

National Medical Device Policy-2017

1. Preamble and Background:

1.1 Government of India has laid emphasis on provision of good quality, affordable and comprehensive healthcare to all its citizens. These values have been enshrined in the National Health Policy (NHP) 2017. In line with this goal, National Health Mission has augmented services which includes free preventive and promotive health mechanisms leading to eradication of diseases such a polio from the face of a nation as big as India; free emergency transport leading of establishment of a network of over 20000 ambulances; free diagnostics; free drugs; free secondary level care, National Dialysis Program, launch of National Health Assurance Program, among other such initiatives directly and positively impacting the demand. Additional to this is a growing Private Health Sector with estimated 19,000 hospitals set to boost medical tourism apart from catering to millions of Indian patients. While Healthcare Human Resources and Pharmaceuticals have remained core areas in which country has achieved self-sufficiency, Medical Devices has remained a sector where focused action is much required.

1.2 Medical Device Industry (MDI) is a multi-product industry responsible for provisioning of wide variety of crucial medical products from simple tongue depressors & glucometer strips to large radiology & electronic modules. Global market for medical devices is over US\$ 220 billion and its trade in India has grown steadily as well. MDI in India is relatively small compared to rest of the manufacturing sector, however an educated guess would place the **Retail Sales** at **over** Indian Rupees **60,000** Crore (US \$ **10** billion) estimate, growing steadily at a rate of 17% CGAR. While domestic manufacturing is concentrated around low cost devices such as Intra-ocular lenses; catheters and syringes; there has been a steady growth in production of implants. Some growth spikes have also been achieved in manufacturing of radiology products by domestic industry while Department of Electronics, Govt. of India itself taking the lead in making of India's first Linear Accelerator- one of the most complicated medical device to be manufactured globally. Most hi-tech products and innovations require well developed eco-system and innovation life cycle support. Medical device industry relies on several complementary industries such as Microelectronics, optics, instrumentation, telecommunication, Nanotechnology, biotechnology and software development. Within MDI, the broad product

classifications that exist are: i) Disposables & Consumables; ii) Hospital Furniture & Surgical Instruments; iii) Electrical & Electronics; iv) Radiology including Magnetic Field and Nuclear Medicine based equipment; v) Implants; vi) Diagnostic Reagents; and vii) Medical Software. Additionally, there is also a Medical Equipment Maintenance service sector which rests on spare parts supply, component manufacturing and life cycle management for equipment **and the biomedical waste disposal and management sector**. Limiting factors on categories (iii) & (iv) form the bulk of concerns with respect to MDI in India.

1.3 MDI in India, although fragmented into Small & Medium Scale Enterprises (MSMEs), there exist well established trade channels for import of high end medical equipment well participated by domestic medical devices traders and manufactures. In the core manufacturing segment, as per DIPP-Dept. of Pharmaceuticals- WHO Country Office for India- AMTZ joint report of 2017, it is estimated that there are about 800 manufactures in the country with average turnover of Rs.45-50 Crore and average export turnover of Rs.17-18 Crore. MDI therefore, is a prime segment that aims to benefit from the mission **'Make in India'**.

1.4 While MDI in India faces a classical set of challenges, primary among them being absence of - robust regulatory framework for medical devices, avenues for pooling and bridging of adequate fresh talent into the sector, pathways for uptake of innovations in supply chain; subsidies and incentives appropriate to the levels of providing a bolus to the industry, rapid pathways for commencement of med tech parks as manufacturing clusters and a single window for progressive follow up of policy measures. Steps have been taken on some of these, such as- Medical Devices Rules 2017 under Drugs & Cosmetics Act; classification of occupational standards under Health Sector Skill Council; incentives for export promotion by Department of Commerce and Government's decision to have more IITs for speeding research. Some of the areas however are still unattended to, and require more concentrated and comprehensive approach. While many of these steps have been comprehensive efforts from Ministry of Health & Family Welfare; Ministry of Human Resource Development; Ministry of Commerce; Dept. of Pharmaceuticals, a need for central information pooling and coordination mechanism has been felt by the Government.

1.5 Recognizing this policy requirement, Government constituted a Task Force under the Chairpersonship of Secretary, Department of Pharmaceuticals (DoP) to address issues relating to promotion of medical devices sector. The Task Force in its report released by Hon'ble Minister of Chemicals and Fertilizers on 8th of April 2015 elucidated a set of recommendations for promotion and progress of MDI in India.

2. Objectives

The National Medical Device Policy-2017 has the objective of contributing to the Make in India drive in medical device sector by (a) Providing measures for adequate facilitation for export promotion and appropriate correction to reduce import dependence (b) Taking specific and time bound steps for building Indian medical device sector into a critical mass; (c) Taking progressive steps for establishment of medical technology manufacturing zones and there linkages to industrial corridors; and (d) Providing a comprehensive direction to all departments within the Government and all stakeholders of the industry for harmonized growth of the sector;

3. Salient Features & recommendation of the policy:

(i) Coordinating & Facilitating Agency: The policy envisages setting up of an autonomous facilitation body “**National Medical Device Promotion Council (NMDPC)**” to be created under the Department of Pharmaceuticals;

Scope: The facilitation body shall have role to provide necessary facilitation and coordination, wherever required, to respective departments and ministries which deal with any aspect of medical devices. The recommendations of the facilitation body would be based on reviews, independent research on technology policy, submissions acquired from industry, suggestions from other departments & ministries and directions of the court of Law. The agency would be free to conduct meetings with industry stake holders to understand diverse issues and recommend to Department of Pharmaceuticals, the appropriate promotive and corrective action plan in the interest of the sector. ***The Department of Pharmaceuticals needs to be renamed as Department of Pharmaceuticals & Medical Devices and in future could be housed in a Ministry of Healthcare Products. The Medical Devices Promotion Council would need***

to be staffed with a mix of personnel from Bio Medical engineering, Product Development, Medical and Marketing backgrounds for enabling interdepartmental coordination and to provide needed expertise

The facilitation body shall:

- a. Provide a single window mechanism for the industry to submit issues relevant to the promotion of medical device industry in India with specific focus on domestic manufacturing
- b. Identify and recommend corrective actions for elimination of unnecessary and unjustified barriers to trade including technical barriers & operational requirements that retard manufacturing and trade
- c. Provide recommendations and facilitating domestic manufacturing industry in gaining access to foreign markets
- d. Undertake research & analysis of relevant data to inform Central & State governments, enforcement agencies as well as other stakeholders about concerns, any rapid action required, or long term strategies to minimize risk on medical devices industry

(ii) Infrastructure creation: The policy recommends creation of infrastructure including scientific & industrial capabilities to facilitate and promote medical devices sector and in particular, medical devices manufacturing in India. To support the program further, the policy recommends:

- a. Facilitating setting up of Medical Technology Industrial Parks by State Government/Central Government/Industry Clusters. Such activities would include but would not be limited to, facilitating approvals for identified projects; undertaking assessments and formulating reports for creation of future manufacturing parks/zones and support their creation in partnership with other departments and ministries;
- b. Facilitating setting up of medical devices testing laboratories that have already been approved/pending approval with various Departments and Ministries of the Government; undertake setting up of more testing laboratories under PPP mode as revenue generating self-sustaining business models while providing for low cost/subsidized testing facility for the industry;

- c. Enabling setting up of Common Incubation Centers (CICs) with appropriate incentive structure and cost sharing mechanisms and establishing technical and financial frameworks for their function

(iii) Quality Promotion: Given that quality of product has implications on their acceptability and applicability and therefore a direct bearing on their markets, the policy recommends:

- a. Facilitation and promotion of industry specific quality standards and benchmarks in consonance with national and international best practices.
- b. Support creation and/or adoption of medical device industry specific manufacturing standards, best practices, technology upgrades in manufacturing, skill building programs; knowledge sharing platforms, and other events for quality promotion of medical devices manufacturing sector;
- c. Promote general awareness on medical devices safety, standards and facilitate sharing of all such relevant information with public, medical professionals, and all other stake holders;
- d. Promote setting up of medical device testing laboratories for pre-market approvals and standardization
- e. Selection and designation of “Centers of Excellence” for product development, validation, and design improvement and improving their access to medical device industry and establishing technical and financial frameworks for such initiatives
- f. Promote regulatory standards, standards of Bureau of Indian Standards (BIS), any voluntary standards as adopted by the medical device industry in India

(iv) Stakeholder engagement: The policy takes consideration of the fact that sufficient and comprehensive stakeholder participation is critical to the progress of the sector and takes a note of the efforts being put forth by all departments & ministries within Govt. of India as well by stakeholders to promote medical devices industry. The policy therefore recommends:

- a. Promotion of knowledge networks with National and International Organizations, Industry Associations, Business Councils, Regulatory agencies & Trade Departments, and Quality Promotion & Standard setting bodies; to facilitate scientific cooperation,

coordination of activities, information exchange, exchange of expertise and implementation of joint projects.

b. Recommend appropriate policy measures to concerned departments & ministries and follow up on their progressive implementation

c. Identification of key barriers to quality promotion and facilitating penetration of quality promotion incentives available under various ministries/departments into medical devices manufacturing sector.

(v) Policy support: Generating adequate impetus to convert medical devices sector into a thriving eco-system remains an important objective to be achieved under the framework and architecture of Medical Device Promotion Policy. Towards fulfilment of this objective, the policy recommends:

a. Identification of existing policy frameworks (such as that of Ministry of Electronics & IT), making periodic recommendations, and issuing necessary notifications; after due deliberations with stakeholders on the subject of providing and facilitating support through 'Preference Market Access' in public procurement. ***Government being the biggest buyer can accelerate domestic manufacturing and can adapt the Preferential Purchase Policy of DIPP with additionally considering Preferential Pricing (as per World Bank Terms) for Indian Medical Device for Indian Public Healthcare Tenders and considering the need to encourage quality and safety provide weight age of 5% for ICMED Certification, 2% for ISO 13485 Certification and similarly 3% for Design India Certification for promoting indigenous development. The Public healthcare system needs to move from Lowest Price basis to Sustainable supply chain basis and penalize suppliers with a poor track record of service and delivery and reward those with proven services as well provide opportunity to new entrants and startups. Considering cash flow limitations ensure timely payments for at least 90% of the payment due by providing corpus with adequate funding in advance***

b. Promoting activities supporting technology transfers increase in market access and those supporting commercialization of innovations;

c. Studying international best practices and recommending evidence based industry promotion strategies including trade incentives such as interest subsidies, concessional

power tariffs, provision of seed capital and/or viability gap funding; to the various departments/ministries as well as to state governments.

d. Providing recommendation on trade promotion, such as tax liberalization measures including but not limited to – **higher** weighted tax deduction on approved expenditure on R & D to cater to high gestation period; extension of R&D tax benefits to Limited Liability Partnerships, duty structure correction to promote domestic manufacturing; duty structure correction on import of raw materials and manufacturing equipment for medical devices; tax and regulatory barriers on import of refurbished and used medical devices, wherever found necessary/applicable; incentivizing component manufacturing and export of medical devices; and formulating guidelines for mergers and acquisition in medical device sector to protect the interest of medical devices industry. ***India's 70-90% over dependence on Imports need to be managed by a planned predictable tariff policy to enable business viability and to make investment in this sector attractive and provide nominal protection in a phased manner. Basic Import Tariff to be at peak rate of duty viz. 10% for Medical Devices (whose Export is over 5 Crores) and Duty on Components to be 5% Next Year and 7.5% thereafter as a Make in India Enabler. Concessional Duty on medical grade Raw Materials may be retained at 2.5% for now, for Next 5 Years. The ITA's which limit Basic Duty to zero in many medical electronic analyzers need to be revisited or these product lines with nil protection need to be supported by Technical Barriers to Trade.***

(vi) Review Norms of FDI Policy: Government had introduced 100% auto approval route for FDI in medical devices for both green field and brown field unlike in Pharmaceutical industry. Studies may be done impact of this policy on investments made in creating manufacturing infrastructure and for diversion to support imports, trading and marketing and if objectives of improved availability of affordable medical devices in India has been achieved. The government may consider demanding all financials of manufacturing activities to be reported separately from trading activities. Review of policy may be done to drive investments into manufacturing rather than for financing import. Government may consider the need to Restrict Shareholding of MNC's and make this conditional e.g. FDI permitted for putting MFG units not for trading/warehousing; MNC 100% owned subsidiary should be permitted to trade only if manufacturing revenue not less than 60%; Restrict Max Shareholding to 40% if Indian subsidiary trading revenue will be over 40% to minimal 20% Shareholding for Indian Public/F.I's and not to consider 100% Auto Approval Routes for 100% FDI in Brown Field Take Over Projects without oversight and review by Department of Pharmaceuticals.

(vii) Intellectual Property & Skill building: Given that 21st century is the era of knowledge and knowledge generation and protection would be the critical to promotion of industry in specialized domains such as medical devices; the policy envisages:

a. Creating platforms with support of Department of Industrial Policy & Promotion and Indian Patent Office, for transfer/operationalization of Intellectual Property for facilitating voluntary technology uptake and up-gradations, through established commercial models

b. Enabling protective measures to protect outright purchase of patents from research institutions and start-ups based within India

c. Supporting Startups by allowing access to LLP's to government R&D funding schemes which currently limit this to only corporate bodies.

d. For assisting product development and to aid demonstration of Regulatory compliances, there is a need for capability development in testing of medical devices. The existing laboratories need to be up gradated and accredited and provide access to low cost access to testing and impediments for doing research on IVD and with tested blood samples need to be addressed. Laboratories in certain Universities with bio technology courses can be encouraged to provide antigens and antibodies and sero conversion panels to IVD industry which currently depends totally on imports.

e. Working with stakeholders such as National Skill Development Agency (NSDA) for promotion of occupational and vocations standards for training of engineering workforce for medical devices industry; undertaking operational research for identification of skill gaps and encouraging satellite training camps in manufacturing hubs in partnership with medical device industry associations as part of their CSR activities/other initiatives of various Ministries/Department such as that of Ministry of MSME.

d. Setting up of Medical Device Skill Development groups for advising the concerned authorities on roles, goals and operational plans for skill building strategies for medical devices sector. Such groups shall have representatives from and shall work in tandem with NSDA, Medical Device Industry Associations, Medical Devices research & teaching

institutions, Ministry of Human Resource Development, Ministry of Micro, Small & Medium Scale Enterprises, Ministry of Health & Family Welfare and other relevant stakeholders

4. Regulations to ensure Patient Safety & Consumer Protection: All major economies use Regulations not only for patient safety but also as Technical Barriers to Trade. China has a very restrictive import policy on medical devices with very opaque import regulations by CFDA and uses this as a Make in China driver to access Chinese market. India needs to similarly use regulations as a Make in India driver but instead of an opaque process use transparency and Ease of Doing Business (EODB) as a differentiator driver as a competing destination for investments. To ensure patient safety and build competence and competitiveness Government should incentivize voluntary QA certification by QCI and expedite legislation for Regulation of all Medical Devices outside the ambit of the Drugs & Cosmetics Act at one go with a defined transition period for enabling capacity building for the manufacturers and Regulatory Framework.

Regulations need to be provided for:

i) Definition of 'Manufacturer' in proposed legislation needs to disallow legalization of Pseudo Manufacturers and Traders to pass themselves off as Manufacturers and thereby misuse the Preferential Purchase Policy. The Government needs to unbundle regulations and create a regulatory framework consisting of a revamped and more competent Indian Healthcare Products Regulatory Authority with separate Divisions for Medical Devices or an independent National Regulatory Authority to regulate the registered manufacturing or subcontracting site in India or globally and the Market Access Authorization Holder (MAAH) whether it's a manufacturer, importer, agent or a marketing company with the assistance of 3rd Party Certification Bodies accredited by NABCB. The State regulators can regulate all the domestic resellers whether whole sale dealer or retailer or healthcare provider. This will encourage Make in India and Made in India.

ii) Voluntary Compliance backed by 3rd Party ICMED Certification from QCI to be considered as a compliance option / reduced oversight under EODB (Ease of Doing Business).

iii) Subsidize, financially support all manufacturers to attain ISO/ICMED13485 Certification and CE Mark.

iv) Enforcement for restricting Reuse of devices labeled as single use.

v) Rules for misleading advertisement and claims on Performance

vi) Rules for User and Healthcare Provider e.g. Provision of Bio Medical engineers in Hospitals to play corresponding role of Pharmacists in hospitals for good warehousing practices, maintenance and calibration of equipment.

vii) For ensuring Consumer Protection labeling of MRP (Max. Retail Price) needs to be enforced on Unit of Sale of all Medical Devices. Role of NPPA / DPCO may not be considered for Medical Devices other than case of devices already notified as Drugs. Alternate measures may be considered e.g. encouraging voluntary self regulated Price Cap or Trade Margin capping Mechanism related to a multiple of Ex-Factory / Import Landed Price in a Phased Manner or bring in a tax based disincentives like 1% Cess on GST on the MRP to act as Disincentive for putting Exorbitant MRP and to incentivize ethically correct Low MRP providers.

5. Conclusion: National Medical Device Policy-201y aims to achieve time bound growth of medical devices industry in India by supporting measures to promote manufacturing as part of ***Make in India***; fostering policy components in tune with ***Digital India & Skill India*** and enabling improved access to medical devices for general public and progressive trade for Medical Device sector with the objective of **“Sabka Saath Sabka Vikas”** meaning **“Collective Efforts Inclusive Growth”**.