IMDRF International Medical Device Regulators Forum

Central Drugs Standard Control Organization (CDSCO)

The National Regulatory Authority of India

About CDSCO

- The **Central Drugs Standard Control Organisation (CDSCO)** under Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority responsible for the regulation of Drugs, Medical Device & Cosmetics in the country.

- **Mandate:** To safeguard and enhance the Public Health by assuring the Quality, Safety and Effectiveness of Medical Products & Cosmetics.

- **CDSCO** in coordination with the **State Drugs Control Authority** ensures the Quality, Safety and Efficacy of these products.

- CDSCO has its **08** Zonal & **07** Sub-zonal offices, **16** Port offices and **08** Central drugs testing laboratories.

- There are 28 States and 09 Union Territories Drug Control Offices throughout the country.

Regulatory framework for Medical Devices in India

- **Drugs & Cosmetics Act, 1940**, a Central Act enforced by both Central and State Governments. This Act is extended to Whole of India.

- The scope of the Act is to regulate the Import, Manufacture, Sale and Distribution of Drugs, Medical Devices and Cosmetics

- **The Medical Devices Rules, 2017 have been incorporated under the said Act & were implemented w.e.f. 01.01.2018.**

- All medical devices have come under the regulation w.e.f. 01.04.2020.

- ✓ Class A & B is licensed by State Regulatory Authority
- ✓ Class C & D manufacturing and Import of all Devices is licensed by CDSCO
- ✓ Exemption for licensing requirement for Class A (non-sterile and non-measuring) Medical Devices.
- ✓ Registration certificate required to sell, stock, exhibit or offer for sale or distribute a medical devices.

- A robust tool is established through **Materiovigilance Programme of India (MvPI)** for reporting and monitoring of adverse events associated with the medical devices in the country.

➢ Notified Bodies and Testing Laboratories:

- At present **14** Notified Bodies are registered with CDSCO for audit of manufacturing site of Class A & Class B Medical Devices in the country.

- **06** Central Medical Device Testing Laboratories (CMDTL) are notified for statuary testing of Medical Devices

- **71** Private Medical Devices Testing laboratories (MDTL) are registered to carry out testing or evaluation of a medical device on behalf of a manufacturer under Medical Devices Rule, 2017

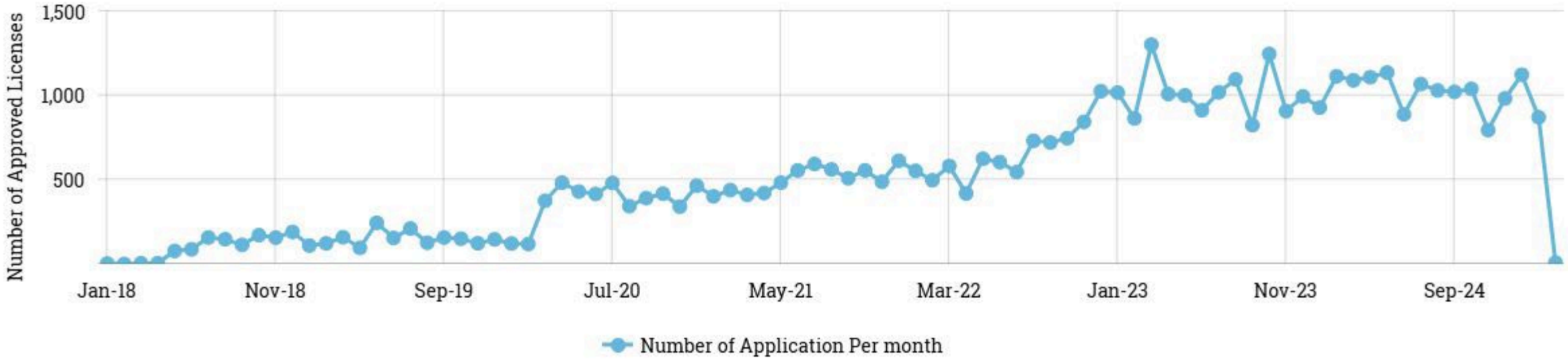
Medical Device Industry in India

- **Market Size-** USD 11 billion in 2020 and expected to grow to 50 Billion by 2030 at growth rate of 14% as per CAGR.
- India depends on imports (upto 80% by value) of its domestic requirements.
- Major manufacturing in the country for Disposables Devices, Implants such as Cardiac Stents, Drug-Eluting Stents, IOL, Orthopaedic Implants and In-vitro Diagnostics Medical Devices
- **Before** implementation of Indian MDR-2017, only about **250** manufacturers were licensed in the country.
- **After** implementation of Indian MDR-2017, total number of manufacturing units approved :

Manufacturing units approved by SLA (Class A & Class B)	Manufacturing units approved by CLA (Class C & Class D)	Total number of **manufacturing units**
~2700	~1000	**~3700**

- Total number of **Import** licenses issued for various classes of devices : **~ 10500**

Trend of Licenses issued under MDR-2017
since 01.01.2018



Participation with IMDRF Activities

- It was a great opportunity for CDSCO and the MoHFW to participate in the consecutive **sessions of IMDRF** since 2023.
- CDSCO has also become an **Affiliate member** of the IMDRF in the **26th session** of IMDRF held in September 2024 at Seattle, USA.
- CDSCO has already nominated officers for active participation in various working groups of IMDRF.
- The officers from CDSCO are also deputed for participating in various online training program organized by IMDRF from time to time to gain updates on the Medical devices regulation.

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Thank you/Questions