HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

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INDIA -REGULATORY UPDATES

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REGULATORY FRAMEWORK

- The **Drugs and Cosmetics Act 1940** is a **Central legislation** enforced by both the Central and State Governments and is applicable throughout India.
- The Act regulates the **import, manufacture, sale, and distribution** of drugs, medical devices, and cosmetics in India.
- Medical devices are regulated under the definition of **“Drug”** as provided in the **Drugs and Cosmetics Act 1940**.
- The **Medical Devices Rules 2017 India** were implemented with effect from **01 January 2018** to establish a robust regulatory framework and align India’s medical device regulations with globally accepted regulatory practices.
- Subsequently, **all medical devices were brought under the regulatory framework with effect from 01 April 2020** through a phased approach.

Regulatory Authorities & Their Functions

DEVICE CLASS → / ACTIVITY ↓	Class A	Class B	Class C	Class D
Import	CLA	CLA	CLA	CLA
Manufacture	SLA	SLA	CLA	CLA
Clinical Investigation	Permission from CLA			
Sale	SLA			
QMS Verification	NB	NB	CLA	CLA

*Note: Prior inspection shall not be required before the grant of manufacturing of Class A devices.

(CLA- Central Licensing Authority ; SLA- State Licensing Authority; NB-Notified Body)

UPDATES IN LEGISLATION

- A unified **online platform** has been developed to facilitate the issuance of various approvals under the **Medical Devices Rules, 2017**, managed by both the **Central Licensing Authority** and the **State Licensing Authorities**.

- Licensing requirements are **waived for Class A medical devices** that are non-sterile and non-measuring.

- A **registration certificate** can be granted for the sale or distribution of medical devices.

- State Governments have the authority to **appoint or establish Medical Device Testing Laboratories** to conduct device testing.

- To enhance post-market surveillance, the **Materiovigilance Programme of India (MvPI)** was launched, with the **Indian Pharmacopoeia Commission serving as the National Coordination Centre (NCC)**. The programme is supported by **six regional training centers** across the country.

UPDATES IN LEGISLATION

- A total of **18 Notified Bodies** are registered with the **CDSCO** to conduct audits of manufacturing sites for **Class A and Class B medical devices** within the country.
- There are **6 Central Medical Device Testing Laboratories (CMDTLs)** designated for statutory testing of medical devices.
- Additionally, **80 other Medical Device Testing Laboratories (MDTLs)** are registered to perform testing or evaluation of medical devices on behalf of manufacturers under the **Medical Devices Rules, 2017**.
- Across the country, **671 Medical Device Adverse Event Monitoring Centres** have been identified to voluntarily report adverse events related to medical devices.

UPDATES IN LEGISLATION

- Various **guidance documents** are being updated, including those on **medical device grouping**, **Essential Principles of Safety and Performance (EPSP) of medical devices**, **grouping guidelines for medical devices**, **Software as a Medical Device (SaMD)**, and **guidance/checklists for conducting inspections of Quality Management Systems**, in alignment with **IMDRF guidance documents**.

- Various tool tips has been introduced to have more clarity on the requirements for submission of various applications.

- The **CDSCO** has established a **dedicated vertical for medical device regulation**, staffed with personnel from engineering, science, and related technical backgrounds. Recruitment processes have also been initiated to strengthen technical manpower in this vertical.

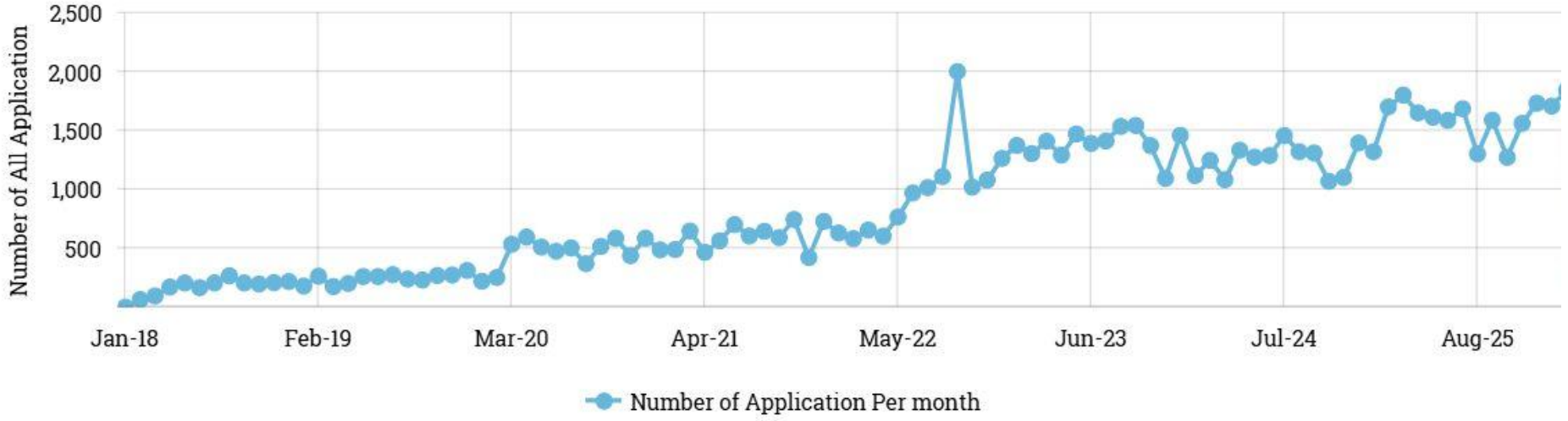
- Efforts are ongoing for the **development of standards for all medical devices in India** through the **Bureau of Indian Standards (BIS)**. BIS, as the nodal agency for standard development and a **"P" member of ISO**, plays a key role in formulating and harmonizing standards within the country..

- An automated system for generating certificates for certain activities has been introduced to reduce regulatory burden and streamline approvals.

Market Size and Manufacturing Scenario

- The Indian medical device market was valued at USD 11 billion in 2020 and is projected to grow to USD 50 billion by 2030, registering a CAGR of 14%.
- India relies heavily on imports, accounting for up to 80% of domestic medical device requirements by value.
- Major domestic manufacturing focuses on disposable devices, implants (such as cardiac stents, drug-eluting stents, intraocular lenses, orthopedic implants), and in-vitro diagnostic devices.
- Prior to the implementation of the Medical Devices Rules, 2017, around 250 manufacturers were licensed in India.
- After the implementation of MDR 2017, the total number of approved manufacturing **units has increased significantly more than 4330 units.**
- Total number of Import licenses issued for various classes of devices : **~ 12245**

Trend of Licenses issued under MDR-2017



Global regulatory convergence /Harmonization

- The **CDSCO** actively participates in various **global training programs** organized by other regulatory agencies.
- It serves as an **observer in the International Council for Harmonisation (ICH)** and is a **member of six ICH working groups**.
- The **Ministry of Health & Family Welfare/ CDSCO** has signed **MOUs with multiple international regulatory authorities and ministries**, including those of the **USA, Japan, UK, BRICS countries, Germany, Brazil, Denmark, and Indonesia**.
- CDSCO has also hosted major global regulatory events, including the **13th and 22nd Asian Harmonization Working Party (AHWP) meetings** and the **19th International Conference of Drug Regulatory Authorities (ICDRA)** in New Delhi.
- India holds **affiliate membership in the International Medical Device Regulators Forum (IMDRF)**.
- Additionally, the country's **vaccine regulatory system** was **re-benchmarked in 2024 against the WHO Global Benchmarking Tool**, reflecting alignment with international standards.

Thank You!