3.	Obstetric And Gynaecological Instruments And Appliances	70
4.	Ear, Nose And Throat Surgery Instruments	82
5.	Ophthalmic Instruments And Appliances	91
6.	Thoracic And Cardiovascular Surgery Instruments	68
7.	Neurosurgery Instruments Implants And Accessories	53
8.	Dentistry	206
9.	Artificial Limbs, Rehabilitation Appliances and Equipment for the Disabled	116
10.	Medical Laboratory Instruments	33

11.	Anaesthetic, Resuscitation And Allied Equipment	65
12.	Hospital Equipment and Surgical Disposal	156
13.	Veterinary Hospital Planning And Surgical Intruments	17
14	Hospital Planning	53
15	EletromedicalDignostic Imaging and Radiotherapy equipment	106
16.	Health Informatics	108
17.	Imaging & Radiotherapy Equipment	0
18.	Biological Evaluation of invitro Diagnostic Medical Devices	40
19.	Medical Biotechnology And Medical Nanotechnology	6
20.	Hospital Bio Medical Waste Management And Infection Control	0
21.	Anatomy and Forensic Sciences Equipment	8

Annexure-3

Note on PLI scheme of Medical Devices

A. Medical Devices covered under PLI scheme for MDs:

S.no.	**Name of the Target Segment**	**Indicative Eligible Products for Category-A applicants**	**Indicative Eligible Products for Category-B applicants**
1.	Cancer care / Radiotherapy medical devices	Rotational Cobalt Machine, Linear Accelerator (LINAC).	Brachytherapy Systems, Radiotherapy Simulation Systems, Workstations-Radiotherapy Planning, Proton therapy system *and other products** in this target segment.
2.	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single photon emission tomography (SPECT), Mammography, Collimator, Flat Panel Detector, Surgical X Ray C-Arm, Fixed LF and HF X Ray Products, X Ray Panels, MRI Coils and Monitors	Cyclotrons *and other products** in this target segment.
3.	Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	Dialyzer, Anesthesia Unit Ventilators, Patient monitoring system, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Syringe Pump, Defibrillators, Stress Test System and Oxygen Concentrator, Dialysis Machine, Peritoneal Dialysis kits Fistula, Blood Line, Haemodialysis Catheter and Transducer Protector, Anaesthesia Unit Gas Scavengers, Anaesthesia Unit Vaporizers, Anaesthesia Unit Ventilators, Bi- Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators,	Needles-Anesthesia, Syringes-Anesthesia,, , Anesthesia Kits, Masks – Anesthesia, , Biopsy Kits-Renal, Dialyser reprocessing system, Lithotripters Extracorporeal –Renal *and other products** in this target segment.

		Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multi-parameter Monitor, Suction Machine.	
4.	AII Implants including implantable electronic devices	Heart Valves, Stents, PTCA Balloon, Dilatation Catheter, Heart Occluders, PTCA Catheter, Hip Implants, Knee Implant and Trauma Implant, Drug Eluting Stents and Drug Eluting Balloons	Cochlear Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses *and other products** in this target segment.

**-Other products – For products not specifically mentioned in the table above, the Technical Committee shall decide whether such products shall be considered eligible under the Target Segment.*

Note: A key component which constitutes major part of the finished medical device (such as Rotating Anode Tube, Stationary Anode Tube, MRI Magnet, Flat Panel Detector and similar components), and has a distinct HS code for itself, will be considered as included in the corresponding target segment.

B. Status of implementation of PLI scheme for Medical Devices & PLI scheme for Pharmaceuticals (where 5 applicants selected under In-Vitro Diagnostics (IVDs) category of Medical Devices).

I. **Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices:**

The Scheme is being implemented through a Project Management Agency (PMA) which is responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities. An Empowered Committee under the chairmanship of CEO, NITI Aayog considered applications for approval under the Scheme.

In total 42 applications were received in two round of application window. Out of 42 applications, 21 applications have been approved with a total committed Investment of Rs.1,059 Crore and expected incentive utilisation of Rs 2,541 crore. 13 projects have already been commissioned for 31 products as on September 2022. Further, Guidelines has been amended on 18.8.2022 for Category –B applicant and Round-III application window opened for application from 01st Sept. 2022 and the last date of application window is 21.11.2022.

The details regarding actual investment up to September, 2022 are as follows:

Description	**Projected for full tenure of the scheme**	**Projections as on March 2023**	**Actual Reported as on Sept. 2022**
Investment (in Rs Cr)	1,058.97	766.94	676.14
Production (in Rs Cr)	33,125.12	3,592.43	630.55
Exports Expected (in Rs Cr)	11,286.91	1,066.40	257.17
Employment (in Nos. of persons)	6,411	3,198	2,940

Status of Projects/ Plants: Investment as per Quarterly review report of September 2022

Target Segment (TS)	**Approvd Projects**	**Approvd Products**	**Products Commisioned**	**Commited Inv. for theScheme Tenure (₹ in crore)**	**Cumulative Projected Investment Upto March 2023**	**Actual Investment Sept. 2022**
TS-1 (cancer care)	**1**	**2**	**2**	**24.50**	**14.30**	**13.89**
TS-2 (Radiology and Imaging)	**7**	**15**	**7**	**372.14**	**304.17**	**235.73**
TS-3 (Anesthetics& Cardio-Respiratory)	**7**	**25**	**16**	**354.50**	**260.54**	**231.89**
TS-4 (All Implantable)	**6**	**7**	**6**	**307.83**	**187.93**	**194.63**

Total	**21**	**49**	**31**	**1,058.97**	**766.94**	**676.14**

II. **Production Linked Incentive (PLI) scheme for Pharmaceuticals:**

To enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector, a scheme called "Production Linked Incentive Scheme for Pharmaceuticals" has been approved by the Government of India on 24th February, 2021. The Scheme has been notified vide Gazette Notification No. - 31026/60/2020-Policy dated – 3rd March, 2021.

The guidelines of the scheme were issued on 1st June, 2021. The scheme covers In-vitro diagnostic devices amongst other pharmaceutical goods. Five (5) industry applicants have been selected under the scheme for In-vitro diagnostic medical devices and the scheme provides for incentives based on their incremental sales for 6 years. The tenure of the scheme is from FY 2020-2021 to 2028-29.

Sl. No.	**Category of Applicants**	**Total Applicants approved**	**Total Committed Investment (₹ in crore)**	**Total Committed Investment up to March 2023 (₹ in crore)**	**Actual Investment up to June 2022 (₹in crore)**	**No. of mfg. locations proposed**	**No. of mfg. locations already commissioned**	**No. of R&D locations**
1	Group C - IVD	5	164	65.54	66	13	10	2

Annexure-4

Initiatives undertaken by the Department of Pharmaceuticals for the promotion of the Medical Devices Sector

- To give a policy guidance, the Department of Pharmaceuticals is working on a National Medical Device Policy with the aim to provide a road map for promotion of medical device industry.

- Recognizing the importance and need for investments in the sector, 100% FDI through automatic route was allowed in the medical devices sector in 2014.

- The ***Medical Devices Rules, 2017*** were notified under the Drugs and Cosmetics Act, 1940 by the Department of Health and Family Welfare. These rules lay out the regulatory framework for medical devices in terms of their quality, safety and efficacy. This expanded the regulatory oversight to the entire gamut of devices and classified them into four categories based on the level of risk associated with the medical devices. About 23 medical devices are under licensing with the remaining devices under different categories expected to come under licensing from October 2022 and October 23.

- In 2019, under the Department of Pharmaceutical's sub-scheme named ***"Assistance to Medical Device industry for Common Facility Centre"***, financial assistance of Rs 25 crore was approved to the Andhra Pradesh MedTech Zone (AMTZ) for setting up a common infrastructure of a superconducting magnetic coil testing facility, which has been completed in 2022.

- In 2020, revised scheme named ***"Scheme for Promotion of Medical Device Parks"*** was launched**.** Under this scheme, financing support of Rs 100 crore each has been approved for creation of common facilities in four ***medical devices parks*** coming up in Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh, which are being developed by these State Governments. This is an infrastructure support scheme wherein the common facilities will be accessed by the industrial units in the parks. These parks will come up as manufacturing hubs and provide enabling ecosystem dedicated solely for medical devices.

- Further in 2020, a scheme named "***Production Linked Incentive Scheme for Medical devices"*** was introduced. The scheme has a financial outlay of Rs. 3,420 crores, over a period of FY 2020-21 to FY 2027-28. The objective of the scheme is to support the domestic manufacturing of certain identified high-technology medical devices through incentivizing domestic manufacturers. The identified medical devices under the scheme are Cancer Care /Radiotherapy medical devices; Radiology & Imaging medical devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices; Anesthetics& Cardio-Respiratory medical devices including catheters of Cardio Respiratory Category and Renal Care Medical Devices; and all Implants including implantable electronic devices like Cochlear implants and pacemakers. Status is given at Appendix-B.

- The scheme ***"Pradhan MantriBharatiya Jan AushadhiPariyojana (PMBJP)"*** are making available close to 250 types of surgical supplies in over 8800 Jan AushadhiKendras at highly affordable prices.

- The National Pharmaceutical Pricing Authority (NPPA) monitors the prices of Non-Scheduled Medical Devices and fixed the ceiling prices for Scheduled Medical devices. In view of the extraordinary circumstances due to COVID pandemic and with the aim of making medical devices affordable, the prices of (i) Pulse Oximeters, (ii) Blood Pressure Monitoring Machines, (iii) Nebulizers, (iv) Digital Thermometers, (v) Glucometers and (vi) Oxygen Concentrators were brought under price cap using Trade Margin Rationalization.

- The Department for Promotion of Industry and Internal Trade (DPIIT) brought out the policy of "***Public Procurement (Preference to Make in India) in 2017"*** and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP thereafter laid out the definition of Class-I, Class-II and Non-Local supplier under the said Policy. Initiatives have been taken under the policy to give preference to domestic manufacturers in public procurement of medical devices done by the hospitals of the Central Government. The Public Procurement (Preference to Make in India) policy is an important pillar of the Atmanirbhar Bharat program.

- The medical device sector in India has participation both from domestic manufacturers as well as multi-national companies. Therefore, owing to the divergence of views of the industry, a "***Standing Forum of Medical Device Industry associations"*** has been set up by the Department of Pharmaceuticals on 25th August, 2021 which provides a platform to the different associations to deliberate on the common issues of the industry and arrive at a consensus before the same are taken up by the Department for examination. The mechanism has been very much appreciated by the industry.

- Constitution of "***National Medical Devices Promotion Council (NMDPC)"*** under the Department of Pharmaceuticals since 5th August 2022. The council consists of stakeholders from Government and industry and provides a platform to deliberate and resolve various issues for ease of doing business and promotion of the sector.

Major Initiatives of other Departments

- To foster Make-in-India product development and nurture the clinical validation ecosystem in the MedTech sector, the Indian Council of Medical Research (ICMR) has established the ***"Medical Device and Diagnostics Mission Secretariat (MDMS)"***. This program aims to support and catalyze research, development and indigenous manufacturing of cost-effective medical devices to strengthen healthcare sector in India and reduce import dependence through a mission mode consortia approach.

- ***"Health Technology Assessment in India (HTAIn)"*** scheme of Department of Health Research conducts studies that provide evidences related to cost-effectiveness, clinical-effectiveness and safety of medicines, devices and health programs to support evidence-based decision making in healthcare services for development of quality and affordable medical devices in the country.

- Health and Wellness Centers across the country are being equipped with medical devices required for primary diagnostic services under "Ayushman Bharat program