50	STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2023-24) SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

PROMOTION OF MEDICAL DEVICE INDUSTRY

FIFTIETH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

February, 2024/ Magha, 1945 (Saka)

CC&F. No. 178

FIFTIETH REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2023-24)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

PROMOTION OF MEDICAL DEVICE INDUSTRY

Presented to Lok Sabha on 08th February 2024

Laid in Rajya Sabha on 08th February 2024

LOK SABHA SECRETARIAT

NEW DELHI

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3. Maulana Badruddin Ajmal
4. Shri Deepak Baij
5. Shri Ramakant Bhargava
6. Shri Prataprao Patil Chikhlikar
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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2022-23)

Dr. Shashi Tharoor - Chairperson

MEMBERS

LOK SABHA

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri C.N. Annadurai
5. Shri Deepak Baij
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22. Shri G.C.Chandrashekhar
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**Nominated w.e.f. 13.02.2023 vide Lok Sabha Bulletin- Part-II Para No. 6251 dated 14.02.2023.*

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31. Vacant

SECRETARIAT

1. Shri Chander Mohan - Joint Secretary
2. Smt. Geeta Parmar - Director

* Vacant *vice* Shri Uday Pratap Singh, MP(LS) who has resigned his seat in LS w.e.f. 06.12.2023. [vide Lok Sabha Secretariat Notification No.21/1(1)/2023/T(B) dated 6th December, 2023]

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2023-24) having been authorized by the Committee do present on their behalf, this Fiftieth Report (Seventeenth Lok Sabha) on 'Promotion of Medical Device Industry' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

2. The Committee (2021-22) had a briefing by the representatives of the Department of Pharmaceuticals on 9th December, 2021. The Committee (2022-23) took oral evidence of the representatives of the Department of Pharmaceuticals on 14th December, 2022. The Committee (2023-24) took further evidence of the representatives of the Department of Pharmaceuticals and Ministry of Health and Family Welfare on 09th October, 2023.

3. The Committee (2023-24) considered and adopted the Report at their sitting held on 07th February, 2024.

4. The Committee wish to express their thanks to the officers of the Department of Pharmaceuticals, Ministry of Chemicals d Fertilizers and the Ministry of Health and Family Welfare for tendering their evidence and placing before the Committee all the requisite information sought for in connection with the examination of the subject.

5. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

6. For facility of reference and convenience, the observations/ recommendations of the Committee have been printed in bold letters at the end of the Report.

***New Delhi*;**
07 *February, 2024*
18 *Magha, 1945 (Saka)*

DR. SHASHI THAROOR
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS.

ACRONYMS/ABBREVIATIONS OF THE TERMS USED IN THE REPORT

ADMI	Association of Diagnostic Manufacturing of India
AIMED	Association of Indian Medical Device Industry
AMTZ	Andhra Pradesh Medtech Zone Ltd.
APICF	Assistance to Pharma Industry for Common Facilities
APIs	Active Pharmaceutical Ingredients
CAPPM	Consumer Awareness, Publicity and Price Monitoring
CIF	Common Infrastructure Facilities
CDSCO	Central Drugs Standard Control Organization
DoHFW	Department of Health and Family Welfare
DoE	Department of Expenditure
DPCO	Drugs Prices Control Order
GST	Goods & Services Tax
HOWM	Hazardous and Other Waste (Management and Transboundary Movement)
IPC	Indian Pharmacopoeia Commission
IFCI	Industrial Finance Corporation of India
IVD	In-vitro Diagnostics
MoEF&CC	Ministry of Environment, Forest and Climate Change
MDMCS	Medical Device Adverse Event Monitoring Centers
MSME	Micro, Small & Medium Enterprises
MTaI	Medical Technology Association of India
MvPI	Materio-vigilance Programme of India
NABCB	National Accreditation Board for Certification Bodies
NMDPC	National Medical Device Promotion Council
NHP	National Health Policy
NIMERs	National Institutes of Medical Devices Education and Research
NIPER	National Institute of Pharmaceutical Education &Research
NPAA	National Pharmaceutical Pricing Authority
NLEM	National List of Essential Medicines
NSWS	National Single Window System
OEM	Original Equipment Manufacturers
PLI	Production Linked Incentive
PMA	Project Management Agency
PMBI	Pharmaceuticals and Medical Devices Bureau of India
PMBJP	Pradhan MantriBhartiyaJanaushadhiPariyojana
PMC	Project Management Consultant
PMRUs	Project Monitoring Resource Units
PPO	Public Procurement (Preference to Make in India) Order
PSURs	Periodic Safety Update Reports
PTD	Price to Distributor
QMS	Quality Management System
QRR	Quarterly Review Report

R&D	Research & Development
SCTIMST	SreeChitraTirunal Institute for Medical Sciences and Technology
SIAs	State Implementation Agencies
SLA	State Licensing Authorities
TMR	Trade Margin Rationalization
TRC	Technical Review Committee

REPORT

PART- I

NARRATION

INTRODUCTORY

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of all medical conditions and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and healthcare insurance industry, thereby helping achieve the key objectives of the National Health Policy (NHP), 2017.

2. The Department of Health and Family Welfare (DoHFW) vide notification dated 11.02.2020, has defined medical devices as all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (v) control of conception.

3. The subject medical device has been allocated to the Department of Pharmaceuticals and Department of Health and Family Welfare in August, 2015. Under the Allocation of Business Rules, 1961 the mandate of the Department of Pharmaceuticals is related to “medical devices – Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Department” and “all matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring”. The

Department of Health and Family Welfare has mandate with regard to “regulatory aspects namely quality, safety, labelling and performance of medical devices”.

4. The medical devices constitute a multi-disciplinary sector, with the following broad classification: (a) Electronic equipment (b) Implants; (c) Consumables and Disposables (d) Surgical instruments and (e) In-Vitro Diagnostic Reagents. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. Major manufacturing of medical devices in the country is happening with respect to disposables such as catheters, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes, and implants such as cardiac stents, drug-eluting stents, intra-ocular lenses and orthopaedic implants.

5. India is one of the fastest growing markets in the global medical devices industry. The medical devices sector in India is a sunrise sector which is growing at a fast pace and is expected to become very important in the future. Medical Device industry is a growing field and the potential for its growth is the highest among all the sectors in the healthcare market. Indian medical devices market stood at USD 11 billion in 2020, projected to grow to USD 50 Billion by 2030 and its share in the global medical device market is estimated to be 1.5%.

6. The Indian market has a significant presence of several multi-national companies with about 80% of the sales generated from imported medical devices. Domestic manufacturing is largely limited to low to moderate technology devices such as cardiac stents, surgical instruments, consumables and disposables etc., although that is fast changing.

7. Further, several segments in the medical device industry are highly capital intensive, with long gestation period, require continuous induction of new technologies, continuous training of healthcare professionals to adapt to new technologies, and involve rapid innovation. Most of the high technology and innovative products originate from a well-developed ecosystem and innovation cycle, which is yet to be fully developed in India.

8. India depends on imports of medical devices to an extent of 70% for its domestic requirements. The Department has stated that though India is net importer of medical devices, export is increasing at a higher rate. The Compound Annual Growth Rate (CAGR) of export over last four years is 13.9% and CAGR of import over the same period is 8.6%. Currently,

India is exporting ventilators, PPEs, diagnostics kits, sanitizers and surgical gloves (2/3 ply), etc.

9. As regards the import status of different segments of medical devices in the country during last four financial years from 2019-20 to 2022-23, it has been informed as under:

(USD Million)

S. No	Segment	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23
1	Consumables & Disposables	1076	1471	1624	1091
2	Surgical Instruments	180	104	169	210
3	Electronics Equipment	3647	3569	5441	4884
4	Implants	415	226	423	540
5	IVD Reagents	527	872	883	767
	TOTAL	**5845**	**6242**	**8540**	**7492**

Source: Directorate General of Commercial Intelligence & Statistics (DGCIS)

10. On being pointed towards the considerable increase in import of surgical instruments from 104 USD million in F.Y. 2020-21 to 169 USD million in F.Y. 2021-22 and import of electronic equipments from 3569 USD million in F.Y. 2020-21 to 5441 USD million in F.Y. 2021-22, the representative of the Department during evidence submitted as under:

> *"we are underlying the fact that there is an increase in the imports, especially, on the electronic equipment side and as well as on the surgical side. We hope that in the coming years, with PLI and other interventions, will reduce the import dependency."*

11. The Committee have been informed that in wake of this higher import dependency, the Department has introduced various schemes for boosting domestic manufacturing of medical devices *viz.* (i) Assistance to Medical Device Industry for Common Facility Centre, (ii) Scheme for Promotion of Medical Device Parks, (iii) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices and (iv) Production Linked Incentive (PLI) Scheme for Pharmaceuticals.

12. When asked about the status and effectiveness of these schemes in reducing the dependency of our country on import of medical devices, the Department has replied as follows : -

(i) Under the scheme “Assistance to Medical Device Industry for Common Facility Centre”, grant-in-aid of Rs. 25.00 crore was provided to Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh, for establishment of Common Facility for Super conducting magnetic coil testing and research facility. The Common Facility Centre developed under the scheme has become operational at AMTZ, Andhra Pradesh for producing super-conducting magnets for production of MRI machines and is beneficial for the MRI manufacturers of the country. This will increase the production of affordable MRI machines.

(ii) Under the scheme “Promotion of Medical Devices Parks”, final approval for financial assistance of Rs. 100.00 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks. First grant of Rs. 30.00 crore each has been released to the four selected Parks.

(iii) Under the PLI Scheme for Promoting Domestic Manufacturing of Medical Devices, with a financial outlay of Rs. 3,420.00 crore and with the tenure from FY 2020-21 to FY 2027-28, financial incentives will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the four Target segments of the scheme, for a period of five (5) years. Under the scheme, total 64 applications were received and 26 applicants have been approved with committed investment of Rs. 1330.44 crore and expected employment generation of around 7950 persons. Total 14 manufacturing plants have been commissioned till date for 36 products.

(iv) Under the PLI scheme for Pharmaceuticals, with the tenure from FY 2020-2021 to 2028-29, 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.

It was added that the schemes viz. Scheme for Promotion of Medical Device Parks, Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices and Production Linked Incentive (PLI) Scheme for Pharmaceuticals are in the early phase of implementation and the benefits of the schemes will be accrued later.

13. As regards the export performance of different segments of medical devices in the country during last four financial years from 2019-20 to 2022-23, the Committee have been informed as under :

(USD Million)

S. No	Segment	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23
1	Consumables & Disposables	1083	1290	1378	1605
2	Surgical Instruments	50	54	71	72
3	Electronics Equipment	998	985	1163	1335
4	Implants	94	99	135	188
5	IVD Reagents	68	104	176	191
	TOTAL	**2293**	**2532**	**2923**	**3391**

Source: Directorate General of Commercial Intelligence & Statistics (DGCIS)

14. The Committee desired to know the factors responsible for restricting the export potential of domestic medical devices in all five segments of medical devices and the steps being taken to make exports of Indian medical devices at par with major exporting countries of the world. In reply, the Department of Pharmaceuticals has stated that the medical devices sector in India is still at a nascent stage. The manufacturing mainly comprises of the low end medical devices. The high technology products are yet to be developed in India which requires a complete ecosystem. The sector in the country suffers from cost of manufacturing disability vis-à-vis competing economies which restrict the export potential of the sector. The Government is working towards that direction to enable a favourable R&D and manufacturing ecosystem by undertaking various programmatic and non-programmatic interventions.

SCHEMES FOR PROMOTION OF MEDICAL DEVICE INDUSTRY

(i) Scheme for Promotion of Medical Device Parks

15. The Committee have been informed that the sub-scheme “Assistance to Medical Device Industry for Common Facility Centre” has been revised and renamed as “Promotion of

Medical Device Parks" which has been approved by the Government of India on 20th March, 2020 for a tenure of 5 year from 2020-2021 to 2024-2025. . It aims at providing common testing and laboratory facilities/centre in four selected Medical Device Parks. The total financial outlay for the scheme is Rs. 400 crore. Out of 16 proposals received from States/UTs, the DoP has given final approval to the States of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh under the scheme. First installment of Rs. 30 crore each has been released to 4 States in 2021-22.

16. On being asked about the reasons for approval given to only 4 proposals out of the total 16 proposals received for setting up of medical device parks and future plan, if any, to cover more States under the scheme, the Department has submitted that the scheme was drafted only to support 4 medical device Parks. The selection of 4 parks was based on the selection criteria mentioned in the scheme guidelines. The scheme is in its early phase of implementation and a need to cover more parks does not arise presently. However, some of the States like Telangana, Rajasthan, etc. are setting up medical device parks with their own funds.

17. The Committee enquired whether Rs.100 crore per medical device park is adequate for setting up of common testing and laboratory facilities. In reply, the Department has stated that the scheme "Promotion of Medical Devices Parks" was prepared in consultation with the medical device industry and it was felt that financial assistance of Rs. 100 crore will be adequate for setting up of common testing and laboratory facilities / centre. Besides, the State Government will also bear cost for other physical infrastructure for establishing the Medical Device Parks.

18. As regards the funds allocated vis-a-vis utilised under the scheme, the details has been given as under :

(Rs. in crore)

Financial Year	Funds Allocated	Funds Released
2020-21	21.05	7.49
2021-22	137.02	137.02
2022-23	120.00	0.8968*

**The release of funds to States depends upon utilisation of funds granted in the previous instalments. Once States make the expenditure, the Central Government is able to quickly*

release the next instalments. The methodology for release of funds based on milestones achieved by States is well laid out in the scheme guidelines.

(ii) Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices

19. The Committee have been informed that the PLI Scheme for Promoting Domestic Manufacturing of Medical Devices has been approved by the Government on 20th March, 2020 and notified on 21st July, 2020 for a tenure of 8 years from the Financial Year 2020-21 to 2027-28.. This Scheme is being implemented through Industrial Finance Corporation of India (IFCI) as Project Management Agency 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.

20. It has further been stated that the Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the medical devices sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The total financial outlay of the Scheme is Rs. 3,420 crore. The four Target Segments of medical devices covered are stated to be as under :-

i. Cancer care/ Radiotherapy medical devices
ii. Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices
iii. Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices
iv. All Implants including implantable electronic devices like cochlear implants and pacemaker.

21. The Committee during their study visit to Andhra MedTech Zone (AMTZ) heard the views of representatives of the Medical Device Industry representatives on the PLI scheme. The Committee were informed that the eligibility criteria under PLI scheme for the first year of production is kept at a very ambitious level of Rs. 60 crore, which is challenging for the industry applicants to attain with the timeline for infrastructure development and product

launch. The industry representatives proposed for reconsideration of the revenue target for the first year.

22. Keeping in view the above, the Committee enquired whether the Department has any proposal to reconsider and decrease the revenue target for the first year under PLI scheme. In reply, the Department has stated that the original Guidelines for PLI Scheme for Promoting Domestic Manufacturing of Medical Devices dated 27.07.2020 required Threshold Minimum Incremental Sales of Manufactured Goods worth Rs. 120 crore for first year, Rs. 240 crore for second year, Rs. 360 crore for third year, Rs. 480 crore for fourth year, and Rs. 560 crore for fifth year. The guidelines were revised to cut down that threshold by half.

23. The Department has further clarified that the applications were received in two rounds for PLI Scheme for Promoting Domestic Manufacturing of Medical Devices, wherein 21 applicants were selected and approved as Category-A applicants. Not all slots as envisaged under the Scheme for the applicants were filled and there remained unallocated budget of Rs. 847 crore out of Rs. 3,420 crore earmarked incentive for the Scheme. Therefore, based on the recommendation of EGoS and approval of Empowered Committee chaired by CEO, NITI Aayog, other members-Secretaries of Department of Pharmaceuticals, Department of Health & Family Welfare, Department of Commerce, DPIIT, Ministry of Environment Forest and Climate Change and Director General of Foreign Trade, a separate category of products called Category-B was created with lower threshold sales and lower net-worth criteria to enable more companies/applicants to participate in the scheme and applications were invited. The devices which had already been subscribed in the earlier rounds of the scheme were taken under Category-A and were excluded from Category-B.

24. The details of incentive rate, threshold incremental sales criteria for Category- A and Category-B applicants and maximum incentive per eligible applicant are given as under :-

Applicants	Rate of Incentive	Threshold Incremental Sales	Maximum Incentive per applicant

Category A applicants	5% for five years scheme period FY 22-23 to 26-27	FY 2022-23: Rs. 60 Crore FY 2023-24: Rs. 120 Crore FY 2024-25: Rs. 180 Crore FY 2025-26: Rs. 230 Crore FY 2026-27: Rs. 280 Crore	FY 2022-23 - Rs.8 Crore FY 2023-24 - Rs.17 Crore FY 2024-25 - Rs. 27 Crore FY 2025-26 - Rs. 32 Crore FY 2026-27 - Rs. 37 Crore **Maximum incentive – Rs. 12 crore per participant**
Category B applicants	5% for five years scheme period FY 22-23 to 26-27	FY 2022-23: Rs. 20 Crore FY 2023-24: Rs. 22 Crore FY 2024-25: Rs. 24.20 Crore FY 2025-26: Rs. 26.62 Crore FY 2026-27: Rs. 29.28 Crore	FY 2022-23 - Rs.2.5 Crore FY 2023-24 - Rs.5 Crore FY 2024-25 - Rs. 8.5 Crore FY 2025-26 - Rs. 11 Crore FY 2026-27 - Rs. 13 Crore **Maximum incentive – Rs. 4 crore per participant**

25. The Committee have further been informed that the Scheme has attracted 64 applications with 42 applications from category-A applicants and 22 applications from Category-B applicants. Out of the same, 26 applicants have been selected which include 19 Category-A and 07 Category-B applicants. The committed investment of these 26 applicants is Rs.1330.44 crore with potential to generate about 7,950 jobs. As per June quarterly review report, 14 projects have been commissioned for 36 products.

26. The particulars with regard to actual investment made up to June, 2023 are given as under :-

Sl. No	Target Segment*	Total approved Applicants		Total Committed Investment (₹ in crore)		Actual Investment up to June 2023 (₹ in crore)	Actual Employment up to June 2023 (No. of Persons)
		Cat A	Cat B	Cat A	Cat B		
1	Cancer care / Radiotherapy medical devices	1	0	24.50	-	20.33	291
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation	6	2	332.14	177.82	336.16	991

	products) and Nuclear Imaging Devices						
3	Anaesthetics & Cardio-Respiratory medical devices including Catheter of Cardio respiratory Category & Renal Care Medical Devices	6	3	300.64	140.61	307.68	1,241
4	All Implants including implantable electronic devices	6	2	307.83	46.90	187.39	1,694
Total		**19**	**7**	**965.11**	**365.33**	**851.56**	**4,217**

27. On being asked whether 5% financial incentive on incremental sales to 26 applicants will be able to boost domestic medical device production under this Scheme, the Department has stated that the 5% incentive rate has been arrived based on the detailed industry consultation, on the existing manufacturing eco-system for the notified medical devices products under four target segments and the import dependence of the components required for domestic manufacturing of the medical devices. There is no insistence of specific domestic value addition, in this PLI scheme, duly considering the present manufacturing ecosystem for the notified medical devices.

28. During evidence, the Secretary DoP informed the Committee about the products that are being manufactured under the PLI scheme as under:

"I want to bring to the notice of the hon. Committee what kind of equipment is being manufactured. The companies selected under various categories and the products they are manufacturing. Linear accelerator which is used for cancer treatment is sanctioned under the scheme and is being manufactured by one company based in Karnataka. Similarly, CT scan, Cath lab, ultrasonography devices are also being manufactured. We have already given sanction for MRI which is being taken up by a company. Manufacturing of mammography device has also been started in Maharashtra and Andhra Pradesh. The MRI coils which we put on body, head or hand are being manufactured by one company based in Maharashtra. Similarly, most of the anaesthesia workstations, syringes etc. are being manufactured in Rajasthan. Oxygen concentrators, hip implants, heart valves including catheters are also being manufactured under PLI scheme. This year, 2022-23, is the first year of manufacturing. We will be getting, in subsequent years, more and more manufacturing."

29. Another representative of the Department of Pharmaceuticals added as under :

"*Once the PLI applicants have started manufacturing, we asked about the different specifications. We shared that list both with the State Governments as well as the Central procurement agencies so that there will be an assured market for them. So, we are making a provision that all the specifications are available with the State Government and also the Central Government. Moreover, there is also a proposal that the PLI applicants can be considered as Class-II Local Supplier with respect to preference in public policy. There is a Make in India Policy wherein we give the domestic manufacturers some advantages over the importers. So, under that, we want to cover all our PLI applicants so that they also have an assured market for their product being manufactured.*"

(iii) Production Linked Incentive (PLI) Scheme for Pharmaceuticals

30. The Commirttee have been informed that 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 scheme provides for incentives based on incremental sales for 6 years (5% for first Four years, 4% for Fifth year and 3% for Sixth year). The tenure of the scheme is from FY 2020-2021 to 2028-29.

31. The Committee desired to know the criteria adopted for selection of only 5 industry applicants under the Scheme and whether this limited selection is sufficient for promoting In-vitro diagnostic medical device industry in India and if DoP has planned to extend the benefits of this Scheme to more applicants. In reply, it has been stated that based on the availability of funds and based on the Industry consultation, the Scheme guidelines were arrived at, wherein, it is envisaged to support 5 IVD medical devices applicants. When applications were invited, 21 In-vitro diagnostic medical devices companies applied, out of which 5 applications selected based on the Evaluation Criteria. Out of 5 selected applications, 4 are MSMEs. There is no plan to extend the Scheme to more applicants, as all 55 slots, envisaged under the scheme, have been filled.

32. The Committee have observed that as per scheme guidelines of PLI for Pharmaceuticals, the total financial outlay is Rs. 15000 crore, out of which Rs. 250 crore have been allocated for In-vitro diagnostic medical devices application, as approved under Group-C

applicants. Financial Year 2022-23 was the first year of performance and incentive of Rs.4.76 crore has been released to one of the IVD applicant.

NON- SCHEMATIC INITIATIVES FOR PROMOTION OF MEDICAL DEVICE INDUSTRY

A. National Medical Device Promotion Council (NMDPC)

33. It has been informed that the National Medical Device Promotion Council (NMDPC) has been set up by the Department for Promotion of Industry and Internal Trade (DPIIT) vide Order dated 07.12.2018. Since Department of Pharmaceuticals (DoP) has the mandate for the promotion of the Medical Device industry, the DPIIT communicated its concurrence for reconstitution of the NMDPC under the chairpersonship of Secretary, DoP with appropriate representation from DPIIT. Accordingly, the NMDPC was reconstituted dated 5.8.2022 with the following objectives:

(i) To act as a facilitating and development body for the Indian MedTech Industry, to achieve the objectives envisaged under the proposed National Medical Devices Policy, 2022, towards the goal of attaining Universal Health Coverage.
(ii) To build synergies in the efforts of various departments in view of the diversity and multi-disciplinary nature of the sector to harness the potential the Indian MedTech sector.
(iii) To hold seminars, workshops and related networking activities to garner views of the Industry and understand global practices in the sector and deliberate on various parameters for inclusion in the Industrial and Trade Policies in Medical Devices.
(iv) To further strengthen the institutional mechanisms established by the Department such as Standing Forum of Medical Device Associations and Regulatory Roundtable meetings to deliberate on the issues put forth by the industry for resolution with the aim of ease of doing business and reduction of the compliance burden.
(v) To support dissemination and documentation of international norms and standards for MDs by capturing the best practices in the global market and facilitate domestic manufacturers to rise to international level of regulatory and on-regulatory needs of Industry
(vi) To deliberate on various issues related to public procurement of medical devices under the Public Procurement Order (Make in India) Policy of DPIIT with the goal to encourage investment and domestic manufacturing in all categories of medical devices.
(vii) To deliberate and make recommendations to the Department of Commerce on the market access issues in exports of medical devices.

(viii) To deliberate on the matters, with an aim to address structural challenges, enhance competitiveness of domestic manufacturers and increase private investments in the sector.

34. Accordingly, the NMDPC, with members from all the stakeholder departments and representatives from all the Medical Devices Industry Associations, provides a platform to deliberate and resolve various issues for ease of doing business and promotion of the sector. The first meeting of NMDPC was held in September 2022 and the second meeting on 25 May, 2023 wherein several issues of Medical Device Industry were deliberated for timely redressal.

35. When the Committee asked about the issues that were resolved by the NMDPC, it was informed as under :

(i) Simplification of vendor registration process of Medical Devices on GeM portal:- In the GeM, Vendor Assessment process has been exempted for all medical devices manufacturers/Original equipment manufacturers (OEMs), where certified copy of valid manufacturing/import License from the concerned Drug Licensing Authority is submitted.

(ii) Exemption of Lead in Medical Devices (with the exception of all implanted and infected products) as listed in Schedule I of E-Waste (Management) Rules, 2022 from the requirement of not beyond a maximum concentration value of 0.1 per cent by weight in homogenous materials of new electrical and electronic equipment and their components or consumables or parts or spares:- As lead is one of the main component of medical devices, the industry had asked for an exemption in the E-Waste (Management) Rules, 2022, and the MoEF&CC has amended the law in line with the industry needs vide, E waste (Management) Amendment, Rules 2023 (issued on January 30, 2023).

(iii) Streamline the transitioning of licensing of Medical Devices:- MoHFW had published G.S.R. 102 (E) dated 11.02.2020 for regulation of medical devices in phase wise manner. Department of Health and Family Welfare at the forum of NMDPC apprised the Industry and other stakeholders with the preparedness for transition to licensing of various categories of medical devices and also informed the forum of various actions taken by the CDSCO and DoHFW with the State Licensing Authorities (SLAs) and the Industry Associations, to streamline the licensing of various categories of medical devices.

36. As regards the issues that are under deliberation at the forum of NMDPC, they are stated to be as follows :

(i) Demand to reduce the double regulatory burden of labeling requirements of Medical Devices:- Medical device manufacturers are obligated to comply with the

labeling and packaging requirements specified under the Legal Metrology Act and Rules. This includes providing accurate and clear information on the label regarding the product's contents, weight, and dimensions. Rule 44 of the Medical Device Rules further casts similar labeling obligation on the manufacturers. The Legal Metrology (Packaged Commodities) Rules, 2011 also requires certain information pertaining to consumer care details, be provided on the labels of packaged commodities. Industry as part of ease of doing business has been requesting for reconciling of labeling regulations. The matter is under deliberation at the forum.

(ii) Compulsory Registration Order, 2012 of MeitY:- As per the Compulsory Registration Order, 2012, no person shall manufacture or store for sale, import, sell or distribute goods which do not conform to the Indian standard specified in the order. Manufacturers of these products are required to apply for registration from Bureau of Indian Standards (BIS) after getting their product tested from BIS recognized labs. Some of the accessories used for medical devices are covered under CRO, 2012 of MeitY. The Industry requested for consideration of exemption of accessories/components pertaining to medical devices from CRO, 2012. 64 product categories have been notified involving electronic and IT goods. It was deliberated whether the components of medical devices could be exempted from the purview of the CRO, 2012, if the manufacturers self-certify that the import of the components is only for the manufacturing of medical devices and not for any other electronic equipment. MeitY is open to examination of component items for exemption if it is to be used only for manufacturing of medical devices. The Industry has been advised to furnish the details to the MeitY for further examination.

B. Standing Forum of Medical Devices Associations

37. The Committee have observed that the DoP has constituted a Standing Forum of Medical Devices Associations on 25th August, 2021 to deliberate upon different issues related to Medical Devices referred to it by the Department and arrive at a set of inputs from Industry for Policy and Program formulation which, in turn, would enable the Department to undertake consultation with the wider range of stakeholders including Regulatory Authorities.

38. On being asked about the issues on which the Standing Forum of Medical Devices Associations has helped, the details are given as follows :

i. **Preparation of a draft Uniform Code for Medical Device Marketing Practices (UCMDMP)** –As of now Medical device industry is required to comply with the provisions of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP), which is in operation since 01.01.2015. This code governs the conduct of pharmaceutical/medical device companies in their marketing practices. The arrangement of UCPMP for Medical device industry is there till the time a separate

code for ethical marketing of medical devices gets operational. The draft uniform code for Medical Device Marketing Practices was submitted by the Standing Forum of Medical Devices Associations. Further progress on the code for Medical Device Marketing Practices is awaiting the outcome of a writ Petition filed in Supreme Court (WP 323/2021) wherein the prayer is to – (i) Give effect of a statute to UCPMP, (ii) For period intervening, law is enacted, by the Hon'ble Court to lay down guidelines or make the code binding with modifications deemed proper. After the outcome /directions of Hon'ble Supreme Court in the matter of UCPMP, further action in UCMDMP will be taken in accordance with Hon'ble Court' ruling. UCMPMD will act as guidance to the medical devices industry. With the adoption of UCMPMD, it is expected that Medical Device promotion will be done within ethical limits and boundaries.

ii. **Task Force on Mapping of Testing Infrastructure for Medical Devices in India**: DoP constituted Task Force under the Standing Forum of Medical Device Associations vide the Department's OM dated 13.04.2022 for landscaping testing labs infrastructure for Medical Devices (MDs) towards smooth transition of licensing of Class –A and B medical devices from 01.10.2022. The Task Force was assigned with the following Terms of References :-

a. To map the Classification of MDs by CDSCO vis-à-vis the available BIS product Standards and arrive at the list / category of MDs with different types of standards available.

b. To arrive at the list of tests and testing equipment that is required to test these Standards.

c. To map the existing infrastructure of labs available in public / private / institutional set-up towards testing of MDs.

d. To submit the Recommendations with the specific actionable points in respect of the laboratory resources required under Medical Device Regulations.

The Report of Task Force on "*Mapping of Testing Infrastructure for Medical Devices in India*" was prepared and was shared with CDSCO for consideration and action.

C. National Medical Devices Policy, 2023

39. The Committee have observed that the National Medical Device Policy, 2023 has been approved by the Union Cabinet on 26.04.2023. Policy aims to facilitate medical devices sector and guide it to achieve its missions through a set of strategies that will be covering six broad areas of interventions. The National Medical Devices Policy, 2023 mentions six (6) strategies for the promotion of the medical device industry: (i) Regulatory Streamlining, (ii) Enabling Infrastructure, (iii) Facilitating R&D and Innovation, (iv) Attracting investments in the Sector, (v)

Human Resources Development and (vi) Brand Positioning and Awareness Creation. The vision of this policy is to emerge as the global leader in the manufacturing and innovation of medical devices by achieving 10-12% share in the expanding global market over the next 25 years.

D. Public Procurement (Preference to Make in India) Order (PPO), 2017

40. It has been informed that the Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153(iii) of the General Financial Rules 2017, issued Public Procurement (Preference to Make in India) Order (PPO), 2017 dated 15.06.2017 which has recently been revised on 16.09.2020. In order to facilitate the implementation of the PPO, 2017, DPIIT vide D.O. dated 14.08.2017 identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO 2017 relating to goods & services related to Pharmaceuticals Sector. DPIIT vide Office Memorandum dated 23.03.2018 has decided that the Nodal Ministry for product category medical devices shall be DoP. 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. Under Para 3(a) of PPO, 2017 dated 16.09.2020, the Department vide Order dated 25.03.2021 has notified 19 medical devices and vide Order dated 16.02.2021 has notified 135 IVDs.-vitro diagnostics (IVD) have been notified under this order.

REGULATORY ASPECT OF MEDICAL DEVICES

A. Price Regulation of Medical Devices

41. The mandate of the National Pharmaceuticals Pricing Authority (NPPA) is to implement and enforce the provisions of the Drugs (Prices Control) Order, 2013 promulgated under the Essential Commodities Act, 1955. NPPA monitors the availability of drugs including medical devices, identify shortages, if any, to take remedial steps.

42. The Committee have been informed that the Ministry of Health and Family Welfare vide S.O. 648(E) dated 11.02.2020 notified all the medical devices intended for use in human beings or animals as “Drugs” under the Drugs and Cosmetics Act 1940 w.e.f. 01.04.2020. Four medical devices viz. Coronary Stents, namely, (i) Bare metal stents and (ii) Drug-Eluting Stents; Contraceptive Devices, namely, (iii) Condoms and (iv) Intra Uterine

Devices (Cu-T) have been included in the National List of Essential Medicines (NLEM) by the Ministry of Health and Family Welfare and in the Schedule-I of Drugs (Prices Control) Order, 2013. Accordingly, NPPA fixed and notified prices of these four medical devices. Further, NPPA vide S.O 2668(E) dated 16.08.2017 fixed the ceiling price of knee implants to control the excessive trade margins of orthopedic knee implants under extraordinary circumstances in public interest. NPPA has also put a price cap on the trade margin of (i) Pulse Oximeter, (ii) Nebulizer, (iii) Glucometer, (iv) BP Monitor, (v) Digital thermometer and (vi)Oxygen Concentrator. With regard to remaining non-scheduled medical devices, which are notified as drugs, NPPA is currently monitoring Maximum Retail Prices (MRPs) under Para 20 of the DPCO, 2013 to ensure that no manufacturer/importers increase the price by more than ten percent of the MRP during preceding twelve months.

43. On being asked whether NPPA plan to expand its price regulation on other medical devices in coordination with Ministry of Health and Family Welfare that are being used widely for treatment in Government Hospitals, it has been stated that NPPA's mandate is to ensure the availability and affordability of drugs/medical devices. The inclusion of drugs including medical devices in NLEM is dealt with by the Ministry of Health and Family Welfare. NLEM issued by MoHFW is the basis for Schedule-I of DPCO for regulation of price of formulations and medical devices by NPPA. Expansion of price regulation to other drugs / medical devices is dependent on its inclusion in NLEM which comes under the purview of MoHFW.

44. The Committee further asked whether NPPA can regulate the prices of other medical devices under Para 19 of DPCO, 2013 in public interest like it is doing for knee implants since 16.08.2017. In reply, it has been stated that Para 19 of the DPCO, 2013 inter-alia authorizes the Government, in extraordinary circumstances, if it considers necessary to do so in the public interest, to fix the ceiling price or retail price of any drug /medical devices for such period, as it deems fit. NPPA has invoked Para 19 from time to time, in extraordinary circumstances (eg. Oxygen concentrator & five medical devices) in view of public interest.

45. With regard to the number of complaints that NPPA has disposed with respect to shortage of medical devices and overcharged medical devices since the implementation of DPCO, 2013 and action that has been taken on those complaints, the Department has informed that from 2018 to till date, 24 complaints/grievances pertaining to overcharging and

10 cases pertaining to shortage of medical devices were received by NPPA. The complaints of overcharging cases are analyzed and notices are issued in the cases, where necessary. The monitoring of over charge cases of medical devices is being carried on at NPPA which is a continuous ongoing process. In addition to the above, shortage of medical devices was also reported during COVID pandemic (2020-2021). The Delhi High court vide judgment dated 17.05.2021 had also directed the NPPA to regulate the prices of medical devices, essential for diagnostic purposes, in general, and specifically for COVID-19 management. Taking cognizance of the various report and Hon'ble High court directions, prices of medical devices, essential for COVID-19 management, NPPA issued Notifications dated 3rd June 2021 and 13th July 2021, which capped Trade Margin at Price to Distributor (PTD) at 70% for medical devices, namely, Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer, and Glucometer. The NPPA coordinated with State Governments, Manufacturers and importers to ensure availability. The State Drug Controllers of the concerned state were directed to ensure availability and check for overpricing, black-marketing, and hoarding.

46. The Committee wanted to know the steps being taken to increase awareness among the general public in various states/districts/blocks/village level about the existing complaint redressal mechanism for overcharged medical devices. In reply, the Department has stated that to spread awareness, the NPPA, the Department implements the “Consumer Awareness, Publicity and Price Monitoring (CAPPM)” Scheme. The Scheme has two components viz., (a) National component and (b) State component. The National component covers the expenditure for publicity through print and electronic media, organizing seminars for consumer awareness, purchase of samples, etc. Under the State Component of the Scheme, Price Monitoring and Resource Units (PMRUs) are set up in the States. PMRU is a registered society under the Chairmanship of the State Drug Controller and aim to create public awareness so that benefits of the DPCO (revised from time to time) trickle down to the grassroots level. The representatives of the NPPA/State Health Department, civil societies, and other stakeholders are members of the PMRU. PMRU conducts training, seminars, and workshops at the State and District levels for consumer awareness and publicity covering aspects relating to the role and functions of NPPA, availability of scheduled and non-scheduled medicines at reasonable prices, care to be taken while purchasing the medicines from the chemists/ retailers and availability of alternative cheaper medicines. The resource persons for the training are provided by the State Drug Controller and by the NPPA, whenever

required. NPPA has also launched the Pharma Jan Samadhan portal and the updated version of the Pharma Sahi Daam App which has a public complaint redressal mechanism, to promote ease of access.

Regulation of Medical Devices for Quality, Safety and Efficacy

(i) Medical Device Rules, 2017

47. The regulation of the medical devices lies with the Ministry of Health and Family Welfare. In order to have a comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Department of Health & Family Welfare, notified the Medical Devices Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940. These rules are effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country. Said rules lay out the regulatory framework for medical devices in terms of their quality, safety and efficacy. The Medical Devices Rules, 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.

48. Further, with these rules in place the regulatory oversight has been expanded to the entire gamut of devices and classified them into four categories based on the level of risk associated with the medical devices which is as under:

Risk Criteria	Risk Class	Examples of Devices
Low	Class A	Tongue Depressors, Analysers, Crepe Bandages
Low-Moderate	Class B	Catheters, Cannula, Hypodermic Needles
Moderate-High	Class C	Orthopaedic Implants, Denta Implants
High	Class D	Heart valves, Cardiac Stents

49. It has been added that under the said rules, import of all classes of medical devices as well as manufacture of Class C & D medical devices are regulated by Central Drugs Standard Control Organization (CDSCO), while manufacture of Class A&B medical devices is regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments. However, sale and distribution of all classes of medical devices are regulated by the SLAs. For import or manufacture of any medical device, the applicant is required to submit details of design, specification, non-clinical as well as clinical data of safety and performance of the devices including regulatory status in other countries etc. for obtaining import/manufacturing license from CDSCO/SLAs. In case of new medical devices i.e. investigational medical devices and new in-vitro diagnostics devices, the safety, efficacy and performance data are evaluated by CDSCO in consultation with the subject expert committee in the relevant therapeutic areas.

50. Further, all In-vitro diagnostics and 37 categories of medical devices were notified under Drugs & Cosmetics Act 1940 and Medical Devices Rules 2017 for regulation. However, consequent to the GSR 102(E) dated 11.02.2020, other non-notified medical devices have also come under regulation and phase-wise licensing System have been implemented, where Class A & Class B medical devices have come under Licensing System from 01.10.2022 and likewise Class C & Class D medical devices have also come under Licensing System with effect from 01.10.2023. Presently all Class A & Class B medical devices are under licensing regime and for new notified Class C & Class D medical device, licensing regime is effective from 01.10.2023. The details in this regard are given in a tabular form as under :

Risk base Class	**Voluntary Registration**	**Mandatory Registration**	**Licensing regime**
Class A & B	01.04.2020 to 30.09.2021 (18 months)	01.10.2021 t 30.09.2022 (12 months)	w.e.f. 01.10.2022
Class C & D	01.04.2020 to 30.09.2021 (18 months)	01.10.2021 t 30.09.2023 (24 months)	w.e.f. 01.10.2023

51. Regarding the status of Medical Device manufacturing units licensed after implementation of Medical Device Rules-2017, it has been informed that out of 3413 manufacturing applications have been received for Class A, B, C & D Medical Device, 2262 manufacturing units license have been issued from 01.01.2018 till date, which include 1571 license for Class A & B manufacturing units and 691 license for Class C&D manufacturing units. However, 123 applications are pending. Further, from 01.01.2018 till date total number of Import licence applications received, approved and pending for various classes of medical devices i.e. Class A, B, C and D are 11523, 8065 and 2956, respectively.

52. On being asked about the concerns related to pendency in disposal of manufacturing license applications with CDSCO and its implications on manufacturing and marketing of medical device products, the Drugs controller General of India has clarified as under :

> *"…in Classes 'C' and 'D' we have sent an initial notification some nine months ago that you start applying in advance so that we can clear the license. We also issued a couple of reminders. As on 1st of October, we have 134 pending applications. They were not 500. Actual number of applications is 134, which in last 10 days would have further reduced to around hundred. That is one point. Secondly, 50 per cent of these applications came in the last one month in spite of our sensitization since last nine months. So, it takes some time for CDSCO to review those applications. So, what we have done is, like we did in Class 'A' and 'B' about a year ago, whosoever has applied before the deadline, which was the 30th September,2023 their applications will be reviewed on priority, and they will not be penalized for next six months even if they do not have the license. That file is under process, and in the next one or two days that notification will come out…"*

ii.Notified Bodies and their role in regulation

53. As regards the Notified Bodies and their role in regulation, the Department of Health and Family Welfare has stated that the Notified body is the body accredited by National Accreditation Board for Certification Bodies (NABCB) for inspection of medical devices for class A and class B. To verify Quality Management System (QMS) conformance at manufacturing site where necessary inspection with respect to class A and class B medical device, thirteen Notified Bodies are registered by CDSCO to carry out its duties and functions, in respect of Class A or Class B medical devices as specified in Part II of the Third Schedule of Medical Devices Rules, 2017.

54. Accordingly, when it was asked whether thirteen Notified Bodies are adequate to ensure world class quality standards in Class A and Class B medical devices, it has been replied that notified bodies registered under Medical Devices Rules 2017 are accredited and adequately equipped to ensure world class quality standards in Class A&B medical devices. The Notified Bodies are having infrastructure to carry out the audit within stipulated time. Further, CDSCO is convening meetings with registered Notified Bodies regularly, to increase their infrastructure to carry out the audit of Class A and Class B as per the time stipulated in MDR 2017.

55. Regarding the notified body for audit of medical devices of Class C and Class D, it has been replied that for Class C &D audits are conducted by Central Medical Device Officers.

iii. Materio-vigilance Programme of India (MvPI)

56. Materio-vigilance Programme of India (MvPI) was formally launched by the Ministry of Health and Family Wefare on 06.07.2015 with an objective to improve Indian patient safety by monitoring, recording, analyzing root cause of adverse events or risks associated with use of medical devices and In-vitro diagnostics & suggesting regulatory bodies for appropriate action with a sole intention of improving patient safety.

57. The Indian Pharmacopoeia Commission (IPC) Ghaziabad is presently functioning as the National Coordination Centre (NCC) with the National Health System Resource Centre (NHSRC), New Delhi as its Technical Support Centre and Sree Chitra Tirunal Institute for Medical Sciences and Technology, Department of Science and Technology, Thriuvananthapuram as Medical Device Adverse Event Monitoring Centre (MDMC) as well as National Collaborating Centre for MvPI.

58. On being asked about the action taken in cases of medical device adverse event and the mechanism by which this information is shared with the general public to protect them from such adverse events during use of a defective medical device, it has been stated that National Coordination Centre Materio-vigilance Programme of India (NCC-MvPI), IPC collate and analyses all the reported cases for their completeness, and clinical relevance and other requirements as per medical device adverse events reporting form and Medical Device Rules, 2017. After initial examination, data is reviewed by subject experts and MvPI partnering organizations (National Health Systems Resource Centre, New Delhi, Sree Chitra Tirunal Institute of Medical Sciences & Technology, Thiruvananthapuram & Central Drugs Standard Control Organization (CDSCO), New Delhi) in order to arrive at a conclusion. Based on this, MvPI issues recommendations, if any, to CDSCO for their information and necessary action at their end. MvPI issues safety alerts to monitoring centres for safety surveillance of medical devices. Further, for the awareness of general public, MvPI publishes information on the IPC website that contains the medical device safety information and details of recommendations shared to CDSCO for regulatory action. In order to create awareness among public for reporting of medical device adverse event, National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI), IPC conducts various awareness program/ workshop/ webinar/ physical meetings under Materio- vigilance program (MVPI) throughout the country

for the stakeholders. MvPI hoardings are made available in the reception, OPDs, nursing stations of medical colleges and hospitals.

59. On the Medical Devices Alert Notices that have been issued since implementation of MDR, 2017, the DoH&FW provided year-wise details of Medical Devices Alert Notices issued by CDSCO:

Year	No. of Alert Notices
2018	04
2019	02
2020	00
2021	04
2022	03

60. The Committee asked whether the Medical Device Adverse Event Monitoring Centers (MDMCS) to monitor and collect adverse events associated with medical devices are adequate to keep sharp vigilance/surveillance on such events in public interest and steps taken to expand this network of MDMCS and strengthen materio-vigilance infrastructure. In reply, it has been stated that as informed by IPC, at present, 397 MDMCS are enrolled under MvPI to monitor and collect adverse events associated with medical devices. In addition to this, more than 852 Adverse Drug Reaction Monitoring Centres (ADRMC) have been established under Pramacovigilance Programme of India (PvPI) to report adverse events/side effects associated with the use of drugs & medical devices also. These centres enhancement is dynamic process. The centers will be enhanced under MvPI in a phase-wise manner. Also, MoHFW has issued a letter to State Health Secretaries regarding the enrolment of district level hospitals/institutions under MvPI. As a result, four States/UTs namely Tamil Nadu, Kerala, Karnataka and Puducherry has issued office order to their respective state's district hospitals/medical colleges to participate in MvPI. Further, Indian Pharmacopoeia Commission-MvPI has also recognized 06 Regional Training centres namely (i) PGIMER, Chandigarh (ii) NIPER, Hajipur (iii)AIIMS, Bhopal (iv) NIMHANS, Bangaluru (v) Alshifa College of Pharmacy Kerala and (vi) AMTZ, Vishakhapatanam for effective implementation of Materiovigilance Programme of India (MvPI).

iv. Medical Device Testing Laboratory

61. On being asked about the status of Medical Device Testing Laboratories functioning in the country and steps taken by the Ministry of Health & Family Welfare to increase the number of Central Device Testing Laboratories which play a vital role in reducing the cost associated with testing and logistics, it has been stated that currently, 6 Central Medical device testing laboratories are notified by Government of India for carrying out statutory test and evaluation of various medical devices. Further, 39 medical device testing laboratories are registered by CDSCO to carry out testing on behalf of device manufacturers for various medical devices. Also, there are 35 listed labs for testing of IVDs. Further, Medical Device Rules, 2017 have been amended vide G.S.R. 409(E) dated 02/06/2023 having provision that State Government may designate any Laboratory having facility for carrying out test and evaluation of medical devices as State Medical Devices Testing Laboratory. All these laboratories are NABL accredited. Further, the laboratories which are NABL accredited and having adequate infrastructure for testing of medical device/IVDs may also apply to CDSCO for registration. CDSCO has also issued Notice in website dated 14.10.2021 & 22.12.2022 (www.cdsco.gov.in). Requesting the laboratories who are NABL accredited and have infrastructure for testing of medical devices, to come forward for Registration as Medical Devices Testing Laboratory, as per Medical Device Rules 2017. Further, CDSCO engages with Bureau of Indian Standards, Quality Council of India and Indian Council of Medical Research 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 afford ability of medical devices in the domestic market. This is a dynamic process.

62. On being asked about the constraints being faced in regulating the quality, safety, labeling and performance of the medical devices, the Department of Health & Family Welfare has stated that as such there are no major constraints for regulation of medical devices except (i) Limited number of Central Medical Device Testing Laboratories and (ii) More number of registration of medical device laboratories for testing of medical devices on behalf of manufacturer.

63. Keeping in view the limited number of Central Medical Device Testing Laboratories for regulation of medical devices, the Committee asked whether the Ministry of Health & Family Welfare has any plan to set up at least one Central Device Testing Laboratories in States that are emerging as medical device industry clusters like Goa, Andhra Pradesh, Kerala etc. In this regard the MoH&FW has stated that Ministry is also in the process of designating other testing facilities, having facility to test medical devices, as medical device testing centre. One proposal of South India Textile Research Association (SITRA) Lab is under consideration.

ISSUES CONCERNING MEDICAL DEVICE INDUSTRY

64. The representatives of the medical device industry associates briefed on the challenges/issues that are being faced by the medical device industry with regard to promotion, production and manufacturing of medical devices. These challenges/issues are mentioned below point wise: -

i) GST & Basic Custom Duty

65. The Medical Technology Association of India (MTaI) has informed that with more than 86 percent import dependency of medical devices, India has one of the highest tariff and cess (13.75%) on medical device imports and around 12% to 18% GST which increases the cost of medical devices and the same needs to be rationalized. On this issue the Department has commented that most of the medical devices fall in standard rate of import tariff and GST rate. Reduction of GST rates on medical devices also creates inverted duty structure and blockage of Input Tax Credit for the medical device manufacturers as per the view of the Department of Revenue. Health Cess was introduced vide Finance Act 2020 and applies on medical devices falling under HSN 9018 to 9022. The Health Cess@ rate of 5% was levied with effect from 02.02.2020.

66. During the evidence held on 14.12.2022, a representative of the Association of Diagnostic Manufacturing of India (ADMI) raised the issue of inverted duty structure on the imported components required for manufacturing of medical devices in India. It was mentioned that there is disparity in duty regulations for finished medical products and their individual components or parts. The current regulations impose higher duties on parts/ components,

creating challenges for cost-effective manufacturing. Further, the ADMI representative stated as under:

"*There is an inward duty structure. Our company manufactures the equipment and reagents. In the case of equipment, the import duty of components is about 8.25 per cent but when somebody is importing the same equipment as a whole, it is zero duty. So, domestic manufacturers will not be able to compete with the imported product*."

67. In this regard, the medical device industry associates of Kerala in an informal discussion during the study visit of the Committee at Kochi on 24.5.2023 mentioned about the harm that inverted duty structure of tax is doing to the domestic manufacturers. The industry representatives stated that today on an imported finished product there is 0% custom duty but on imported raw material/electronic parts there is 30% duty.

68. When Committee desired to know the response of the Department of Pharmaceuticals on import duty that is being levied on imported raw materials/electronic parts and steps taken/ proposed to protect domestic manufactures from inverted duty structure on imported components like electronic chips etc. which are necessary for promotion of domestic medical devices, the Department has stated that Basic Standard rate under Custom Tariff Act for raw materials, parts or accessories (which are used for manufacturing of medical devices) are generally Nil, 2.5%, 5%, 7.5%, 10%, 15%, 20% etc . Further, a study was conducted by Foundation for MSME clusters namely "Boosting the Indian Medical Device Industry", the findings of which are :-

a. According to 43 per cent of the respondents, high cost of raw material is a major challenge to export in the medical device industry. While nearly half of the respondents' import plastic resin parts, 40 percent import molded parts and 28 percent import reagents, alloys and electronic parts.

b. The major imported raw materials are

Nature	Name
Electronic Componen	Sensors, X-Ray Tubes, IC chips, motor
Metal compounds	SS wire, SS cannula, platinum tungsten alloy, nitinol (Nicke Titanium) wire, copper, etc.
Plastics	Tubing (plastic, TPU, PTFE, catheter), PP, PVC, synthe resin, plastic wares, Packaging film, ET, TT
IVD related	Antigen, antibodies, reagents, enzymes, especially DN polymerase, bile salts, MISPA, ELISA, microbiology grad

	agar, chromogenic substrates, oligonucleotides
Semi-finished	Haemodialysis catheters, dialyzer, special interfa connector, flow regulator

69. As regards the steps taken /proposed to protect domestic manufacturer from inverted duty structure, they are stated to be as under:

1. Over the years, measures taken by the Government, such as PLI schemes, medical device parks, single window clearance, perpetual licenses, etc. have attracted investments in R&D and manufacturing of high-end devices and components. Global players such as GE Healthcare, Philips, and Medtronic have set up their R&D and innovation centres in India and have started manufacturing of a few components locally. Also, under Production Linked Incentive (PLI) Scheme, applicants are selected for manufacturing key component which constitutes major part of the medical device.
2. Phased Manufacturing Programme: The Department of Pharmaceuticals (DoP) has prepared a phased manufacturing programme (PMP) in consultation with Department of revenue (DoR) to promote domestic manufacturing of medical x-ray machines and specified sub-assemblies/parts/sub-parts thereof by notifying enhanced basic customs duty (BCD) for financial years 2021-22 to 2024-25. At the forum of NMDPC, the need for expanding the PMP to other eligible medical devices is under deliberation to encourage the domestic production of medical devices and reduce the country's dependence on imports in this sector.
3. Based on the request from the industry and the information available on the sufficient domestic manufacturing capacity, 40 products where BCD is currently zero have been recommended to the D/o Revenue for increase in BCD.
4. National Medical Device Policy (NMDP), 2023 notified by Department of Pharmaceuticals, wherein, support is envisaged for Phased Manufacturing (PMP) of critical components to ensure continuous access and availability of medical devices without supply chain disruptions in order to boost the domestic manufacturing."

70. With regard to this issue the representative of DoP, also stated that:

"…. with respect to tariff and imports, the Department does it with the help of the industry in a phased manufacturing programme. Once we develop a local manufacturing capacity, we will see that import duty is increased. We did it last year in consultation with the State for the high-end instruments where we have enough local manufacturing capacity. There is a demand to expand this programme to other category of products where we have sufficient local manufacturing."

ii) Research and Development

71. During the evidence held on 14.12.2022, one of the medical device industry associates representing Association of Indian Medical Device Industry (AIMED) while emphasizing on the role of government as key player in supporting R&D submitted as under:

"most of the manufacturers in the high-end medical devices are greenfield manufacturers. .....The first thing that we have to understand is the importance of R&D. As far as these devices are concerned, there is a huge amount of R&D that goes in there. Does Government want to become a risk holder in the R&D process? Unless you have R&D, you will never be able to do that….If you look at the journey of a new medical device, - and Government becomes a stakeholder or risk mitigator in the first few years, for example, where a huge cost goes towards R&D – you must also understand one thing that every device which you create is not successful. You also need to budget for the cost of failures. Is the Government helping initially in R&D?"

72. Tendering reply on the status of Research & Development policy, the representative of the Department has informed as under:

"The department is bringing in a specific policy for R&D in pharma and medical device sector which is also at the advanced stage of approval by the Cabinet. Maybe in a couple of weeks, it may also be approved. We are also proposing some interventions under that. There are two interventions. One is to develop Centre for Excellences in Government institutions, including that for medical devices. The other one is for the specific research project to be supported under this scheme. The EFC notice is under preparation. We hope that we will try to fill some gap from the R&D side."

73. The Committee further asked about the strategy being adopted by the Department to facilitate research and innovation in medical device sector as the currently the Schemes of the Department are limited to providing Common Facility Centre's and Production linked Incentives. In response, it has been informed that in order to encourage R&D in pharmaceuticals and medical devices sectors and create an ecosystem for innovation to make leader in drug discovery and innovative medical devices through incubating an entrepreneurial environment, the Department has formulated draft 'National Policy on R&D and Innovation in the Pharma- MedTech Sector in India'. Incentivizing investment in research and exploring various funding mechanism are part of the objectives of the policy. Further enhancing academia industry collaboration is part of the draft policy. The Policy has recently been launched by the Department on 26.09.2023.

74. Further, for promotion of Research and Innovation in Pharma-Med Tech, the Department has submitted during further evidence held on 9.10.2023 that the Cabinet recently

in its meeting held on 25.07.2023 has approved the Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP) with an outlay of Rs. 5000 crore for a period of 5 years i.e., 2023-24 to 2027-28. The Scheme was notified on 17.08.2023. The Scheme has two components:

Component A: Strengthening the Research Infrastructure through Centres of Excellence (CoEs) in the seven existing National Institutes of Pharmaceutical Education & Research (NIPERs), institutes of national importance under the aegis of the Department at a tentative cost of Rs. 700 crore (including recurring and non-recurring cost) over a period of five years.

Component B: Promotion of Research in Pharma Med-Tech sector wherein financial assistance to the companies/ projects will be provided for both for in-house and academic R&D in six specified priority areas, viz.:-

- Area/ Product 1 [New Chemical Entity (NCE), New Biological Entity (NBE), Phyto-pharmaceuticals (natural products)],
- Area/ Product 2 [Complex generics and Biosimilars],
- Area/ Product 3 [Precision medicines],
- Area/ Product 4 [Medical devices],
- Area/Product 5 [Orphan Drugs] and
- Area/ Product 6 [Antimicrobial Resistance (AMR)].

iii) Human Resource Development in Medical Device Sector:

75. Developing a skilling ecosystem that supports the medical device sector by a steady supply of skilled work force across the innovation value chain (e.g., scientists, regulators, health experts, managers, technicians, etc.) is necessary for the growth of the sector. The DoP has stated that there is plan to establish Institutes of National Importance (INIs) on the lines of National Institute of Pharmaceutical Education & Research (NIPERs) for the medical devices industry.

76. The National Institute of Pharmaceutical Education & Research (NIPER) has been set up to provide human resources/talent pool for pharmaceutical industry. These institutes are established as a registered society under the Societies Registration Act, 1860 and given statutory recognition by an act of Parliament, NIPER Act, 1998 and declared as an Institute of

National Importance. Currently, there are seven National Institutes of Pharmaceutical Education and Research (NIPERs) *viz*. (i) NIPER, Mohali, Punjab (ii) NIPER, Hyderabad, Telangana (iii) NIPER, Ahmedabad, Gujarat (iv) NIPER, Kolkata, West Bengal (v) NIPER, Guwahati, Assam (vi) NIPER, Raebareli, Uttar Pradesh and (vii) NIPER, Hajipur, Bihar.

77. The Committee therefore asked whether courses on medical devices in the existing NIPERs would be adopted in all NIPERs till the time separate Institutes of National Importance for medical devices industry are being set up. In reply, the Department has stated that noting the shortage of skilled manpower to meet the demand of Medical Devices Industry, four of the seven NIPERs (Mohali, Hyderabad, Guwahati and Kolkata) have started M Tech (Medical Devices) courses, in addition to M Pharma (Medical Devices) and PhD (Medical Devices) courses already running at NIPER, Ahmedabad. Other NIPERs may start such courses based on requirement and availability of requisite infrastructure and facilities.

78. The Department has further informed that a new scheme on 'Human Resource Development in Medical Devices Sector' has been approved with an outlay of Rs. 480 crore for a period of 3 years under which financial assistance to government institutions for running multi-disciplinary dedicated courses in medical devices will be provided. The Scheme has appraised in the SFC meeting held on 14.07.2023.The scheme is proposed to have two components as under:-

A. Support for running post graduate courses (MS/M.Tech/ PG Diploma) in Medical Devices in existing institutes.

B. Capacity development in Medical Devices - design, production and testing.

79. The main objective of this scheme is to fill the existing gap in the education and research in medical device sector and to ensure quality teaching, training and nurturing excellence in Medical Devices education for generating critical mass of trained human resource in multidisciplinary areas of Medical Devices Technology required and create R&D ecosystem for the sector.

iv) Human Resource and Training for Regulation of Medical Devices

80. With regard to training and recruitment of manpower for regulation of medical devices, the Drug Controller General of India during briefing meeting held on 14.12.2022 submitted as under:

"Further, with regard to training of manpower and also stakeholders, various workshops are imparting training to various stakeholders, including State Licensing Authorities for an effective implementation of Medical Devices Rules……With regard to these 6000 plus different kinds of medical devices which are growing day by day, the manpower requirement is also required. Accordingly, 236 medical device officers have been notified in the Central Drugs Standard Control Organization. Similarly, quantities are also notified by the State Licensing Authorities. In addition to already existing 23 drug inspectors for the medical devices, three assistant drug controller for medical devices with bio-medical engineering and engineering backgrounds are appointed. They are already appointed and they are working since last 3-5 years in our Department. Recently, the Government of India in July, 2022 have approved the 219 posts at various levels – from the lowest level of medical device officer to the supervisory level officer and then joint medical device officer and then, the additional drug controller level of officers. So, manpower from bio-medical engineering and other engineering stream with experience is utilized for this purpose."

81. However, during further evidence before the Committee held on 9.10.2023, the Committee had observed that no progress was made in recruitment of manpower for regulation of medical device as 236 notified posts and 219 created posts were not yet been filled.

v) National Standards for domestically produced medical device

82. The Goa Pharmaceutical Manufacturing Association during an informal discussion held during the study visit of the Committee at Goa on 22.05.2023 informed that there is dire need for creation of national standard for all medical device manufactured in India. It was informed that due to absence of National Standard for all medical devices manufactured in India, domestic manufacturers are forced to follow WHO/American/ European standards and this also limits the export of Indian made medical devices in other countries. Further, the medical device industry associates of Kerala during an informal discussion held during the study visit of the Committee at Kochi on 24.05.2023 stated that a wide variety of testing standard are to be complied by the manufactures, even for low risk class medical devices and procurement agencies also comes with different standards which imposes challenge for the manufacturer to follow which standard therefore a National Standard for all types of Medical Devices should be created to ease domestic manufacturers with this concern.

83. Hence, when the Committee asked about the status of standards for all medical devices manufactured in the country. It has been informed that as per Rule 7 of Medical Devices Rules, 2017, 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. If BIS Standards are not available, medical devices shall conform to the ISO/IEC standards and other pharmacopoeia standards. In case these categories of standards are also not available, manufacturer's validated standards may be used.

84. In this regard, it has further been stated that Bureau of Indian Standards (BIS), the National Standards Body of India, through various technical committees under Medical Equipment and Hospital Planning Department (MHD), has published 1540 Indian Standards on Medical Devices. BIS has also prepared a 5-year Standards National Action Plan (SNAP) for the year 2022-2027 in which sector-wise priority areas (including medical devices and healthcare) for standardization have been identified which are being taken up and prioritized by the respective technical committees.

vi) Single Window System/ Unified Application Portal

85. The Committee have learnt from the views provided by industry representative from Andhra Pradesh MedTech Zone (AMTZ) that the present certification process for medical devices is complex and time-consuming causing delays in product launches. Multiple regulatory bodies having separate application processes for medical device approvals and create inefficiencies and confusion. Therefore, AMTZ representative suggested that to enhance efficiency and reduce administrative burdens, a unified application portal should be developed where manufacturers could submit a single application to be reviewed by all relevant regulators.

86. Taking this issue forward when the Committee asked about the plan of the Ministry of Health and Family Welfare towards simplifying the certification/regulation process for medical device by developing a unified application portal/single window system, it has been stated that the Ministry is in the process of integrating the existing Medical Device online portal with the departments/ministries concerned, like Bureau of Indian Standards (BIS), Atomic Energy

Regulatory Board (AERB), Ministry of Electronics and Information Technology (MeitY), Department of Animal Husbandry and Dairying, etc. so that CDSCO can get various permissions/approvals from these departments/ministries on the same portal. After consultation with the stakeholders, CDAC has been identified as a developer to develop a unified application portal/single window system. CDAC has conducted the feasibility study of this project.

vii) Regulation of Refurbished/Pre-owned Secondhand Medical Devices

87. The Committee during evidence held on 14.12.2022 was informed by the representative from Association of Diagnostic Manufacturing of India (ADMI) regarding non-regulation of second hand instruments used in our country at large scale that compromises on quality of diagnostics. In this regard it was submitted as under :

"In the 'In Vitro Diagnostics', in the higher segment, a lot of second-hand instruments are coming…..There should be a regulation on importing or dumping of second-hand instruments so that the Indian manufacturers or the imported products can also be sold fairly in the Indian market. It will help with correct estimation."

88. To follow up this issue the Committee asked about the regulation for such devices, in this regard it was stated that Ministry of Environment, Forest and Climate Change (MoEF&CC) is regulating the import and use of refurbished/second-hand medical devices in our country. MoEFCC has notified Hazardous and Other Waste (Management and Transboundary Movement) (HOWM) Rules, 2016 and its amendments. The import/export of hazardous and other waste is regulated thorough the said HOWM Rules, 2016. The import of 'Used Electrical and electronic assemblies' falls under Schedule III Part B (Basel No. B 1110) which can be imported by the actual user only after obtaining necessary permission from MoEF&CC. Further, used critical care medical equipment covered under Basel No. B 1110 of Schedule VI of the HOWM Rules, 2016, and is prohibited for import for re-use. In view of the representations received from Medical Associations and Medical Companies regarding admissibility of import of pre-owned/ used medical equipment by the actual user, the same were referred to the Technical Review Committee (TRC) constituted in the Ministry for examination. The TRC in its recommendations clarified that import of Used

Electrical and electronic assemblies including used medical devices' falls under Schedule iii Part B (Basel No. B 1110)] which can be imported by the actual user only after obtaining necessary permission from MoEF&CC. However, in case the items falling under [Schedule III Part D (Basel No. B 1110)], Ministry permission is not required subject to re-export within one, two and three years apart from condition that import permitted in the country only to actual users from Original Equipment Manufacturers (OEM) and subject to verification of documents specified in Schedule VIII of these rules by the Custom Authority. Further, Ministry has amended HOWM Rules, 2016 *vide* Notification dated 23rd, December, 2022 and allow import of High End and High Value Used Medical Equipment by actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user.

89. However, the Committee has also been informed that there is no specific provision under Medical Device Rules, 2017 with regard to regulation of the refurbished medical devices

90. Further when the Committee enquired about the percentage of medical device market that makes up refurbished/pre-owned second hand medical devices and laboratory instruments in India and steps that are being taken to ensure the safety and quality standards of such products, the DoH&FW has replied that no such details are available.

91. With regard to the details of separate assessment centers for measuring the residual shelf life of refurbished/pre-owned second hand medical devices and laboratory instruments, it has been informed that no such details are available.

PART-II

OBSERVATIONS AND RECOMMENDATIONS

General

1. The Medical devices sector is an essential and integral constituent of the Indian healthcare sector. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thus helping achieve the key objectives of the National Health Policy (NHP) 2017 in terms of the provision of good quality, affordable and comprehensive healthcare to all citizens. However, the Committee find that, at present, India's medical device industry manufacturing is limited to low to moderate-end medical devices like consumables, disposables and implants and there is a high import dependence to the extent of 70 percent in the case of high-end medical devices like electronic equipment's, advance surgical instruments and IVD Reagents to meet our domestic requirements.

The Committee's attention has been drawn to various issues impeding the growth of the medical device industry which, *inter-alia,* include a miniscule investment in research and development, less tax concessions, problem of inverted duty structure for domestic manufacturers, low capital investment, long gestation period in the induction of new technology, lack of skilled manpower, less trained healthcare professionals, lack of industry academia collaboration and limited price and quality regulation etc., which need immediate attention of the Government. The Department of Pharmaceuticals has stated to have taken certain schematic and non-schematic initiatives to promote the medical device industry in the country, which are broadly discussed in the succeeding paragraphs. Considering that the initiatives taken by the Department since 2015, when the medical device was first added to its mandate, are yet

to fructify to actually play a deciding role in the promotion of the medical device industry in our country, the Committee sincerely hope that the Department will take all required measures to effectively and timely execute their initiatives for promotion of the medical device industry and create a well-developed manufacturing ecosystem to counter the domestic manufacturing disabilities and strengthen domestic manufacturers competitiveness in the international market.

Import and Export of Medical Devices

2. The Committee note that the medical devices is a sunrise sector which is growing at a fast pace and its market in the country is expected to grow to USD 50 Billion by 2030. It is, however, a matter of concern that, at present, 80 percent of the sales of medical devices in our country comprise imported medical devices. The import value of high-end technology medical devices, viz. surgical instruments, electronic equipments and In-Vitro Diagnostic Reagents during 2019-20 was 180 USD million, 3647 USD million and 527 USD million, respectively. Further, during 2022-23, the import value in these segments was increased to 210 USD million, 4884 USD million and 767 USD million, respectively. This is despite the fact that the Department in the year 2020 launched various schemes to promote medical device industry like Production Linked Incentives (PLI) and Promotion of Medical Device Parks, etc. Besides, during 2022-23, even quantum of exports in these segments was only 72 USD million, 1335 USD million and 191 USD million, respectively, which was far less than the imports during the year.

In view of the foregoing, the Committee find that the promotional schemes of the Department has so far proved unproductive. Again, in view of the fact that it would be extremely difficult to sustain exports of medical devices in the absence of a strong and stable domestic medical device industry, the Committee impress upon the Government

to make all out efforts to remove the bottlenecks for effective implementation of their promotional schemes. There is no denying the fact that India has a huge growth potential in the manufacturing of medical devices. The Department, however, need to aim at inter-ministerial and inter-governmental strategies for the implementation of its promotional schemes by offering manufacturers competitive advantage for manufacturing in India, so that it is more profitable to manufacture in India than to import the medical devices.

Scheme for Promotion of Medical Device Parks

3. The Committee note that the scheme for the 'Promotion of Medical Device Parks' has been approved and four medical device parks would be set up in Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh with an outlay of Rs. 100 crore each, for the establishment of common testing and laboratory facilities. The First installment of Rs. 30 crore has been released to these States in 2021-22. It is unfortunate that even a modest amount of Rs. 120 crore for four States remained unspent during 2022-23 and only Rs. 89 lakh were utilized. As stated, the release of the next installment depends upon the utilization of funds granted in the previous installments. The Committee are of the opinion that the whole scheme has no meaning if funds allocated are not utilized by the respective States. There is a need for regular monitoring with regard to the progress of the project in coordination with the State agencies so that remedial measures are taken and successful creation of Common Infrastructure Facilities under the scheme is ensured. The Committee are unhappy with the tardy progress in implementation of the schemes and urge the Department that the scheme should be implemented with all seriousness. Besides,

possibilities of expanding the schemes to other States, where the medical device industry is more vibrant, should be explored.

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

4. The Committee note that the Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153 (iii) of the General Financial Rules 2017, issued the Public Procurement (Preference to Make in India) Order (PPO), 2017 dated 15.06.2017 and the same has been revised on 16.09.2020. Further, the Department, being the nodal Department for implementing the provisions of PPO, 2017 for product category 'medical devices' vide order dated 16.02.2021 and 25.03.2021, has notified 135 in-vitro diagnostics (IVD) and 19 medical devices, respectively, having sufficient local capacity and local competition in the country. Thus, PPO, 2017 has given preference to domestic manufacturers in public procurement of medical devices done by the hospitals of the Central Government. The Committee feel that PPO, 2017 can prove to be a significant pull for a number of medical device companies to manufacture medical devices in India and, therefore, recommend that the Department should make their PLI Scheme broad-based to gradually cover all the medical devices under it so that more medical device and IVD can be notified under Public Procurement Order.

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

5. The primary objective behind the launch of Production Linked Incentive (PLI) Scheme to promote domestic manufacturing of medical devices is stated to be to create a manufacturing ecosystem for domestic manufacturers. Under this Scheme, the Government will provide an incentive of Rs. 3420 crore to Greenfield projects within a

span of five years from 2022-23 to 2026-27. The Committee note that out of 64 applicants, 26 applicants viz. 19 Category-A and 07 Category-B applicants, with criteria for threshold incremental sale of Rs. 60 crore and Rs. 20 crore, respectively in the first year, i.e. 2022-23, have been selected. Each of the Category-A and Category-B applicants will be receiving a maximum incentive of Rs. 121 crore and Rs. 40 crore, respectively. The Department, as per scheme guidelines, will disburse an incentive of Rs. 60 crore and Rs. 120 crore to Category-A applicants; Rs. 20 crore and Rs. 22 crore to Category-B applicants for the year 2022-23 and 2023-24, respectively based on their threshold incremental sales performance.

The Committee are satisfied to learn that 26 selected applicants who have committed an investment of Rs. 1330.44 crore made investment of Rs. 851.56 crore upto June, 2023. Further, as per the June, 2023 Quarterly Review Report, 14 projects have been commissioned for 36 medical device products related to cancer care, radiology & imaging, anesthetics & cardio respiratory and implants like pacemakers etc. Again, after the launch of the Scheme, various companies have initiated the production of high-end medical devices like Linear accelerator, CT scan, Cath lab, ultrasonography devices, mammography devices, MRI coils etc. Besides, the Department has also proposed to consider PLI applicants for preference in public procurement, which will give assured market to their products.

In view of the foregoing, the Committee trust that the aforesaid PLI schemes guidelines and proposed initiatives, if followed in letter and spirit, would yield the desired result. At the same time, the Committee are of the opinion that in order to make the scheme more effective, there is a need to increase the number of beneficiaries to boost the production of medical devices and the Department should make sincere efforts in this direction. Further, it is desired that the Department, being the nodal

authority, should hold regular interactions with Medical Device Industries associates in all the States/UTs and take their feedback/inputs to make the Scheme more attractive while encouraging the medical device manufacturers for domestic production of high-end medical devices.

Production Linked Incentive (PLI) Scheme for Pharmaceuticals

6. Under the scheme PLI for Pharmaceuticals, the Department has planned to provide an amount of Rs. 250 crore as an incentive to domestic manufacturers on incremental sales for in-vitro diagnostic (IVD) devices production for the period 2020-21 to 2028-29. The Committee are constrained to observe tardy implementation of the scheme as out of 21 applications received under the scheme, the Department has selected only 5 industry applicants and among them 4 are from the MSME sector. The year 2022-23 was the first year to assess the incremental sales on the production of the selected applicants and an incentive of just Rs. 4.76 crore has been released to one of the IVD applicant out of the total proposed incentives of Rs. 250 crore to the beneficiaries. Given the demand and size of IVD manufacturing medical device industry in our country, the Committee are not satisfied to note the selection of only 5 applicants and allocation of only Rs. 250 crore for a period of seven years which is effective from 2022-23 to 2028-29 for the manufacturing of in-vitro diagnostic devices. In view of the fact that in-vitro diagnostic device is one of an important high-end device having 70 to 80 percent import dependencies, the Committee would like to be assured that whatever might be the constraints, serious efforts will be made to successfully implement the scheme. The Committee would also like to be apprised of the incentives disbursed to applicants during 2023-24.

NON- SCHEMATIC INITIATIVES FOR PROMOTION OF MEDICAL DEVICE INDUSTRY

National Medical Device Promotion Council

7. The Committee learn that the Department for Promotion of Industry and Internal Trade (DDPIIT) on 07.12.2018 had set up National Medical Device Promotion Council (NMDPC), with members from all the stakeholder departments and representatives from all the Medical Devices Industry Associations, to deliberate and resolve various issues for ease of doing business and promotion of the sector. The Council has been reconstituted on 05.08.2022 under the Chairpersonship of Secretary, Department of Pharmaceuticals with appropriate representation from DPIIT. The Committee are happy to learn that the NMDPC has been able to resolve issues viz. (i) the Vendor registration process of Medical Devices on GeM portal has been simplified for all medical device manufacturers (ii) Exemption of Lead in Medical Devices as listed in Schedule I of E-Waste (Management) Rules, 2022 and the Ministry of Environment, Forest and Climate Change (MoEF&CC) has amended the law in line with the industry needs and (iii) Transitioning of licensing of Medical Devices has been streamlined. Ministry of Health and Family Welfare (MoHFW) had published G.S.R. 102 (E) dated 11.02.2020 for regulation of medical devices in phases. There are, however, certain issues which are still under deliberation of NMDPC viz. (i) the demand of industry to reduce the double regulatory burden to comply with labeling and packaging requirements specified under the Legal Metrology Act and Medical Device Rules and (ii) Request of the Industry for consideration of exemption of accessories/components pertaining to Medical Devices from Compulsory Registration Order, 2012 of Ministry of Electronics and Information Technology (MeitY), according to which no person shall manufacture or store for sale, import, sell or distribute goods which do not conform to the Indian standard specified

in the order. The Committee have been informed that MeitY is open to examination of component items for exemption if it is to be used only for the manufacturing of medical devices. The Industry has been advised to furnish the details to the MeitY for further examination.

Considering these matters being deliberated in NMDPC to be of the utmost importance as they are associated with medical products labeling and standards having implications on quality and safety of medical device products, the Committee desire that both the matters may be deliberated upon, in depth, in the Council weighing all the pros and cons before coming to a resolution. The Committee would like to be kept informed of the updated status in this regard.

<u>Standing Forum of Medical Devices Associations</u>

8. It is further learnt that the Department of Pharmaceuticals has constituted a Standing Forum of Medical Devices Associations on 25th August, 2021 to deliberate upon the different issues related to medical devices and it has given inputs for the draft Uniform Code for Medical Device Marketing Practices (UCMDMP). The Committee learn that presently, due to litigation pending on this matter in the Supreme Court, the conduct of pharmaceutical/medical device companies is governed by the Uniform Code of Pharmaceutical Marketing Practices (UCPMP). After the directions of the Hon'ble Supreme Court in the matter of UCPMP, further action in UCMDMP will be taken. Once the UCMDMP is adopted, medical device promotion will be done within ethical limits and boundaries. In addition, the Standing Forum also headed a task force on the mapping of testing infrastructure for medical devices and has submitted its Report to the Ministry of Health and Family Welfare (M/o H & FW) for consideration and action.

The Committee feel that with the transition towards licensing of all types of medical devices, the requirement of testing equipments and testing infrastructure for Class A, B, C and D type of medical devices will increase and in this regard the recommendations given by the Standing Forum on Medical Device Associations will be of immense value. The Committee, therefore, desire the Department of Pharmaceuticals to ensure that the M/oH&FW/ CDSCO soon consider the Report of the Standing Forum of Medical Device Associations and take suitable and timely action on its recommendations.

Price Regulation of Medical Devices

9. The Committee note 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(NLEM) by the Ministry of Health and Family Welfare, and hence covered under Schedule-I of the Drugs (Prices Control)Order, 2013. The ceiling prices of these 4 scheduled medical devices are notified by National Pharmaceutical Pricing Authority (NPPA). In the year 2017, NPPA vide S.O 2668(E) dated 16.08.2017 fixed the ceiling price of knee implants to control the excessive trade margins of orthopedic knee implants under extraordinary circumstances. Later, during the post-Covid crisis, a Delhi High Court judgement dated 17.05.2021 directed NPPA to regulate the prices of medical devices. Resultantly, Gazette Notification No. 2161 (E) dated 3rd June 2021 and Notification No 2808 (E) dated 13th July 2021 were issued to cap the Trade Margin at Price to Distributor (PTD) at 70% for medical devices, namely, Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer.

In view of the foregoing, the Committee are of the considered opinion that the devices which are required for critical care to the patients should be listed under National List of Essential Medicines. The Committee, therefore, strongly recommend that the Department of Pharmaceuticals should take up the matter with NPPA, for inclusion of other medium and high-end medical devices which are used for critical care of the patients, at highest level with the Ministry of Health and Family Welfare, in public interest.

<u>Regulation of Medical Devices under Medical Device Rules, 2017</u>

10. The Committee note that the Department of Health and Family Welfare is responsible for the regulation of quality, safety, labelling & performance of medical devices and in this respect, Medical Device Rules, 2017 have been formulated under the Drugs and Cosmetics Act,1940. Further, Central Drugs Standard Control Organization (CDSCO) regulates import of all classes of medical devices and manufacture of Class C&D medical devices whereas the State Licensing Authorities (SLA), appointed by the State Governments, are responsible for the regulation of the manufacture of Class A&B medical devices as well as sale and distribution of all classes of medical devices.

The Committee further note that, as per MoH&FW Notification GSR 102(E) dated 11.02.2020, all non-notified medical devices are presently under regulation. Accordingly, Class A and B medical devices have come under licensing regime w.e.f. 01.10.2022 and Class C&D medical devices have come under licensing regime w.e.f. 01.10.2023. Henceforth, for manufacturing and marketing of any type of Class A, B, C and D medical device, a manufacturer has to get license for its respective regulator i.e. CDSCO or State Licensing Authorities. In this regard, the DoH&FW has stated to have received 3413 manufacturing license applications so far and out of the same 2262 applications have been approved. The Committee are satisfied to learn that all those

manufacturers whose applications are pending will still be allowed to sell their products for the next six month without any penalty. The Committee would like to be ensured that all the necessary arrangement will be made to complete the process of the issuance of license to the manufacturers of all kind of devices in a time-bound manner.

Notified Bodies and their role in regulation

11. The Committee have been informed that under Medical Device Rules, 2017, 13 Notified Bodies have been registered to audit and inspect manufacturing sites of Class A&B medical devices for quality standards. For Class C&D medical devices, audits are conducted by Central Medical Device Officers.

The Committee, however, are not satisfied to note that there are only 13 Notified Bodies to undertake audit duties and inspections of medical devices at manufacturing sites. The Committee, therefore, desire that immediate measures be taken to increase the number of Notified Bodies and equip them with suitable technical infrastructure and manpower to carry out audit functions for handling humongous task of ensuring quality, safety and efficacy of Class A&B medical devices manufactured in our country. Further, the Committee trust that the Department of Health & Family Welfare would take utmost care to ensure that the Central Medical Device Officers are well equipped and trained to carry out audits of Class C&D medical devices in the country.

Materio-vigilance Programme of India (MvPI)

12. The Committee note that the Materio-vigilance Programme of India (MvPI) is in operation since 10.02.2015 to ensure the safety and efficacy of medical devices in the country. Indian Pharmacopoeia Commission (IPC) Ghaziabad is a National Coordination Centre for MvPI. In the case of medical device adverse events, IPC issues

recommendations to CDSCO to take necessary regulatory action. MvPI publishes medical device safety information on the IPC website for public awareness and conducts various workshops/webinars/physical meetings throughout the country for the stakeholders. Also, safety alerts are being issued to monitoring centres for Medical Device Adverse Event for safety surveillance of medical devices. As has been informed, there are 397 Medical Device Adverse Event Monitoring Centres enrolled under MvPI. Besides, the MoH&FW has issued letter to the State Health Secretaries regarding the enrolment of district level hospitals/institutions under MvPI and, in response, States/UTs of Tamil Nadu, Kerala, Karnataka and Puducherry have issued an office order to their respective State's District hospitals/medical colleges to participate in MvPI. In addition, IPC-MvPI has also recognized 06 Regional Training centres, *viz.* (i) PGIMER, Chandigarh (ii) NIPER, Hajipur (iii) AIIMS, Bhopal (iv) NIMHANS, Bangaluru (v) Alshifa College of Pharmacy Kerala and (vi) AMTZ, Vishakhapatanam for the effective implementation of MvPI.

While appreciating the initiatives taken to expand the network of Adverse Events Monitoring Centres, the Committee would desire that continuous efforts be made to enroll more number of Adverse Event Monitoring Centres in view of the actual requirements of such centres in the country to keep a strict vigil over such incidents.

13. The Committee note to their surprise that in the years 2018, 2019, 2020, 2021 and 2022, the number of alert notices issued by CDSCO for Medical Device Adverse Event, were only 4, 2, 0, 4 and 3 respectively. The Committee desire that factors responsible for the less number of such alert notices should be looked into and remedial measures be taken for the effective implementation of the Materio-vigilance Programme of India (MvPI) so as to ensure the safety and efficacy of medical devices in the country.

Medical Device Testing Laboratory

14. The Committee note with concern that there are only 6 Central Medical Device Testing Laboratories notified by the Government for carrying out the statutory test and evaluation of various medical devices. Further, there are 39 medical device testing laboratories registered by CDSCO to carry out testing on behalf of device manufacturers for various medical devices and 35 listed labs for the testing of IVD. All these laboratories are NABL accredited. Since there is shortage of Government labs, CDSCO is relying on other NABL accredited laboratories. The Committee are of the considered opinion that 6 Central Medical Device Testing Laboratories are grossly inadequate, keeping in view the size of the country. As the testing facility for medical devices plays a crucial role in deciding the quality and cost of domestically produced medical devices, it would be appreciated if at least one Central Medical Device Testing Laboratory is set up in proximity of medical device industry clusters in the country. Such measures, if undertaken, would definitely help in reducing the cost of production which ultimately will improve the availability and affordability of medical devices in the domestic market. The Committee, therefore, strongly recommend that the Department of Pharmaceuticals should take up the matter for setting up of more Central Medical Device Testing Laboratories in the country with the Ministry of Health & Family Welfare/CDSCO at the highest level and expeditiously take concrete steps in this regard.

GST and Custom Duty

15. The Committee take note of the domestic manufacturing disabilities such as high GST rates (around 12% to 18 %) on domestically produced medical devices and low

custom duty on imported finished medical devices in comparison to Basic Custom Duty on raw material, subparts, parts etc. that has created a vicious circle of high dependence on imported medical devices. The Department of Revenue has, however, clarified that the reduction in GST rates creates an inverted duty structure and blockage of input tax credit.

It has been brought to the notice of the Committee that inverted duty structure occurring due to anomaly in the levying of Basic Custom Duty Rates has caused major disadvantage to domestic medical devices manufactures as the cost of domestically produced item is higher in comparison to the imported item. In this regard, the Department of Pharmaceuticals has introduced Phased Manufacturing Programme (PMP), wherein the Department of Revenue has to increase the basic custom duty in a phased manner on the Medical X-Ray Machines and specified sub-assemblies/parts/sub-parts. In addition, based on industry request and sufficient domestic manufacturing capacity, the Department has also requested the Department of Revenue to increase Basic Custom Duty on 40 finished products to protect the interest of the domestic manufacturers.

The Committee are of the view that the medical devices sector is at a nascent stage of development and in order to promote private players investment, it is necessary to make the domestic products competitive, which require Government support in terms of reducing the GST rates for domestically produced medical devices considering international competition in export market and the 'Make in India' initiative. Moreover, there is also a need to support the domestic manufacturers by giving them attractive custom duty concessions on the import of electronic components, metal compounds, plastics resins, reagents etc. used for manufacturing medical devices as a

short term measure till the time the industry does not attain self-sufficiency in the manufacturing of raw material, subparts, parts, etc. The Committee further desire that Phased Manufacturing Programme (PMP) may gradually be extended to other medical devices in a time-bound manner.

Investment in Research and Development

16. According to medical device industry associates, for high-end medical device research there is a need for Government investment in R&D as medical device manufacturer end up investing a huge amount on R&D, which includes cost of failures as well. The Committee are happy to note that the Department has recently launched the 'National Policy on R&D and Innovation in the Pharma-MedTech Sector in India' on 26.09.2023 to encourage R&D in pharmaceuticals and medical devices sectors and create an ecosystem for innovation in drug discovery and innovative medical devices by incubating an entrepreneurial environment. This policy will incentivize investment in research, exploring various funding mechanism and enhancing academia-industry collaboration. Also, a new Scheme for the Promotion of Research and Innovation in Pharma-Med Tech (PRIP) has been launched on 17.08.2023 with an outlay of Rs. 5000 crore for a period of 5 years from 2023-24 to 2027-28. This scheme reflects the intent of the R& D policy. One component of this scheme aims at Strengthening the Research Infrastructure through Centres of Excellence (CoEs) to be established in the seven existing National Institutes of Pharmaceutical Education & Research (NIPERs), at a tentative cost of Rs. 700 crore (including recurring and non-recurring cost) over a period of five years. The second component of this Scheme will provide financial assistance to the companies/ projects for both in-house and academic R&D in six specified priority areas including medical devices. The Committee are hopeful that with

the launch of the Policy on R&D as well as the Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP), R&D infrastructure will be strengthened and enabling ecosystem for research will be created in NIPERs.

Human Resource for Medical Device Industry

17. One of the major issues being faced by the medical device industry in our country is the lack of skilled manpower. The Department has stated to have set up the National Institute of Pharmaceutical Education & Research (NIPER) to provide human resource for pharmaceutical industry. Further, four among the seven NIPERs at Mohali, Hyderabad, Guwahati and Kolkata have started M Tech (Medical Devices) courses in addition to M Pharma (Medical Devices) and PhD (Medical Devices) courses already running at NIPER Ahmedabad. The Committee are happy to note that a new Scheme on 'Human Resource Development in Medical Devices Sector' has been approved with an outlay of Rs. 480 crore for a period of 3 years for financial assistance to government institutions for running multi-disciplinary dedicated courses in medical devices. The Committee would like to be apprised of the status with regard to the implementation of the Scheme.

The Committee further note that, keeping in view the specific technical requirements of medical device industry, it is proposed to establish the National Institute for Medical Device Education and Research (NIMERs) on lines of NIPERs. While appreciating the initiatives being taken for human resource development to fulfill the need of the medical device industry, the Committee trust that initiatives so taken will be implemented in letter and spirit and utmost care will be taken to ensure that they do not face any resource crunch.

18. The Committee was apprised during the evidence held on 14.12.2022 that 236 Medical Device Officers (MDO) have been notified in CDSCO and States have also notified MDO's as per Medical Device Rules, 2017. 23 Drugs Inspector (Medical Devices) and 03 Assistant Drugs Controller (Medical Devices) with engineering background were appointed in Medical Device Division. In addition, 219 new posts at various levels from the lowest level of medical device officer to the supervisory level officer, joint medical device officer and additional drug controller level officers have been created by the Department of Expenditure on 13 July 2022.

The Committee are of the opinion that the recruitment process for 236 notified and 219 created posts, which is pending for more than a year, would have serious implications on regulation as well as issuing licenses to manufacturers. The Committee, therefore, desire the Department of Pharmaceuticals to impress upon the Ministry of Health and Family Welfare/CDSCO to expedite the process of recruitment and appointment on aforesaid posts and keep them apprised of the same. Further, The Committee would like to be ensured that the recruitment of specialized cadre of Medical Device Officers for performing the crucial task of regulation and audit of medical devices would be done within the prescribed timeline without fail. Moreover, CDSCO should also follow up recruitment of Medical Device Officers with States that have notified such posts as per Medical Device Rules, 2017.

<u>Training for Regulation of Medical Devices</u>

19. The Committee note that the Ministry of Health & Family Welfare has been imparting training to State Licensing Authorities for an effective implementation of

Medical Device Rules, 2017. However, the Committee learnt from the representatives of the medical device industry during an informal discussion that much more handholding and training is required for all stakeholders in the Medical Device ecosystem for proper understanding of the recently announced rules, regulations and procedures in this regard. The Committee, therefore, recommend that more training programmes/workshops/interactive sessions should be conducted with concerned States Licensing Authorities and representatives of the medical device industry for clear understanding and effective implementation of Medical Device Rules, 2017.

National Standards for domestically produced medical device

20. The Committee have been informed during an informal discussion with the medical device industry representatives at Goa and Kochi held in May, 2023 that the absence of national standards for all domestically produced medical devices is a matter of concern for the industry. The Bureau of Indian Standards (BIS) lays down the standards for medical devices and has published 1540 Indian Standards for medical devices. The Committee note that there are 6000 plus medical devices in the market and are growing day by day. Therefore, in the absence of National Standards for medical devices manufactured in India, domestic manufacturers are forced to follow the WHO/American/ European standards, which also limits the export of Indian made medical devices in other countries. Further, a wide variety of testing standards are to be complied by the manufactures even for low risk class medical devices and procurement agencies also come with different standards which poses challenge to the manufacturer.

The Committee learn that BIS has now prepared a 5-year Standards National Action Plan (SNAP) for the year 2022-2027 in which sector-wise priority areas (including medical devices and healthcare) for standardization have been identified, which are being taken up and prioritized by the respective technical committees. The Committee, therefore, strongly urge the DoP/BIS to expedite the process of setting up National Standards for all types of medical devices to save the interest of domestic medical device manufacturers. Further, the Committee would like the Department of Pharmaceuticals to convince MoH&FW/CDSCO for using a 'National Mark' for all medical devices that comply with BIS/IEC standards to ease procurement related concerns and facilitate exports as well.

Single Window System/ Unified Application Portal

21. It has been brought to the notice of the Committee by the medical device industry representatives that the presence of multiple-regulators have made the setting up of industry and manufacturing medical devices a time taking process which impairs investment, often causing delays in product launch. Currently, the licensing framework for medical devices is spread across several legislations, guidelines and policies (including the Medical Devices Rules, 2017 and Drugs and Cosmetics Act, 1940), and is governed by a host of regulators, including the Central Drugs Standard Control Organisation, National Pharmaceutical Pricing Authority and State Licensing Authorities. Hence, the current regulatory landscape is complex, which inhibits business. The Committee, however, find some consolation in the fact that the National Medical Devices Policy, 2023 envisages to have Single Window Clearance System for the medical devices sector in line with the National Single

Window System (NSWS) for medical devices sector, integrating all the regulators of the MedTech Sector. Further, the Ministry of Health & Family Welfare are in the process of integrating various departments/ministries concerned, like the Bureau of Indian Standards (BIS), Atomic Energy Regulatory Board (AERB), Ministry of Electronics and Information Technology (MeitY), Department of Animal Husbandry and Dairying, etc. with the Medical Device Portal. The Committee are hopeful that the proposed system for the licensing of medical devices would minimise duplication of efforts and compliance burdens for licensing medical devices. The Committee urge the Department to take immediate necessary steps to expedite the creation of a Single Window System/Unified Application Portal for medical device industry so as to enhance the ease of doing business in this sector.

<u>Regulation of Refurbished/Pre-owned Second-hand Medical Devices</u>

22. The Committee are constrained to observe that presently, there is no specific provision under Medical Device Rules 2017, to regulate refurbished/pre-owned second-hand medical devices. The Ministry of Environment, Forest and Climate Change (MoEF&CC), however, is regulating the import and use of refurbished/second-hand medical devices under Hazardous and Other Waste (Management and Transboundary Movement) (HOWM) Rules, 2016. Further, import of high-end and high value medical devices has been liberalized after MoEF&CC amended HOWM rules vide its notification dated 23.12.2022. The Committee are deeply concerned to note that CDSCO does not maintain any data/record for safety and quality standards of such products and neither assessment is being done to evaluate their ill effects on public health.

The Committee are of the considered opinion that, due to laxity in regulatory framework with regard to quality, safety and efficacy assessment of second-hand/used medical devices, the standard of health services in our country is being compromised. Besides, the easy importation of refurbished medical devices is weakening the 'Make in India' initiative. Also, it should be kept in view that market in developing countries like India is generally price sensitive, resulting in the strong emergence for refurbished medical devices, as such medical devices are cheaper and save out-of-pocket expenditure of the patients to a large extent. The Committee, therefore, strongly recommend that the needful be done at the earliest to ensure safety, quality and efficacy of imported second-hand medical devices by regulating them under Medical Device Rules, 2017, in the best interest of the public at large. Also, in order to safeguard the interest of domestic manufacturers, it becomes imperative to restrict the import and use of such products which are being manufactured in India and initiatives are required to be taken in this direction. The Department of Pharmaceuticals should take up these issues with the Ministry of Health & Family Welfare/ CDSCO on an urgent basis.

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New Delhi;
07 February, 2024
18 Magha, 1945 (Saka)

DR. SHASHI THAROOR
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS.

APPENDIX-I

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2021-22)

MINUTES OF THE SECOND SITTING

The Committee sat on Thursday, the 09th December, 2021 from 1500 hrs. to 1630 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Smt. Kanimozhi Karunanidhi- Chairperson

MEMBERS

LOK SABHA

2 Shri Ramakant Bhargava

3 Shri Prataprao Patil chikhilikar

4 Shri Rajeshbhai Naranbhai chudasama

5 Shri Parbhubhai Nagarbhai Vasava

6 Shri Satyadev Pachauri

7 Smt. Aparupa Poddar

8 Dr. M. K. Vishnu Prasad

9 Shri Arun Kumar Sagar

10 Dr. Sanjeev Kumar Singari

11 Shri Pradeep Kumar singh

12 Shri Uday Pratap Singh

RAJYA SABHA

13 Shri Ayodhya Rami Reddy Alla

14 Shri G.C. Chandrashekhar

15 Dr. Anil Jain

16 Shri M. V. Shreyams Kumar

17 Shri Jaiprakash Nishad

18 Shri Anthiyur P. Selvarasu

19 Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri N. K. Jha	-	Director
2.	Shri C. Kalyanasundaram	-	Additional Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Shri Panna Lal	-	Under Secretary

WITNESSES

I. REPRESENTATIVES OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1.	Ms. S. Aparna,	Secretary
2.	Dr. N. Yuvaraj	Joint Secretary

II REPRESENTATIVE OF THE MINISTRY OF HEALTH AND FAMILY WELFARE

1.	Dr. Mandeep Kumar Bhandari,	Joint Secretary

III. REPRESENTATIVES OF NATIONAL PHARMACEUTICALS PRICING AUTHORITY

1.	Sh. Kamlesh Kumar Pant,	Chairman
2.	Smt. Vinod Kotwal	Member Secretary

IV. REPRESENTATIVES OF OTHER ORGANISATIONS

1	Shri S. Eswara Reddy,	Joint Drugs Controller (India), Central Drug Standard Control Organisation
2	Dr. Rajeev Singh Raghuvanshi,	Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission
3	Shri P. V. Mathew,	Scientist E, Bureau of Indian Standards

2. At the outset, the Chairperson welcomed the Members of the Committee and the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) to the sitting of the Committee which was convened to have a briefing on the subject "Promotion of medical device industry. Drawing the attention of the witnesses to Direction 58 of the 'Directions by the Speaker' regarding confidentiality of the proceedings during deposition before the Parliamentary Committees, the Chairperson asked the Secretary, Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) to brief the Committee on the subject.

3. The Secretary and other witnesses accordingly gave an overview on various issues relating to the subject matter through Power Point Presentation, which *inter-alia* included the mandate of the Department of Pharmaceuticals under Allocation of Business Rules, 1961, overview of Medical Device Industry in India, Indian Medical Device Market, Medical Device Regulation in India, salient Features of MDR-17, notification to regulate all devices, registration of Medical Devices' Manufacturers, Medical Device Testing Laboratories, regulation of Pricing by the National Pharmaceutical Pricing Authority (NPPA), Foreign Direct Investment in Medical Device Sector and schemes of the Department for the promotion of Medical Device Industry.

4. The Members then raised certain specific queries on various issues connected with the subject, which *inter-alia* included huge difference between import and export of Medical Devices, Research and Development in the Medical Device Industry, manufacturing of Medical Devices under the Atma Nirbar Bharat, huge dependency on China and steps to reduce it, Construction of Medical Parks, details of Production Linked incentive Scheme for promoting domestic manufacturing of Medical Devices (PLI schemes) and its

implementation.

5. The Chairperson thanked the Secretary and other representatives of the Ministry for furnishing valuable information on the subject matter and responding to the queries of the Members.

6. A copy of the verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

APPENDIX-II

MINUTES OF THE FOURTH SITTING OF THE

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2022-23)

The Committee sat on Wednesday, the 14 December, 2022 from 1600 hrs. to 1815 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Dr. Shashi Tharoor - Chairperson

MEMBERS

LOK SABHA

2. Shri C. N. Annadurai
3. Shri Deepak Baij
4. Shri Ramakant Bhargava
5. Shri Prataprao Patil Chikhilikar
6. Shri Rajeshbhai Naranbhai Chudasama
7. Shri Sanjay Jaiswal
8. Shri Satyadev Pachauri
9. Shri Arun Kumar Sagar
10. Dr. Sanjeev Kumar Singari
11. Shri Pradeep Kumar Singh
12. Shri Uday Pratap Singh
13. Shri Indra hang Subba

RAJYA SABHA

14. Dr. Anil Jain

15. Shri Arun Singh

16. Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri Vinay Kumar Mohan	-	Joint Secretary
2.	Shri N. K. Jha	-	Director
3.	Smt. Geeta Parmar	-	Additional Director
4.	Shri Kulvinder Singh	-	Deputy Secretary

WITNESSES

II. REPRESENTATIVES OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1.	Shri. Arun Baroka	Secretary, Department of Chemicals & Petro-chemicals (Additional Charge, Department of Pharmaceuticals)
2.	Shri Sanjay Rastogi	AS&FA
3.	Dr. N. Yuvaraj	Joint Secretary

II. NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)/ PHARMACEUTICALS AND MEDICAL DEVICE BUREAU OF INDIA (PMBI)

1.	Shri Kamlesh Kumar Pant	Chairman, NPPA
2.	Shri Ravi Dadhich	CEO, PMBI

III. MINISTRY OF HEALTH AND FAMILY WELFARE

(DEPARTMENT OF HEALTH AND FAMILY WELFARE)

1.	Dr. V.G. Somani	Drug Controller General

IV. MEDICAL DEVICE INDUSTRY

1.	Mr. Arnab Basumallik,	Co-Chair, Medical Technology Association of India, (MTaI)
2.	Mr. Gurmit Chugh,	Managing Director, Association of Indian Medical Device Industry(AIMED)
3.	Mr. Thomas John,	President, Association of Diagnostics Manufacturers of India (ADMI)

2. At the outset, the Chairperson welcomed the Members of the Committee and informed them that as directed by the Hon'ble Speaker, the Library, Reference, Research, Documentation and Information Service (LARRDIS) will make a presentation to apprise the Hon'ble Members about the (i) various new initiatives taken towards capacity building for augmentation of Research, (ii) new initiatives in the Parliamentary Library, (iii) creating awareness about the rich resources/repositories of the Parliament Library, (iv) training programmes by PRIDE, (v) the various aspects of the resources and capacity building initiatives by HS in the area of research, training, Parliament Library, etc. Accordingly, LARRDIS made the power point presentation. The Members sought certain clarifications which were responded to by the officers of the LARRDIS.

3. Thereafter, the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Ministry of Health and Family Welfare (Department of Health and Family Welfare) and Medical Device Associations were called-in. The Chairperson welcomed the witnesses to the sitting of the Committee convened to have oral evidence on the subject “Promotion of Medical Device Industry". After inviting the attention of the witnesses to Direction 58 of the ‘Directions by the Speaker’ regarding confidentiality of the proceedings during deposition before the Parliamentary Committees, the Chairperson asked the Secretary, Department of Pharmaceuticals and others to brief the Committee on the subject.

4. The Secretary, Department of Chemicals & Petro-chemicals (Additional Charge, Department of Pharmaceuticals) and other witnesses accordingly gave an overview on

various issues relating to the subject through Power Point Presentation, which *inter-alia* included (i) the mandate of the Department of Pharmaceuticals vis-a-vis Department of Health and Family Welfare under Allocation of Business Rules, 1961 (ii) Central Sector Schemes of the Department of Pharmaceuticals and respective budget allocations (iii) various regulators for Medical Devices (iv) overview of Medical Device Industry in India (v) Export and Import of Medical Devices (vi) Foreign Direct Investment (FDI) in Medical Device sector (vii) Medical Device clusters (viii) non-schematic interventions *viz.* Standing Forum of Medical Devices, National Medical Devices Promotion Council, Export Promotion Council for Medical Devices and (ix) Efforts by National Institutes for Pharmaceuticals Research and Education (NIPERs) for Medical Devices and National Medical Device Policy etc.

5. Since regulation of quality, safety and efficacy of medical devices is under the Ministry of Health and Family Welfare, the Drug Controller General of India briefed the Committee on issues viz. (i) salient features of Medical Device Rules-2017 (ii) standards of Medical Devices (iii) Medical Device testing laboratories (iv) post marketing safety surveillance (Materiovigilance Programme of India) etc. Thereafter, Chairman, National Pharmaceutical Pricing Authority (NPPA) briefed the Committee about the steps taken to regulate prices of Medical Devices as per provisions of Drugs (Prices Control) order 2013.

6. Thereafter, the representatives of the Medical Device Associations made their submissions on their concerns which *inter-alia* included (i) harmonizing regulations with best global practices (ii) develop strong materio-vigilance infrastructure (iii) easing of state level restrictions (iv) incentivization of Research and Development (R&D) projects (v) rationalize tax structure and give tax break on exports for domestic manufacturers (vi) strict regulation on usage of second hand medical devices (vii) dedicated infrastructure for training health professionals in medical devices (viii) investor friendly industry ecosystem (ix) creation of a predictable pricing policy by implementation of Trade Margin Rationalization (TMR) and (x) medical devices which are not domestically manufacture get exemption from the local content requirement and not to have a USFDA/EU-CE restrictive clause in Public Procurement Policy etc.

7. The Members, then, asked questions on various issues relating to the subject, which *inter-alia* included (i) reasons for delay in framing Medical Device Policy (ii) reasons for rising imports and declining exports under different segments of Medical Devices (iii) lack of

Research and Development support to Medical Device Industry (iv) need for single window system to address issue of overregulation (v) steps taken towards analyzing cost and benefit of PLI schemes (vi) impact of second hand medical devices on public health infrastructure (vii) reasons for regulating prices of only four medical devices by NPPA (viii) need for increasing medical device testing labs and strengthening of post marketing safety surveillance by Department of Health and Family Welfare and (ix) details of Production Linked Incentive Scheme (PLI schemes) for promoting domestic manufacturing of Medical Devices (x) Scheme for promotion of Medical Device Parks and there implementation etc.

8. The representatives replied to the questions of the Members. The Chairperson thanked the representatives of the Department of Pharmaceuticals, Department of Health and Family Welfare and representatives of the Medical Device Associations for sharing valuable information on the subject and responding to the queries of the Members.

(The witness then withdrew)

A copy of the audio-recorded proceedings of the sitting has been kept.

The Committee then adjourned.

APPENDIX-III

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

(2023-24)

Minutes of the Third Sitting of the Committee

The Committee sat on Monday, the 09th October, 2023 from 1400 hrs. to 1545 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Dr. Shashi Tharoor – CHAIRPERSON

Shri Satyadev Pachauri - In the Chair (Till the Chairperson joined)

MEMBERS

LOK SABHA

2. Shri Prataprao Patil Chikhlikar
3. Shri Satyadev Pachauri
4. Shri Arun Kumar Sagar
5. Shri Muniyan Selvaraj
6. Shri Pradeep Kumar Singh
7. Shri Parbhubhai Nagarbhai Vasava

RAJYA SABHA

8. Shri G. C. Chandrashekhar
9. Shri Ram Nath Thakur
10. Shri Vijay Pal Singh Tomar

SECRETARIAT

5.	Smt. Geeta Parmar	-	Director
6.	Shri Kulvinder Singh	-	Deputy Secretary
7.	Shri Panna Lal	-	Under Secretary
8.	Ms. Sonia Sankhla	-	Committee Officer

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1.	Ms. S. Aparna	-	Secretary
2.	Shri Awadhesh Kumar Choudhary	-	Senior Economic Advisor
3.	Shri Ravindra Pratap Singh	-	Joint Secretary

II. NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)/ PHARMACEUTICALS AND MEDICAL DEVICE BUREAU OF INDIA (PMBI)

1.	Shri Kamlesh Kumar Pant	-	Chairman, NPPA
2.	Shri Parth Gautam	-	Dy. CEO, PMBI

III. REPRESENTATIVES FROM MINISTRY OF HEALTH AND FAMILY WELFARE

1.	Dr. Rajeev Singh Raghuvanshi	-	Drug Controller General of India (DCGI)
2.	Ms. Aradhana Patnaik	-	Joint Secretary

2. At the outset, the Member in the Chair on behalf of the Chairperson welcomed the representatives of the Department of Pharmaceuticals and Ministry of Health and Family Welfare to the sitting of the Committee convened to take their further evidence on the subject 'Promotion of Medical Device Industry'. Their attention was drawn to the Direction '58' of the 'Direction by the Speaker' regarding confidentiality of the proceedings of the Committee.

3. The Secretary and other witnesses of the Department of Pharmaceuticals through a power point presentation apprised the Committee with regard to the growth of the Medical Device Industry, Export and Import status, Initiatives for promotion of Medical Device Industry in terms of implementation of various Schemes of the Government *viz*. Promotion of Medical Device Parks, PLI for Medical Devices with details of the participants and products already commissioned, PLI scheme for Pharmaceuticals which cover the In-Vitro Diagnostic (IVD) segment of Medical Device, newly launched scheme Assistance to Medical Device Clusters for Common Facilities etc., Efforts made towards creation of Human

Resources for the industry by introducing M. Tech, M. Pharma and PhD courses in some of the NIPERs as well as promotion of research in Pharma-Med Tech by setting up Centre of Excellence on Medical Devices at NIPER Ahmedabad. Information was also shared with regard to other important initiatives taken which include launch of National Medical Device Policy 2023, National Medical Devices Promotion Council and Export Promotion Council for Medical Devices, etc.

4. Thereafter, a representative of the Ministry of Health and Family Welfare briefed the Committee on the mandate of the Ministry and Central Drugs Standard Control Organization (CDSCO), the regulatory agency which is in regulation of quality, safety and efficacy of Medical Devices including the status of medical device applications after implementation of Medical Device Rules-2017, progress made in registration of more private Medical Device Testing Laboratories by CDSCO, status of Materio-Vigilance Programme of India and human resource recruitment for regulation of Medical Devices etc.

5. Then, the representative from National Pharmaceutical Pricing Authority (NPPA) informed the Committee on the price regulation of medical devices as per Drugs Price Control Order, (DPCO) 2013 according to which ceiling price is fixed for scheduled medical devices and for Non-scheduled medical devices, price monitoring is being done with cap of not more than 10 percent increase on MRP in a year.

6. The Chairperson later on joined the sitting and raised certain queries with regard to drafting of uniform code for the marketing practices of medical devices by the Standing Forum of Medical Device Associations, intervention of the Department for making suitable changes in eligibility criteria for applicants under PLI Scheme, steps proposed for expansion of Medical Device Testing Laboratories, import of pre-owned medical devices and issues related to pendency of medical device manufacturing applications, etc. The Members of the Committee expressed their concerns over slow implementation of the schemes, efforts made towards simplification of the certification/registration process for medical devices by developing a unified application portal/single window system, measures taken/proposed for addressing inverted duty structure and steps taken for popularizing Materio-vigilance Programme of India among general public, etc.

7. The representatives of the Department of Pharmaceuticals and Ministry of Health and Family Welfare responded to some of the queries of the Members.

8. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information and asked them to furnish the replies to the queries raised by the Members during the sitting which remained unanswered.

9. A copy of the verbatim record of the proceedings of the sitting has been kept.

(The witness then withdrew).

The Committee then adjourned.

APPENDIX-IV

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2023-24)

Minutes of the Seventh Sitting of the Committee

The Committee sat on Wednesday, the 07th February, 2024 from 1530 hrs. to 1600 hrs. in the Chamber of Hon'ble Chairperson, Room No. 219, 'B' Block, Parliament House Annexe Extension Building, New Delhi.

PRESENT

DR. SHASHI THAROOR- Chairperson

MEMBERS

LOK SABHA

2. Shri C. N. Annadurai
3. Shri Prataprao Patil Chikhalikar
4. Shri Rajeshbhai Naranbhai Chudasama
5. Smt. Aparupa Poddar
6. Shri Arun Kumar Sagar
7. Shri Pradeep Kumar Singh

RAJYA SABHA

8. Dr. Anil Jain
9. Shri Arun Singh
10. Shri Vijay Pal Singh Tomar

SECRETARIAT

1.	Shri Chander Mohan	-	Joint Secretary
2.	Smt. Geeta Parmar	-	Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Shri Panna Lal	-	Under Secretary
5.	Ms. Neelam Bhave	-	Committee Officer

2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee. Thereafter, the Committee took up for consideration, the following Draft Reports: -:-

(i) Fiftieth Report on the subject 'Promotion of Medical Device Industry' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers;

(ii) XXX XXX XXX XXX

(iii) XXX XXX XXX XXX

3. Giving an overview of the important Observations/Recommendations contained in the draft Reports, the Chairperson solicited the views/suggestions of the Members.

4 After some deliberations, the draft Reports were adopted by the Committee without any amendment.

5. The Committee then authorized the Chairperson to finalize the Reports and present/lay the Reports in both the Houses of Parliament in the current session.

The Committee then adjourned.