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भारत सरकार / Government of India

रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers

औषध विभाग / Department of Pharmaceuticals

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जनपथ भवन, नई दिल्ली

दिनांक: 10 मार्च, 2022

PUBLIC NOTICE

Subject:- Approach paper on Draft National Medical Devices Policy 2022 for consultation - reg

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of medical conditions, diseases, illnesses, and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thereby helping achieve the key values enshrined in the National Health Policy (NHP) 2017 in terms of provision of good quality, affordable, and comprehensive healthcare to all citizens.

02. In order to drive the growth of the sector, a approach paper has been prepared with the aim to facilitate an orderly growth and provide a clear direction to meet the underlying objectives of accessibility, affordability, safety and quality, while ensuring focus on self-sustainability and innovation.

03. To have a wider stake-holder consultation, the approach paper is hereby published **(Annexure)** to seek specific comments from the Public/Industry/Medical Device Industry Associations to have the approach paper converted into a robust Policy framework.

04. It may be kept in mind while giving the inputs that the Policy would aim to give a broader direction for the development of the sector and may not contain specific proposals on tax, incentives etc. **The feedback/inputs may be provided at nmdp-2022@gov.in (in both PDF and Word document) by not later than 25.03.2022.**

05. This issues with the approval of Competent Authority.

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Annexure

Approach Paper

on

National Medical Devices Policy, 2022

(Draft For Stakeholder Consultation)

Glossary of Terms

AI	Artificial Intelligence
AIF	Alternative Investment Funds
AIMED	Association of Indian Medical Device Industry
A*STAR	Agency for Science, Technology and Research
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy
BCD	Basic Customs Duty
BIS	Bureau of Indian Standards
Bn	Billion
CBDT	Central Board of Direct Taxes
CDSCO	Central Drugs Standard Control Organisation
CoE	Center of Excellence
CFC	Common Facilitation Center
CSIR	Council of Scientific and Industrial Research
CSR	Corporate Social Responsibility
D&C	Drugs and Cosmetics
DALY	Disability Adjusted Life Years
DGCI	Drugs Controller General of India
DCFC-MD	Development of Common Facility Centers for Medical Device
DHR	Department of Health Research
DoP	Department of Pharmaceuticals
DPCO	Drug (Prices Control) Order
DPIIT	Department for Promotion of Industry and Internal Trade
DST	Department of Science and Technology
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investments
FEMA	Foreign Exchange Management Act
FII	Foreign Institutional Investors
FIPB	Foreign Investment Promotion Board
FVCIs	Foreign Venture Capital Investors
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GFR	General Finance Rules
GHTF	Global Harmonization Task Force
GMDN	Global Medical Devices Nomenclature
GST	Goods and Services Tax
HSSC	Healthcare Sector Skill Council
ICMED	Indian Certification for Medical Devices
IEC	International Electro Technical Commission
IISc	Indian Institute of Science
IVD	In Vitro Diagnostic
IP	Intellectual Property
IPO	Initial Public Offering
ISO	International Standards Organization
ITI	Industrial training institute

LSSSDC	Life Science Sector Skill Development Council
MDPCO	Medical Devices Prices Control Order
MDR	Medical Devices Rules
MDSAP	Medical Device Single Audit Program
MEIS	Merchandise Exports from India Scheme
MEITY	Ministry of Electronics and Information Technology
MOOC	Massive Open Online Courses
MoE	Ministry of Education
MoHFW	Ministry of Health and Family Welfare
MoF	Ministry of Finance
Mn	Million
MSDE	Ministry of Skill Development & Entrepreneurship
MTAB	Medical Technology Assessment Board
NABCB	National Accreditation Board for Certification Bodies
NHP	National Health Policy
NIELIT	National Institute of Electronics and Information Technology
NIMDER	National Institute of Medical Device Education and Research
NIPER	National Institute of Pharmaceutical Education and Research
NLEM	National List of Essential Medicines
NLP	Natural Language Processing
NMDA	National Medical Device Authority
NMDPC	National Medica Device Promotion Council
NPPA	National Pharmaceutical Pricing Authority
NSDC	National Skill Development Corporation
PE	Private Equity
PLI	Production Linked Incentive
PMDA	Pharmaceuticals and Medical Devices Agency
PMKVY	Pradhan Mantri Kaushal Vikas Yojana
PMP	Phased Manufacturing Programme
PPP	Public Private Partnership
QMS	Quality Management System
R&D	Research and Development
RBI	Reserve Bank of India
SDG	Sustainable Development Goals
SEBI	Securities and Exchange Board of India
SEIS	Service Exports from India Scheme
STEM	Science, technology, engineering, and mathematics
TGA	Therapeutic Goods Administration
UCMDMP	Uniform Code for Medical Device Marketing Practices
UGC	University Grants Commission
UK	United Kingdom
UMDNS	Universal Medical Device Nomenclature System
US$	United States Dollar
US/USA	United States of America
VC	Venture Capital
VCF	Venture Capital Funds
WTO	World Trade Organisation

Approach Paper to National Medical Device Policy, 2022

1 Preamble and Background

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

1.2 The current market size of the medical devices sector in India is estimated to be $11 bn [1] and its share in the global medical device market is estimated to be 1.5% [1]. India is counted amongst the top 20 global medical devices market and is the 4thlargest medical devices market in Asia after Japan, China, and South Korea [3]. The medical devices sector in India is still at a nascent stage. The Indian medical device market has a significant presence of multiple multi-national companies with about 80% of the sales generated from imported medical devices backed by multiple approvals, certification of accredited organizations and capacity to produce verified clinical trial record.

1.3 The growth of medical device sector in India is primarily driven by growing and ageing population, increased per capita and disposable income, demand for healthcare infrastructure, rise in preventive testing and spread of healthcare services and insurance [4]. In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector. Recently, the Indian medical devices sector's contribution has become even more prominent as India supported the global battle against COVID-19 pandemic through the production of medical devices & diagnostic kits, e.g., Ventilators, RT-PCR kits, IR Thermometers, PPE Kits & N-95 masks [5].

1.4 The current policy aims to facilitate an orderly growth of the medical device sector to meet the underlying objectives of accessibility, affordability, safety and quality, while ensuring focus on self-sustainability and innovation. Through this policy, the Department of Pharmaceuticals is

driven to help the sector realize its full potential by creating a robust regulatory framework with feedback mechanisms, building an enabling ecosystem for medical device manufacturing within the country, focusing on innovation for high end technology, providing support in training and capacity building programs and promoting higher education to foster fresh talent and skilled resources in line with the industry requirements. Encouraging domestic production of medical devices is in consonance with the Government's *'Atmanirbhar Bharat Abhiyan'* and '*Make in India*' campaign.

2 Initiatives undertaken by the Government:

2.1 Recognizing the importance of the sector, medical devices were included in the Make in India campaign launched and 100% FDI on the automatic route was allowed in Medical Devices in 2014. The Department of Pharmaceuticals has been allocated the responsibility for promotion of the medical devices.

2.1.1 In 2019, under the Scheme "Assistance to Medical Device industry for Common Facility Centre, financial assistance of Rs 25 crore was approved to Andhra Pradesh MedTech Zone (AMTZ) for a superconducting magnetic coils project which is under implementation.

2.1.2 In 2020, focused interventions to increase domestic manufacturing were introduced. The Production Linked Incentive PLI Scheme for Medical devices was introduced with an outlay of Rs. 3,420 crores to incentivize manufacturers in four target segments of high-end medical devices based on achieving investment and incremental production targets over a period of FY 2020-21 to FY 2027-28. The four target segments selected on the basis of domestic requirement with a view to build self-sufficiency are Cancer Care /Radiotherapy medical devices, Radiology & Imaging Medical Devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices, Anaesthetics & Cardio-Respiratory Medical Devices including Catheters of Cardio Respiratory Category and Renal Care Medical Devices and All implants including Implantable Electronic Devices.

2.1.3 In addition, a scheme to support for financing of common facility projects in four medical devices parks was introduced in 2020 with an outlay of Rs. 400 crore wherein four States will be supported for creation of common facility projects which will be used by the industrial units to be set up in the medical device parks. These industrial parks are

expected to be developed as manufacturing hubs for medical devices with associated testing, skilling and research facilities.

2.1.4 The Medical Devices Rules, 2017 notified by the Ministry of Health and Family Welfare under the Drugs and Cosmetics Act 1940, laid out the regulatory framework in terms of quality, safety and efficacy for medical devices. This expanded the regulatory oversight from 15 specified devices to the entire gamut of devices, categorized into four classes for regulation as per their risk categorisation.

2.1.5 The National Pharmaceutical Pricing Authority (NPPA) has stepped up price monitoring of essential medical devices and made interventions to cap margins on retail prices, where warranted in the case of some medical devices such as stents, oxygen concentrators and other Point of care devices.

2.1.6 To improve access, the Government has made available 240 types of surgical supplies in over 8500 stores or Jan Aushadhi Kendras at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana.

2.1.7 Health and Wellness Centres are being equipped with medical devices required for primary diagnostic services under Ayushman Bharat program.

2.1.8 The medical device sector has diversity of views and therefore to encourage a consensus-based approach for the larger good of the sector, a Standing Forum of Medical Device Industry Associations has been set up by the Department of Pharmaceuticals to provide a platform for discussion on various challenges being faced by the sector and arrive at well-rounded views.

2.2 All such initiatives are further detailed at **Annexure-1**.

3 Need for Medical Devices Policy

3.1 The growth and potential of the medical devices sector has been discussed in the previous sections. A holistic policy to accelerate this growth and exploit the potential is the need of the times. While the Government has initiated several schemes and programs through different departments to encourage the medical devices sector, the current policy proposes to put in place a comprehensive set of measures for ensuring sustained growth and development of the sector. Secondly, in view of the diversity of products segments covered in the medical devices sector, the regulatory, trade and promotion support is spread over several departments and agencies in the Government both at the Centre and State levels. There is a need to bring together the range

of interventions into a coherent policy framework that would facilitate focused and efficient support and facilitation for the sector by the respective agencies. Further, the transition from partial regulation of selected medical services to the complete regulation and licensing of all medical devices is underway and expected to be completed by October 2023, requiring more clear articulation in terms of quality assurance and certification.

3.2 The Department of Pharmaceuticals, as the nodal department for the promotion, production and manufacturing of medical devices in India, has formulated this Policy building upon a patient-centric approach and acknowledging the need to address structural challenges, enhance competitiveness of domestic manufacturers, increase private investments, and innovate in technology through fundamental research and knowledge driven enterprise.

4 **Policy Framework**

4.1 Vision:

The Medical Devices sector will be placed on an accelerated growth path to increase access and affordability of products and services of excellent quality to meet the evolving health care needs of patients, by building an innovative and globally competitive industry in India, supported by best of class infrastructure, enabling ecosystem, streamlined regulatory framework and quality manpower. This would enable India to emerge as the global leader in the manufacturing of medical device products, duly ensuring accessibility to patent-centric, innovative and affordable healthcare products for better healthcare outcomes.

It is envisaged that by 2047,

- India will be one amongst Top 5 Global manufacturing hubs in terms of value and technology for Medical Devices
- India will be home to 25 MedTech $Bn companies and **home & originator** to **25 high-end futuristic technologies in MedTech**
- India will emerge as **Champion** in **critical components**, **cancer diagnostics**, **medical imaging, ultrasonic scans**, **molecular imaging**, & **PCR technologies**
- India will achieve **10-12%** of **Global Market Share of Medical Devices** Sector to arrive at a **$100-300 Bn industry**

- India will have about **50 Medical Devices Clusters** across India for faster clinical testing of Medical Devices to boost product development and innovation

4.2 Strategic Objectives

The efforts of the government is to reduce import dependence from 80% to below 30% in next 10 years and ensure self-reliance quotient of 80% in Med-Tech by ensuring Make in India with SMART milestones**.**

The National Medical Devices Policy 2022 lays down a clear roadmap for accelerated growth of the medical devices sector while promoting safety and quality to systematically achieve key principles & objectives of the National Health Policy 2017 viz.

4.2.1 **Access, Equality & Universality:** The policy strongly advocates to reach the masses and provide equity and universality in the absence of physical infrastructure through automation and providing virtual presence.

4.2.2 **Affordability:** The policy aims to improve clinical outcomes through early diagnosis of diseases and increased accuracy in treatment to reduce the lifetime cost of disease burden.

4.2.3 **Patient Centred & Quality Care:** The policy aspires to improve the quality of care by improving clinical outcomes and convenience of the patients.

4.2.4 **Preventive & Promotive Health:** The policy strives to make people more aware and vigilant, enabling them to lead a healthier lifestyle by achieving extensive application of medical devices in early screening and diagnosis for early detection / prevention and management of diseases.

4.2.5 **Security:** The availability of the medical devices for the diagnostic, therapeutic, clinical and research purposes should depend on the strong local manufacturing capabilities, with lesser dependence on imports.

4.3 Focus Areas

In order to achieve the above objectives, the policy delineates following Focus Areas for policy support and programmatic intervention, as listed below.

4.3.1 **Quality Standards and Safety of the Devices** in order to provide safe devices to the consumers, in harmony with the global standards.

4.3.2 **Regulatory Streamlining** in order to optimize regulatory processes and multiplicity of agencies associated with business licensing mechanism for enhanced ease of doing business, along with harmonization with global standards to ensure standardization.

4.3.3 **Building Competitiveness through Fiscal and Financial Support** for stimulating the development of local manufacturing ecosystem with private sector investments.

4.3.4 **Infrastructure Development** in order to provide best in class physical foundation, including medical devices parks with common facilities such as testing centres, to improve cost competitiveness and enhance attraction of domestic manufacturers in medical device sector.

4.3.5 **Facilitating R&D and innovation** with a focus on enhanced collaboration, global partnerships, and joint ventures among key stakeholders to bridge the gap between academic curriculum and industry requirements while also co-ordinating in innovation and R&D projects.

4.3.6 **Human Resource Development** to ensure relevant curriculum at higher education level for enabling the clinician-engineering partnership along with skilling of various stakeholders comprising doctors, technicians, service engineers with a focus on creation of high-end jobs with in-demand skill sets across the innovation value chain.

4.3.7 **Awareness Creation and Brand Positioning** with a focus on proactive communication by Government in creating awareness on the sector in key domestic and global forums and positioning India as a hub for manufacturing of medical devices as part of the “Make in India, Make for the World” initiative.

The detailed focus areas are given at **Annexure-2**.

5 Policy Interventions under the Policy

5.1 Regulatory Streamlining

The Medical Devices Rules (MDR), 2017 (Amended in 2020), under the Drugs & Cosmetics Act, 1940 notified by the Ministry of Health &Family Welfare, regulates the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country

[22]. International forums such as WHO, IMDRF and MDSAP have prescribed global standards for risk-classification, nomenclature, QMS and post-market surveillance [40], which have been adopted by India as part of the MDR 2017.

The manufacturing of low-risk Class A and low-moderate risk Class B are regulated by the State Licensing Authority (SLA) while the Central Licensing Authority or the CDSCO regulates the moderate high-risk Class C and high-risk Class D medical devices. Further, the CDSCO regulates the import and clinical investigation of all medical devices while the SLA regulates the sale of medical devices [23]. Further, the MoHFW had also launched the Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices in the country in July 2015[24]. The Government has recently notified all Medical Devices as drugs under the Drugs & Cosmetics Act, 1940 w.e.f. 1st April 2020 [25].

Further, vide Notification No. GSR 102(E) dated 11.02.2020, the registration of these devices has been kept voluntary for a period of 18 months w.e.f. 1st April 2020, post which the registration of Class A & B devices shall be mandatory within 12 months and registration of Class C & D devices shall be mandatory within 24 months, after 18 months of voluntary registration period is over, thereafter, all medical devices will need to be licensed under the Medical Devices Rules, 2017 as amended by Medical Devices (Amendment) Rules, 2020, *except 37 categories of medical devices*. Subsequent to the request of the Industries, CDSCO has notified that Licensing of Class A & B Medical Devices will be effective from 01.10.2022 and Licensing of Class C & D Medical Devices will be effective from 01.10.2023 .

A wide range of regulatory approvals necessitated by the variety of sciences and industry segments related to the medical devices sector creates high compliance and regulatory burden. The transition period in licensing by the CDSCO is an added challenge as manufacturers have to adjust to new processes over a predetermined timeframe.

The patient-centric approach to the development of the medical devices sector requires that effective and comprehensive regulations be applied for ensuring manufacture and sale of safe and quality medical devices. Within this overarching goal, regulatory streamlining is aimed at providing a transparent and predictable regulatory environment to promote ease of doing business and reduce compliance burden (both on cost and time-related dimensions) for manufacturers through the introduction of a single window clearance system, harmonization with global standards, and effective administration of price regulation mechanisms to achieve affordable healthcare for all.

The following interventions are proposed in order to address the above:

5.1.1 **Single Window Clearance System' for Licensing of Medical Devices**- Online System for Medical Devices', an online single window portal of CDSCO, for filing applications for medical device manufacturing license, import license and clinical investigation [34], shall integrate all the key stakeholders involved with the regulatory processes associated with the medical device ecosystem. Details are given at **Annexure-3**.

5.1.2 **Quality Compliance and Standardization: -** The policy envisions that the Indian standard setting bodies such as BIS shall gradually expand the standards in terms of processes, products, and performances to enhance the level of standardization, certification and quality and enable indigenous industry to gain global competitiveness with the following features:

5.1.2.1 Promote the adoption of Global Medical Devices Nomenclature (GMDN) or Universal Medical Device Nomenclature System (UMDNS)

5.1.2.2 Ensure compliance with requisite regulatory requirements in research phase to facilitate development of market-ready products from the design phase itself and ensure faster approvals. The standards setting organization shall guide researchers, innovators, entrepreneurs through research and design phases of product development and prepare them for the testing phases

5.1.2.3 Provide consideration to International Test Reports for product compliance without further testing requirements [42]

5.1.3 **Price Control and Uniform Code for Marketing**

To increase access to affordable healthcare, the prices of all medical devices in India are regulated by the Drug (Prices Control) Order (DPCO), 2013 which also requires all manufacturers and importers of Medical Devices to declare the MRP on the label [45]. The DPCO is administered and enforced by the National Pharmaceutical Pricing Authority (NPPA).

All medical devices have been brought under the price regulation framework of DPCO 2013 w.e.f. 01.04.2020, subsequent to their notification as drugs by MoHFW Notification dated 11.02.2020. Till date, ceiling price fixation and trade margin rationalization have

been applied to selected Medical devices. Further, the prices of medical devices cannot be increased by the manufacturer by more than 10% within a given 12-month period [47].

5.1.3.1 The policy aims to incorporate a framework for a coherent pricing regulation, to make available quality and effective medical devices to all citizens at affordable prices. The NPPA shall be strengthened with adequate manpower of suitable expertise to provide effective price regulation balancing patient and industry needs and incorporating innovation and life cycle costs as factors in pricing regulation of medical devices.

5.1.3.2 In order to ensure ethical marketing of medical devices, Department shall propose & work with industry to implement a Uniform Code for Medical Device Marketing Practices (UCMDMP).

5.2 Infrastructure Development, with the focus on Common Infrastructure Facilities and Testing Laboratories.

Presence of high-quality infrastructure is vital for the growth of the medical devices sector in the country. In India, the "Promotion of Medical Device Parks" scheme notified by DoP vide Gazette notification no. 31026/08/2020-MD, dated 21.07.2020 provides common testing and laboratory facilities at one place to reducing the manufacturing cost significantly and to create a robust ecosystem for medical device manufacturing [67]. To illustrate, India's first dedicated medical device park, the Andhra Pradesh Medtech Zone Ltd. (AMTZ) was set-up in 2016 in Vishakhapatnam by the Government of Andhra Pradesh with specialized laboratories, warehousing, and testing centers and housing more than 150 independent manufacturing units [68].

As per the Medical Device Rules (MDR) 2017, the CDSCO grants registration to designated Medical Device Testing Laboratories to carry out test or evaluation of the medical devices on behalf of manufacturers [72]. The MDR 2017 also provides for the establishment of Central Medical Device Testing Laboratories for testing and evaluation of medical devices and functioning as an appellate laboratory [73]. It is also mandated that all medical device testing laboratories need to be duly accredited by the National Accreditation Body for Testing and Calibration Laboratories (NABL).

5.2.1 The policy recommends setting-up of Medical Device parks with common infrastructure facilities and additional NABL accredited testing laboratories. Easy access to standard testing and infrastructure facilities through creation of world-class common facilities result in significant reduction of cost of production, introduction of manufacturing of high-end devices, increased competitiveness and better availability and affordability of medical devices in the domestic market.

5.2.2 The policy envisages to:

i. Facilitate the establishment of the medical device parks with common infrastructure facilities in proximity to economic zones with requisite logistics connectivity as envisioned under the National Industrial Corridor programme [70]and the proposed National Logistics Policy 2021[71].

ii. Support of State Governments in setting-up of medical device parks and strengthening existing medical device clusters in their respective states from their own resources. The State Governments may allot land, on priority basis, to such parks and extend incentives such as capital investment subsidy, stamp duty exemption, conversion charges to medical devices parks and the units set up in such parks, under their respective policy for the development of medical devices sector.

iii. Develop additional NABL accredited laboratories for medical device testing to ensure quality, safety and efficacy of the medical devices marketed in the country. Such facilities shall provide low cost testing facility for the industry, prevent duplicity of testing and reduce overall local product development costs. NIPERs would be encouraged to have Testing laboratories for specific medical devices. Further, additional testing laboratories will be created under PPP mode with Government setting-up the facilities which will be maintained and managed by professional agencies and recurring expenses will be borne by the industry.

iv. Support for setting up of Common Infrastructure centers which would include Common Testing Labs & Tool room, Enterprise Software & shared Hardware, Shared service like Legal, Accounting, Technology, Patents, Investment Banking and entrepreneurship development cells.

5.3 Facilitating R&D and Innovation

Medical Device sector is highly innovation and technology intensive. Globally, countries have created dedicated fund to promote R&D and innovation in medical devices, for instance, the Government of Japan founded the Japan Agency for Medical Research and Development (AMED) and provided a budget of US$ 133 mn (or JPY 14.6 bn) to carry out multiple projects for the development of advanced medical devices [74].

Over the years, measures taken by the government, such as PLI schemes, medical device parks 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. Many start-ups and SMEs such as InnAccel, EzeRx, Tricog Health, Pandorum Technologies among others, are working towards leveraging new-age technology for designing, developing and testing medical devices that solve priority healthcare problems.

The policy envisages to promote innovation and Research and Development (R&D) by focusing on creating a dedicated fund, enhancing industry-academia linkages, promotion of innovation hubs, centers of excellence and intellectual property protection.

5.3.1 Funding Innovation and R&D: The Policy proposes to allot a dedicated fund for encouraging joint research involving existing industry players, reputed academic institutions and SMEs/Start-ups. The proposed fund shall:

i. Extend grants to support research and development activities targeted at leveraging state-of-the-art technology for domestic manufacturing of medical equipment and enhancing the quality of healthcare delivery to result in better clinical outcomes

ii. Be available to support consortiums comprising established industry players, reputed academic institutions and/or SMEs/Start-ups to undertake joint R&D projects with pre-defined agreements around intellectual property related issues

5.3.2 **Promoting Industry-Academia Linkages & Innovation Hubs:** The proximity of the academic institutions with the industrial clusters provides an enabling environment for industry-academia collaboration and promote R&D and innovation.

5.3.2.1 The Policy strongly recommends the Government to designate **Centers of Excellence (CoE)** in premier academic and research institutions that are granted government accreditation to serve the objectives of building world-class institutions and attract global faculties focusing on key themes of relevance for India on medical

technology innovation and R&D. The CoEs would support product development and validation having existing requisite facilities and expertise to support

i. Product development: design and prototyping
ii. Validation and certification of the medical use of devices
iii. Adopt, implement, and advocate policies on efficacy and safety testing b. The CoEs may be linked with Central Health Universities and shall focus on emerging technologies, such as Artificial Intelligence (AI), Internet of Things (IoT), Robotics, Nanotechnology, Telemedicine and Advanced Analytics for Aided Diagnosis, etc[75].

5.3.2.2 The Policy envisages to undertake purposeful investment in few priority institutes to build CoEs focusing on medical technology innovation and R&D that

i. Drive focused research and active global collaboration on key themes of relevance for India in medical technology;
ii. Drive continuous focus on strengthening the capabilities (through collaboration with foreign professors, adjunct faculty from industry) and upgrading infrastructure;
iii. Get significantly high levels of funding with per capita funding close to western university levels;
iv. Play a leadership role in outreach program to bring smaller institutes under their wing.

5.3.2.3 The Policy further promotes setting-up of innovation hubs housing a network of academic institutions, start-ups, clinical settings, funding agencies, etc. to create a health technology ecosystem within the innovation hubs by providing 'plug and play' infrastructure. To achieve this, the Government shall

i. Encourage indigenous industries to set-up innovation hubs
ii. Scale up existing hubs to maturity ensuring co-location of academia, public R&D centres, industry, start-ups, incubators, etc.
iii. Ensure requisite financial and regulatory support to the enterprises
iv. Establish at least one world-class Accelerator/Incubator by inviting global accelerators and incubators to set up their programs in different States

v. The educational institutes shall also partner with industry and allow industry experts to teach courses as envisioned by the National Education Policy 2020.

5.3.3 **Intellectual Property**

India has enacted strong Intellectual Property (IP) laws that conform to World Trade Organization (WTO) norms. Recently, the Patent (Amendment) Rules 2020 have further streamlined the patent filing process[81]. The shortest time taken to grant a patent recently has been just 67 days from the filing of the request for examination.

As on 31st December 2019, 1,454 of the 1,700 expedited applications received had already been examined and 671 patents granted. Globally it is observed that universities and research institutions have been given ownership of the intellectual property (IP) stemming from discoveries made in part from federally funded scientific research, e.g., the Bayh-Dole Act 1980 in the USA and the Germany's Inventor's Law. Such incentives have led to an increase in academic patenting and start-ups resulting from academic tech transfer.

5.3.3.1 The policy aims to strengthen IP rights by closely working with DPIIT in the field of medical devices to promote increased investment and attention to domestic transfer and innovation in the sector.

5.4 Fiscal and Non-fiscal measures to attract Investments in the Sector

The measures taken by Government to infuse the required financial support to the Industry is given at Annexure. Further, the Indian medical device sector received an investment of US$ 432 Mn from 43 venture capital (VC)/ private equity (PE)/ Angel Funding deals between 2010 to 2015[64]. Further, the Foreign Direct Investment (FDI) witnessed strong inflows in the sector after the Government permitted upto 100% FDI under automated route for manufacturing medical devices in January 2015. Over the last five years (2015-2020), India received US$ 600 million with key investments from countries such as Singapore, United States, Europe and Japan [65].

5.4.1 The policy envisages to introduce additional measures in order to promote indigenous manufacturing of medical devices, promote an ecosystem for manufacturing, and build competitiveness as outlined under:

5.4.2 Encouraging Private Investments and External Resources Funding:

The Policy envisages to encourage private investments in medical device sector by creating an ecosystem for risk-based financing through active outreach engagement such as inviting VCs for screening of start-ups to incubate.

5.4.3 **Promoting Start-ups and Entrepreneurship**

The Government of India has taken up several measures to support the vision of making India a hub for biotechnology-based innovation and research. Biotechnology Industry Research Assistance Council (BIRAC) under the Department of Biotechnology has supported 500 start-ups and entrepreneurs which generated about 155 Intellectual Property (IP) Rights, supported 30 Bio-incubators across India and around 100 products/technologies developed.

5.4.3.1 The National Medical Devices Policy 2022 envisages to engage, leverage, and systematically build upon the initiatives of Startup India initiated by DPIIT to actively participate in supporting startups in the medical devices sector.

5.5 **Human Resource Development**

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. Availability of skilled manpower remains a challenge in the development of the medical device sector in India.

As per a survey by AMTZ, approximately half of the workforce in medical device sector is unskilled [82], indicating the necessity for developing skills to enhance productivity levels. There are less than 20 courses related to biotechnology engineering across the country [83]. The National Institute of Pharmaceutical Education and Research (NIPER) has instituted skill development trainings programs for pharmacy and science students for different role in medical device sector and conducts regular skill development training programs under Skill Vigyan Program [84]. There is limited sector-related training provided in the sector.

Universities in advanced countries are working with industry partners to improve education and training in the medical device sector. *For instance, Australian universities have worked with industry partners and the Medical Technology Association of Australia (MTAA) to design a program for PhD graduates, which aims to focus their transition into the MedTech industry*

towards areas with significant unmet market and clinical needs[85]. Further, vocational training is being encouraged by providing free training. *For instance, states in Germany provide free training services to companies as a non-cash incentive that improves the quality of the local labour force[86].*

5.5.1 The policy envisages to set up National Institutes of MedTech (Medical Devices Education and Research (NIMERs), on the lines of NIPERs, as Institutes of National Importance (INIs).

5.5.2 The policy further envisages to formulate a National Registry for priority which correlates to skills required in production of specific technologies as may be identified. The National Registry will maintain a data bank having the details related to latest technology being used in medical device sector and the skill required to do the production with that specific technology.

5.5.3 The policy strongly advocates for the financing of such skills through hands-on trainings, internships/training in specialized industrial locations by all departments and ministries as par with Junior Research Fellow (JRF) stipends made available by UGC to Universities. The financing of stipends is recommended to be made to industry associations, industrial hubs, manufacturing zones and incubation centres.

5.6 Awareness and Brand positioning

A large part of India's population remains less informed about the latest advancements in medical electronics. There is a need for strengthening the channels of stakeholder engagement where the world of academia, clinical hospitals, industry, funding institutions (PE/VC funds, central banking organization) and the Government can converge and collaborate to unlock India's capacity in medical devices science and innovation.

It is observed that advanced economies proactively build strong external stakeholder relationships with Health Professional Organizations, Consumer Groups, Trade Associations, Patient Advocacy Organizations, Think Tanks and other stakeholders and conduct large scale events and conference to support the innovation in the medical devices.

5.6.1 The policy aims to enhance and improve stakeholder engagement in order to

a. Promote awareness on medical devices safety, standards and ensure proactive communication and outreach on the value proposition with public through regular sessions and outreach workshops in both online and offline mode[91]
b. Conduct webinars, workshops, and round-table conferences to learn from successful medical device investment countries and adopt models by other nations that have achieved success in attracting investments for their medical technology industries[92]
c. Promote more forums to bring together ecosystem players and stakeholders for sharing knowledge and best practices and build strong networks across the sector[93]
d. Promote and encourage industry to participate in various national and international events and by leading a joint delegation of Government and industry to exhibitions and conferences
e. Organize an annual national event focused on showcasing and promoting medical devices in the country
f. Conduct promotional events and roadshows abroad for the promotion of the Indian medical device sector
g. Conduct regular feedback sessions to collect grievances and suggestions for further improvisation

5.6.2 **Promotion of Made in India for the World**: The policy envisages initiating movements such as “Innovate in India”, “Skill in India”, and “Heal in India” which will fuel the ecosystem in order to produce a critical mass on the demand side that will promote local manufacturing [96]

6 Monitoring and Evaluation

6.1 The proposed interventions and incentives can help catalyse innovation and accelerate growth of the Indian MedTech industry. The policy also recognizes the pivotal importance of Sustainable Development Goals (SDGs) and the goals outlined in the National Health Policy, 2017.

6.2 Following Output / Outcome metrics are being defined across major building blocks to measure the success of the implemented interventions and incentives proposed by the National Medical Devices Policy 2022. The following table captures proposed Output / outcome metrics along with the proposed targets for FY 2025.

Proposed Performance Metrics

Metrics	Existing (FY 21)	Target (FY 25)
Market Size	US$ 11 billion	US$ 50 billion

6.3 These interventions will help deliver both 'Qualitative' and 'Quantitative' impact for the country

6.4 **Quantitative output/Outcome Indicators:**

i. **Exports and Forex inflow**: Total exports by the industry in FY21 were US$ 2.5 Bn.
ii. **Increase in Global market share**: Achieving these goals will mean Indian medical devices industry can improve its global market share and will position India as the true "Diagnostic Capital of the World"

6.5 **Qualitative Output / Outcome Indicators:**

i. **Equity in Access**: Ensure all healthcare system beneficiaries have equal access to medical devices across all categories.
ii. **Affordability**: Facilitate affordable use of medical equipment across the public and private healthcare system while sustaining participation of credible manufacturers.
iii. **Adequate quality and safety**: Ensure necessary safeguards for adherence to requisite quality standards and maintain requisite precautions while using medical equipment.
iv. **Self-sustainability or 'Aatmanirbharta'**: Promote development of indigenous manufacturing ecosystem for medical device sector, with sustained investments in requisite hard and soft infrastructure to reduce dependence on imports for medical devices[98].
v. **Improvement of overall healthcare index and reduced disease burden for India and other emerging economies:** The Indian medical device industry can support Government's vision of providing universal healthcare by providing access to quality medicines and medical devices at affordable prices. As more and more patients come under treatment, this could help reduce the disease burden in the country substantially. Thrust on innovation will help increase the DALY (Disability Adjusted Life Years) in India and other emerging markets comparable to that of developed economies such as the US and UK by 2030.
vi. **Creation of high-end jobs in R&D and Innovation:** Setup of dedicated innovation hubs and a broader innovation ecosystem will enable creation of more high-end jobs with in-demand skillsets across the innovation value chain (e.g., scientists, regulators, health experts).

vii. **Opportunity to attract back Indian talent with expertise in R&D and Innovation:** A strong innovation ecosystem will help to attract back high-quality talent from across the world, further catalysing R&D and innovation in the country.

viii. **Contribution to Sustainable Development Goals (SDGs):** The interventions contribute directly to progressing towards the completion of SDG 3 (Good Health and Well-Being), particularly 3.8.1. (Coverage of essential health services), and indirectly to SDG1 (No Poverty), SDG5 (Gender Equality), SDG8 (Decent Work and Economic Growth), SDG 9 (Industrial innovation and infrastructure), SDG10 (Reduced Inequalities), and SDG11 (Sustainable Cities and Communities) by 2030.

7. Policy Validity

The Department of Pharmaceuticals with the approval of competent authority, may review and amend various aspects of this Policy from time to time, depending upon the experience gained during implementation, market dynamics, feedback from stakeholders, etc. The National Medical Device Policy 2022 shall be valid for a period of 10 years [99] following which the policy shall be revised.

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Annexure-1

Government Initiatives for the Medical Devices Sector

The Government of India has recognized medical devices as a sunrise sector under the 'Make in India' campaign in 2014. Subsequent Union Budgets have announced several measures to encourage manufacturing [14], streamline regulatory approvals [15], and announced attractive fiscal incentives [16]. To further promote the medical devices sector in the country with a focus on indigenization and reducing share of imports, the Government has implemented following key incentives and schemes: :

A. Scheme for Promotion of Medical Device Parks:

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

Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre" has been revised and renamed as ***"Promotion of Medical Device Parks***" which has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities/centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is ₹ 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to ₹ 100 crore. Under the Scheme, the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

A total number of 16 States submitted their proposals under the scheme. The Government has in-principally approved financial assistance for common infrastructure facilities for 4 medical

device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh, with the scheme being implemented by a State Implementing Agency. The States of Himachal Pradesh, Tamil Nadu, Uttar Pradesh and Madhya Pradesh have submitted their Detailed Project Reports (DPR). Final Approvals have been given to the States of TN, UP and MP and the DPR proposal of Himachal Pradesh, is under evaluation for final approval.

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

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

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

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

In total, 42 applications were received in two rounds of application window spread across the four target segments of the Scheme. Out of which, 21 applications have been approved with a

total Committed Investment of Rs. 1,059.33 Crore. The setting up of these plans will make the country self-reliant to a large extent in the specified target segments in the Medical Devices Sector.

C. Production Linked Incentive (PLI) scheme for Pharmaceuticals:

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

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

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

1. **Standing Forum of Medical Devices Associations**

A Standing Forum of medical device Industry associations has been set up on 25th August 2021 by the Department of Pharmaceuticals to provide a platform for discussion on various challenges

being faced by the sector and arrive at well-rounded views The Department has constituted a Standing Forum of various Medical Device associations which deliberate on various issues with all the stakeholders including regulators and then the forum comes up with workable solutions after the consensus is built between various associations.

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

2. **Interactions with the Industry and the Regulators**

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

3. **Regulatory Roundtable during Annual Flagship event of the DoP**

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

E. Besides the above**,** DPIIT on 07.12.2018 has setup a **National Medical Device Promotion Council (NMDPC)** and DoP actively participates in the council meetings to redress the issues of the medical devices sector, in coordinating with other departments.

F. **Public Procurement (Preference to Make in India) Order, 2017:** The Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry issued the Order and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP issued its guidelines in May 2018 prescribing that domestically sourced components must contribute to 25-50 per cent of the cost of medical devices to qualify for public tenders, which would be subsequently increased in a phased manner to 25-75% over a period of time [27]. Also, Department vide Order dated 16.02.2021 & 25.03.2021 has notified 135 in-vitro diagnostic medical devices and 19 medical devices where there is sufficient local capacity and local competition available in the country, under Para 3(a) of PPO Order dated 16.09.2020 to enable procurement of the notified items only from the "Class-I local suppliers" The exercise is being resorted on regular basis, to update the details of Indian Manufacturers of Medical Devices with the the Central Procurement Agencies.

G. In order to attract investments in this sector, the Government has allowed **100% foreign direct investments (FDI) in medical devices sector** with estimated inflows of around USD 2.17 billion from April 2000 to December 2020[12].

Annexure-2

Detailed Focus Areas under National Medical Devices Policy, 2022:

Convergence of Pharma & MedTech

- Framework for converging devices with drugs can help develop new products and enable companies deliver innovative and sustainable solutions. Will bring access to **better funding and sharing of resources**

R&D

- D**isease-focused research** to emerge with innovative technologies in MedTech for both India locally and for the world
- **Increase share** of MedTech companies **in R&D to ~50%**
- **Development of Research Funds** to support research discovery, increase support of academia professionals
- **Improve** the number of **medical devices patents per capita** in the world & enable **digitally advanced healthcare system with rapid R&D**
- Provisioning of **state government initiatives**, **VC, in-direct funding** support, & establishment of Cooperative Research Centres (**CRCs)**

Investing in Technologies

- Create environment with **cross-fertilization of disciplines** to lead to MedTech innovation
- Implementation of **1000 Ideas Programme & other supplementary initiatives per year** to allow **~25* futuristic technologies** to be **homegrown in India** & India as the **originator of technologies** such as **Robotics, 4D, Organ Bioprinting, Laser Physics,** etc.
- **Profiling of top 3* technologies** used globally for Medical Devices manufacturing for development
- Implementation of **Artificial Intelligence (AI)** in conjunction **with equipment manufacturing**
- **Startup Bridges & Launchpads** across **leading countries** to **bring resources**, **exchange knowledge**, and **explore expansion opportunities**

Product development

- Focus on **Personalized Diagnostics** through health data usage, generation, and capture
- Accelerating product development using technologies such as **in silico development capability** utilization
- Government **facilitation in technology transfers (ToT) with simplified steps**
- **Government partnership with innovative companies** to fuel growth in the next 25 years

Human Capital: Inter-disciplinary approach

- Combine expertise in Medical Imaging with the talent pool available in **software and IT**
- **Convergence of Biologists & Engineers** to align the requirements of the Medical Technology industry
- Achieve continued backward integration through **industry-academia** collaborations
- **Infrastructural** & **mentoring support** to institutions, medical college, and startups for actionable research
- **Cluster development** to identify and address opportunities and unmet needs
- Creation of an **ecosystem to attract incubators & entrepreneurs** in Pharmaceuticals & Medical Devices to transform startups to scale-ups

Affordability: Patient Centric Ecosystem

- Build a **positive perception & acceptability** of domestic products on the tenets of **quality, accessibility, & affordability**
- Achieve a **balance between the patients concern for affordability and industry's concern** for adequate returns on investment for growth and sustainability
- Adoption of **Public Private Partnerships (PPP)** to reduce the cost of healthcare, drive efficiency, and quality improvements

Sustainability

- Promoting **Good and Green Manufacturing Practices**, **cutting GHG emissions** through renewable energy to align with **Hon'ble PMs vision of "Panchamrita" to fight climate change**

- Facilitate and effectively **implement environmentally sound management of biomedical & e-waste**, saving reusable medical devices from the incinerator
- Achieving efficient **quality-driven**, **continuous** & **non-touch manufacturing**

Funding: Innovation

- Increase **spending by Government** to enhance opportunities in Pharmaceuticals & Medical Devices centric **research projects**
- Funding **high-risk projects** by relevant government departments, **look beyond import substitution**
- Requirement of **long-term & large investments** in **pure research** in Medical Devices by the government & the private sector in partnership & collaboration
- Need for **fiscal support and investment for the development of critical components** required for Medical Equipment manufacturing

Enabling Ecosystem

- **Enabling pricing environment with no price control on newly developed innovation** in India to encourage research & innovation
- Incentivize **core technology projects** and exports through **tax refunds and rebates**
- Investment **support** and **incentivizing private sector** for innovation and digital transformation
- Strengthen the **backward integration** in Medical Devices to **achieve global competitiveness**
- Creation of **central hub of pool of vendors & workers**
- **Dedicated mechanism** for **engagements** with **International Regulatory Agencies and Sectoral Councils/ Associations** (Priority Countries)
- **Digitized system** for facilitation of approvals & process optimization

Global Value Chains

- **Reduction of operational & supply chain burden** for new MedTech manufacturers

- Identifying **critical suppliers, de-risking & decarbonizing** the supply chain, and **promoting local sourcing**
- **Cross-industry collaboration** groups of **transporters, shippers, airlines, etc.**
- **Growing and expanding in newer geographies** beyond US, such as, China, Japan, Latin America

Annexure-3

Highlights of the features of Single Window System for licensing

a. Online submission of applications with upload facility of all supporting documents.
b. Digital checklists and information wizards to guide on the forms to be filled, supporting documents to be submitted and process to be followed, to reduce subsequent clarifications that may be required.
c. Artificial Intelligence (AI) backed dossier review and deficiency identification using natural language processing (NLP) and automated document management workflows to enhance efficiency and reduce human errors.
d. Scheduling of inspections as may be required with prior intimation and recording of inspection findings and sharing of the same with the applicant.
e. Virtual meeting platforms hosted on the digital interface for purposes of addressing queries/clarifications on the process for application, issues/grievances associated with the application process.
f. Real-time dashboards for live tracking of application status (by applicant as well as timeliness of action by concerned Government departments), including receipt of digital certificates post completion of processing of application.
g. Publish the summary of approvals with inputs from relevant authorities & departments.

Annexure-4

Data on Medical Devices Sector

- Medical devices industry in India has the potential to reach $50 bn by 2025. Around 65% of the manufacturers in India are domestic players operating in the consumables segment and catering to local consumption with limited exports. MNCs lead the high technology end of the Medical Devices market with extensive service networks. There are 750–800 domestic Medical Devices manufacturers in India, with an average investment of $2.3–2.7 mn and an average turnover of $6.2-6.9 mn. There are six Medical devices manufacturing clusters – Gujarat / Maharashtra / Karnataka / Haryana / Andhra Pradesh & Telangana / Tamil Nadu.
- The global medical devices sector has grown significantly in the last decade and is estimated to reach USD 433 billion by 2025, growing at a compound annual growth rate of 4.1% from 2020 to 2025[6]. The market is dominated by United States of America (40% share), European market (25% share) and Japan (15% share) etc. Furthermore, the medical devices industry is also growing in the emerging markets. For e.g., Thailand's medical device market valued at USD 27 billion in 2019 is expected to grow by 8-10%[7], Brazil's current medical device market is worth approximately USD10.5 billion & is growing at a CAGR of 5.8%[8], and China's medical device sector currently valued at USD 96 billion is growing at a pace of more than 20% for several years[9].
- The per capita spend on medical devices in India is very low at USD 3, compared to global average of per capita consumption of USD 47 as well as the per capita consumption of developed nations like USA at USD 415 and Germany at US$ 313[11].
- It is observed that both exports as well as imports of medical devices in FY 2019-20 increased over previous FY levels, with exports growing at 7.2% to reach USD 2.29 billion while the imports grew at 2.5% to reach USD 5.85 billion. The top five export destinations for India included the USA, China, Germany, Singapore and France which contributed to around 40% of the total exports in FY 2019-20; while the imports from the top five sources (USA, Germany, China, Singapore and Netherlands) stood at 60% [13].
- The domestic players, who constitute around 65% of the medical device manufacturers in India, focus on low-cost low-technology devices such as consumables and disposables catering to local consumption with limited exports. There are 750–800 domestic medical device manufacturers in India, with an average investment of USD 2.3–2.7 million and an average turnover of USD 6.2-6.9 million. The medical device sector in the country has the potential to grow at a cumulative annual growth rate of 35.4% and reach USD 50 billion by 2025 and become a global hub of medical devices production.

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[94] As per representation & suggestions received from industry stakeholders

[95]https://www.investindia.gov.in/siru/india-pharmacy-world

[96]As per representation & suggestions received from Department of Pharmaceuticals

[97]https://pharmaceuticals.gov.in/business-allocation

[98] In FY 20, pharma and med-tech imports amount to ~US$ 10 Bn, of which medical devices account for ~52%

[99] Industry representation