Update on the Implementation of Medical Device Rules in India

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Presentation Overview

- Drugs & Cosmetics, Act,1940
- Medical Device Rules & its salient features
- Status of Implementation of MDR, 2017
- Way-forward for Implementing and Strengthening ease of doing business
- Challenges

Medical Devices Rules, 2017

- Medical Device rules are effective from 01.01.2018, under the Drugs and Cosmetics Act 1940 -
- To regulate the Clinical Investigation, Import, Sale and Distribution of the medical devices in the country.
- The Medical Devices Rules, 2017 are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices, which will foster Make in India also.

Scope of the regulation

Medical Device Rules,2017 shall be applicable to:

(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) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940); and

(iii) 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);

The Govt of India has notified…

S. No	Name of the device	Earlier to jan	Date of notification
1	Disposable Hypodermic Syringes	SLA	17-03-1989
2	Disposable Hypodermic Needles	SLA	17-03-1989
3	Disposable Perfusion Sets	SLA	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera	SLA	27-08-2002
5	Cardiac Stents	CLAA	06-10-2005
6	Drug Eluting Stents	CLAA	06-10-2005
7	Catheters	CLAA	06-10-2005
8	Intra Ocular Lenses	CLAA	06-10-2005
9	I.V. Cannulae	CLAA	06-10-2005
10	Bone Cements	CLAA	06-10-2005
11	Heart Valves	CLAA	06-10-2005
12	Scalp Vein Set	CLAA	06-10-2005
13	Orthopedic Implants	CLAA	06-10-2005
14	Internal Prosthetic Replacements	CLAA	06-10-2005
15	Ablation Devices	*CLAA	25-01-2016

Following products are notified as ‘drugs’ but under MDR-2017 regulated as Medical Devices

- Sutures and Ligatures
- Disinfectants
- Blood Grouping Sera
- Surgical Dressing
- Umbilical Tapes
- Condoms
- Intra Uterine Devices
- Vaginal Tubal Rings
- Blood Bags

Salient Features of MDR, 2017

- Risk based classification
- Provisions of Notified Bodies
- Quality Management System in line with ISO 13485 has been adopted;
- Provisions related to the ‘Essentials Principles of Safety and Performance’ for manufacturers have been specified in the Rules;
- Separate provisions for regulation of Clinical Investigation of investigational medical devices (i.e. new devices) have been made at par with international practice.
- Provision is made to designate or establish Central Government medical device testing laboratories to verify conformance with the quality standards.

Risk based classification……

- **Medical devices shall be notified by the Central Government and classified by the CLA based on the classification rules specified in the *First Schedule* of the drafted rules.**

- **Following are the risk Classes and the classification criteria based on the severity of risk associated with the medical device.**

Risk Criteria	Risk Class
Low	Class A
Low-Moderate	Class B
Moderate-High	Class C
High	Class D

Medical Device Rules,2017 Chapters

Chapter- I	Title, Application, Commencement, Definition
Chapter - II	Classification of MD, Grouping of MD, Essentials Principles
Chapter - III	Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,
Chapter - IV	Manufacture of MD-Application, Inspection, grant of lic, conditions of lic, Suspension, Cancellation, Appeal, Test License
Chapter - V	Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use
Chapter - VI	Labelling requirement
Chapter - VII	Clinical Investigation- Permission, Medical management, Compensation, Inspection
Chapter - VIII	Permission to import or manufacture medical device which does not have predicate medical device
Chapter -IX	Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body
Chapter -X	Regulation of Laboratories for carrying test or evaluation
Chapter - XI	Sale of Medical Devices
Chapter - XII	Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Medical Device Rules, 2017-Schedules

Schedule Number	Title
First	Classification of MD and IVD
Second	Fee
Third	Registration and functions of Notified Bodies
Fourth	Documents required for grant of mfg and Import licence
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

New Definitions

- Medical Device
- Substantial Equivalence
- Predicate device
- Investigational Medical Device
- New *in-vitro* diagnostic
- Clinical Investigation
- Manufacturer
- Notified Body
- Clinical Performance Evaluation

Scope of Notified Bodies

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license/registration

Manufacture of Medical Device for Sale or Distribution

Class A and B

- Manufacturer shall apply through an identified online portal of Ministry with requisite documents as per Fourth schedule and fees specified in Second schedule.
- No audit for class A device prior to grant of license.
- The audit may be carried out within 120 days from the date of issue of license.
- The audit for Class B device is necessary prior to the grant of manufacturing license and the audit shall be carried out within 90 days from the date of application.
- The notified body shall furnish its report to SLA within 30 days.

Manufacture of medical Device for Sale or Distribution

Class C and D

- The application shall be made with requisite documents and fees through online portal of the Central Government to CLA.
- CLA may use the services of any expert and of a notified body and may carry out an inspection within a period of 60 days from the date of application.
- No inspection of a medical device manufacturing site for grant of loan license to be carried out if the site is already licensed to manufacture such devices.
- After completion of inspection , the inspection team shall forward the report to CLA through online portal.

Standards of medical Devices

The medical device shall conform to the standards laid down by BIS or may be notified by Central Government from time to time. If, such standards are not available then ISO, IEC or any other pharmacopoeial standard. If all are nor available then device shall conform to the validated manufacturers standard

Regulatory Authorities

Device Class / Activity	Class A	Class B	Class C	Class D
IMPORT	CLA	CLA	CLA	CLA
MANUFACTURE	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
SALE	**SLA**			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA

***Note:** **Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.**

Medical Device Clusters in India

Haryana

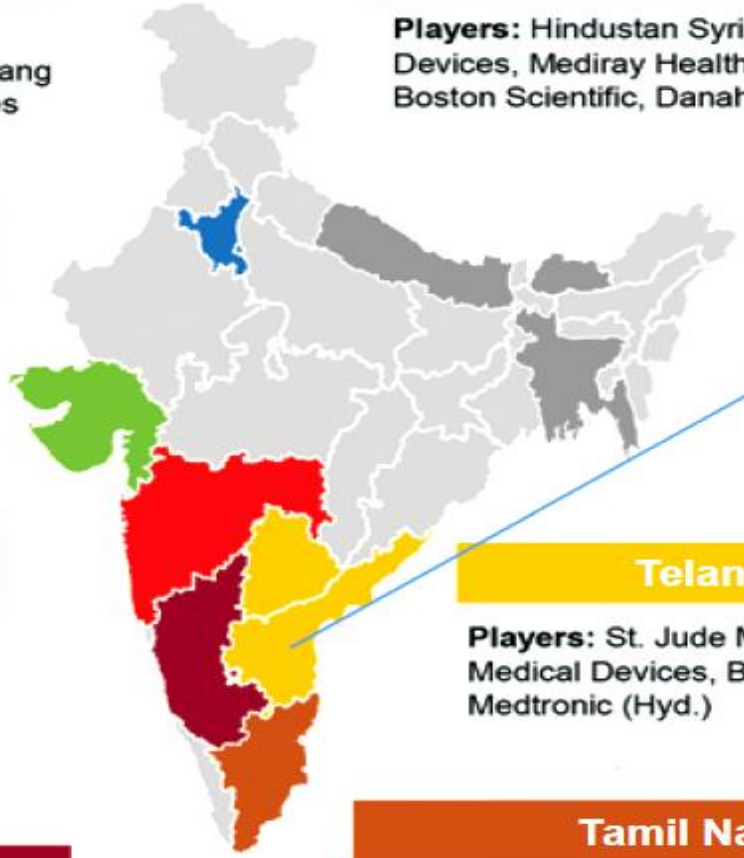
Players: Boston Scientific Corp., Becton Dickinson India, Hindustan Syringes, Narang Medicals, Poly Medicure, BL Life Sciences

Delhi (NCR)

Players: Hindustan Syringes and Medical Devices, Mediray Healthcare, 3M Co., Boston Scientific, Danaher Co.

Gujarat

Players: 3M Co., Bayer AG, Meril Life Sciences, Envision Scientific, Invent Bio-Med, Sahjanand Medical Technologies



Maharashtra

Players: Johnson & Johnson, Smith & Nephew, Philips Healthcare, Siemens, Nipro Corp., Danaher Corp, Trivitron Healthcare, Remi Laboratories

Telangana

Players: St. Jude Medical, Relysis Medical Devices, B Braun (Hyd.), Medtronic (Hyd.)

Karnataka

Players: GE Healthcare, Biocon, Medived, Skanray, Bigtec Labs, Skanray Technologies, Prognosys Medical, Opto Circuits, Biorad Medisys, Vascular Concepts, Confident Dental Equipments

Tamil Nadu

Players: Roche, Trivitron Healthcare, Opto Circuits, Perfint Healthcare, Cura Healthcare, Appaswami Associates, Phoenix Medical Systems, Schiller

Regulatory Landscape: Government Support & Initiatives for Medical Devices Sector

Regulatory Landscape Strenghtening

- Materio-vigilance Programme of India
- Delinking of Schedule M-III
- Significant experience for Manufacturing Supervisor
- Presription of Shelf-life for medical devices
- Exemption for Custom Made Medical Devices
- Clarification of Standards for medical devices
- Drugs and Cosmetic (Amendment) Bill, draft for stakeholder views
- Draft National Medical Device Policy, 2015

Tax/ Duty Modifications

- Subsidies and exemptions to MSMEs
- Corrections in the Inverted Duty Structure to boost domestic manufacturing of medical devices
- Budget initiatives

Infrastructure Boost

- 'Make In India' Campaign to boost domestic manufacturing
- Setting up of Medical Device Parks in three states
- Setting up of Medical Device Testing Labs in two states

Other Favourable Initiatives

- Exemption from Phase I clinical trials for medical devices
- Development of ICMED scheme for certification of medical devices

Status of Implementation of MDR, 2017

- New Medical Device Online portal is functional for uploading the applications for Import License and Manufacturing License of Medical devices and IVDs, for post approval changes, registration of medical devices testing laboratories , clinical investigation etc.

- Classification of Medical Devices and IVDs has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.

Status of Implementation of MDR, 2017

- Medical device online portal is functional for the registration of Notified Bodies. Four notified bodies have been registered and information is available on the CDSCO website.

- Grouping of Medical Devices and IVDs along with essential principle checklist has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.

- Notification of Medical Device Officer and Medical Device Testing Laboratories have been published.

Status of Implementation of MDR, 2017

- CDSCO organised workshops to impart trainings to State Licensing Authorities i.e. Delhi, Rajasthan and stakeholders for the effective implementation of Medical Devices Rules, 2017.
- For addressing various questions on regulatory practices in medical devices, Frequently Asked Questions (FAQ) on medical devices and in vitro diagnostics is uploaded on CDSCO website. Also regular interactions are taking place with all the stakeholders to resolve their regulatory practices issues.
- Guidance on Performance Evaluation of In-vitro Diagnostic Medical Devices have been published on the website.
- Public relation office is established by CDSCO to guide the start-ups and innovators.

Status of Implementation of MDR, 2017

- 16 Technical Committees of BIS are framing the standards of Medical devices and IVDs.
- Compilation of Rules/Standards/FAQs by IPC.
- 5 officials from India are trained on Medical Device Regulation at PMDA academy.

Status of Implementation of MDR, 2017

Launch of Support Cells for WHO PQS for IVDs in India

- For providing guidance to the Indian manufacturers for the WHO Prequalification of *In Vitro* Diagnostics Programme in India

1) National Institute of Biologicals in North India
2) Andhra Med-tech Zone in south India

Status of Implementation of MDR, 2017

- As per MDR-2017 the details of Licenses issued

1. Import License – **130**
2. Test manufacturing License – **50**
3. Test License for Import – **47**
4. Manufacturing License for Class C & D by CLA – **15**
5. Manufacturing License for Class A & B by SLA's – **14**
6. Permission to conduct Clinical performance evaluation for new IVD – **1**
7. Permission to import medical device which doesn't have predicate device – **1**
8. Permission to conduct clinical investigation for new medical device - **1**

Launch of WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services
at
National Coordination Centre- Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India

Materiovigilance Programme is initiated under PvPI

- National Coordination Centre (IPC, Ghaziabad).
- National Collaboration Centre (Sree Chitra Tirunal Institute of Medical Sciences and Technology, Tiruvananthapuram).
- Technical Support and Research Centre (National Health System Resource Centre- NHSRC).

More steps are being taken for implementing and strengthening ease of doing business

- Online processing.
- Establishment / Designation of more number of medical device testing infrastructures.
- Capacity building of the regulatory and industry professionals.
- Trainings of regulatory professionals and the industry.
- Simplifications and convergence of rules and practices as per international and national expectations so as to ensure patient safety.

More steps are being taken for implementing and strengthening ease of doing business

Further devices to be taken under regulations:

1. All Implantable Devices
2. MRI
3. PET
4. CT Scan
5. X-Ray
6. Ultrasound
7. Dialyser
8. Cell Separator
9. Glucometer
10. Nebulizer
11. Blood Monitoring System
12. Organ Preservative Solution

CHALLENGES

1. Conformatory Assessment facilities for Medical Devices

2. Serological panels and Testing Labs for IVD kits

THANK YOU…