India Medical Device Regulation -updates

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Presentation Overview

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

Introduction

- 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, 1940 & Rules, 1945

- **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**

FUNCTIONS OF REGULATOR (Centre)

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 REGULATOR(STATES)

Functions of State Licensing Authorities

- Licensing of Manufacturing Site for Drugs including API and Finished Formulation
- Licensing of Establishment for sale or distribution of Drugs
- State Drug Testing Laboratories
- Monitoring of Quality of Drugs and Cosmetics marketed in the country
- Investigation and prosecution in respect of contravention of legal provision
- Recall of sub-standard drugs

Definitions of medical device under the Act

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"

History of MD Regulations

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

The Govt. of India has notified….

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

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.

Requirements for Import Licence

❖ 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

Non-notified IVDs

Certificate for the performance testing of the products from Accredited Test Laboratory/ NIB Testing

Notified Medical Devices & IVDs

Appoint an Indian Agent having valid License issued by SLA and POA for applying Registration Certificate

Filing application for Registration Certificate in Form 40 with requisite fees along with the documents as per Schedule DI and DII

CDSCO reviews application in conformance to requirements prescribed by D&C rules. If the device is new, it will be referred to SEC for its opinion.

Once applicant fulfills the requirements, Registration Certificate (Form 41) is issued with validity of 3 years.

Indian Agent or Distributor in India identified by Indian Agent and apply (Form 8) for obtaining Import License (Form 10) as per the requirements of D&C Act, and Rules made thereunder

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.

Flow Chart : Manufacturing License

License is required for manufacture of notified Medical Devices under D&C Act, 1940 and Rules, 1945, whereas for both notified and non-notified IVD's License is required

SLA
(for 3 notified Medical Devices)

CLAA (for 10 notified Medical Devices)

Filing application in Form 27 along with requisite fees and required documents such as plant lay out, particulars of the staff, Plant Master File and Device Master File of the applied product

Inspection of the premises by SLA.

Inspection shall be carried out jointly by CDSCO and concerned SLA.

Deficiency, if any observed during the inspection shall be verified by way of inspection. After satisfying the requirements, the SLA prepare license in Form 28 and forward to CLAA for approval

SLA issue the License in Form 25/26 and 28 with validity of 5 years

Periodic Inspection of the premises shall be carried out to verify the GMP compliance

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**

Concerns with present regulations

- Definition of Devices
- Requirements for Clinical Investigation/ Evaluation
- Adverse Event Reporting
- QMS Requirements for manufacturers
- Standards of Medical Devices
- Registration requirements
- Classification

Initiatives Taken- Guidance Documents

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

Initiatives taken - amendments to Rules

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**

Initiatives taken- Amendments to rules

- 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

Proposed Regulations

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

Drugs and Cosmetics(Amendment) Bill 2015

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

Status of proposed Act

- **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**

Conclusion

- 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