BCIL

Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India

सत्यमेव जयते

MAKE IN INDIA

AiMED

Comprehensive Regulation of Medical Devices

Developing Roadmap for fostering India's Medtech Sector

Supported by:
Department of Pharmaceuticals (DoP)

Organized by:
Association of Indian Medical Device Industry (AiMeD)
and Biotech Consortium India Limited (BCIL)

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Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Date: 30th September, 2019

FOREWORD

I am delighted to write this foreword for the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India supported "Conference on Comprehensive Regulation of Medical Devices" being organized by Association of Indian Medical Device Industry (AiMeD) and Biotech Consortium India Limited (BCIL), New Delhi. The Medical device sector under the "Make in India" initiative of the Government has been recognized as the "Sunrise sector" with immense growth potential. Medical devices play a role not only in screening, diagnosing and treating patients but also in restoring patients to normal lives and in regularly monitoring health indicators to prevent diseases. With technological advancements, the role of medical devices is now expanding to improve quality of care across each stage of the healthcare continuum.

The Ministry of Health and Family Welfare, through CDSCO, Government of India has introduced the Medical Device Rules, 2017 ("2017 Rules"), effective in the country since January 1, 2018. The Medical devices are currently regulated under the Drugs and Cosmetics Act, 1940, with no separate legislation. In tune with the global practice, the 2017 Rules have introduced a risk-based classification system for regulation of medical devices. As of now, only 24 categories of notified medical devices are regulated under these rules. Other devices will come under the purview of regulations from time-to-time.

Department of Pharmaceuticals, through the National Pharmaceutical Pricing Authority (NPPA) has taken various measures to control prices of medical devices and implants for enabling affordable access to the consumers. NITI Aayog, Department of Pharmaceuticals, Ministry of Health and Family Welfare and other Ministries have taken some policy initiatives to strengthen this sector. Although many efforts have been taken, others need to be taken including voluntary compliance/ certification by Medical device industry to ensure patient safety, policies for supporting manufacturers to attain ISO/ICMED13485 compliance, policy for restricting Reuse of devices labeled as single use etc. for ensuring Patient Safety & Consumer Protection.

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I see that this Conference will provide a platform for deliberations among all key stakeholders from Government, Industry, Academia, & Indian medical device industry associations for deliberating on some of these challenges and suggest possible policy frameworks that could be carved and implemented for promoting indigenous Medtech sector in the country for the societal impact and patient benefit.

It is envisaged that this Conference will serve as a tool for promoting Medtech sector in the country. It will help in developing a Roadmap for fostering India's Medtech Sector by deliberating on key issues for comprehensive regulations of medical devices for ensuring patient safety and consumer protection and raise the "Brand India" for Medical devices to global pedestal.

I wish this Conference a huge success!!

(Dr. P.D. Vaghela)

ABBREVIATIONS

ACCCP	ASEAN Coordinating Committee on Consumer Protection
ACCSQ	ASEAN Consultative Committee on Standards and Quality
AECC	ASEAN Economic Community Council
AERB	Atomic Energy Regulatory Board
AIMED	Association of Indian Medical Device Industry
AMDD	ASEAN Medical Device Directive
AMTZ	Andhra Pradesh Medtech Zone
BCIL	Biotech Consortium India Limited
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
CAB	Conformity Assessment Body
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
CIC	Common Incubation Centers
CSSD	Central Sterilized Services Department
DBT	Department of Biotechnology
DIPP	Department of Industrial Policy and Promotion
DOP	Department of Pharmaceuticals
DOT	Department of Telecommunications
EEG	Electroencephalography
ENT	Ears Nose and Teeth
EODB	Ease Of Doing Business
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FSSAI	Food Safety and Standards Authority of India
GMP	Good Manufacturing Practices

GOI	Government of India
GST	Goods & Services Tax
HTA	Health Technology Assessment
IAPO	International Alliance of Patients' Organizations
IBSC	Indian Biomedical Skill Consortium
ICMED	Indian Certification of Medical Devices Scheme
IHPRA	Indian Healthcare Products Regulatory Authority
ISO	International Organization of Standardization
IVD	*In-vitro* Diagnostic Devices
MAAH	Market Access Authorization Holder
MDI	Medical Device Industry
MEITY	Ministry of Electronics and Information Technology
MHRA	Medicines and Healthcare products Regulatory Agency
MOEF	Ministry of Environment, Forest and Climate Change
MOHFW	Ministry of Health and Family Welfare
MSME	Ministry of Micro, Small and Medium Enterprises
NABCB	National Accreditation Board for Certification Bodies
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NABL	National Accreditation Board for Testing and Calibration Laboratories
NITI	National Institution for Transforming India
NMDA	National Medical Device Authority
NMDPC	National Medical Devices Promotion Council
NPPA	National Pharmaceutical Pricing Authority
PPP	Public Private Partnership
QCI	Quality Council of India
USD	United Stated Dollars
WHO	World Health Organization

ACKNOWLEDGEMENTS

Association of Indian Medical Device Industry (AiMed) and Biotech Consortium India Limited (BCIL) would like to thank the following stakeholders for their support and contribution to the Conference on Developing Roadmap for fostering India's Medtech Sector, Comprehensive Regulation of Medical Devices:

- Ministry of Health and Family Welfare (MoHFW)
- Ministry of Chemical and Fertilizers (MoC&F)
- Indian Council of Medical Research (ICMR)
- Department of Pharmaceuticals (DoP)
- National Institution for Transforming India (NITI Aayog)
- Central Drug Standard Control Organization (CDSCO)
- Department of Biotechnology (DBT)
- National Pharmaceutical Pricing Authority (NPPA)
- Department of Electronics and Information Technology (DeITY)
- Kalam Institute of Health Technology (KIHT)

The following contributors are acknowledged:

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Overall Guidance:

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Agenda of the Conference

Developing Roadmap for fostering India's Medtech Sector

Conference on Comprehensive Regulation of Medical Devices

Organized by Department of Pharmaceuticals in association with Association of Indian Medical Device Industry (AiMeD) and Biotech Consortium India Limited (BCIL)

Date: October 5, 2019

Venue: India Habitat Center (Silver Oak Hall)

Agenda

Opening Session		
Welcome Address	**About the Conference and its Objectives** Dr. Purnima Sharma, MD, BCIL	9:30 AM
Opening Remarks	**Need for Comprehensive Regulation of Medical Devices:** Mr. Rajiv Nath Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)	9:40 AM
Special Remarks	Dr. P. D. Vaghela, Secretary, Department of Pharmaceuticals (DoP)	09:50 AM
Key Note Address	Dr. Mandeep Bhandari, Jt. Secretary, Ministry of Health (MoH)	10:00 AM
Special Remarks	Dr. Vinod Paul, Member, Niti Aayog	10:10 AM
Inaugural Address	Hon'ble Chief Guest Dr. Harsh Vardhan, Minister of Health and Family Welfare, Government of India	10:20 AM
Vote of Thanks	Mr. Gurmit Chugh, Managing Director, Translumina & Jt. Coordinator, Implants, AiMeD	10.30 AM

Tea/Coffee Break		10:40 AM
Technical session –1	**Comprehensive Regulation of Medical Devices-** ***Where we are and Way forward***	
Presentation 1 AiMeD Representative	Medical Device Regulations: Key Challenges faced by Indian Medical device manufacturers Mr. Vivek Mangalwedhkar, Managing Director, S H Pitkar & Jt. Coordinator, (HWG – Regulations)	11:00-11:10 AM
Presentation 2 CDSCO Representative	Medical Device Rules 2017- Where we are and its Outstanding Issues Dr. V G Somani, DCGI, CDSCO	11:10-11:30 AM
Panel Discussions	Opportunities and Challenges for Patient Safety and Incentivizing Quality Assurance Standards **Moderator** Ms. Rama Venugopal, Jt. Coordinator, South – AiMeD **Panelists** **1.** Mr. Prakash Bachani, Head, MHD, BIS **2.** Mr. Vivek Mangalwedhkar, Managing Director, S H Pitkar & Jt. Coordinator, (HWG – Regulations) **3.** Prof. Bejon Misra, Founder, Patient Safety and Access Initiative of India Foundation **4.** Ms. Sashi Rekha, Ex-Director, NABCB – QCI **5.** Dr. Ravi Kant Sharma, DDC (I) **6.** Dr. Sandeep Singh, Professor of Cardiology, AIIMS **7.** Dr. Jitendar Sharma, Medical Technologist	11:30-12:30 PM
Interactive session- Question and Answers		12:30-12:50 PM
Summing-up and Recommendations – Dr. Suchita Markan, AGM, BCIL		12:50-01:00 PM
Lunch Break		01:00- 02:00 PM

Technical session – 2	**Defining Strategy Consumer Protection & Affordable Access via Price Control and Ethical Marketing**	
Presentation 1 AiMeD Representative	Excessive MRP: Stifling India's Medical Device growth Story Mr. Rajiv Nath, Forum Coordinator, AiMeD	02:00- 02:15 PM
Presentation 2	Government Initiatives for Affordable access of Medical devices**:** Shri Alok Kumar, NITI Aayog	02:15- 02:30 PM
Panel Discussions	Achieving Affordability and Access to Quality Medical devices through Price Control and Ethical Marketing **Moderator:** Mr. Gurmit Chugh, Managing Director, Translumina **Panelists** 1. Dr. Y K Gupta, Ex Dean, AIIMS & Principal Advisor THSTI-DBT 2. Mr. Rajeev Chhabra, Managing Director, Orthocare & Jt. Coordinator, Ortho, AiMeD 3. Mr. Pardeep Sareen, CGM- Marketing, Hindustan Syringes & Medical Devices Ltd., AiMeD 4. Ms. Malini Aisola Health researcher, co-convener of All India Drug Action Network (AIDAN) 5. Dr. K K Aggarwal, President, HCFI 6. Smt. Ritu Dhillon, Member Secretary, NPPA	02:30- 03:30 PM
Interactive session- Question and Answers		03:30- 04:30 PM

Valedictory Session		
	Welcome Address by Mr. Rajiv Nath, Forum Coordinator, AiMeD **Summary of Key Recommendations from the Conference** by Dr. Suchita Markan, AGM, BCIL **Address** by Smt. Ritu Dhillon, Member Secretary, NPPA **Address by** Dr. Mandeep Bhandari, Jt. Secretary, Ministry of Health (MoH) **Address by** Prof. Balram Bhargava, Secretary, Department of Health Research and Director General, Indian Council of Medical Research (ICMR) **Valedictory Address** by Sh. Mansukh Mandaviya, Hon'ble Minister of State, Ministry of Shipping and Ministry of Chemicals & Fertilizers	04:30- 05:10 PM
Vote of Thanks and Closing Remarks – Mr. Rajiv Chibber, Vice President, Sahajanand		05:10 PM

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Introduction

Introduction

The Indian medical device sector, included under Make-in-India initiative of the Government of India, has huge market potential and is witnessing a double-digit growth rate. The medical device and equipment market in India is estimated at over US$15 billion currently, experiencing an annual growth rate of 15% and has the potential to be a US$50 billion industry by 2025, as per Industry estimates. India being an emerging market is also evolving as a potential manufacturing hub for the key global medical device players and some medical device companies such as Philips, GE Medical systems, Start-up Bio-Ved (San Francisco), and so on, have set up their hubs in India.

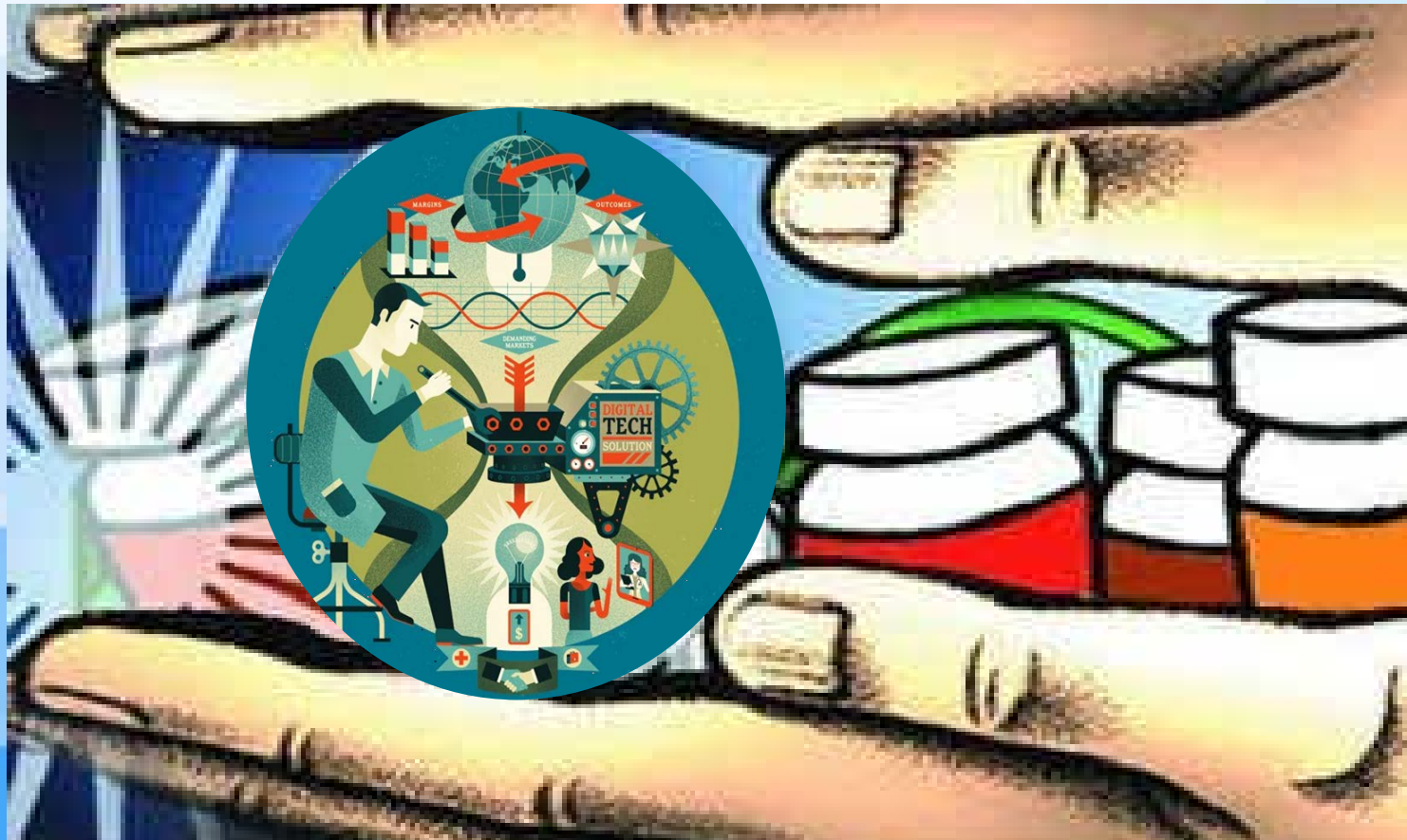
India is till date dependent on imports for its medical device needs with more than 80% of medical devices being imported from USA, Singapore, Japan, etc. Several initiatives have been taken by the Government through various schemes for promoting innovations and development of indigenous affordable medical devices. There are a range of Medical Device Clusters that have emerged due to supportive state-level policies as well as the availability of skilled labor. Andhra Pradesh Medtech Zone (AMTZ) has been set-up in Visakhapatnam as an exclusive Medical Devices Park for supporting indigenous manufacturing in the country. There are a few other Medical Device parks planned to be set-up across India. The Centre Government released the Medical Device Rules, 2017 and ensured its operationalization, from January 1, 2018. The new set of regulatory practices aims to prepare India to meet its Medical devices needs. These new rules shall thus enhance ease of doing business and ensure availability of quality medical devices across the country. Also, for the very first time, periodic renewal of licenses will not be required. Consequently, manufacturing and import licenses will be valid until it is suspended or cancelled. The new rules also aim to promote a culture of self-compliance by manufacturers of medical devices.

However, these falls short of a promise to have a separate ministry for pharmaceuticals and medical devices and provides regulation for only 24 categories of medical devices notified by the Government. Further, imports involve a lot of rebranding, re-labeling and condemned pre-owned equipment finds their way into the country. Although first step has been taken by the Government by introducing Medical Devices Rules in the country, however, a lot needs to be done to provide comprehensive regulation of Medical Devices.

It is estimated that there are about 800 – 1000 medical device manufactures in the country with average turnover of US$ 5 million and average export turnover of US$ 1.5 million. The sector faces many challenges including ensuring product quality, regulatory compliance, price control, multiple regulators, archaic laws, duty structure etc. Need has been felt for integrated efforts to promote this sector to tap the emerging medical device market in India and provide access to safe, effective and quality medical device to the patients.

The booklet covers policy documents and the proposed road-map for enabling comprehensive regulation of Medical Devices including patient safety and consumer protection laws. Frequently asked questions on the Medical Devices Rules 2017, drafted by the CDSCO, GoI have also been included in the booklet for references by the medical device industry and other stakeholders.

Policy Documents for Enabling Comprehensive Regulation of Medical Devices



Policy Documents for Enabling Comprehensive Regulation of Medical Devices

A. Building Manufacturing Capabilities for Medical Devices in India- Blue Print & Policy Roadmap

1. Preamble and Background

Governments of most developing countries have laid emphasis on provision of good quality, affordable and comprehensive healthcare to all its citizens. While Healthcare Infrastructure and Human Resources are areas in which most countries have achieved self-sufficiency, Medical Device sector has usually remained a laggard where focused action is very much required.

Medical Device Industry (MDI) is a multi-product diversified engineering industry ranging from simple tongue depressors and glucometer strips to large radiology & electronic modules. Global market for medical devices is over US$ 220 billion. In India it is relatively small compared to rest of the manufacturing sector; guesstimates would place the Retail Sales at over US $ 15.00 billion (Rs. 105,000 Cr.), growing steadily at a rate of over 15-17% CAGR. Within MDI, the broad product classifications that exist are: i) Disposables & Consumables; ii) Surgical Instruments & Implants; iii) Equipment & Electronics & iv) Diagnostic Reagents. Domestic manufacturing is concentrated around low cost devices such as intra-ocular lenses, catheters and syringes; as well as production of implants. Some growth spikes have also been achieved in manufacturing of radiology and ultrasound products, Cath labs and linear accelerator.

It is estimated that there are about 800 -1000 manufactures in the country with average turnover of US$ 5 million & average export turnover of $ 1.5 million. Imports in the country crossed Rs. 38800 Cr.in year 2018-19(Figure 1) and exports crossed 1.8 Billion $ (Rs. 12700 Cr.*).* Market Share of imported medical devices is estimated to be about 80% and 90% for Medical Electronics.

Indian Medical Devices Industry is highly import dependent. India is a big market for majorly five (5) countries, including USA, Germany, China, Singapore and Netherland

(Figure 2). The major share of medical device import in the country is from USA while, Germany stands second in terms of highest quantum of import of medical devices.

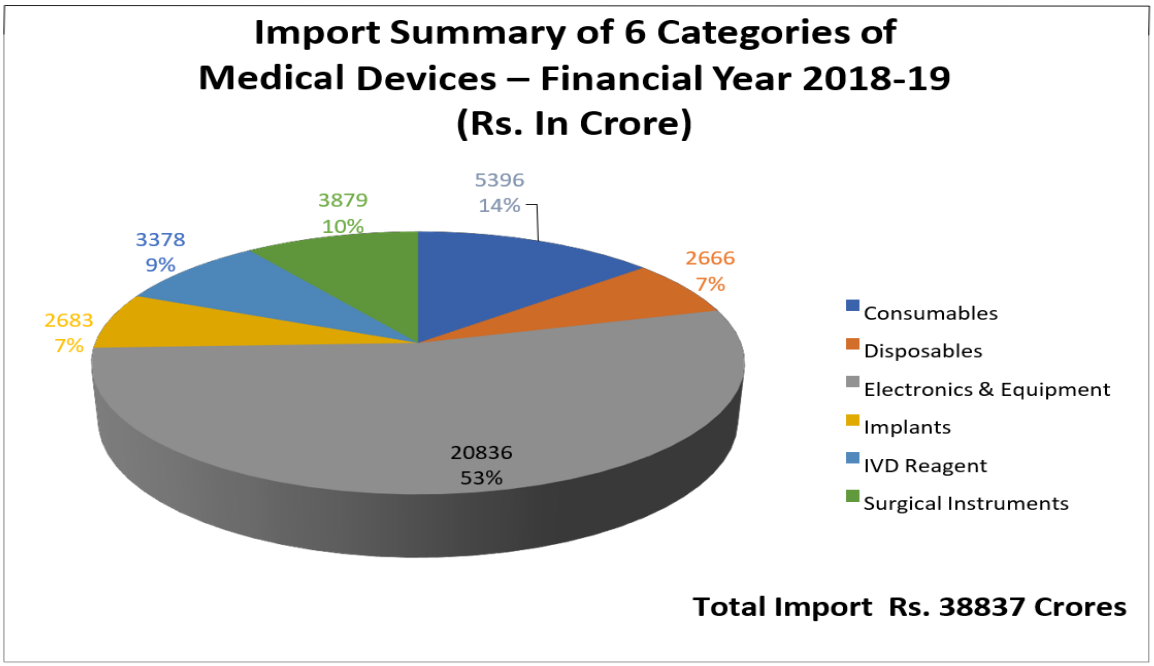


Figure 1: Import of 6 categories of Medical devices in India

There are majorly six (6) categories of medical devices which are imported in India such as Surgical Instruments, IVD Reagent, Implants, Electronics Equipment, Disposables and Consumables. Electronics equipment share a large section of imports from all the five countries as depicted in Figure 3.

Between FY12 to FY16, the import of medical devices in India has increased by 16.8 per cent, whereas export increased by 25.7 per cent. Amongst the exporters' portfolio, USA was the chief destination for exports and contributes close to 15 per cent of the export trade. Singapore, Germany and China were other leading export destinations with shares of 7.0 per cent, 6.7 per cent and 6.4 per cent respectively. The European Union (including Germany) cumulatively constitutes 21.7% of the total export trade from India. USA, Germany, China, Japan, and Singapore constitute the five largest exporters of high technology medical equipment to India. Figure 4 highlights the exponential increase in the export of medical devices from India.

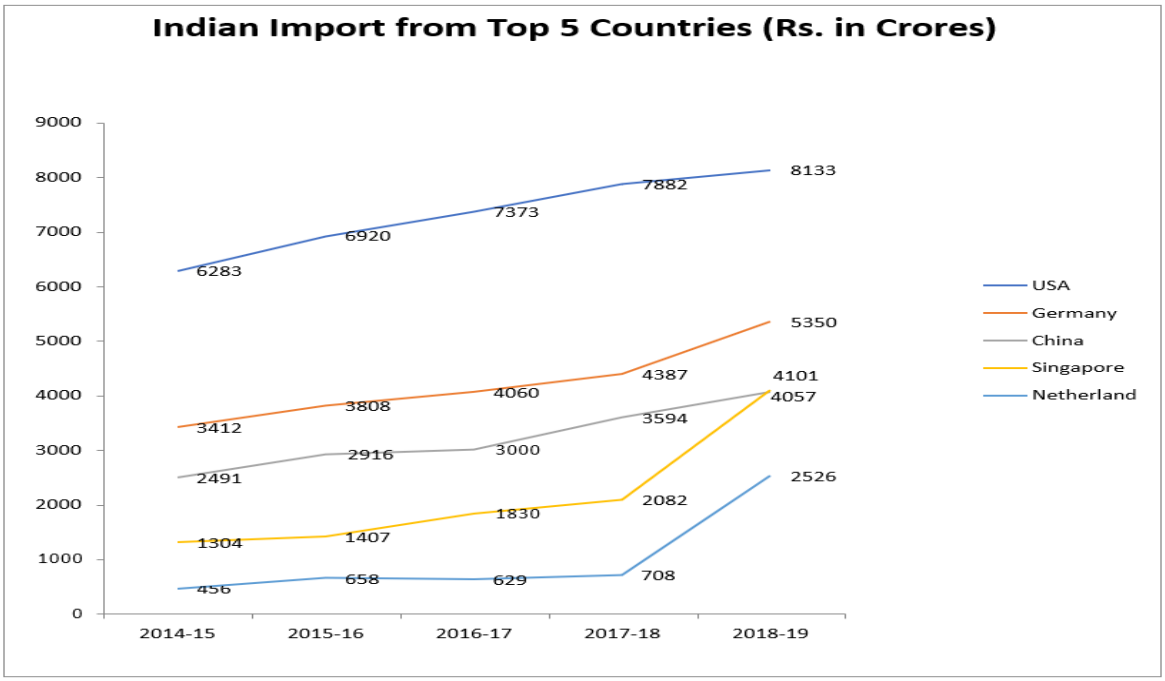


Figure 2: Year-wise status of imports in India for medical devices from top 5 countries

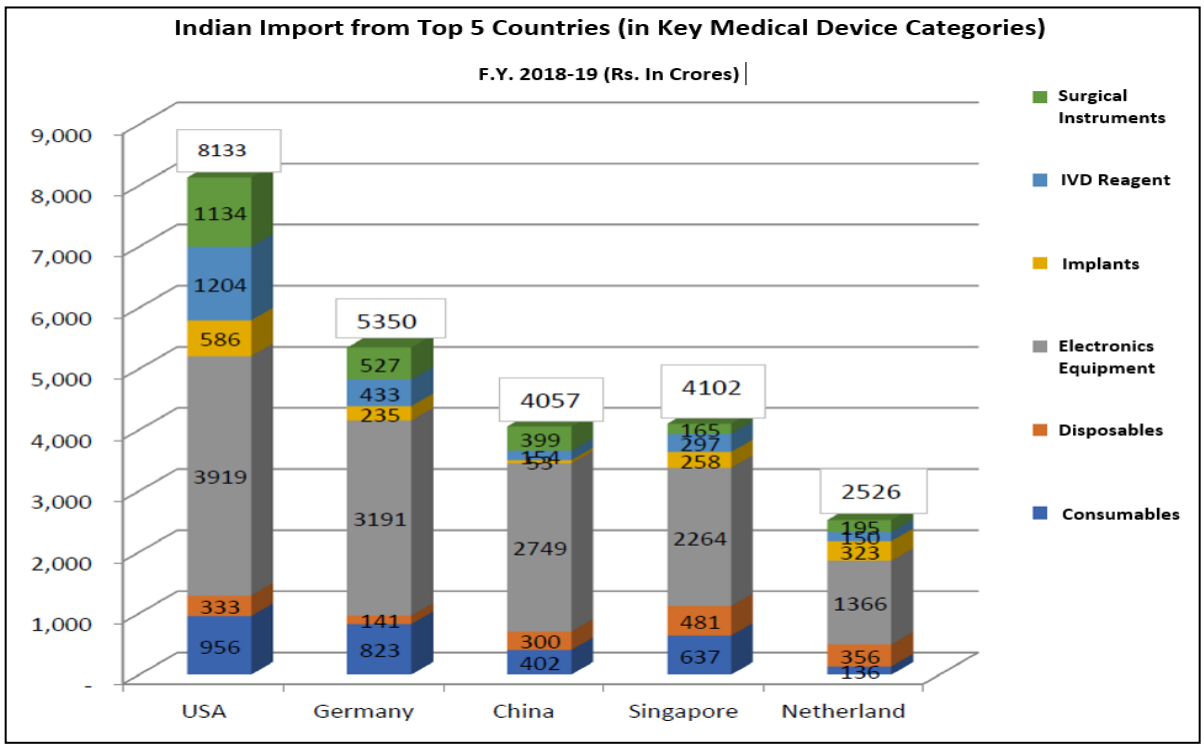


Figure 3: Country-wise status of imports in India for six (6) medical device categories

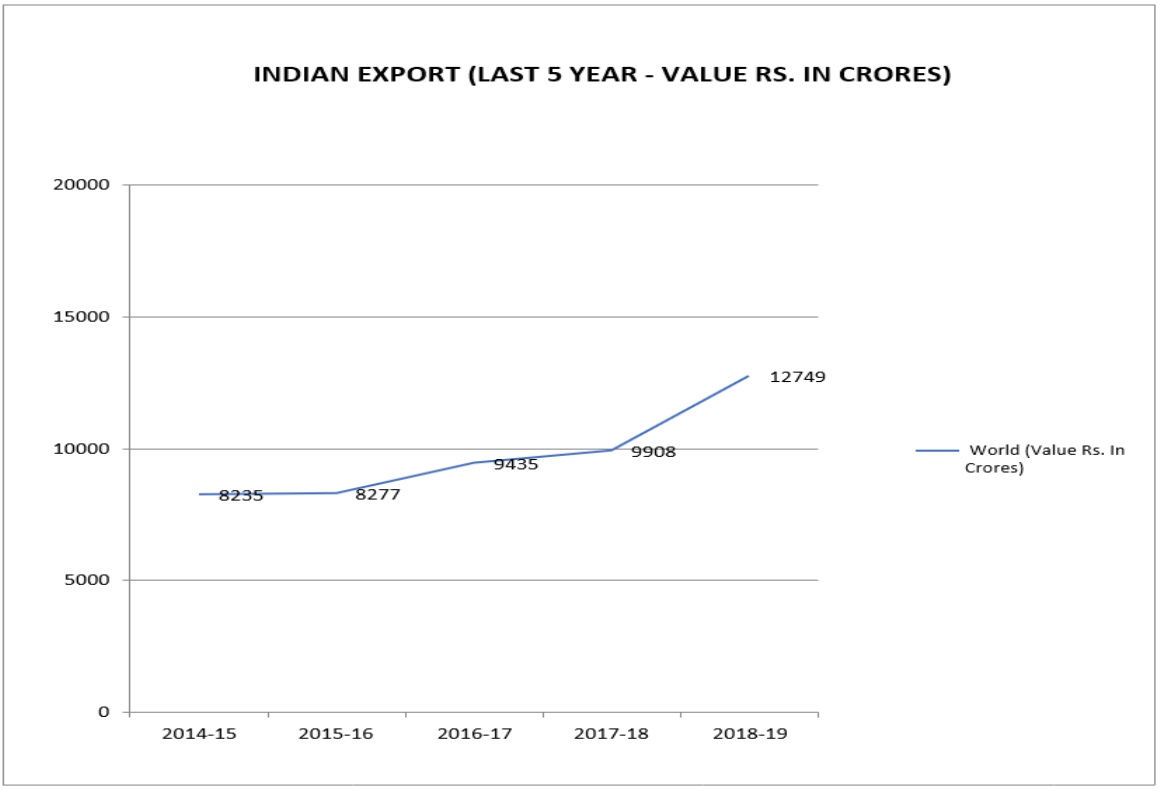


Figure 4: Year-wise status of export of medical devices from India.

Diagnostic imaging medical device export trade has grown by 27.2 per cent from USD 210 million (Rs.1,365 crore) in FY12 to USD 267 million (Rs.1,736 crore) in FY16. Medical Consumables export trade has grown by 26.1 per cent from USD 228 million (Rs.1,482 crore) in FY12 to USD 288 million (Rs.1,872 crore) in FY16. *In-vitro* Diagnostic devices export trade has grown by 58.7 per cent from USD 24 million (Rs.156 crore) in FY12 to USD 39 million (Rs.254 crore) in FY16. In the current scenario i.e. in the year 2018-19 the export is further increasing. This exponential increase in export of medical devices may be because of the limitation in the enabling policies in India for medical devices manufacturing and trading within the country. The medical devices of India with stringent safety and quality profile have acceptability in USA, the highly regulated market. Moreover, there is an increase in the exports in recent past, which shows credibility of devices exported from India.

While MDI in India faces a classical set of challenges, primary among them being lack of motivation to manufacture medical devices with non-viable margins due to ease of low cost imports (including pre-owned equipment) coupled with absence of robust regulatory

framework for medical devices, avenues for pooling and bridging of adequate fresh talent into the sector, lack of pathways for uptake of innovations in supply chain; lack of subsidies and incentives appropriate to the levels of providing a bonus to the industry. Steps have been taken to address some of these, such as - Medical Devices Rules 2017; classification of occupational standards under Health Sector Skill Council; Competency mapping of biomedical engineers under IBSC (Indian Biomedical Skill Consortium) incentives for export promotion by Department of Commerce; Preferential Procurement Order guidelines for procurement by public healthcare under GOI, initiation of AMTZ medical devices park in Andhra Pradesh and another one by Telangana; establishment of Kalam Institute of Healthcare Technology to accelerate indigenously developed technologies 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 Science and Technology, Department of Biotechnology & BIRAC, Ministry of Commerce & Industry and Quality Council of India; Department of Pharmaceuticals, Niti Aayog and Ministry of Electronics, however, a need for central information pooling and coordination mechanism has been felt by the Government and the Industry.

2. Salient Features &Recommendations

To deliberate on some of the challenges faced by the Industry, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India (GoI) constituted Task Force. The task force elucidated a set of recommendations for boosting growth of MDI in India in its report on 8th of April 2015. The key recommendations which come out from this meeting are given below:

2.1. Coordinating & Facilitating Agency:

The policy envisages setting up of an autonomous facilitation body **"National Medical Device Promotion Council"** to be created under the Department of Pharmaceuticals to provide necessary facilitation and coordination, to various departments and ministries. Additionally, Industry recommended that the Department of Pharmaceuticals needs to be renamed as Department of Pharmaceuticals and Medical Devices and in future could be housed in a new Ministry of Healthcare Products. The NMDPC would need to be

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

Note: *In Dec 2018 at the 4th WHO Global conference for medical devices at Vishakapatnam, the Commerce & Industry Minister Shri Suresh Prabhu announced the establishment of the NMDPC under DIPP (Dept. of Industrial Policy & Promotion).*

2.2. Infrastructure creation:

The policy recommends setting-up of Medical Technology Industrial Parks and medical devices testing laboratories under PPP mode as revenue generating self-sustaining business models while providing for low cost/subsidized testing facility for the industry and setting up of Common Incubation Centers (CICs) with appropriate incentive structure and cost sharing mechanisms and establishing technical and financial frameworks for their function. The industry recommends development of common technology clusters, sharing common manufacturing facilities, ancillaries, common testing facilities and a CAPEX sharing model with a revenue supporting stream.

2.3. Intellectual Property & Skill building

The policy envisages:

a. With support of 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. For assisting product development and to aid demonstration of Regulatory compliances, there is a need for developing capability in testing of medical devices. The existing laboratories need to be upgraded and accredited. Assure low cost 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;

d. 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.

2.4. Quality Promotion

Given that quality of product has implications on their acceptability and applicability and therefore a direct bearing on their markets, its recommended to have policies for:

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, knowledge sharing platforms, and other events for quality promotion of medical devices manufacturing sector;
c. Creating 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. 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.

Note: *On March 15, 2016 Quality Council of India launched Indian Certification for Medical Devices, a voluntary QA certification scheme along with AiMed (Association of Indian Medical Devices Industry) to help Indian manufacturers establish their credentials with the medical profession.*

3. Policy support sought by industry

3.1. Government being the biggest buyer can accelerate domestic manufacturing with a Preferential Purchase Policy with Preferential Pricing (as per World Bank Terms) for Indian Medical Devices for Public Healthcare Tenders and consider the need to encourage quality and safety provide weight age for ICMED (Indian QA Certification for medical devices) and ISO 13485 QMS Certification and similarly for Design India Certification for promoting indigenous development. The Public healthcare system needs to move from Lowest Price basis to UN system of 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.

3.2. Promoting activities supporting technology transfers, increase in market access and those supporting commercialization of innovations.

3.3. Application of international best practices in evidence-based industry promotion strategies including manufacturing incentives such as interest subsidies, concessional power tariffs, provision of seed capital and/or viability gap funding.

3.4. Providing 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; tax and regulatory barriers on import of pre-owned medical devices, wherever found necessary/applicable; incentivizing export of medical devices; and formulating guidelines for mergers and acquisition in medical device sector to protect the interest of medical devices industry.

3.5. 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 needs to be increased from 0-7.5% to 15% for Medical Devices and duty on components to be 7.5% as a Make in India enabler. Concessional duty on medical grade Raw Materials may be retained at 2.5% for now, for next few years.

3.6. Supportive Clinical environment is also desired by the Industry. Policy to encourage government hospitals & medical colleges that would partner with domestic

manufacturers in clinical evaluation as per regulatory requirements and HTA (Health technology assessment) studies with reasonable charges and publication of studies of clinical outcomes.

3.7. Restrictions on import of preowned medical equipment until India has a robust regulatory framework to ensure patient safety and calibration.

4. 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 to assess 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 maximum 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.

5. Regulations to ensure Patient Safety & Consumer Protection:

Industry seeks a Policy to ensure patient safety and build competence and competitiveness is needed whereby Government should incentivize voluntary Indian Certification for Medical Devices by QCI (Quality Council of India) 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 potential misuse the Preferential Purchase Policy. The Government needs to unbundle regulations and create a regulatory frame work 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.

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. Policy needed to financially support all manufacturers to attain ISO/ICMED13485 Certification and CE Mark.

iv. Policy needed to restrict reuse of devices labeled as single use. Rules are also needed for Reprocessing of medical devices.

v. Rules for misleading advertisement and claims on Performance; 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.

vi. Rules for User and Healthcare Provider.

vii. To protect consumers and ensure ethical marketing policies are sought that discourage unethical practices to induce hospitals and retailers to push brands to patients on basis of high trade margins and will create a disincentive to label medical devices with exorbitant Retail prices which will also help boost domestic ethical manufacturing.

Figure 5: Enabling medical device policies in Make-in-India Ecosystem.

Conclusion: A National Medical Device Policy framework needs to achieve time bound growth of medical devices industry by supporting measures to promote manufacturing as part of *Make in India* and enabling improved affordable access to medical devices for general public with the objective of **"Sabka Saath Sabka Vikas**" meaning **"Collective Efforts Inclusive Growth"**.

B. Need for Comprehensive Regulation of Medical Devices

The medical devices and diagnostics in India are regulated by Central Drugs Standards Control Organization (CDSCO), under the Ministry of Health and Family Welfare (MoHFW), Government of India. To regulate the medical devices in the country, medical Devices Rules were announced by the Government in the year 2017. Only 24 Devices (Figure 6) are being regulated MoHFW through CDSCO & SDC's under Drugs & Cosmetics Act of which only one Medical Electronics Product is regulated viz. cochlear implants. Intervention of MoHFW is required to regulate all Implants and a few Medical Electronics Equipment. The key challenges provisions introduced by the Government through the Medical Devices Rules 2017are represented in Figure 7.

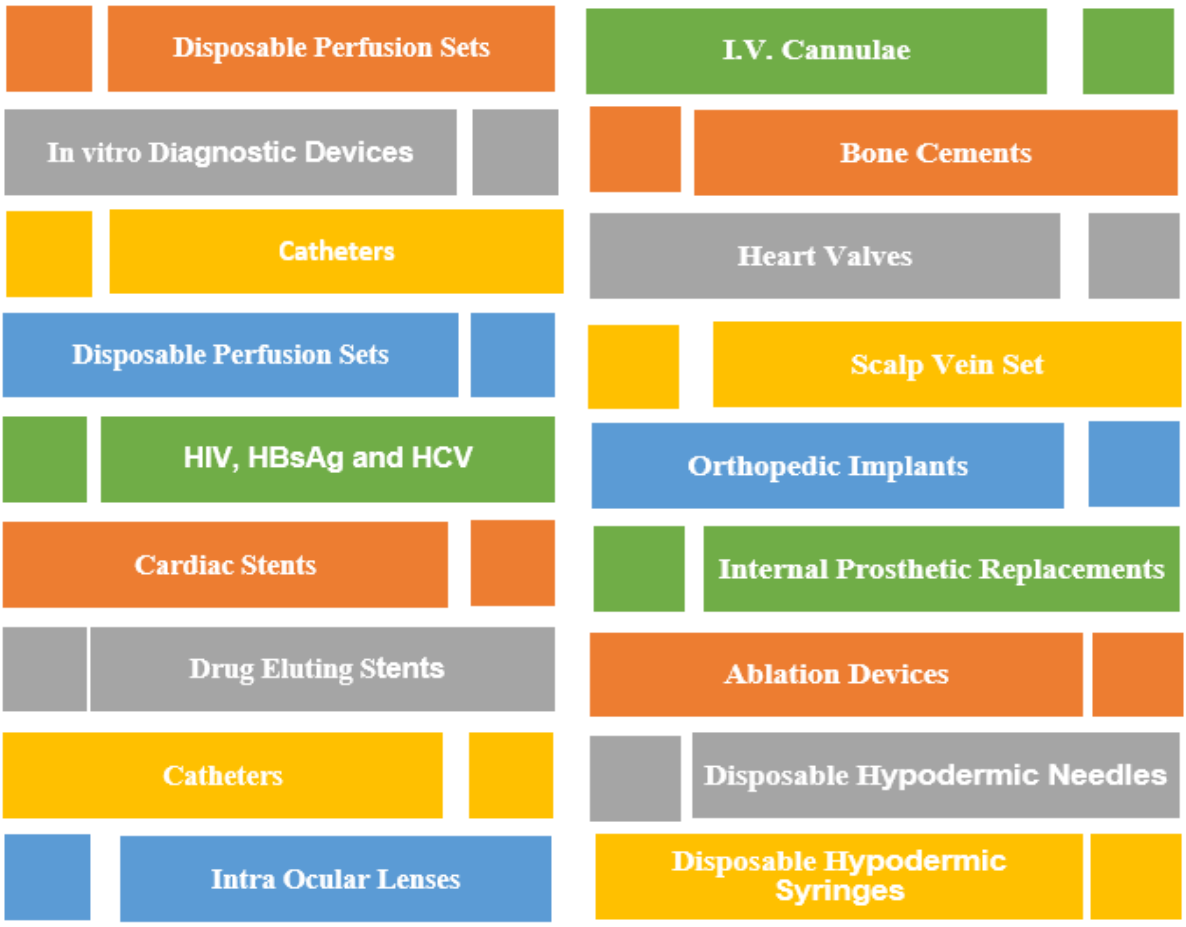


Figure 6: Categories of medical devices regulated in India

The Medical Devices Rules have introduced risk-based clarification of medical devices, as per global standards. Considering the huge import dependency and need for indigenous manufacturing for catering to the local needs, the medical devices industry proposed area strategies to cater to the unmet needs of the country.

Considering the wide diversity of Medical Devices as Engineering & Consumer Goods it is imperative to encourage existing Manufacturers of Engineering Goods to diversify into Medical Devices with similar technology base e.g. Hospital Beds by Furniture Producers, Under Pads and Clinical Diapers by Baby Diaper Producers, Television Manufacturers to make Bedside Display Monitors etc. It is imperative to have a separate Law Book in addition to the separate Rule Book (other than Pharmaceutical based D&C Act). The Group of Ministers had rightly decided not to go for a separate Chapter as an amendment of the existing D&C Act and sought a separate Regulatory Framework for Medical Devices. The steps taken in the past to regulate Medical Devices as Pharmaceuticals has made India increasingly Import Dependent and a decreasing desire of investment in Manufacturing is evident. The small industries may not afford to hire a Pharmacist or even a Professionally Qualified Regulatory Expert. Do we need an MNC / Large Industry dependent Supply Chain Environment by creating an entry Barrier for the Small and medium-sized Enterprises SME?

Figure 7: Key Changes of the new Medical Devices Rules 2017

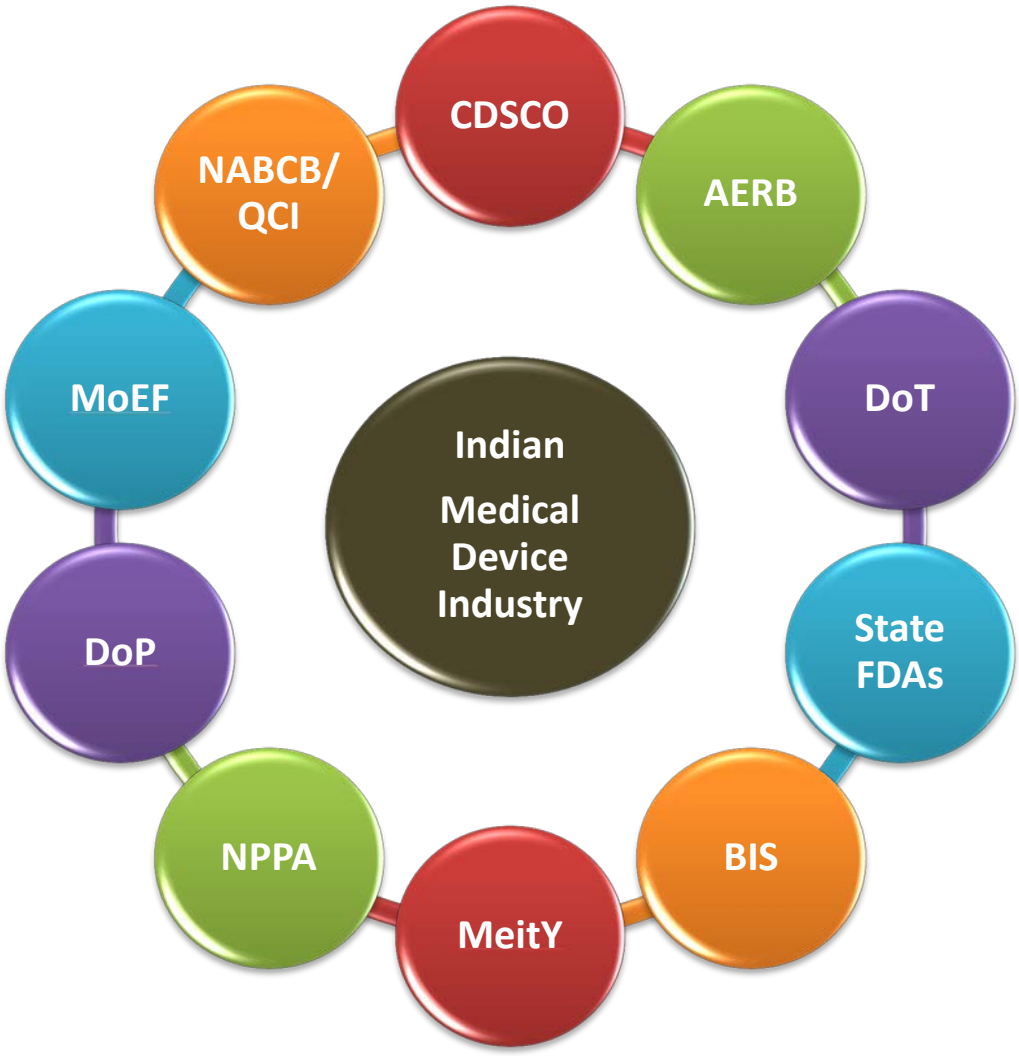


Figure 8: Multiple authorities involved in the approval process of regulatory pathway.

World over Regulations are used strategically as a Non-Tariff Barrier to protect Domestic Industry, in addition to protecting the interest of the Consumers & Patients. Additionally, Countries follow a 'Standards' strategy to give competitive advantage to domestic Manufacturers. India announced its excellently planned National Strategy for Standardization on 18th June 2018 and we need to implement this in Medical Devices.

Multiple ministries and or Government departments are involved in addressing various factors of compliance or regulation by the industry, which makes the procedure cumbersome for the indigenous manufacturers (Figure 8).

Regulatory Framework for Medical Devices proposed by the Medical Devices Industry

There should be a separate Law Book – separate Rule Book and separate Regulatory Authority (or a revamped CDSCO) as an Indian Healthcare Products Regulatory Authority (IHPRA) on the lines of FSSAI with a Chairman and CEO as also by UK's MHRA.

In traditional mode of regulations worldwide earlier, Government was the Regulator and prescribed requirements for manufacturing and directly checked Compliance through Inspectors and directly punished errant manufacturers thereby creating conflict of interest and breeding ground for corruption. As regulators worldwide are getting increasingly stretched for resources and the required technical expertise the various components of a Regulatory Framework are getting unbundled and India needs to imbibe similar Best Practices and bring in regulatory reforms.

Regulations in India needs to be layered to separate Role of Legislature from those of a Regulator and those of a supervising Accreditation Body to assist the Regulator, including Third-Party Conformity Assessment Bodies who will Audit the Manufacturer in lines with principle of subsidiarity, our Key Policy principle (3.2). ***Minimum Government – Maximum Governance*** (Figure 9).

In India there has been no onus on Manufacturers to demonstrate Compliance. There is a need to provide this layer whereby Manufacturers voluntarily use accredited 3rd Party Conformity Assessment Bodies to verify & certify their Compliance level to regulations. This will also create higher international acceptance for Indian Products. Systems need to be created to do market surveillance and monitor adverse events to enable needful systemic action to prevent reoccurrence of such incidences for enabling greater Patient Safety.

While this has now been taken care of in recently introduced Medical Device Rules 2017, effective 1st January, 2018 for Low Risk Class A & B Devices. It also needs to be considered for Medium & High-Risk Devices. Ideally the Law should give sense of Direction to Framework of Rules, which is still missing and the Rules can only be applied on Devices Notified as Drugs under the current Drugs & Cosmetics Act, item by item.

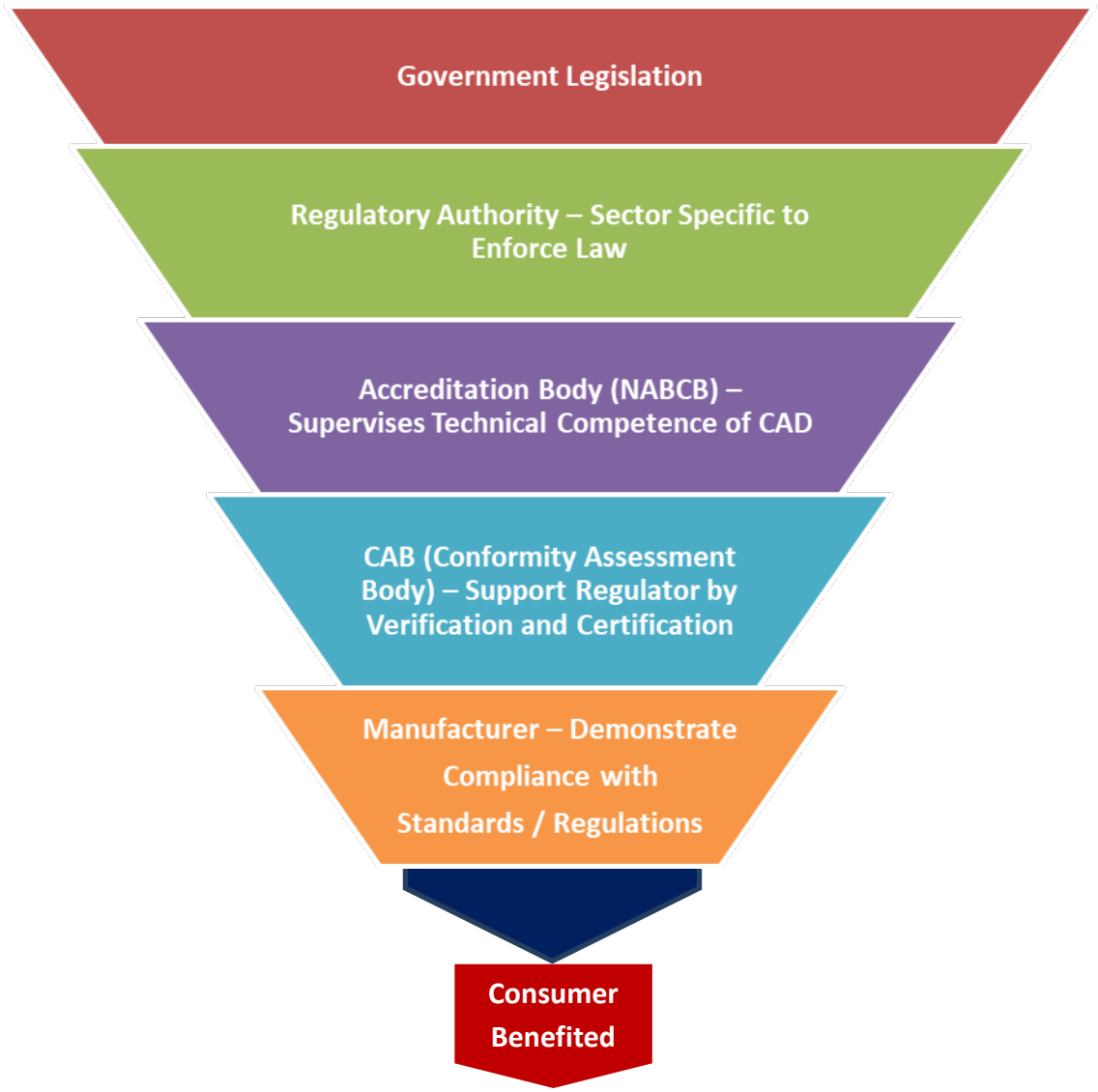


Figure 9: Minimum Government – Maximum Governance the Emerging Structure

The Way Forward

All Medical Devices need to be regulated at one go and not item-by-item. Medical devices need to be so defined that any product which falls within the definition is automatically covered under the regulation and does not need to be notified. This is the approach followed in most developed countries like Europe and USA.

We need stricter regulation as to what gets imported. Most reputed brands have no issues. But a lot of rebranding, re-labeling and condemned pre-owned equipment finds its way into our country. This has to be stopped. Many of these Equipment are obsolete and are imported or

dumped into the country in the name of cheap imports and affordable access and Pseudo Manufacturers are undermining the country's traditional manufacturing base. While subcontracting is ok, Pseudo manufacturing needs to be discouraged. Actual manufacturing activity needs to be encouraged whereby there is a Domestic Content of over 50% (25% for Medical Electronics initially) as defined by Department of Pharmaceuticals for DIPP's Public Procurement Order and change of sub tariff heading of at least assembly or processing of inputs to produce output of another sub tariff heading takes place.

Regulatory Control need to split and shared between Centre, State & CAB's e.g. Centre for Policy, Licensing Registration of Market Access Authorization Holder whether Manufacturer / Importer / Marketing Company and State Authorities to Regulate Logistics & Sales – Reseller / Wholesaler / Retailer & Hospital and Central Regulatory Authority delegates Task of Conformity Assessment to NABCB Accredited Certification Bodies for all Classes of Devices whether Low Risk or High Risk as an option for Manufacturer to demonstrate Compliance to them. The National Regulatory Authority need to have power for speedy administrative action and for putting things RIGHT. There should be Minimal / No reliance of judiciary and legal criminal action should be against Manufacturer other than for willful non-Compliance of serious nature leading to an Adverse Event. Reliance of judiciary / police and criminal action should be on non- registered units or for any major offences. Regulations need to encourage – Make in India & Made in India. Transition period of 3 to 5 years needs to be provided for a phased implementation.

Though Factories of Medical Devices fall under the concurrent list of Seventh Schedule for the Constitution of India a separate Medical Device Bill with a Central Regulatory Authority will be possibly opposed by many Stakeholders specifically State Regulators as a loss of power after having regulated 24 Categories of Devices under the Drugs & Cosmetics Act. In absence of a Sector specific Technical Regulations of Medical Devices, we recommend as an initial phase, for using BIS (Bureau of Indian Standards) Act instead of Drugs & Cosmetics Act, and Government of India via MOH&FW may consider to issue a Notification as a QCO (Quality Control Order), as suggested by DOCA, to make initially IS / ISO 13485 (Quality Management System for Regulatory Purpose) Certification or even certification to Schedule 5 of MDR, 2017 to promote uniformity with some additional regulatory requirements mandatory through NABCB Accredited

Certification Bodies duly notified by CDSCO as in MDR, 2017 and CDSCO (or MOH&FW) acting as Regulator maintaining a web based Registry of Market Access Authorization Holders whether these are Importers or Manufacturers or Marketing Organizations. Similarly, certain Product Standards of BIS can be made mandatory by a QCO.

Under the BIS Act, it is a practice that the relevant Ministries issue the quality control orders. The regulations issued by Ministry of Steel and DIPP are examples to these.

NABCB is already accrediting Certification Bodies for Voluntary Quality Assurance Indian Certification for Medical Devices (ICMED) Scheme and IS / ISO 13485 Certification. This accreditation & IS / ISO: 13485 Certification of Medical Devices can now be considered to be made mandatory for ensuring Patient Safety as a base requirement and later the Regulatory Framework for Medical Devices in terms of product standards can be built additionally around this in a phased manner.

Meanwhile, Manufacturer need to be supported in Capacity Building for Compliance to ISO: 13485 and Medical Device Rules and / OR ICMED Certification for ensuring Global Competitiveness.

Indian Certification for Medical Devices (ICMED) Scheme

To fill the regulatory vacuum in quality certification space for medical devices in the country, the Association of Indian Medical Device Industry (AiMeD) jointly with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) rolled out a voluntary quality certification scheme for Medical Devices. ICMED Certification http://www.qcin.org/icmed-medical.php, on March 15, 2016 World Consumer Day.

The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers and for enabling capacity building for Manufacturers for Regulatory Approvals. This move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

The Certification Scheme was created by a Technical and a Certification Committee under a Steering Committee with Representation from 22 Organizations like DOC, MOH&FW, CDSCO,

NHSRC, QCI, NABCB, NABH, NABL, BIS, CCC, IMA, AHPI, AiMeD, CII, EEPC etc. under the Chairmanship of Dr. M K Bhan and is available as ICMED 9000 for Low Risk Devices and ICMED 13485 for Moderate Risk and High Risk Devices .

To ensure need to have the highest Quality Standards, the Certification Scheme is built over the base Standard ISO 13485 (Quality Management System for Regulatory Purposes) which had 184 Compliance Requirements. The ICMED 13485 has in addition 23 Regulatory Requirements, 13 Essential Requirements for ensuring Patient Safety and with 16 Labeling Requirements for ensuring Consumer Protection. The Certification is available through NABCB Accredited Certification Bodies of International repute for this Scheme viz. Intertek, UL, TUV Intercert, TUV SUD & TUV Rheinland. Other Certification Bodies that have sought Approval / Accreditation from NABCB are DNV, Quality Austria, BSI, ICS, IR CLASS, Zenith & AGSI.

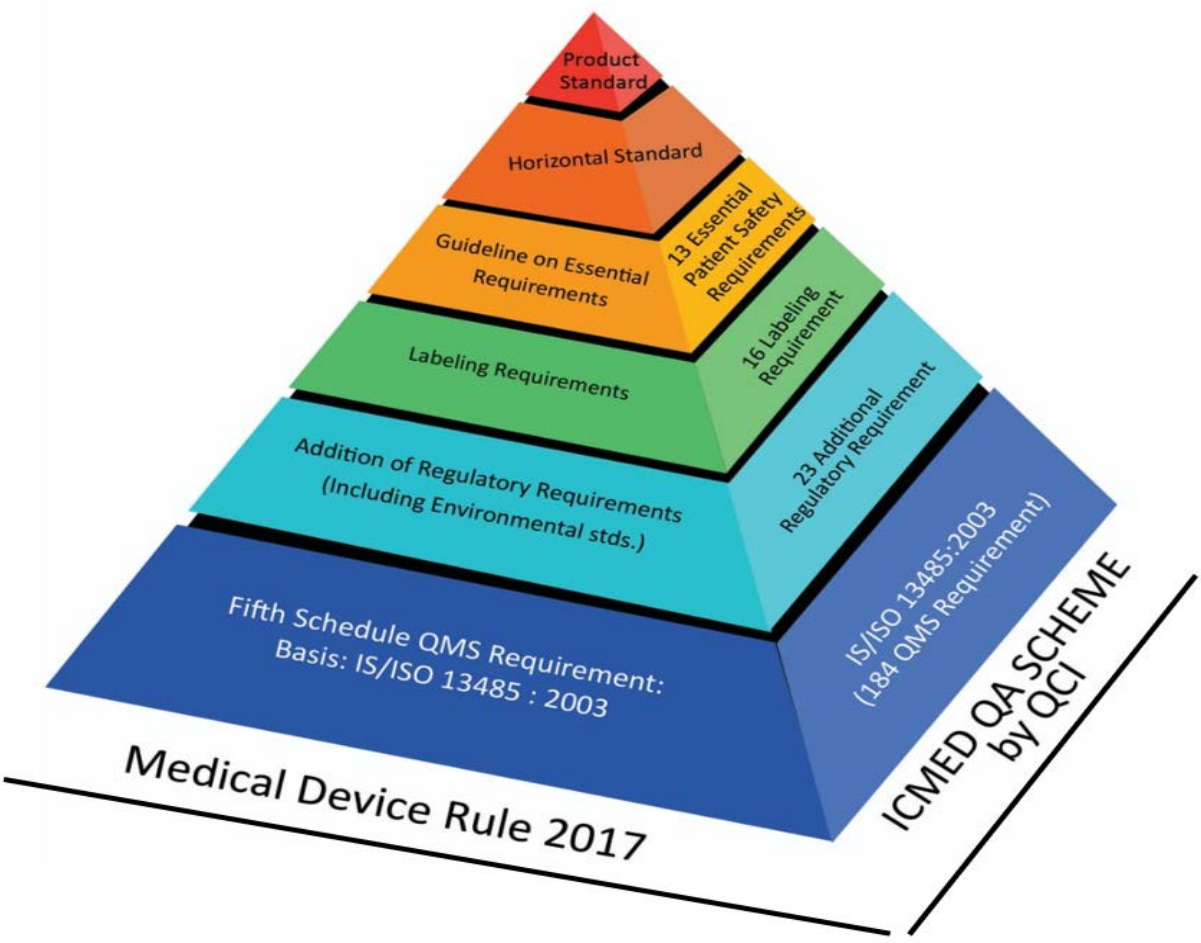


Figure 10: QA/QMS Under Mandatory MDR and Voluntary ICMED: 13485

It's a growing practice worldwide that certification to standards which may encompass regulatory requirements is accepted as demonstration of compliance. EC actually publishes a list of harmonized standards certification to which is assumed to be deemed compliance. Closer home, FSSAI has a provision in its regulations to recognize certification to national/international standards. In fact, in food sector, the international body, Codex Alimentarius Commission, is developing guidance on how regulators can take cognizance of 3rd party assurance schemes. So, if compliance to QMS as per Schedule 5 is prescribed as compulsory, cognizance can be taken of certification to any equivalent voluntary standard – be it ISO 13485 or ICMED 13485 and audit time for MDR, 2017 reduced to lessen the cost burden on the industry.

International Mutual Recognition Agreements

To gain respect and ease of access for Indian Medical Devices, India has an opportunity to work with its neighbors. In Europe, the medical devices regulations were harmonized initially as a Medical Devices Directive and more recently as European Medical Devices Regulations which permits free movement of goods within EU member nations while safeguarding its citizens from unsafe products by permitting usage of a CE mark to distinguish regulatory approval .Realizing benefits of trade and ease of doing business, in 2015, the ASEAN Medical Device Directive (AMDD) agreement was signed by all the 10 ASEAN countries – Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. The agreement is to be fully implemented by 2020. ASEAN Economic Community Council (AECC), a body entrusted with the responsibility for the implementation and monitoring of strategic measures and sectoral work plan through periodical review of key performance index. The primary purpose of this body is structured as to have an oversight of all sectors and to use its terms of reference to direct and ensure that the synchronization of cross-sectoral work will not only be feasible but accelerated and delivered at a pace far greater than its predecessor. Taking into account sectors that are crucial to consumer protection and product safety under the respective working group such as ASEAN Consultative Committee on Standards and Quality (ACCSQ) and ASEAN Coordinating Committee on Consumer Protection (ACCCP), it is submitted that in order to enhance consumer protection in product safety, ACCSQ and ACCCP shall develop product safety mechanism in the form of a directive or policy to overcome unsafe products in ASEAN countries.

India needs to integrate itself with these initiatives in ASEAN. Taking benefit of NABCB (National Accreditation Board of Certification Bodies) being an IAF (International Accreditation Forum) member and part of PAC – Pacific Accreditation Cooperation that includes ASEAN member countries as first step QCI-NABCB needs to seek Mutual Recognition Agreement for the Voluntary QA ICMED Certification with AMDD and later this can be progressively followed by seeking India to be a party to the AMDD as a member country with full compliance and harmonized regulations (Figure 10). This will enable the medical devices being made in India to have easy access and an accelerated regulatory approval mechanism to enable exports into these 10 countries. The voluntary certification scheme for medical devices, "Indian Certification for Medical Devices (ICMED) Scheme" was launched on 15thMarch 2016 at New Delhi on the occasion of World Consumer Rights Day jointly with Consumer Online Foundation in the collaboration of Quality Council of India (QCI) and Association of Indian Medical Device Industry (AiMeD) (Figure 11).

Figure 11: Release of ICMED Scheme Documents on World Consumer Rights Day 15th March 2016 in presence of Mr. Amitabh Kant, CEO - NITI Aayog, Dr V. K. Subburaj, Secretary – DoP, Mr. Rajiv Nath, Founder and Forum Coordinator - AiMed and other dignitaries at the event.

C. Policy Draft on- Affordability in Medical Device Sector

The Medical Device Market in India which is over 1,05,000 Crore Rupees at Retail and Institutional level is mainly dominated by imports. Corporate Hospitals and MNC's have pledged for 0% Import Duty on medical devices over the last 10 years *without any proof of passing reduction of Maximum Retail Price (M.R.P) to Consumers.* Retailers and hospitals prefer to use imported Devices with derived higher profitability as in many cases imported Unit Packs do not carry M.R.P but this is labelled only on their Shelf Box which enables them to charge any Price as per their discretion by claiming goods are for Institutional sales and not for sales over the Retail Counter so M.R.P is not applicable. Domestic Manufacturers needed to print M.R.P on unit pack and are complying to such requirements.

On the Devices that did carry MRP, the market has witnessed huge disparities in MRP between brands of various Suppliers for same / similar Products as a higher MRP (and higher Trade Margin) strategy to induce Retailer & Hospitals to push their brand. The market is not operating based on open competition to drive down prices but is skewed leading to rapid artificial inflation as Domestic Manufacturers also increase their MRP to catch-up and offer similar profitability.

Department of Consumer Affairs, Vide Notification No. 629 (E) dt: 23rd June 2017 has made it mandatory for all Medical Devices including those Notified as Drugs to have MRP on Unit Pack and if sold by a Hospital to Patient then they can't claim the status of Institutional Customer. Additionally, Country of Origin is now mandated to be labelled on the Unit Pack.

Future steps for Ministry of Consumer Affair & Ministry of Finance

1. **Compliance enforcement:**
   1.1 **Ensure Compliance** of the recently updated Rules & labelling requirement of mandating printing of MRP on each Unit Pack of the Consumer good (including Medical Devices) at the time of import, by deputing a Port Officer for checking each shipment of Consumer goods (including Medical Devices) as is the modus operandi being followed by Drug Controller of India for the Pharmaceuticals whereby the Port officer / ADC Port issues the clearance for each shipment of Pharmaceutical products to the Customs Officer as per the Drugs & Cosmetics Act.

It is easier to control the Problem at the originating stage with few teams of officers rather than having a large Army of Inspectors trying to control thousands of Retail Outlets and Hospitals.

1.2 Many State Level and World Bank assisted Public Health Tenders have a Price benefit of 10 to 15% for Indian Origin goods to help establish the Domestic Industry of Medical Devices. In the absence of enforcement of labelling of Country of Origin, Manufacturer traders have the same benefit as would be available to an Indian Manufacturer who has spent a considerable amount of money to establish a factory and infrastructure to manufacture these Devices. Moving forward, the Compliance needs Enforcement.

2. Now that GST has been introduced and there is a Uniform Tax Structure, Government may consider to Regulate the maximum Mark up between Ex-Factory (weighted average price) and the Maximum Retail Price since Ex-Factory price is coming down by competition but retail prices are shooting up to induce Indian Retailer / Corporate Hospitals to push their brands by offering superior trade margins. This is a never-ending race and the Consumer is needlessly suffering with this artificial inflation. To address this issue the following provisions are proposed to be taken up by the stakeholders:

2.1. **Tax Based Disincentive for addressing Exploitatively High MRP:** Initially, discourage Inflationary maximum retail price revisions by an innovative Tax Mechanism for Devices not Notified as Drugs, e.g. apply 1% GST Cess on MRP as a Tax based disincentive on MRP to penalize Importers & Manufacturers with high MRP and incentivize low MRP to give Consumers Protection from artificial inflation.

2.2. **For Devices Notified as Drugs,** we recommended consideration of keeping the MRP at a defined maximum Multiple of the Ex-Factory Sales Value or the Import Landed CIF Price based on the feedback from the Orthopaedic Industry and other AiMeD Members.

Maximum Trade Mark Up (MRP to Ex-Factory)		
Description	**Orthopedic Implants**	**Other Medical Devices**
Any item over Rs. 1 lacs	2 x (50% Margin)	2 x (50% Margin)
1000 rupees to 1 lac	4 x (75% Margin)	3 x (66% Margin)
Less than 1000 rupees	6 x (85% Margin)	4 x (75% Margin)

*Both MRP and Ex-Factory / Import Landed Price to include GST

*Orthopaedic Implant have a higher logistics, distribution and service support cost than other Medical Devices

The above measures will correct the market back to open competition whereby the Retailer / Hospital will be procuring on basis of his procurement cost and quality of Product rather than being induced by unreasonably high trade margins at times.

While Department of Consumer Affairs had kindly considered to amend the Packaging & Commodities Rules to address some of these issues, however, implementation needs to be enforced with help of Ministry of Finance, CUSTOMS and Ministry of Finance, Department of Revenue and Department of Pharmaceuticals. The DoP through NPPA needs to work out a formula to help consumers without harming Industry and Healthcare Service Providers.

The Glossary & concept of trade margin regulation as given below:

1. **MRP** = Mfrs Price (on which GST is initially charged) + %age of Trade Mark up,
2. Manufacturer can be overseas manufacturer or indigenous manufacturer.
3. The first point of sale is the price at which manufacturer, whether indigenous or overseas, sells to the trade and is the price point on which GST is charged the first time.
4. On Overseas Manufacturer, GST is charged on Import CIF landed price in BIE (Bill of Entry)
5. On Indigenous Manufacturer, GST is charged on Ex-Factory Price Transaction Sale Value post discounts before goods leave the Factory Gate
6. We recommend 85% as the maximum trade margin on MRP but recommend consultation with IMA, AWHP, AIOCD, SMTA etc. for their views on what's rational.
7. Indian Manufacturers have to be equated with overseas manufacturers and not with importers. Importers are Traders and by seeking 1st point of sale to be incorrectly defined as Price to Distributor by Importers they seek to be kept out of Trade Margin

Rationalization and this will be a very big competitive disadvantage for Indian Manufacturers who seek level playing field with overseas Manufacturer.

The Concept Note of NITI Aayog states that there is a consensus on quantum of Margins. We are unaware what that is and think that there is confusion on Trade Margin & Mark up.

8. Trade Margin is Profit on Selling Price e.g. MRP.

$$\textbf{Trade Margin} = \frac{\text{MRP} - \text{Ex-Factory Sale Value} \times 100}{\text{MRP}}$$

9. Mark Up is Profit over buying value e.g. Mfrs. Ex-Factory Sale Value

$$\textbf{Mfrs. Ex-Factory Sale Value} = \frac{(\text{MRP} - \text{Ex-Factory Sale Value}) \times 100}{\text{Ex-Factory Sale Value}}$$

10. To reduce MRP of most medical devices by possibly less than half of current, AiMeD recommends GoI must implement the following:

S.No.	AiMeD recommendations to reduce MRP
1.	Cap Trade Margins of Devices priced over Rs. 1 Lacs to 50%
2	Cap Trade Margins of Devices priced over Rs. 1000 but < Rs 1 Lacs at 66%
3	Cap Trade Margins of Devices priced less than Rs. 1000 at 75%.
4	For Orthopaedic Implants for (ii) & (iii) above, cap these to 75% & 85% respectively.

11. If, however intention is to Cap Mark Up over Mfrs. Price then AiMED recommends

S.No.	AiMeD recommendations
1.	Cap Mark Up of Devices priced over Rs. 1 Lacs @ 200% i.e. 2X of Mfrs. Sale Value Price
2	Cap Mark Up of Devices priced over Rs. 1000 but < Rs 1 Lacs @ 300% i.e. 3X of Mfrs. Sale Value Price
3	Cap Mark Up of Devices priced less than Rs. 1000 @ 400% i.e. 4X of Mfrs. Sale Value Price.
4	For Orthopaedic Implants, for (ii) & (iii) above, cap these Mark-ups @ 400% & 600% respectively i.e. 4 x & 6 x of Mfrs. Sale Value Price.

Rationale: On Mfrs. Price add freight to next point of supply chain e.g. Importer / Consignee Agent, his gross margin to cover salary , rental, inventory carrying costs & sales & service financing costs, sales overheads e.g. insurance, cost of expired stocks, costs of statutory overheads , net margin etc. and then, freight to next point of sale e.g.

Distributor/dealer &similar add on expenses and margins then onto next reseller / wholesaler/ Stockist then onto next reseller/ jhollaywallah then onto next reseller i.e. retailer/chemist/ physician/nursing home/hospital. There can be up to 7 supply chain points to service villages in interiors of a vast country like India and if Government of India & consumers wish no stock outs at last mile we sincerely suggest to let's start with above caps and review impact after one-two years and then study possibility of further calibrated reduction.

12. AiMeD recommends for price control, Government of India must implement the following in a calibrated manner to discourage High MRP and stop usage of High Trade Margins as a marketing ploy:

S.No.	AiMeD recommendations
1.	Tax based disincentive on all Non-Notified Devices e.g. 1% GST Cess on MRP
2	Capping Trade Mark-ups over Mfrs. Price on Notified Devices
3	Price Caps on few Priority Devices, especially those with a wide price disparity.
4	Delist "Essential Devices" Priority is definable, Essentiality is questionable.

Speakers Profile

Speaker Profiles

Dr. Harsh Vardhan,
Union Minister for Science & Technology, Earth Sciences and Environment, Forest and Climate Change and Minister of Health and Family Welfare, Government of India

Dr. Harsh Vardhan, Union Minister for Science & Technology, Earth Sciences and Environment, Forest and Climate Change and Minister of Health and Family Welfare, Government of India has a long and distinguished record of public service, leaving his indelible mark in all fields of activity undertaken. An ENT surgeon by profession to start with, Dr. Vardhan branched out into public life in 1993, when he got elected to the Delhi Assembly from the Krishna Nagar constituency in east Delhi. This marked the beginning of a scintillating run in electoral politics. Dr Vardhan's public life has been marked by outstanding achievements in the fields of health, education, law, science & technology and environment. He was instrumental early in public life, through his mass, country-wide campaign, in wiping out polio from the face of India. Subsequently, he was at the forefront of the battle against tobacco and drug abuse and was instrumental in the enactment of several laws including the Delhi Prohibition of Smoking in Public Places & Non-Smokers Health Protection Act to tackle these problems. Subsequent to this the Supreme Court directed all states to replicate this law and 12 States enacted similar laws. He for the first time implemented the Rational Drug Policy which was recognized by the WHO as the Delhi Model and was adopted by many countries.

Mr. Mansukh Mandaviya,
Ministry of Shipping and Minister of State for Chemical & Fertilizers, Government of India

Mr. Mansukh Mandaviya is the Minister of State (Independent Charge) for Ministry of Shipping and Minister of State for Chemical & Fertilizers in Government of India. Mr. Mandaviya was born in a small village named Hanol in Palitana district of Gujarat state in a middle-class farmer's family. He holds a Postgraduate degree in Political Science from Bhavnagar University. Mr. Mandaviya was very active in politics and serving people since his youth. He became a member of ABVP and soon he grabbed his

position as a state executive committee member of ABVP, Gujarat unit. Seeing his intellect, skills and the zeal to work hard he was appointed as a leader of YuvaMorcha and then the president of Palitana BJP unit. He also holds a record of being the youngest MLA in Gujarat. Working hard to serve the people and uplifting them was his only goal and thus he organized two Padyatras of 123 Km and 127 Km for the cause of Girl Education, BetiBachao, BetiPadhao and VayasanHatao. At a young age of 38, he was elected as a member of Rajya Sabha. He was also a part of various standing committees in various fields. With his hard work and intelligence, he was appointed as Secretary for state unit BJP in 2013 and General Secretary in 2014. Later in 2014, he was appointed as Gujarat State Incharge of BJP's High-tech & Mega Membership Drive Campaign which led to 1 crore people joining BJP in Gujarat. Mr. Mandaviya is well known for his intellectual analysis and thought leadership, which he also exhibited in his speech on "2030 Agenda for Sustainable Development" at the United Nations. He has travelled to lot many countries to explore their policies & management to help India grow at the fastest pace. On 5th July 2016, he sworn in as a Minister of State for Road Transport & Highways, Shipping and Chemical & Fertilizers in Government of India. Serving as a minister, he has implemented a lot of plans and thoughts to get the work done quickly and efficiently.

He was re-selected for the Second Term for Member of Parliament, Rajya Sabha during March, 2018.

With his decisive and bold leadership, he has helped increasing the per day road construction speed, decreasing the cost of Urea and other fertilizers, establishing more than 4000 Jan Aushadhi stores to provide more than 800 medicines at affordable rates and reducing the cost of heart stent and knee implants. Above this, he has not left any stone unturned to help the common man, farmers and businesses. He has played a vital role in the growth and development of New India with his hard work, organizational skills and intellect. Again in 2019, he sworn in as a Minister of State (Independent Charge) for Ministry of Shipping and Minister of State for Chemical & Fertilizers in Government of India.

Dr. P D Vaghela,
Secretary, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India

Dr. Vaghela is serving as Secretary, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India. Dr. P.D. Vaghela is an IAS officer from 1986-batch and holds an MBA in finance from BK School of Business Management, Gujarat University. His career started as developmental head of two district councils in the state, from 1990 to 1995. He was district magistrate for three states in the year 1996 to 2001. In 2008, he was appointed as chairman of Kandla Port, where he served for five years before being named commissioner of commercial tax. The Modi government empanelled him as secretary in July last year.

Dr Balram Bhargava,
Secretary, Department of Health Research,
Ministry of Science and Technology, and
Director General, Indian Council for Medical Research,

Professor Balram Bhargava, is currently Secretary, Department of Health Research, (Ministry of Health & Family Welfare), Government of India and Director General, Indian Council of Medical Research (ICMR). Prof. Bhargava is Professor of Cardiology at All India Institute of Medical Sciences (AIIMS), New Delhi. Prof. (Dr) Balram Bhargava was born in Lucknow, 21st July 1961. He is an outstanding cardiologist, one of the foremost leaders in biomedical innovation, public health, medical education and medical research. He developed the indigenous Platinum Iridium coil coronary stent and has been instrumental in clinically evaluating and establishing medicated Indian stents. He is an innovator par excellence with innovations touching everyday lives with very huge social impact for which he has started the Society for Less Investigative Medicine (SLIM). He is currently providing leadership for creative disease prevention, early detection and transport system for sick cardiac patients; mission DELHI (Delhi Emergency Life Heart-attack Initiative) by trained motorcycle first respondent paramedics.
Prof. Bhargava has been awarded the SN Bose Centenary Award by the Indian National Science Congress, the National Academy of Sciences Platinum Jubilee Award, the Tata Innovation Fellowship the Ranbaxy Award, OP Bhasin Award, Vasvik Award and more recently the UNESCO Equatorial Guinea Prize for Life Sciences; Dr. LEE Jong-Wook Memorial Prize for Public Health, 2019 by WHO Hqrs, Geneva. He is also a recipient of the Padmashri award.

Prof. Vinod K. Paul
Member, NITI Aayog,
Government of India

Prof. Vinod Paul, a pediatrician by training, has been on the faculty of the Department of Pediatrics, All India Institute of Medical Sciences, New Delhi, since 1985, and head of the department for nearly a decade. Prof Paul has been closely associated with India's health policy and programs in various roles for over three decades. India's child and maternal health programs bear imprint of his research and expertise.

As a globally recognized academic and public health exponent, Dr Paul chaired the Technical Advisory Group on Women's and Children's Health for WHO South East Asia Region. He has been a co-chair of the board of the Partnership for Maternal, Newborn and Child Health (PMNCH).

The Government of India appointed Dr Paul as a Member of the National Institution for Transforming India, the NITI Aayog, in August 2017 where he leads the Health and Nutrition verticals. He has played a pivotal role in formulating the POSHAN Abhiyaan and the Ayushman Bharat initiative.

Prof. Paul has recently been appointed as the Chairman of The Board of Governors of Medical Council of India. Prof. Paul is a fellow of all the three science academies of the country, and a recipient of the Dr. B. R. Ambedkar Centenary Award for Excellence in Biomedical Research and the Public Health Champion award. He was conferred the prestigious Ihsan Dogramaci Family Health Foundation Prize by WHO at the 2018 World Health Assembly.

Dr V G Somani
Drugs Controller General of India,
Central Drugs Standard Control Organization

Dr V G Somani is appointed as Drugs Controller General of India through All India open selection held by UPSC on 10th July 2019. Earlier, he had already worked as Drugs Controller General (India) in 2011 on additional charge. Dr V G Somani was lastly working as Joint Drugs Controller (India) having 21 years of vast experience in Central Drugs Standard Control Organisation (CDSCO). He is highly qualified and well experienced in the field of GMP, GCP, GRP, GDP, Dossier Review, GLP etc. and worked on all posts in the hierarchy of Central Drugs Control Department including as Drugs Controller General of India. He is a well-known speaker and trainer of various national and international/ WHO scientific bodies. He has done his M. Pharm and full time PhD on UGC Fellowship in Pharmaceutical Sciences and has presented various papers in national and international conferences. Being meritorious student, he was awarded scholarship/fellowships since schooling days i.e fourth standard till completion of PhD in various forms.

He has been selected and now working as Chairman of WHO's Member State Mechanism (MSM) of 194 countries on substandard and falsified medical products at Geneva, Switzerland vide World Health Assembly (WHA) resolution 65.19 which is very prestigious post for India to safeguard India's interest for making affordable generic medicines acceptable in the world inspite of opposing lobby from the western world. He was an expert for Bihar Public Service Commission for selection of Drugs Controller of Bihar. He had been panellist speaker on Rajya Sabha TV as Drugs Controller General of India, in programme 'Sarokar on fake medicines', which is available on YouTube. He is known for simplification of complex regulatory processes to ensure access to safe, efficacious and quality medicines including generic and innovative products.

Mr. Prakash Bachani
Scientist E & Head
Medical Equipment & Hospital Planning Department
Bureau of Indian Standards, the National Standards

Mr. Prakash Bachani, Scientist E & Head (Medical Equipment & Hospital Planning Department). He has 34years experience in Bureau of Indian Standards, the National Standards Body of India, having worked in Standard Formulation, Laboratory and Certification Activities. At the Technical level, he has overseen Product Certification, System Certification (QMS), Hallmarking of Gold and Silver, Standards Formulation (Electrotechnical and Medical Equipment & Hospital Planning), Laboratory Management. He has participated in various international seminars and meetings organized in the country in the field of electrotechnical as well as in Medical Equipment and Devices. He has also presented several papers on Standardization, Certification etc. in the field of Electrical Engg. and Medical Equipment at various National and International meetings / seminars. He is GOLD MEDALIST in MIE (Electrical Engg.), Institution of Engineers, India.

Dr Y K Gupta
National Scientific Advisor,
Pharmacovigilance Programme of India

Dr. Y.K. Gupta M.B.B.S (1974), M.D (Pharmacology, 1979) from King George's Medical College, Lucknow, is Professor and Head, Department of Pharmacology and Spokesperson, All India Institute of Medical Sciences (AIIMS), New Delhi. He earlier served as Sub Dean, A.I.I.M.S (1996 – 2001). and Director, Indian Institute of Toxicology Research (IITR, CSIR), Lucknow from 2003 to 2005.Dr.Gupta is incharge of National Poison Information Centre and is also National Scientific Co-coordinator of Pharmacovigilance Program of India (PvPI).He has been honored with fellowships of National Academy of Medical Sciences (FAMS), Indian Pharmacological Society (FIPS), National Academy of Science (FNASc), Indian Academy of Neurosciences (FIAN) and Society of Toxicology (India) (FST). He has more than 180 publications in International and National journals and several chapters in books to his credit.Dr Gupta is recipient of several awards including Young Scientist Medal from Indian National Science Academy, Shakuntala Amirchand Prize (Indian Council of Medical Research : ICMR), Chandrakanta Dandiya Prize, G. Achari Oration Award (Indian Pharmacological Society : IPS), Major General S. L. Bhatia Oration Award (Association of Physiologist and Pharmacologist of India : APPI),

AEB Honours Award (Academy of Environmental Biology), C. L. Malhotra Prize (Association of Physiologist and Pharmacologist of India : APPI) etc.
Dr. Gupta is currently President of Society of Toxicology, India and Dean Indian Society for Rational Pharmacotherapeutics, and was President of the Indian Pharmacological Society (2005- 2006). He is the Editor of the Indian Journal of Physiology and Pharmacology (Pharmacology Section) and member editorial board of several International and Indian journals.
He is the Chairman of National Committee of IUPS-IUPHAR of Indian National Science Academy (INSA), Member of IUPHAR –IOSP committee and member of Advisory Committee on Safety of Medicinal Products (ACSoMP) of WHO, chairman of Equivalence Committee and member Ethics Committee of Medical Council of India. He has been member of Project Advisory Committee / Research Council / Scientific Advisory Committee and Task force of CSIR, ICMR, DST and DBT and Chairman, SAC of National Institute of Occupational Health (NIOH-ICMR). He is chairman of national GLP technical committee of DST, member of the Scientific Body of Indian Pharmacopoeia (IP) and Chairman of Expert Committee on Clinical Medicine and Pharmacology of IP.
He was the Governing body member of Indira Gandhi Postgraduate Institute of Medical Education and Research, Patna. He was the Chairman of National Essential Medicine List Committee 2011 of Ministry of Health & Family Welfare, Government of India and also the Chairman of the working group of High Powered Inter-Ministerial Coordination Committee to look into the matters of implementation Government commitment to provide quality medicine at affordable prices.

Dr. K K Aggarwal
Consultant Cardiologist, President of Heart Care Foundation of India and Honorary Secretary General of the Medical Council of IndiaGovernment of India

Recipient of Padma Shri (2010), National President of the Indian Medical Association (2016-17), Dr. BC Roy National Award (2005), National Science Communication Award and Vishwa Hindi Samman (2015) awards, Krishan Kumar Aggarwal belongs to the class of 1975. A Consultant Cardiologist, President of Heart Care Foundation of India, and the Honorary Secretary General of the Medical Council of India, Krishan is gifted with a multifaceted and dynamic personality. His pursuit of excellence continues in the roles of physician-scientist, academic teacher, writer, editor, administrator and a public health activist. Dr. Krishan was the fourth postgraduate student to obtain MD (Medicine) from MGIMS.
Gold Medalist and Nagpur University topper throughout a medical career, Krishan obtained MD (Medicine) from MGIMS in 1983.
After obtaining MD, he joined Moolchand Medcity, New Delhi where he currently serves as a senior consultant, Physician and Cardiologist and Dean, Board of Medical Education. The first to use clot busters in patients with acute myocardial infarction (1984), he introduced color Doppler echocardiography in North India in 1987.Group Editor-in-chief of IJCP Group of Publications and

emedinews- the first national daily medical newspaper, Krishan is well known for the several roles he plays: a compulsive writer, an eloquent columnist and a much sought-after TV anchor. He is also a Limca Book of World Record Holder for the maximum people trained in the life-saving technique of Hands-only CPR.

Mr. Alok Kumar
Advisor, Health & Nutrition, Financial Resources, and Administration and
NITI Aayog, National Institution for Transforming India

Mr. Alok Kumar is working as Adviser (Health & Nutrition, Financial Resources, and Administration), NITI Aayog (National Institution for Transforming India) Government of India. He is a UP (Uttar Pradesh) cadre Indian Administrative Service (IAS) officer of the 1993 batch. He has a B.Tech. in electrical engineering from Indian Institute of Technology (IIT) Delhi and a Masters degree in public policy from the Woodrow Wilson School, Princeton University. He is currently working as Adviser (Health & Nutrition, Financial Resources, and Administration) at the NITI Aayog (National Institution for Transforming India) – the apex policy think tank for the Government of India. NITI Aayog has been designated by the Government of India to be the nodal body for monitoring of the implementation of the SDGs (sustainable development goals). Previously he has held several senior positions in the government, including a stint at the Staff College training senior civil servants in India. Alok Kumar has abiding interest in issues related to health policy.

Dr. Purnima Sharma
Managing Director,
Biotech Consortium India Limited, New Delhi

Dr. Purnima Sharma is the Managing Director of Biotech Consortium India Limited (BCIL), New Delhi. BCIL is a public limited company promoted by the Department of Biotechnology, Ministry of Science and Technology, Government of India and the all India financial institutions for facilitating biotechnology commercialization. The company has been in existence for more than two decades and has made a

significant contribution to biotech sector by providing valuable services in areas such as technology evaluation and transfer, IP management, consultancy, biosafety, capacity building and manpower development to the Central and State Governments, academia, research institutions and industry.
Dr. Purnima Sharma is a doctorate in Experimental Medicine from Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, the prestigious autonomous institution and deemed Medical University of national importance of the Ministry of Health, Government of India with Post Doctoral experience from IIT, Mumbai, and has to her credit many awards for excellence in academics.
She has more than 25 years of experience in the area of technology evaluation and transfer, management of IPR, project consultancy including DPRs for setting up Incubators and Science Parks, managing start-up ecosystem, public-private partnership funding schemes, entrepreneurship development etc. She has coordinated transfer of more than 50 technologies in various sectors of life sciences. She has also conducted a number of sectoral studies and market research studies on different biotech products.
She is a member of a number of national and state level committees responsible for biotech development and commercialization and also a member of The National Academy of Sciences, India (NASI), the first science academy of the country dedicated towards cultivation and promotion of science & technology in the country.

Dr. Suchita Markan
Assistant General Manager,
Biotech Consortium India Limited, New Delhi

Dr. Markan is working as Assistant General Manager in Biotech Consortium India Limited (BCIL). She has done PhD from Department of Experimental Medicine and Biotechnology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh and Executive General Management from IIM, Lucknow. She is leading management of techno legal of School of International Biodesign for more than ten years and Heading the Technology Transfer Activities at BCIL.
She has extensive experience and expertise in the Biomedical Device sector. She is a thought leader in the biomedical device innovation space assisting Government and policy makers to draft appropriate policies for boosting this sector. She has been leading the techno-legal and fellowship management of Department of Biotechnology, Government of India supported flagship program for boosting biomedical device innovation-Stanford India Biodesign programme, renamed as School for International Biodesign for more than eleven years. She is providing strategic IP management, business plan development, licensing advisory and mentorship to more than 125 entrepreneurs and about 20 start-ups in the medtech domain. She has managed number of strategic collaborative programs aimed at fostering biomedical device innovation and entrepreneurship development with AIIMS, IIT Delhi, Stanford University, USA, QUT

Australia, Tottori University, Japan, Hiroshima University-Japan, J&J-COSAT USA, Siemens etc. She is member of number of national level committees for biotech development and commercialization and has numerous international publications to her credit.

Dr Jitendar Sharma
Industry Expert, Medical Technologies

Known in policy forums as the "Med Tech Man of India", Dr. Jitendar Sharma is former Managing Director & CEO of Andhra Pradesh MedTech Zone (AMTZ) which is Asia's first medical devices manufacturing city besides being the Adviser for Health to Govt. of Andhra Pradesh, India and Executive Director of Kalam Institute of Health Technology (KIHT)- a technology policy research body set up with the support of Govt. of India. He is adjunct faculty at University of Adelaide, Australia; and program Director for Health Technology Assessment (HTA) fellowships in India. He has been founder of 6 organizations and architect of Universal Health Coverage for the state of Andhra Pradesh- the first state in India with 50 million people to declare UHC.

He is also the National Chairperson for Indian Bio-Medical Skill Consortium which is an active congregation of over 20 national academic institutions. Awarded among the "100 most impactful healthcare leaders" in global listing by Health & Wellness Congress, Dr. Sharma served as the Founder Head of Healthcare Technology Division and Head of Health Financing Divisions at National Health Systems Resource Centre (NHSRC) under Ministry of Health & Family Welfare, Government of India. He was also the Founder Director of WHO Collaborating Centre for Medical Devices in India. His past experience includes that as Hospital Administrator at Sri Sathya Sai Medical Institutions-one of India's largest not for profit health organizations, as consultant to the World Bank for health financing, as Expert Consultant to the World Health Organization, Geneva and advisor to Health Technology Innovation Centre at Indian Institute of Technology (IIT).

Dr. Sharma has authored seven books, twenty research papers and six compendiums on technical specifications for medical technologies besides contributing to a number of WHO reports on health technologies, health financing and Non-Communicable Diseases. He has been a key designer and coordinator for several health programs in India and teaches courses on health policy & health technology in several countries.

Dr. Preeti Sudan
Secretary, Ministry of Health & Family Welfare
Government of India

Dr. Sudan is admired for her administrative skills at all levels. Sudan's recent role in policy delivery during Kerala Floods helped thousands of civilians residing in relief camps. She handled and looked after one of the most tragic floods to have hit Kerala. Her post flood disease control operations mechanism proved to be highly effective and saved thousands in Kerala.

She is one of the key pillars in the world's largest health protection scheme AYUSHMAN BHARAT YOJNA. Speaking recently on the subject, she had said, "NHPS or National Health Protection Scheme is essential part of entire program and most essential to this entire scheme is the selection of beneficiaries, how to go for hospitalisation and what diseases we will be covering". Sudan has proved her administrative acumen in a male-dominated system. She also served as Special Secretary, Ministry of Women & Child Development and as Joint Secretary in the Ministry of Defence. In her Cadre, she has a distinguished track record of serving in Finance & Planning, Disaster Management, Tourism and Agriculture. She is M Phil in Economics & Post Graduate in Social Policy and Planning from London School of Economics. She has also served as Consultant in the World Bank at Washington.

Sudan hails from Haryana and also had served for ministry of defence for union government and ministry of revenue and disaster management department for Andhra state government. Agriculture cooperation, tourism and industry are the other different departments she had served for in her previous roles. Public finance management training from Washington, USA had also added to her performing skills.

Dr. Mandeep Kumar Bhandari
Joint Secretary, Ministry of Health & Family Welfare
Government of India

Dr. Bhandari IAS (Jammu & Kashmir 2001) presently posted as Joint Secretary in Government of India, Ministry of Health & Family Welfare. In year 2018, he has been the Private Secretary to Hon'ble Human Resource Minister, Ministry of Human Resource Development, Government of India. He has served the

Government of India in multiple ministries at various positions since year 2003. His responsibilities at the current position are in Drugs & Cosmetics Act (Strengthening of State Drug Regulatory Authority), Drugs & Food Quality Control (Strengthening of State Food Regulatory System), Central Drugs Standard Control Organization (CDSCO), India Pharmacopeia Commission (IPC), Food Safety & Standards Act 2006 and Food Safety and Standards Authority of India (FSSAI), National Institute of Biologicals (NIB), Clinical Establishment(Registration and Regulation) Act 2010, Transplantation of Human Organs Act 1994, Administrative matter of HLL & HSCC and Intellectual Property Rights

Mr. Rajiv Chhibber
Vice President External Affairs,
Sahajanand Medical Technologies

Mr. Rajiv Chhibber is a Senior Corporate Affairs, Policy, Communications and Media Strategist with experience across Pharmaceuticals/Medical Devices Industry, Development Sector (Health, Environment, Climate Change, Energy and Sustainable Development) and Education Industry.

At SMT, Mr. Chhibber is responsible for driving strategic priorities and business vision with the Central and State governments, Regulatory agencies, Industry bodies, NGOs and Associations in addition to advising on policy matters, advocacy, managing complex reputational issues, Outreach and stakeholder engagement for the adoption of portfolio products while working closely with the senior management and global leadership.

Mr Chhibber hold a master's degree in Journalism and Mass Communication and a bachelor's degree in English Literature from Delhi University. He has a post-graduate diploma in Newspaper and Feature writing (Montgomery College, University of Maryland, USA) and pursued a Public Health Leadership in-professional course in NCDs from Emory University, Atlanta USA (2014-15) and a Communications Development Programme in Public Health Engagement by Wellcome Trust, UK at the London School of Hygiene and Topical Medicine (LSHTM), UK, (March 2016).

He was awarded an Honorary Doctorate from Aztec's University (UNESCO), Mexico in the year June 2019 the field of "Global Public Health Communication and Policy". He is a member of various government committees / sub-committees in areas of public health advocacy, nutrition, tobacco control, NCDs, and climate change in addition to being on various committees of CII, FICCI, USIBC and American Chambers of Commerce (AmCham).

He is a Member of Asia-Pacific Association of Communication Directors (APACD), Hong Kong, (2014-2020), the International Society for Disease Surveillance, CDC Atlanta, USA and the on the Advisory Board of the International Human Rights Council representing India. He is a Founding Member of Public Relations Society of India and the Founding Member of Climate Action Network, South Asia (CANSA),

a civil society led South Asia Chapter of a global platform that advocates on climate change, energy, power and related issues on sustainable development.

Mr. Rajiv Nath
Managing Director
Hindustan Syringes & Medical Devices Ltd.
& Forum Coordinator, AiMeD

Mr. Rajiv Nath is Managing Director of Hindustan Syringes & Medical Devices Ltd. which is having a turnover of over 600 Crores. He is President of All India Syringes & Needles Mfg. Association. (AISNMA). He is also the Founder and Forum Coordinator – Association of Indian Medical Device Industry (AiMeD) with over 350 Members nationwide whereby Medical Device Manufacturers of all types of technologies have been attracted nationwide on one Platform. He was born in 1962 and entered his family business i.e. Hindustan Syringes & Medical Devices Ltd. (HMD) soon after he finished his college in 1984.

Mr. Nath has started from the scratch i.e started his career on the shop floor of HMD to have first-hand technical experience of all the ground realities & learning basic production techniques of Medical Devices Industry. HMD has capacity of manufacturing over 6 Billion Disposables per annum. HMD's turnover has grown from a mere Rs. 2 crores to over Rs. 600 crores in the year 2017, an impressive growth rate of over 300 times in less than 35 years. Mr. Rajiv Nath has dared to challenge the rules of the market & wrote his own script with respect to syringe design, packaging and presentation. HMD created a niche for their disposable syringe "DISPOVAN" which is today the most popular brand in Syringe market in India with over 60% market share and thereby displaced renowned MNC's – an inspirational case study for other Indian Entrepreneurs. As Forum Coordinator of AiMeD,

Mr. Nath has taken many initiatives of establishing a collaborative framework with various Dept. of the Govt. and Media to bring to their attention issues troubling the industry and attract investments into India in his quest to make India as the Preferred Manufacturing Destination and the leading supplier of Medical Device worldwide. AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including consumables, disposables, equipment's instruments, Implants, electronics and diagnostics. With a Primary Membership of over 350 Manufacturers and additionally of over 200 Associate Members representing the interest of over 700 Manufacturers of Medical Devices to address the manufacturer's problems. (www.aimedindia.com).

Dr. Ravi Kant Sharma
Deputy Drugs Controller (India),
Ministry of Health and Family Welfare, Govt. of India

Dr. Ravi Kant Sharma, Ph.D is working as Deputy Drugs Controller (India) at CDSCO (HQ), FDA Bhawan New Delhi. At present he is dealing with the work related to the manufacturing, import and registration of Medical Devices and in-vitro diagnostic kits. He was actively involved in drafting the Medical Device Rules 2017 which is already implemented from 1st January 2018. He was also leading the International Cell established at CDSCO (HQ) and is involved in collaboration with the Regulators of other countries in the areas of training, sharing of best practices, and observer during audit, harmonization of standards and other information exchange.

He has more than 25 years of experience in CDSCO and has worked in different fields like approval of IND, New Drugs, Import and Registration of Pharmaceuticals, Blood Products and was also involved in Airport and zonal office activities. He actively participated in nationwide drug survey and quality risk based inspections carried out in India. He played vital role for implementation of SUGAM- portal for on-line submission of applications pertaining to import and registration of Medical Devices and in-vitro Diagnostics. Under his supervision Medical Device Division got ISO-9001 Certification. He participated in many National and International seminars/workshops in various areas of Drugs Regulations and has undergone training from USFDA, PMDA & WHO.

Ms. Sashi Rekha
Ex-Director
National Accreditation Board for Certification Bodies-QCI

Ms. Sashi Rekha is an Ex-Direcor of National Accreditation Board for Certification Bodies-QCI, India. Ms. Rekha has a graduation in Food Technology from the University of Agricultural Sciences, Hebbal, Bangalore and a post-graduation in Food Technology from CFTRI, Mysore. She has worked with Cadburys India Ltd. for two years looking after production and quality control of ice cream in franchisee ice cream factories.

She then joined the Bureau of Indian Standards (National Standards Body) and has worked with them at Hyderabad, Bangalore, Chennai and Delhi in Product Certification, Management Systems Certification, Laboratory as well as Standards formulation activities for over 21 years.

Prof. Bejon Kumar Misra
International Consumer Policy Expert, Visiting Professor, Institute of Management (BHU), Varanasi

Awarded the "Distinguished Alumni Award" 2012 by the Institute of Management, BHU. Award Winner of World No-Tobacco Day 2013; from the South-East Asia Region of World Health Organisation (WHO), Recognized by National Bank for Agriculture and Rural Development (NABARD), as a Rural Innovator.

Prof. Misra has 45+ years of professional career with 33+ years in the Consumer Education and Advocacy in India and globally. 18+ years as an International Expert on User (Consumer) Focus; for developing Strategies and capacity building programs in developing countries on Quality Management Systems, for public and private entities to build customer centric culture within the organisation.

At present Governing Board Member of the Quality Council of India (QCI), Board Member of NABH and NABET. Expert Committee Member on Patient Safety Implementation Program, Govt. of India. Special Invitee on the Steering Committee of National Foundation of CSR (NFCSR), Former Member of the Food Safety and Standards Authority of India (FSSAI) Adviser to the Government of Odisha on Consumer-Friendly Interventions; Former Board Member of International Alliance of Patients' Organisations (IAPO), London (UK) and Senior Advisor to Alliance for Safe Online Pharmacies (ASOP).

Prof Misra served as member on several Expert Groups, on framing Government Policies like the Mashelkar Committee for Review of Drugs Regulatory System and Tandon Committee on the Scientific and Technological Measures to Counter Spurious and Sub-standard Drugs and Diagnostic Centres in India. CORE Group Member of the World's Largest Study on the extent of Spurious & NSQ medicines in the supply chain. Founder Publisher: of an English Monthly Consumer Magazine; THE AWARE CONSUMER. Founder Board Member of Consumer Online Foundation, Partnership for Safe Medicines (PSM) India Initiative; Healthy You Foundation and Patient Safety and Access Initiative of India Foundation Travelled to more 35 countries as the leader or member of country delegations; on various international negotiations on health and food safety related issues.

Mrs. Rama Venugopal

Jt. Coordinator, South – AiMeD, Executive Director
Value Added Corporate Services Pvt Ltd, Chennai

Mrs. Rama heads Value Added, a 29-year-old Management Consulting organization offering wide range of consulting solutions to various industries like Manufacturing, Healthcare, IT/ITES on Management Systems Consulting, Strategic Advisory Services like M&A, Funding facilitations, Joint Venture Collaborations etc.

She has 25 years Consulting experience with 20 + plus years connect with Healthcare sector in South India having worked across various verticals like Hospitals, Diagnostic Labs, Blood Banks, CROs, Medical Devices, Healthcare Technology Companies etc. She holds a degree in Commerce and has got 26 years of rich Experience - spreading over Marketing, Sales, Business Development & Operations in Management Consulting. Having worked across all the sectors, she is fairly knowledgeable about the business challenges faced by these sectors. She is a member of TiE Chennai, where she has picked up her passion for Mentoring Startups & heads Entrepreneurship Development Cell at Andhra Chamber of Commerce. Her passion is working for #Make In India initiatives and she represents Association of Indian Medical Devices Industry – AIMED, as South India's Jt Coordinator. She also works closely with CII's TN Healthcare initiatives jointly with Star Health Insurance in Tamil Nadu. She has won the Best Women Healthcare Entrepreneur Award from IMA, Goa in 2017.

Mr. Pardeep Kumar Sareen
CGM – Marketing
Hindustan Syringes & Medical Devices Ltd.
Technical Officer – AiMeD

Mr. Pardeep Kumar Sareen has broad knowledge in medical device manufacturing with a total experience of 41 years (5 years in pharma and rest in medical devices) including 36 years with HMD Group of Companies. He is the CGM – Marketing of Hindustan Syringes & Medical Devices Ltd. Also, he is the Technical Officer – Association of Indian Medical Device Industry (AIMED). He was born in 1954 and is a Science Graduate from Delhi University. A people's person with an affable personality, always comes up with fresh thoughts, unique insights and a bucket full of passion to the organization.

Dr. Sandeep Singh
MD, DM, FACC, Professor of Cardiology,
Executive Director, School of International Biodesign,
All India Institute of Medical Sciences, New Delhi, India

Dr. Sandeep Singh holds the position as Professor of Cardiology at the prestigious All India Institute of Medical Sciences (AIIMS), New Delhi. He has vast teaching experience, spanning over thirty years in the fields of Medicine & Cardiology. Presently, he is involved in various multi-center trials on cardiac devices and has authored more than 80 peer-reviewed publications and many chapters in the books. He has also been awarded the International Award of 'Excellence in Cardiology' during the VIII World Congress on Clinical, Preventive Cardiology and Imaging-2013. He has held the positions of Editorial Secretary for the Indian Heart Journal and as Executive Member of the Cardiological Society of India (Delhi Branch).

He also holds the position as Executive Director at the 'School of International Biodesign' at AIIMS, New Delhi focussing on frugal innovation of biomedical devices and strengthening the roots of biodesign process in India and internationally. His post-doctoral certification in the Stanford-India Biodesign Program in the year 2008 gave him the platform to be co-inventor of many cost-effective novel devices and have several patents on his name. He has been awarded the prestigious 'Tata- Innovation Award' of the Department of Biotechnology, Government of India in recognition of his outstanding contribution in translational research and creation of innovative platform technologies. He was the winner of the 'BMJ India Award' in the field of Innovation in Healthcare Technology in the year 2014.

Ms. Malini Aisola
Health researcher,
co-convener of All India Drug Action Network (AIDAN)

Ms. Malini Aisola is a researcher and public health advocate working on policies impacting affordability and access to medicines and other health products. As a Co-Convenor of the All India Drug Action Network (AIDAN) she works on regulations that relate to pricing of drugs and devices, irrational use of drugs and intellectual property barriers to access. She is a vocal advocate for patient safety and needed

regulatory reforms along with the patients of faulty J&J hip implants. She is also affiliated with the Campaign for Dignified and Affordable Healthcare, a forum of that advocates for regulation of the private healthcare sector and greater scrutiny of systemic unethical practices through reforms, for ethical and respectful treatment of patients. She is a member of Jan Swasthya Abhiyan (People's Health Movement in India) and Medico Friend Circle. Malini has previously worked with Knowledge Ecology International (Washington DC), the Public Health Foundation of India, Lawyers Collective and Oxfam India. She is an alumna of the University of Delhi, University of Illinois at Urbana-Champaign, University of Wisconsin-Madison, London School of Hygiene and Tropical Medicine and London School of Economics and Political Science, and is currently a student of law.

Ms. Ritu Dhillon
Member Secretary,
National Pharmaceutical Pricing Authority

Ms. Ritu Dhillon IAAS is Member Secretary, National Pharmaceutical Pricing Authority and Joint Secretary, Pharmaceuticals, Government of India. In her 23 years of service she has served in various senior capacities with the government across sectors. Her experience with the health sector includes being the Senior Financial Advisor and Chief Vigilance Officer with Indian Council Of Medical Research, the apex national biomedical research body and Financial Advisor of PGIMER, at Chandigarh. She has served as Principal Director with Comptroller and Auditor General of India apart from holding posts of Assistant and Deputy Accountant General of Punjab and Haryana, earlier. She was served as Additional Chief Administrator with Punjab Urban Planning Authority. She helped initiate collaboration with National Institutes of Health (NIH), USA and also participated in a NIH Funds Management Programme. Her short audit assignments include the procurement audit of UN headquarters at New York and heading the Aviation sector audit of UNHAS at WFP, Rome. She speaks English, Hindi, Punjabi and French.

Mr. Rajeev Chhabra
Founder Orthocare
& Jt. Coordinator, (Orthopedic Vertical Group), AiMeD

Mr. Rajeev Chhabra, Founder of Ortho Care, took up the business in trading and manufacturing of Medical Equipment and Instruments in 1985. After the inception of Ortho Care, he was dedicated to Orthopaedic Implants and Instruments. Rajeev is the Founder member of AIMED and first president of Orthopaedic Implants Manufacturers' Association (OIMA) in India and also closely works with CDSCO, NPPA and the Ministry of Pharmaceuticals for the betterment of Orthopaedic Industry in India.

Mr. Gurmit Singh Chugh
Managing Director, Translumina Therapeutics and
Jt. Coordinator, Implants, AiMeD

Mr. Gurmit Singh Chugh, is the Managing Director of Translumina Therapeutics, A company that truly resonates the 'make in India" spirit. The company was recently in national Headlines for acquiring its parent company Translumina Germany for whom his company worked as a distributor 10 years back. His company has also created the longest safety and efficacy data of Drug Eluting Stents in the World which was a big surprise to the Med tech fraternity as they never expected a Indian company reaching such heights.

He is a Master in International trade from the prestigious IIFT, Delhi. He started his career as a Medical Representative in Schering Plough USA and left his last professional engagement as Marketing Head of Boston Scientific in 2004 after gaining rich experience in the field of High and Medical Devices

Translumina Therapeutics was started in 2011 with a facility in Dehradun with an objective to manufacture high End Medical Device for Cardiac Treatments with highest level of quality and clinical evaluation at an affordable price. To compete at global scale, he created close partnerships with various med tech companies and Large Hospitals around the world to get access to clinical and engineering support. Mr. Gurmit, who represented his state in basketball, has a keen interest to mentor and lecture young Indian entrepreneurs in the Med Tech field by discussing his struggle while he trekked his tough journey with immense prejudice and discrimination of Indian made products in Indian and global markets.

Mr. Vivek Mangalwedhkar

Managing Director, S H Pitkar &

Jt. Coordinator (HWG – Regulations)

Mr. Vivek Graduate mechanical engineer-1984. Started working for Sales of Orthopaedic medical devices in 1987. Joined S H Pitkar Orthotools P Ltd as director in 1991. He has been responsible for overall growth of the company since then. Primarily responsible for Sales, Marketing, finance,HR, and regulatory. Working closely with various departments to regulate medical devices over 10 years.

Ms Shubhra Singh,
Chairperson
National Pharmaceutical Pricing Authority (NPPA)

Shubhra Singh, a 1989 batch IAS officer of the Rajasthan cadre. She is the new chairperson of the National Pharmaceutical Pricing Authority (NPPA) and assumed office in November 2018. She was formerly with the Department of Industrial Promotion and Policy (DIPP) under Minister of Commerce and also the Principal Chief Resident Commissioner of Rajasthan. Ms. Shubhra Singh was also Executive Director, Indian Trade Promotion Organisation (ITPO), New Delhi under the Dept of Commerce, Govt of India. In Rajasthan, she held the post of Director Census in 2010-11, and other important positions in the state and district level. She is double M.A. (English & Political Science) and her home town is Meerut.

Participants and their affiliations

List of Participants

S.No.	**Name & Designation**	**Address**
1.	Mr. PK Sharma	HMD
2.	Mr. Nitin Mahajan	Mitra Industries Pvt. Ltd.
3.	Mr. Vijay Vojhala	Patient Safety Group
4.	Dr. Sanjiiiv- Chairman	PWMAI
5.	Mr. Gurjeet Kohli - General Secretary	PWMAI
6.	Dr. Kavita Singh	Mission Director National Biopharma Mission
7.	Ashok Madan	IDMA
8.	Mr. Uday Munjal	Invest India
9.	Mr. Mukul	MeitY
10.	Anuj Mathur	ASSOCHAM
11.	Anshul Gupta	ASSOCHAM
12.	Dr. Prakamya Gupta	ICMR
13.	Agnideep Mukherjee	NMDP
14.	Mr Ajai Basil	NHSRC, MOH&FW
15.	Mr Anjaney Shahi	NHSRC, MOH&FW
16.	Mr. Sachin Chaturvedi	RIS
17.	Dr. Harpal Singh	IIT
18.	Mr. Srinivas Reddy	AMTZ
19.	Mr. Hardeep Vohra	National Biopharma Mission
20.	Nikhil Patel	Credence Management Corporation
21.	Abhinav Thakur	Accurex Biomedical Pvt. Ltd.
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Frequently Asked Questions

Frequently Asked Questions on Medical Device Rule, 2017

1. **If a license is granted in Form 25 or Form 28 before or after publication of GSR 1337(E) dated 27.10.2017, what will be validity period of such license?**

   As per notification, GSR 1337(E), dated 27.10.2017 the license issued under Form 25 or 28, unless sooner suspended or cancelled, shall remain valid perpetually.

2. **What will be status of application for renewal of license issued in Form 25 or Form 28 which are pending for approval by licensing authority or central licensing approving authority on or after 27.10.2017?**

   As per notification, GSR 1337(E), dated 27.10.2017, the Drugs and Cosmetic Rules, As per provisions in Rule 75 and Rule 76 the word "renewal" is omitted however, the licensee shall deposit license retention fee and documents as per the provisions of Current Medical Device Rules 2017.
   It is advised to all manufacturers of medical devices for compliance with the conditions and with the requirements of Medical Devices Rules, 2017 by online processes before the due date of the payment of applicable license retention fee.

3. **What will be the status of the application for grant of license are applied before 01.01.2018 but are still in process and not granted the license?**

   The application for grant of license which are applied before 01.01.2018 but are still in process and not granted the license, the applicant will need to pay balance fees and also reapply on the online portal as per the Current Medical Device Rules 2017.

4. **What will be the status of manufacturing license / additional product issued by State Licensing Authority before 01.01.2018 and sent for approval to CLAA?**

   Manufacturing licenses of a medical devices covered under CLAA scheme and signed for granting by State Licensing Authority before 31.12.2017, may be considered for approval by CLAA with the condition that licensee shall fulfill requirements of Medical Devices Rules, 2017 after 01.01.2018. Further, if such licenses are signed by State Licensing Authority after 27.10.2017, it shall be granted in accordance with GSR 1337 dated 27.10.2017 and those which are signed by SLA before 27.10.2017 shall be granted as per earlier provisions with validity period.

5. **What will be procedure to obtain additional products on existing valid licenses, in similar category of Medical Devices/IVD's after 01.01.2018?**

   Application form, fees and documents will have to be submitted on new Medical Device portal as per MDR-2017 to obtain the new license.

6. **What will be status of those applicants for import, who applied for registration or Import License before 01.01.2018 on old Sugam, but could not get it, due to incompletion of document or query raised?**

   Such applicants shall re-apply in new CDSCO MD online portal with additional balance fees and documents as per Medical Devices Rules, 2017 which may include new application form, new Power of Attorney, covering letter detailing the sequence of event & proofs thereof including proof of old fees paid. Such old applications on old Sugam may get advantage of old submissions/ fees till 30.07.2018 based on Medical Devices Rules, 2017.

7. **What will be applicability /utility of old sugam for applicants, with respect to existing Registration Certificate/ import Licenses?**

   Old sugam will remain operative for post approval changes of existing Registration Certificate and Import Licenses (as on 1.1.2018) till their expiry or till 30.07.2018, whichever is later as per Medical Devices Rules, 2017.

8. **For importing of raw materials / components intended to be used for further manufacture of Finished Medical Devices under a valid manufacturing license issued under the provisions of Drugs and Cosmetic Act and Rules thereunder, whether the importer needs to obtain the import license for such raw materials / components?**

   As per existing practices and circulars, in such cases, no import license is required.

9. **What will be the status of competent person existing on the license before 01.01.2018 for manufacturing and testing?**

   As per the saving clause of Rule 97 prescribed in Medical Devices Rules, 2017 those competent persons will continue to remain so.

   Note: *The first nine questions and answers applies to IVD's also*

10. **By when will the revised Notified Medical Device listing be made available?**

    As per Medical Device Rules 2017,

    (i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);

    (ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and

    (iii) 15 classes of Medical devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) Government of India may notify more devices under section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 in due course of time which will be displayed on the CDSCO website.

11. Will business continuity be considered for devices already in market, but not yet notified, if they are brought under the list of notified devices?

Once devices are brought under notified categories, the manufacturer / importer has to comply with Medical Device Rules 2017.

12. What would be the transition timeline given to manufacturers and importers w.r.t grandfathering of already existing devices?

If the device is already in the market and government of India notify the same under 3(b)(iv) of Drugs and Cosmetics Act, 1940 (23 of 1940) then the device will be regulated under the Medical Device Rules 2017.

13. In which form permission to import small quantities of medical devices for personal use can be obtained?

A patient can apply in Form MD-20 with all requisite documents and permission can be given in Form MD-21.

14. What is the process for classification verification with CDSCO or notified body prior to submission?

The Central Licensing Authority shall, classify medical devices referred to in Rule 2, based on their intended use and other parameters specified in the First Schedule. Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organization (CDSCO): Provided that the Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature.

15. What if the classification of a product being imported is different in GHTF countries from the classification in India?

In such cases, the higher class of Medical device will be considered.

16. Where can we get a list of authorized Notified bodies?

The list of the registered Notified bodies with CDSCO will be made available on the website.

17. What are the requirements to be a registered Notified body?

The requirements are laid down in Part I of Third Schedule of Medical Devices Rules, 2017.

18. Will the manufacturer have an option to choose Notified body?

The Notified body accredited under sub-rule (1) of Rule 13 shall be competent to carry out an audit of manufacturing sites of Class A and Class B medical devices to verify their conformance with the Quality Management System and other applicable standards as specified under these rules in respect of such medical devices as and when so advised by the State Licensing Authority.

19. If Notified body is not having competency to evaluate specific class(es) of devices, what would be the process?

As per the Medical devices Rules 2017, the National Accreditation Board for Certification Bodies (NABCB) shall lay down the conformity assessment activities for Accreditation of Notified bodies prior to registration with CDSCO.

20. For devices, already in market and notified later, would the requirement of local clinical investigation/evaluation be waived off?

The medical device on the basis of their intended use will be deliberated on case to case basis & data available, to substantiate their safety and effectiveness. The matter may also be placed before SEC.

21. Sub- clause (ii) lists 'insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?

As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) are included in the definition of medical devices.

22. Sub- clause (ii) lists 'Insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?

As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

23. In the event CDSCO considers any devices to be regulated beyond the notified devices as additional devices or as subset of device, what will be the process of regulating such device?

The devices which are already notified or to be notified by Government of India shall be regulated as per Medical Device Rules 2017.

24. Will a list of products classified into Class A, B, C and D be released by CDSCO or the companies have to do a self-classification of the products as per their understanding of the definition of the risk factors?

List of devices based on risk classification is published on the CDSCO website which is dynamic in nature.

25. If the list will be provided by CDSCO then would it be classified according to their therapeutic specialty (Cardiovascular, Dental etc.) to provide ease of location of the product?

Yes, the devices are classified as per the Risk based classification which is at par with the classification adopted in other countries is already displayed on the CDSCO website.

26. Will the risk-based classification be harmonized with the already existing and established global classification systems?

Yes.

27. Will a single import license fee apply to a grouped submission?

Any person who intends to apply for grant of license in respect of medical devices for - (i) import; (ii) manufacture for sale or for distribution; and may group all or any medical device in accordance with the guidelines to be issued from time to time by the Ministry of Health and Family Welfare in the Central Government, by taking into consideration the technological changes or development in the field of medical devices and in vitro diagnostic medical devices. If the principle technology, platform, intended use and product specification are different then separate fees needs to be submitted.

28. If a manufacturing firm is complying with ISO/IEC standards, would it still need to follow BIS standards?

(i) 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.

(ii) Where no relevant standard of any medical device has been laid down under sub- rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

(iii) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

29. Will a Notified body with two years auditing experience, outside India, be eligible for registering as a Notified body for carrying out audit of Class C & D medical devices?

Yes, they have to be registered with NABCB and CDSCO before being considered for auditing.

30. What is the timeline for carrying out the inspection for class C & D and grant of license?

For class C and class D the inspection will be carried out by Central Licensing Authority within a period of 60 days from the date of application and Central Licensing Authority may grant license if satisfied that the requirements of these rules have been complied within a period of forty five days from the date the inspection report has been received.

31. In case of Multi pack of a medical device is it sufficient to provide a single IFU (Instructions for use) if the medical devices are to be used by Health Care Professionals?

The medical device when offered for sale shall be accompanied by either its package inserts or user manual.

32. Will e-IFU (electronic Instructions for use) be permitted under the new regulations?

In Medical Device Rules 2017, e-IFU is not specified.

33. Several low-risk medical devices are supplied without an IFU. Where such a low-risk device is offered for sale, an IFU is not applicable and may not be supplied. Will this be allowed if a justification is submitted to the licensing authority (LA) at any time of registration?

The medical device when offered for sale shall be accompanied by either its package insert or user manual as per Rule 26 part (x) of Medical Device Rules 2017.

34. Could there be multiple importers for the same product (i.e. same legal & actual manufacturer)?

Yes, an authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

35. In case of multiple importers for same product:

a. For subsequent applications to obtain import license for already registered product & site by another agent under Medical Devices Rules, 2017 do all the documents related to site and product need to be submitted?

The new agent has to submit the legal documents like MD-14, new Power of Attorney, fees, wholesale/manufacturing licenses, Label, IFU and copy of import license issued to earlier agent along with the undertaking from the manufacturer stating that there is no change in the Device master file, Plant master file and other regulatory documents submitted to CDSCO by the earlier agent (name, address & Import License number) for registration.

b. How will Post Marketing Surveillance (PMS) be managed? Who will have reporting responsibility?

PMS is the responsibility of the licensed holder/authorized agent.

c. In case of new medical device, does each applicant need to obtain investigational device approval or once first importer obtains the investigational device approval the subsequent importers can simply obtain Import license?

Every applicant viz. authorized agent or manufacture has to obtain separate investigational device approval for new medical devices.

36. Would there be a provision to list multiple sites for a specific product on an existing certificate which has multiple products?

For the import of additional product from different manufacturing site the Indian agent has to submit fee for additional site as well as for the product and, the import license will be issued with fresh validity. In case the importer desires to get endorsed the additional product then product fees is required to be submitted and the import license will be issued with the same validity as of the existing license.

37. If yes, then what will be the procedure to endorse an additional manufacturing site (legal or actual) into an existing license?

As explained in Q no. 34.

38. What is the timeline for grant of approval for additional products from same site (in Form MD-15-Licence to import medical device)?

As per Rule 36 sub-rule (1), the Central Licensing Authority may, on being satisfied, grant license in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

39. What is the timeline for grant of approval for additional manufacturing site?

As explained in Q no. 38.

40. In the event of an inspection of an overseas manufacturing facility, what is the expected timeline subsequent to date of submission?

On receipt of an application under sub-rule

(i) of Rule 34, the Central Licensing Authority, may cause an inspection of the overseas manufacturing site either by itself or by any other person or body to whom the power has been delegated for the purpose.
(ii) The applicant shall be liable to pay a fee as specified under the Second Schedule in respect of expenditure required in connection with the visit to the overseas manufacturing site under sub-rule (1).
(iii) The Central Licensing Authority may, on being satisfied, grant license in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

41. After completion of inspection of an overseas manufacturing facility what will be the Central Drugs Standard Control Organization's timeline for submitting their findings?

The Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

42. If product is manufactured in countries other than the ones listed in Rule 36 sub-rule (3) – will clinical investigation in India be waived off for all classes?

As per Rule-36 sub-rule (4) where a medical device is imported from countries other than those referred to in sub-rule (3), the license in case of Class C and Class D medical devices may be granted after its safety and effectiveness has been established through clinical investigation in India as specified under provisions of Chapter VII of these rules.

Where a medical device, is imported from countries other than those referred to in sub-rule (3), the license in case of Class A or Class B medical devices may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

43. Does the license retention fee need to be accompanied with any support documentation? If yes, what are these documents?

The Firm needs to comply all the conditions laid down in the import license as per Rule 38.

44. Can Importer affix the India specific details as a sticker on retail pack in India or would the manufacturer be required to do so prior to shipping to India?

As per Rule-44 (n) importer can provide the label, in case of imported devices, by way of stickering, when such details are not already printed, includes import license number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture.

45. Can the date of manufacture/sterilization/expiry be mentioned as DD/MM/YY or M/YY?

As per Rule- 44 (e) the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life".

46. Are labeling rules applicable on transparent covers or any wrapper, case or other covering which is used for the purpose of packing/transport or delivery?

As per Rule-44 the particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed.

47. What are the satisfactory evidences to be provided to get approval for Shelf Life more than 5 years?

Satisfactory accelerated and real time data as per international norms on the products including field samples should be provided.

48. To import a medical device which does not have a predicate would the clinical trial be waived off in the event of CE marking?

No. The results of clinical investigation in India may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the United Kingdom or the United States of America or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device.

49. Will licenses currently valid but expiring immediately after 1st Jan 2018 be considered valid until 31st July 2018 or 30th June 2019 as per Rule 97 'Savings'?

As per Rule 97 (i) The license or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

50. Will the license issued in 2017 having validity up to 2020 be valid till 2020 as per new Medical Device Rule 2017?

As per Rule 97 (i) The license or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

51. For licenses expiring in early 2018 does the firm need to submit renewal 9 months in advance or simply pay retention fee, on expiry, as specified in new rules?

As per Rule 34 (1) An authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

52. How would the import license (with different RC holders) transit into the new system?

As per Rule 34 sub-rule (1) Individual import licenses have to be applied with requisite fees and documents.

53. What would be the mechanism for adding the new products in the existing registration certificate which will be valid after 1st Jan 2018 till 2020?

As per Rule 34 sub-rule (1) An authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

54. Will there be any provision to grant extended validity to the existing licenses by paying the fee difference, few relevant undertakings and certificates instead of submitting the complete Device Master File (DMF) & Plant Master File (PMF)?

As per Rule 34 sub-rule (1) an authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

55. What fee would be applicable for the manufacturing site, if the importers wish to register devices belonging to multiple classes (A/B/C/D)?

As per the second schedule the Firm needs to submit the fee for different classes of the products. If the manufacturer is manufacturing all classes of the product then fees pertaining to higher class needs to be submitted.

56. For cases, where real-time data is not available at the time of submission of application, accelerated stability for how many weeks or months to be submitted to support the claimed shelf life initially? Can we submit three months accelerated stability data as compliant with relevant ISO standards?

As per Fourth Schedule, part III, Appendix II (7.8); if available, real-time aging data shall be submitted to support the claimed shelf life. However, if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life. After completion of the real time stability analysis, real-time stability data shall be submitted in support of the claimed shelf life.

57. Does the requirement in the fourth schedule which specifies that the manufacturers have to submit an undertaking that they comply with the provisions of the fifth schedule applicable to application for license to manufacture?

Undertaking signed stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule needs to be submitted in case of manufacture of Class B, C and D medical devices.

58. Is Fifth Schedule applicable for importers?

Fifth Schedule is applicable for manufacturers.

59. Whether any change in labeling which is not among the details mentioned under Chapter- Labeling of medical devices (Rule 44) need to be notified? For e.g., if the label is universal for India and Philippines and there is change of manufacturing of license no. In the Philippines label part as per their local regulations, need to be notified?

Label excluding change in font size, font type, color, label design is a major change as per Sixth Schedule and prior approval needs to be taken from Central Drugs Standard Control Organization.

60. Will change in authorized Agent require fresh License?

Change in Indian agent will require fresh License

61. Whether GMP compliance and GMP certification is applicable to medical devices and IVDs as per Medical Devices Rules, 2017 as it asks for compliance to Quality Management System (QMS) & there is no mention of need for compliance to GMP?

As per Medical Devices Rules, 2017, there is no mention of requirement for compliance to GMP, but there is need for compliance to QMS and other rules. Therefore, now, there is no requirement of GMP certificates for Medical Devices & IVDs.

62. Despite no mention in rule for domestic purposes, if requested by importing country, who will issue the WHO GMP certificate for medical devices and IVDs?

Licensing Authority who has issued the valid license to manufacture for sale will continue to issue WHO GMP certificate (Only on the request of importing country).

63. Who will issue the other certificates like Non-Conviction Certificate, Validity Certificate, Market Standing certificate etc. which are not mentioned in rules but are required on request of procurement / tendering agencies?

The Licensing Authority who has issued license shall issue such certificates.

64. Who shall issue Free Sale Certificate of notified regulated medical devices and IVDs?

As per Medical Devices Rules, 2017, Central Licensing Authority (CLA) shall issue Free Sale Certificate of notified regulated medical devices and IVDs.

65. What are the surgical dressings covered under regulations?

Surgical dressings including bandages which are intended to be used on wound or injured skin or tissues are covered under regulation.

66. In the light of New Medical Device Rules 2017, how absorbent cotton will be regulated? Whether as Drug or Medical device and in which class?

Absorbent cotton will be regulated as a part of surgical dressings as a Medical Device under Risk class A as per the provisions of Medical Device Rules, 2017.

67. Whether bandages which do not come in contact with wound or used for providing support/compression are regulated?

Bandages which do not come in contact with wound or injured skin or tissue or used for providing support/compression are not covered under the category of surgical dressings.

68. Whether casting tapes or splints are regulated?

Casting tape/Splints intended to be used for external immobilization of fractures/sprains as prescribed by doctor are regulated.

69. What is regulatory expectation to ensure quality of components (raw materials which are to be used for further manufacturing of finished medical devices including In vitro diagnostic medical devices under the valid license for manufacturing?

With respect to quality of components/raw materials to be used for further manufacturing of finished medical devices under the valid license for manufacturing, it is required that these components need to qualifying quality standards and Quality Management System (ISO 13485) and, if imported, need to have Free Sale Certificate of their finished product in the GHTF countries. The documentary evidence of the same shall be submitted to the licensing authority (who is issuing manufacturing license) at the time of grant of license & subsequently, as & when required. Further, it shall also be available for audit/inspection, whenever required.

70. Is there any provision for issue of GLP certificate in MDR-2017 under Drugs & Cosmetics Act?

There is no provision in MDR-2017 under Drugs and Cosmetics Act for issue of GLP certificate.

71. Is there any provision for exemption of Annexure A of Fifth schedule in Medical Device Rules, 2017 in respect of environmental requirements for catheters/ Ablation Device/ IV Cannulae/ Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles/ Perfusion sets, if the product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use?

As per Fifth Schedule of MDR 2017, Clause 7.5.1.2 regarding control of production and service provision — Specific requirements and clause 7.5.1.2.1 regarding cleanliness of product and contamination control.

The manufacturer shall establish documented requirements for cleanliness of product if:-

(a) Product is cleaned by the manufacturer prior to sterilization or its use; or

(b) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use.

Further, it is clarified that, if the product is cleaned in accordance with clause (a) or clause (b) above, the requirements content in clause (a) and (b) of sub-paragraph 6.4 do not apply prior to the cleaning process.

72. Whether separate GMP/QMS is issued by CLA/SLA for Medical Device & In vitro Diagnostic products for the purpose of tender/procurement

The Existence of manufacturing license under Medical Device Rules 2017 indicate conformance of fifth schedule (Quality Management System) of MDR-2017 & Separate GMP/QMS are not prescribed for issuance by CLA/SLA under Medical Device Rules-2017.

References

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