



India Medical Device Regulation -updates

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Introduction

- Current regulation
- Proposed amendments to Drugs and
 - **Cosmetics Act**
- Conclusion





- > Total market Size USD 3 Billion
- Growth Rate 15%
- Imports 75% of the total market size
- > Notified Medical Devices are regulated as "Drugs"
- > 14 categories of notified devices are regulated at present
- ~ 350 indigenous manufacturers





Current regulations







- Drugs & Cosmetics Act a Central Act, enforced by both Central and State Governments
- Contains provisions for regulating import, manufacture and sale of drugs including notified medical devices and cosmetics.
- Medical devices regulated as 'drugs' no separate provisions





Regulatory Functions of Centre (CDSCO/NRA)

Approval of new drugs and clinical trials

Import Registration and Licensing

Licensing of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices

Banning of drugs and cosmetics

Grant of Test License, Personal License, NOCs for Export

Testing of Drugs





Functions of State Licensing Authorities







Section 3 (b) (iv)

"Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board"





Initially 3 devices are notified as Drugs	March,1989
Schedule M-III	February, 1994
The Second notification (IVD)	August, 2002
The Third notification	October, 2005
(10 category of Medical Devices notified as	
Drugs)	





The Govt. of India has notified....

S. No	Name of the device	SLA/CLAA
1	Disposable Hypodermic Syringes	
2	Disposable Hypodermic Needles	
3	Disposable Perfusion Sets	State Licensing
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera	Authority
5	Cardiac Stents	
6	Drug Eluting Stents	
7	Catheters	
8	Intra Ocular Lenses	
9	I.V. Cannulae	Both State and
10	Bone Cements	Central Licensing
11	Heart Valves	Authority
12	Scalp Vein Set]
13	Orthopaedic Implants	
14	Internal Prosthetic Replacements	

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Requirements for Registration

- Both manufacturing site and devices are required to be registered.
- Foreign manufacturer to have Indian subsidiary or appoint Indian agent.
- Foreign manufacturing site inspection, if required.

LEGAL DOCUMENTS-

- Application in Form 40.
- Fees [USD 1500 for site & USD 1000 for each device]
- Power of Attorney

REGULATORY DOCUMENTS-

- Free sale certificates from any one of the country USA, EU, Japan, Australia and Canada.
- Wholesale License / Manufacturing Licence of the Indian Agent

TECHNICAL DOCUMENTS

- Information as per Schedule DI including Plant Master File
- Information as per Schedule DII including Device Master File
- Labeling, IFU, package inserts, etc

Timeline: 9 months is prescribed in the D & C Rules. However, average 3-4 months time from the date of receipt.







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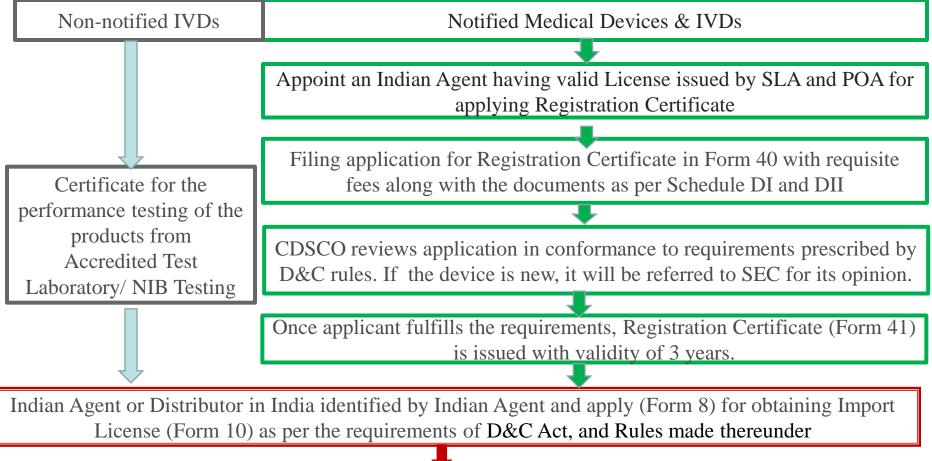
- STATUTORY DOCUMENTS-
- Application in Form 8.
- Fees [INR 1000 FOR SINGLE DEVICE & INR 100 FOR EACH]
- Undertaking in Form 9
- ✤ REGULATORY DOCUMENTS-
- Regulatory approval Certificates
- ✤ TECHNICAL DOCUMENTS
- COA/Specification/MOA/Labeling, IFU, package inserts, etc.
- ✤ Timeline: 30 days.
- Validity: Both Registration certificate and Import License is valid for three years.



Flow Chart: Registration and Import



Only notified Medical Devices requires Registration and Import License under D&C Act, 1940 and Rules, 1945, For non-Notified IVD's only Import License is required



After reviewing, Import License in Form 10 valid up to the validity of Registration Certificate (Form 41)



Exemptions for Registration

- ✤ In case of emergencies the licensing authority may with the approval of Central Government, issue an import license in Form-10 without the issuance of Registration Certificate.
- Import of device required for personal use for any patient.
- Government hospitals can import devices for their own patient.
- Devices imported for device development.
- Devices imported for manufacture and export by unit located at SEZ.



Requirements for Manufacturing Licence

- Licensing procedure for manufacturing of Medical Devices
- ✤ Application in Form 27 along with following details:
- Approved Manufacturing Premises Plan/Layout.
- Full particulars of competent and regular technical staff
- ✤ Site Master File and Device Master File for each category of device.
- Details of Standards followed by the company for product evaluation
- package insert, device labels etc.
- ✤ ISO 13485:2003, Full Quality Assurance/CE Design Certificate (if any)
- Licence fees of Rs.6000/- and an Inspection fees of Rs. 1500/- and additional fees at the rate of Rs.300/- for a each additional item of Device.
- Inspection by State or joint inspection by State and Central.
- Issue of license in form-28
- Validity of Licence: 5 years
- Mandatory to inspect the site at least once in year.

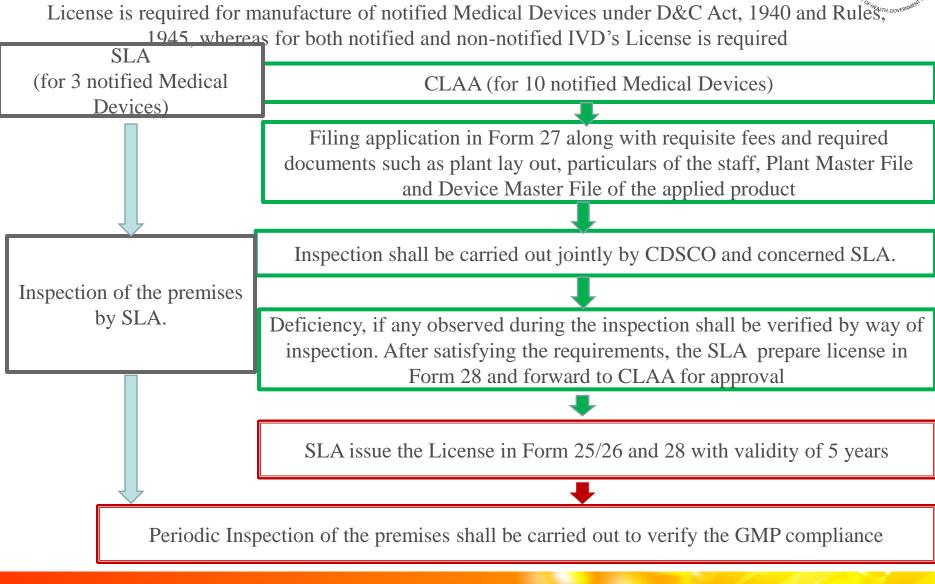




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Flow Chart : Manufacturing License







Requirement for new notified devices

- > No predicate device approved by CDSCO
- Application for new devices
- Referred to Subject Expert Committee
- Requirement of clinical trial to be reviewed by the committee
- Conduct of trial
- Submission of data for evaluation
- Permission for new notified devices



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- ***** Definition of Devices
- Requirements for Clinical Investigation/ Evaluation
- Adverse Event Reporting
- **OVER SET UP: OVER UP: OVERUPUP: OVER UP: OVERUPUP: OVERUPUP:**
- **Standards of Medical Devices**
- Registration requirements
- * Classification



 Established guidelines for import and manufacturing of Medical Devices (MD) and In vitro diagnostics (IVD).

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- Established pre-screening checklist for application for registration and import
- Constituted Subject Expert Committee for evaluation on New Medical Devices and In-Vitro Diagnostics.
- Conducting regular training programme for Drugs Inspectors of CDSCO and State Inspectors.
- ✤ FAQ are posted on CDSCO website.
- Initiated for reduction of stipulated timelines for processing of applications.



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Salient Features:-

- Amendments to Qualification of Technical Staff
- Specific Labeling Provisions
 - Domestic
 - Export
- Exemption for custom made devices
- Standards for Medical Devices
- Shelf Life of Medical Devices

Note: gsr 690(E) dated 25.09.2014







➢Quality Management System – for Medical Devices and In-vitro Diagnostic (IVDs) kits in line with ISO 13485 under finalization for publication.

Materiovigilance program for Medical Devices being framed











Drugs and Cosmetics(Amendment) Bill 2015



- Drugs, Medical Devices and Cosmetics Act
- New Definitions for Medical Device, Manufacture, Clinical Investigation, Substantial Equivalence
- Separate Chapter for Medical Devices.
- Clinical Investigation Requirements
- Designated MD Testing Centers
- "Medical Device Officer" in place of "DI"
- Medical Devices Technical Advisory Board.
- Classification of Medical Devices based on risk
- Standards for Medical Devices
- Role of Notified Bodies
- Penal Provisions







Authorities:

For Import and Manufacturing of Medical Devices

Central Drugs Standard Control Organization

For Sale and Distribution of Medical Devices

State Drugs Authorities

Notified bodies will administer quality of low and moderate risk devices





- CDSCO CONTROL OR CDSCO
- Will be placed before the Parliament in the forthcoming session for consideration.
- Four subgroups were constituted to prepare Rules for:
- Manufacturing
- Sales and Distribution
- Import
- Clinical Evaluation





- Presently not all devices are regulated
- No separate regulations
- Proposed amendments to Act
- >All devices to be regulated under proposed Act
- Proposed medical device regulation harmonized



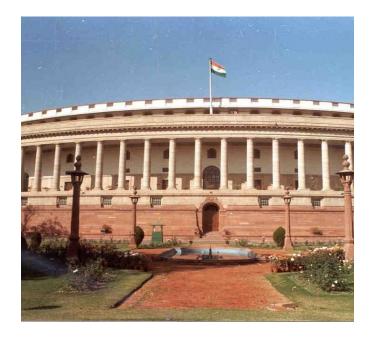




Website: cdsco.nic.in







Thank you



