Medical Device Regulations In India

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Assistant Drugs Controller(I)
Central Drugs Standard Control Organisation
New Delhi
Objective of Drugs & Cosmetic Act 1940 & Rules 1945:

To ensure safety, efficacy and quality of products
Preamble:

To regulate Manufacture, Sale, Distribution and Import of
1. Drugs
2. Cosmetics
3. Biologicals (Vaccines)
4. Medical Devices
Drug is in concurrent list of Indian Constitution
   It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940
Functions of CDSCO

- Approval of new drugs and clinical trials
- Import Registration and Licensing
- Licensing of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices
- Amendment to D &C Act and Rules
- Banning of drugs and cosmetics
- Grant of Test License, Personal License, NOCs for Export
- Testing of Drugs
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
- Approval of 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
Central Drugs Standard Control Organization

Drugs Controller General (I)

- HEAD QUARTER
  - New Drugs
  - Clinical Trials
  - Imports
  - Biological
  - Medical Devices
  - Export
  - QC
  - Pharmco.Vig
  - Legal etc

- ZONAL OFFICE (6)
  - GMP Audits
  - Enforcement
  - Draw drug Samples

- SUB ZONAL OFFICE (4)
  - GMP Audits
  - Coordination with States

- PORT OFFICE (13)
  - Import
  - Export

- LABORATORY (7)
  - Testing of Drugs
  - Validation of Test protocols
Drug Testing Laboratories

National Laboratories: 7
State Labs: 31
For Vaccines: CRI, Kasauli
For r-DNA and Diagnostic kits: NIB, Noida
For Medical Devices (Mechanical Contraceptives): Central Drug Testing Laboratory (CDTL), Chennai

Import and Export of Drugs from notified ports only
Medical Devices are notified as DRUGS under Drugs & Cosmetics Act.

Section 3 (b) (iv) defines, Medical Devices as

- Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals

- GMP Requirements are specified under Schedule M III
- Rule 109-A Labeling of Medical Devices
- Rule 125-A Standards for Medical Devices

"Currently, 14 medical devices have been notified as Drugs"
<table>
<thead>
<tr>
<th>S.No</th>
<th>Name of the device</th>
<th>Notification Number</th>
<th>Date of notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disposable Hypodermic Syringes</td>
<td>GSR 365 (E)</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>2</td>
<td>Disposable Hypodermic Needles</td>
<td>GSR 365 (E)</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>3</td>
<td>Disposable Perfusion Sets</td>
<td>GSR 365 (E)</td>
<td>17-03-1989</td>
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<tr>
<td>4</td>
<td>In <em>vitro</em> Diagnostic Devices for HIV, HbsAg and HCV</td>
<td>GSR 601(E)</td>
<td>27-08-2002</td>
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<td>5</td>
<td>Cardiac Stents</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>6</td>
<td>Drug Eluting Stents</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>7</td>
<td>Catheters</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>8</td>
<td>Intra Ocular Lenses</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>9</td>
<td>I.V. Cannulae</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>10</td>
<td>Bone Cements</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>11</td>
<td>Heart Valves</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>12</td>
<td>Scalp Vein Set</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>13</td>
<td>Orthopedic Implants</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>14</td>
<td>Internal Prosthetic Replacements</td>
<td>S.O. 1468 (E)</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>Sr. No</td>
<td>Name of the device</td>
<td>Picture</td>
<td>Material of construction</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------</td>
<td>---------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Disposable Hypodermic Syringes</td>
<td></td>
<td>Plastic</td>
</tr>
<tr>
<td>2</td>
<td>Disposable Hypodermic Needles</td>
<td></td>
<td>Stainless steel</td>
</tr>
<tr>
<td>3</td>
<td>Disposable Perfusion set</td>
<td></td>
<td>Plastic</td>
</tr>
<tr>
<td>4</td>
<td>Cardiac Stents</td>
<td></td>
<td>stainless steel and cobalt chromium, titanium</td>
</tr>
<tr>
<td>No</td>
<td>device</td>
<td>construction</td>
<td>intended use</td>
</tr>
<tr>
<td>----</td>
<td>---------------------</td>
<td>------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5</td>
<td>Drug Eluting Stents</td>
<td>Stainless steel, titanium and cobalt chromium (Drugs: Paclitaxel, Everolimus, Rapamycin)</td>
<td>It keep the arteries open in the treatment of Coronary heart disease.</td>
</tr>
<tr>
<td>6</td>
<td>Catheter</td>
<td>Silicon rubber, latex</td>
<td>It allow drainage, administration of fluids or gases, or access by surgical instruments</td>
</tr>
<tr>
<td>7</td>
<td>Intra Ocular Lenses</td>
<td>(PMMA) Polymethylmethacrylate</td>
<td>It is used for the treatment of cataracts.</td>
</tr>
<tr>
<td>8</td>
<td>I.V. Cannulae</td>
<td>Plastic</td>
<td>It can be inserted into the body, often for the delivery or removal of fluid</td>
</tr>
<tr>
<td>9</td>
<td>Bone Cements</td>
<td>(PMMA) Polymethylmethacrylate</td>
<td>It fills the free space between the prosthesis and the bone.</td>
</tr>
<tr>
<td>Sr. No.</td>
<td>Name of the device</td>
<td>Picture</td>
<td>Material of construction</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------</td>
<td>---------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>10</td>
<td>Heart Valves</td>
<td></td>
<td>Synthetic material, Animal origin (Bovine, Procine)</td>
</tr>
<tr>
<td>11</td>
<td>Scalp Vein Set</td>
<td></td>
<td>Plastic</td>
</tr>
<tr>
<td>12</td>
<td>Orthopaedic Implants</td>
<td></td>
<td>Stainless steel, Nitinol, Titanium, cobalt chromium</td>
</tr>
<tr>
<td>13</td>
<td>Internal Prosthetic Replacements</td>
<td></td>
<td>Hydroxyaptite</td>
</tr>
<tr>
<td>14</td>
<td>In vitro Diagnostic Devices for HIV, HBsAg and HCV</td>
<td></td>
<td>Nitrocellulose membrane</td>
</tr>
</tbody>
</table>
Devices are not Drugs

One size does not fit all
<table>
<thead>
<tr>
<th>Drug</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on Chemistry &amp; Pharmacology</td>
<td>Based on Engineering</td>
</tr>
<tr>
<td>Safety and Efficacy</td>
<td>Safety and Performance/Accuracy</td>
</tr>
<tr>
<td>Clinical Trials (4 Phases)</td>
<td>Clinical Evaluation (Feasibility/Pivotal)</td>
</tr>
<tr>
<td>GMP</td>
<td>QMS</td>
</tr>
<tr>
<td>Local and Systemic Toxicity</td>
<td>Biocompatibility</td>
</tr>
<tr>
<td>Long Product Life Cycle</td>
<td>Short Product life Cycle</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>Device Malfunction</td>
</tr>
<tr>
<td>Drug</td>
<td>Device</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>Clearly specified, For Eg. Paracetomol</td>
<td>Based on design, effectiveness and Intended use</td>
</tr>
<tr>
<td></td>
<td>Design changes quiet frequently like Mobile models.</td>
</tr>
<tr>
<td>Regulated by licensing system</td>
<td>Regulated by notified bodies (in most of the countries)</td>
</tr>
<tr>
<td>Clearly specified labeling requirements</td>
<td>As per ISO Symbol are used</td>
</tr>
<tr>
<td>Bulk or Formulation</td>
<td>Components or Accessories or Assembled or Finished product</td>
</tr>
<tr>
<td>Around 65 years experience</td>
<td>Only Seven years experience</td>
</tr>
</tbody>
</table>
Drugs

- Drug interactions
- Wrong drug/wrong dose

Devices

- Malfunction
- User error

Figure 1. Typical Therac-25 facility
**Drugs**
- Clinical trial
- Clinical endpoints

**Devices**
- Risk-based
- Surrogate endpoints
Organogram of Medical Device Division, CDSCO (HQ)

Drugs Controller General of India (Dr. G. N. Singh)

Deputy Drugs Controller (India) (Dr. S. Eswara Reddy)

Assistant Drugs Controller (India) (Dr. Ravi Kant Sharma)

Medical Devices Cell

- Drugs Inspectors
  - Mr. Sanjay Agarwal
  - Ms. Nisha Kaushik
  - Mr. Ashish Rai
  - Mr. V. Sooraj

- Technical Data Associates
  - Ms. Kavita Jayswal
  - Mr. Pradeep Verma
  - Mr. Ashish P. Pant
  - Mr. Sourabh Gupta
  - Ms. Pallavi Matta
  - Mr. Kashish Kumar

Diagnostics Cell

- Drugs Inspectors
  - Mr. Sella Senthil
  - Mr. Saurabh Jain

- Technical Data Associate
  - Mr. Atul Kumar
  - Mrs. Kanna
Functions of Medical Device Division

- Import Registration and Licensing of Medical Devices
- Approval of New Medical Devices
- Manufacturing License to Indigenous Manufacturer under CLAA Scheme
- Grant of Test License
- NOCs for Import/Clarifications
- Neutral Code For Export
- Clinical Trials
Import, Registration and Licensing

Mfg sites and Products are required to be Registered

Issue of Registration Certificate in Form 41

Issue of Import License in Form 10 / 10A

Rules related to grant of Registration Certificate and Import License

Information required for registration of Mfg site and Product

Timeline as per D & C Rules
For RC: Rules, 9 Months
For Import License: 3 Months

Registration Certificate (RC) and Import License - Valid for 3 years
**Import Procedure**

- **Application For Registration**
  - (Form- 40/ Schedule D(I)/ Schedule D(II), Power of Attorney)

- **Registration Certificate issued by CDSCO**
  - (Form-41)

- **Application For Import License**
  - (Form-8, Form 9)

- **Drug License**
  - Sell, Stock & Exhibit by SLA

- **Import License issued by CDSCO**
  - (Form- 10)

**Application Fees:**

- **Mfg. Site Registration**
  - 1500 USD per Site

- **Product Registration**
  - 1000 USD per product

- **Application Fees:**
  - INR1000 (22 USD)
Approval of New Medical Devices

1. Apply in Form 44 as per Schedule Y
   TR6 Challan of Rs. 50000/

2. Review of Clinical Trial Protocol, Published reports, literature, Package Insert etc. by CDSCO

3. Evaluation By Medical Device Advisory Committee

4. On Basis of Recommendations of MDAC

5. Permission Under Rule-122A granted

Registration and Form-10
Six Medical Device Advisory Committees Constituted

- MDAC - Cardiovascular
- MDAC - Dental
- MDAC - Reproductive and Urology
- MDAC - Orthopedics
- MDAC - Ophthalmic
- MDAC - Miscellaneous
## Clinical Trial Regulation

**Requirements and Guidelines - Schedule Y**

| Rule 122 A | Permission to import new drug |
| Rule 122 B | Permission to manufacture new drug |
| Rule 122 DA | Definition of Clinical trials |
| Rule 122 E | Definition of New Drugs* |
Regulation of Clinical Trials:

- Clinical Trials are regulated under the provisions of Drugs and Cosmetics Rules

- No clinical trials of New Drugs can be conducted without permission
Initiatives taken

- IND Committee for evaluation of Investigational New Drugs

- 12 New Drug Advisory Committees (NDACs) for Evaluation of clinical trials and new drug approvals

- 6 Medical Devices Advisory Committees

- Mandatory registration of Clinical Trials (Clinical Trial Registry of India)
Concerns in Clinical Trials

- Review of Clinical Trial applications
- Obtaining Informed Consent of subjects
- Examination of reports of Serious Adverse Events (SAEs)
- Compensation for clinical trial related injury or death
- Monitoring of Clinical Trials
- Functioning of Ethics Committees
CLAA Approval for Indigenous Manufacturer

The “Guidance Document on Application for Grant of Licence in Form-28 for Manufacture of Medical Devices in India under CLAA Scheme” indicates the application requirements for a medical device manufacturing license.

The manufacturing site is jointly inspected by the CDSCO Officials and State Drugs Control Officers.
Application in Form-27 along with fees, DMF & PMF

DCGI
Review & Examination
Directs Zonal office for Joint Inspection

State Licensing Authority

Zonal Office

Joint Inspection Report

The State Licensing Authority after Joint Inspection and verification forward the license in triplicate to CLAA for approval.

The license shall be issued in Form 28 after due approval of CLAA.
Diversity of medical devices

Source: US FDA CDRH 2005 Strategic Plan (modified)
Definition of term “Medical Device”

**Intended primary mode of action**

**Drug eluting stent**

- Primary intended mode of action
  - stent opens artery
- Secondary action
  - drug reduces inflammation and restenosis of artery

➢ Regulated as a device
**Intended primary mode of action**

**Drug cluting stent**
- Primary intended mode of action
  - stent opens artery
- Secondary action
  - drug reduces inflammation and restenosis of artery
- Regulated as a device

**Drug cluting disc**
- Primary intended mode of action
  - chemotherapy for brain tumour
- Secondary action
  - local delivery of drug by device
- Regulated as a drug
Pre-filled Insulin

Definition

Is a syringe a medical device?

Inert Material

Definition

Is a syringe a medical device?
Definition

Is a contact lens a medical device?
Definition

Is a contact lens a medical device?
Medical device?

Latex Examination Gloves Textured Lightly Powdered
Thank you for your kind attention