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Role of State Licensing Authority and Central Licensing Authority in Class B Medical Devices Under CDSCO

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Abstract: *The Medical Device Rules (MDR), 2017 under the CDSCO, regulate medical devices in India. Certain licensing procedures are necessary for Class B medical device, which include infusion sets, dental crowns, bone plates, and other moderate-risk devices. The functions and roles of the Central Licensing Authority (CLA) and State Licensing Authority (SLA) in overseeing Class B devices are examined in this paper. The stepwise approval process, the relative roles of SLA and CLA, and the main difficulties experienced by producers are also highlighted in the paper. Manufacturers, students, and regulatory experts will all benefit from this review by having a better understanding of Indian medical device laws.*

Keywords: Medical Device Rules 2017, CDSCO, SLA, CLA, Class B Devices, Regulatory Affair

I. INTRODUCTION

Medical devices play a crucial role in healthcare systems across the globe. The World Health Organization (WHO) defines a medical device as:

"Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes."

Medical purposes include diagnosis, prevention, monitoring, treatment, alleviation of disease, investigation, replacement, modification of anatomy, or support of physiological processes.

The Medical Device rules (MDR), 2017 in India, which are based on the Drugs and Cosmetics Act, 1940, regulate medical devices. Any instrument, apparatus, appliance, implant, substances, or other item designed for use in humans for the diagnosis, treatment, or mitigation of disease or condition is considered a medical device, according to MDR 2017. To ensure the quality and safety of medical devices in India, this legal recognition was a significant advancement.

Class	Risk level	Examples
Class A	Low Risk	Surgical dressings, tongue depressors
Class B	Low to Moderate risk	Dental crowns, bone plates, infusion sets
Class C	Moderate to high risk	Cardiac stents, orthopedic implants
Class D	High Risk	Heart valves, implantable defibrillators

II. AIM & OBJECTIVES

Aim

To study and understand the regulatory roles and responsibilities of the State Licensing Authority (SLA) and the Central Licensing Authority (CLA) in the approval, licensing, and monitoring of Class B medical devices as per the Medical Device Rules, 2017 under the CDSCO, India.

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Objectives

- To outline the regulatory framework governing medical devices under the Medical Device Rules (MDR), 2017.
- To identify the specific functions and jurisdictions of SLA and CLA in the regulation of Class B medical devices.
- To compare the licensing procedures and approval processes handled by SLA and CLA.
- To highlight the collaborative mechanism between central and state authorities to ensure device quality, safety, and compliance.
- To understand how regulatory oversight ensures effective implementation and harmonization of medical device control across India

3.1 Indian Regulatory Framework

The Drugs and Cosmetics Act of 1940 and the Drugs and cosmetics Rules of 1945 controlled medical devices as "drugs" in India until 2017. This strategy had several drawbacks, including the fact that most medical devices were left unregulated as well as just 15 types of equipment were classified as "drugs". The licensing processes were unclear, and there was no specific risk-based classification.

3.2 Regulatory Authorities under MDR 2017

Central Drugs Standard Control Organization (CDSCO):
Function astheNational Regulatory Authority (NRA).
Headed by the Drug Controller General of India (DCGI).
State Licensing Authorities (SLA):
Operate under respective State Drug Controllers.
Handle manufacturing, loan and wholesale license for Class A and B devices.
Conduct grant renewals and inspections.

3.3. Importance of MDR 2017 for Industry and Patients

MDR 2017 has several benefits:
Patient safety: Ensures only quality-assured, tested devices reach the market
Simplicity of Doing business
Global Harmonization: By conforming to IMDRF guidelines, Indian gadgets become more export-ready
Accountability: Clearly defined roles for Notified Bodies, SLAs, and CLAs
Post-Market Vigilance: Continuous monitoring of devices even after approval

IV. STATE LICENSING AUTHORITY (SLA)

4.1 Definition and Legal Basis

The state Licensing Authority (SLA) is the statutory body authorizes by the State Government to carry out regulatory duties associated with medical device licensing under the Drugs and Cosmetics Act of 1940 and the Medical Device Regulations (MDR) of 2017.
The "Licensing Authority", as defined by Rule 19 of MDR 2017, is the body designated by the State Government to provide licenses for the production or loan-license of Class A and Class B medical devices in that state or Union Territory.

4.2 Legal Framework

Drugs act Cosmetics Act, 1940
Provides the overall legal foundation for regulating manufacture, sale, and distribution of drugs and medical devices in India.

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Medical Device Rules, 2017

Cameintoforceon 1st January 2018, providing a risk-based, device-specific framework.

Chapter IV (Rules 19-26) specifies the legal authority, functions, and powers of SLA.

For Class A and B device licenses, SLA serves as the appropriate authority.

Under DCGI, the Central Licensing Authority (CLA) has the authority to grant licenses for higher-risk devices (Class C & D).

4.3 Significance of SLA Legal Authority

SLA serves as the first point of regulatory control for low- and moderate-risk devices, ensuring compliance at local level.

Legal empowerment allows SLA to take enforcement actions such as suspension/cancellation of licenses, seizure of products, and prosecution in case of violations — thereby safeguarding public health.

4.4 Advantages of State-Level Control

- **Decentralization:** Faster processing due to state-level accessibility
- **Better Monitoring:** Local officers can perform on-site inspections more efficiently
- **Encouragement for SMEs:** Easier for small/medium manufacturers to approach SLA
- **Promotes Make in India:** Simplified process encourages local manufacturing

4.5 Stepwise Process for Obtaining Class BManufacturing License

- Application submission
- Scrutiny by SLA
- Site Inspection/Notified Body
- Review of Inspection Report
- Grant of license
- Post-Licensing Obligation

Timelines and Fees:

Timeline: In accordance with MDR 2017, SLA must process and issue manufacturing licenses within 45 days of the application date (if no deficiencies are found).

Fees:

Class A/B manufacturing license application fee: □5,000 per site

Extra cost per devices: □500 per device category

The renewal fee is the same as for a new license

4.6 Limitations/Challenges:

- **Variability among states:** Different states may have different interpretation/efficiency
- **Limited Resources:** Some states lack trained staff or infrastructure
- **Delays in QMS Audit:** Depending on Notified Bodies can slow down the process
- **Coordination issues**: Need smooth data sharing between SLA and CLA to avoid duplication

V. CENTRAL LICENSING AUTHORITY

5.1 Definition and Legal Basis- CLA

In India, the highest regulatory body in charge of issuing national medical device approvals and licenses is the Central Licensing Authority (CLA). Under the direction of the Drug Controller General of India (DCGI), the CLA functions under the Central Drugs Standard Control Organization (CDSCO).

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As per Rule of MDR 2017:
"Central Licensing Authority means the Drugs Controller General of India, or such other officer as may be authorized by the Central Government to perform the functions of the Central Licensing Authority under these rules."
This means that the CLA is legally empowered to grant licenses, permissions, and approvals for medical devices where centralized decision-making is required particularly for high-risk devices (class C and D), imported device, and new/innovative devices not previously marketed in India.

5.2 Legal Framework and Jurisdiction

Drug and Cosmetics Act, 1940

Forms the parent legislation for regulating medical device as "drugs" under Section 3(b)(iv).
Provides power to the Central Government to appoint controlling authorities such as DCGI.

Medical Device Rules (MDR), 2017

Chapter V (Rules 27–33) outlines CLA's authority over Class C and D device import and manufacture licenses.
Chapter VI (Rules 34–63): Governs clinical investigation of new devices, which is exclusively under CLA's jurisdiction.
Chapter IX (Rules 85–94): CLA is the coordinating authority for post-market surveillance, market recall, and adverse event reporting

5.3 Scope of CLA Authority:

Area of Regulation	Role of CLA
Manufacture of class C & D devices	Grant manufacturing (MD-9) and loan licenses (MD-10) after technical review and inspection
Import of Devices (Class A-D)	Grant import license (MD-15) for all devices regardless of risk class
Clinical Investigation & Performance Evaluation	Approve clinical investigation protocols (MD-23) for new devices
New Device Approval	Evaluate Safety and performance data for devices not previously approved in India
Policy development	Issue guidelines, clarification notices, and updates aligning Indian regulation with global standards
Coordination with SLA	Provide technical support and coordinate on post-market surveillance, recall and enforcement actions

5.4 Forms and Application Process

Purpose	Application form	License/permission granted
Import license	MD-14	MD-15
Manufacturing license (Class C/D)	MD-7	MD-9
Loan license (Class C/D)	MD-8	MD-10
Clinical investigation permission	MD-22	MD-23
Test license (for R&D)	MD-16	MD-17

5.5 Appeals and Legal Remedies:

If an application is rejected, the applicant may file an appeal under Rule 94 of MDR 2017 to the Central Government within 45 days.
This ensures transparency and fair regulatory decision-making.

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5.6 Significance of CLA in Public Health:

National Consistency: CLA ensures a centralized, consistent decision-making procedure for imports and high-risk devices.

Global Alignment: Helps Indian manufacturers export internationally by bringing Indian requirements into line with ISO 13485, IMDRF, and US/EU laws.

During public health situations, such as COVID-19, crisis management plays a crucial role in facilitating the accelerated approval of ventilators, personal protective equipment, and test kits.

Functions of CLA

Grant of Manufacturing Licenses (Class C & D)

Evaluate applications (Form MD-7/MD-8) and issues licenses (MD-9/MD-10) after technical review and inspection.

Import License Approval

Reviews and grants import licenses (MD-14/MD-15) for all medical devices, regardless of risk class.

New Device approval

Assesses safety, performance, and quality data for devices not previously approved in India before allowing market entry.

Clinical investigation permission

Grants' approval for clinical investigation protocols (MD-22/MD-23) and oversees conduct of studies.

Technical Review & Expert Consultation

Refers to high-risk applications to Subject Expert Committees (SEC) for scientific evaluation.

Post-Market Surveillance & Vigilance

Coordinates collection and evaluation of adverse event reports (MDAE), orders recalls and corrective actions if needed.

Policy Development & Notifications

Issues guidelines, SOPs, and regulatory updates to harmonize national requirements with global standards.

Coordination with SLA and International Agencies Provides technical guidance to SLA, collaborates with WHO, IMDRF, and foreign regulatory bodies for regulatory convergence.

Responsibilities of CLA:

Drug-Eluting Stent Approval (Example: new stents approved in 2018 with price control notification).
Implantable device licensing (pacemakers, knee implants)
Permission to import new kits during COVID-19.
License to manufacture high-risk devices, such as ventilators, cardiac, catheters, and dialyzers.

Advantages and limitations of Central Control

Advantages:

Uniform national decision-making
Single-window approval for complex cases
Better scientific review
Easier global harmonization

Limitation:

High workload for CLA- backlog possible
Limited physical presence
Manufacturers from remote states may face communication delays.

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VI. COMPARATIVE STUDY

6.1 Comparative Table: SLA vs CLA

Aspect	State Licensing Authority (SLA)	Central Licensing Authority (CLA)
Jurisdiction	State-level operates under respective state drug controller	National level operates under CDSCO, headed by DCGI
Device Classes regulated	Class A (low risk) and Class B (low-moderate risk)	Class C (moderate-high risk) and Class D (high risk) devices also regulates imports of all classes
Application Forms	MD-3 (manufacturing), MD-4 (Loan license)	MD-7 (manufacturing), MD-8 (loan license)
License Issued	MD-5 (manufacturing), MD-6 (Loan license)	MD-9 (manufacturing), MD-10 (Loan license), MD-15 (import)
Inspection	Conducted by SLA officers with Notified Body involvement	Conducted by CDSCO officers, sometimes with expert committees
Decision Timelines	45 days (as per Rule 20 of MDR 2017)	45-60 days (depending on device risk and data review)
Technical Review Depth	Relies on NB audit report for QMS compliance; limited internal technical review	Involves Subject Expert Committee (SEC) and technical panel review for high-risk devices
Scope of Control	Primarily manufacturing licenses for domestic Class A/B devices within state	Manufacturing, import, clinical investigation, and new device approvals
Advantages	Faster approval, better local accessibility, promotes MSME participation	Uniform national decision-making higher scientific scrutiny, global harmonization
Challenges/limitation	Variability in interpretation between states, staff/resource gaps	Centralized workload may cause delays, limited physical presence in remote states

Decision Pathway for Licensing

Step 1: Identify Device Class (A, B, C, or D) as per MDR 2017, Schedule I.
Step 2: If Class A or B → Apply to State Licensing Authority (SLA) through Sugam Portal.
If Class C or D → Apply to Central Licensing Authority (CLA).
Step 3: If Import (any class) → Application must go to CLA **(regardless of class).**
Step 4: Submit required forms (MD-3/MD-4 for SLA or MD-7/MD-8/MD-14 for CLA).
Step 5: Authority verifies documents, conducts site inspection/audit.
Step 6: If compliant → License issued (MD-5/6 for SLA or MD-9/10/15 for CLA).
Step 7: Manufacturer must comply with post-licensing obligations (record-keeping, vigilance reporting)

Discussion and Challenges

Key Observations

The dual structure of CLA and SLA balance decentralization with scientific rigor.
SLA supports small procedures and promotes made in India by enabling quicker approvals for Class A/B products.
CLA protects patient safety nationally by ensuring rigorous scientific review for Class C/D devices.

Challenge	Impact	Possible Solution
State-to-state variability	Different interpretation of MDR 2017 leads to inconsistent decisions	Develop harmonized SOPs and training modules
Limited resources at SLA	Delayed inspections and license	Increase manpower and infrastructure

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	approvals	
Dependence on Notified Bodies	Delays if NB audit is late	Create more NBs and reduce geographic coverage gaps
Communication gaps with CLA	Delays in escalations, duplication of work	Better integration of Sugam Portal and real-time data sharing
Post-market surveillance gaps	Under-reporting of adverse events	Strengthening Materiovigilance Programme of India (MvPI)

7.2 Recommendations

Single-Window Clearance: Combine SLA & CLA interface digitally for seamless approvals.
Training Programs: Capacity building for state officers and NB auditors.
Strict Timelines: Enforce Rule 20 timelines with tracking dashboard.
Awareness Campaigns: Encourage manufacturers to report adverse events under MvPI.
Harmonization with Global Standards: Align with IMDRF, ISO 13485 to make Indian devices globally competitive.

VIII. CONCLUSION

This review highlights emphasizes how India's medical device regulatory framework, which is governed by MDR 2017, ensures a risk-based, progressive approach to regulation by efficiently dividing responsibilities between the Central Licensing Authority (CLA) for Class C & D devices and imports and the State Licensing Authority (SLA) for Class A & B devices. While CLA offers scientific examination and consistent national decision-making for higher-risk categories, SLA allow for quicker, decentralized approvals for lower-risk devices. This dual approach encourages patient safety, regulatory transparency and the expansion of local production, despite obstacles including state-to-state inconsistency and reliance on Notified Bodies. Enhancing post-market surveillance, standardizing SOPs, and increasing digital integration can all help to increase productivity and create a strong medical device regulatory environment in India.

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