2014 India Medical Device Regulatory Updates

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Taj Mahal, Agra

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India's Demographics -- Overview

Population	1.2 billion
Rural / urban population	69% / 31%
Birth rate	2.2%
Mortality rate	0.7%
Life expectancy (years)	66 (M) / 69 (F)
Population profile (years):	
< 15 / 15-64 / >64	29% / 65% / 6%
Literacy rate	63%
Unemployment rate:	8%

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India's Medical Device Market

- India's medical device market is growing faster than at any time in the last decade, with a projected growth rate of 12-16% over the next several years.
- With a population of 1.2 billion and a growing middle class, India has the potential for strong growth.
- India's medical device market is dominated by foreign device companies, which control roughly 70% of the market.

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India's Medical Device Market

- Local non-multinational medical manufacturers are small, low tech, generally low cost, and medium quality; some are FDA/CE approved
- Multinational medical companies also manufacture/ import into India

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India's Medical Device Market

- Market size : $4.2 billion
- Imports : 70%
  Recent annual growth rate : 12%
- Projected growth rate up to 2015 : 12 – 16%

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India: Market Characteristics

- Quality of service in the private sector is good
- Government sector is low on quality and availability: patients prefer private treatment if they have money

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Insurance & Reimbursement

- Many private multinational insurance companies like Blue Cross and Sun Life have entered the Indian market
- There are a variety of popular public sector supported insurance companies
- Medicines, medical devices and services are provided/ reimbursed within the applicable cost limits

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Indian Medical Device Regulatory Structure

- Medical devices in India are still regulated under the Drugs & Cosmetic Act of 1945
  - This includes manufacturing, import, sale, and distribution
- The principal regulatory authority is the Central Drug Standards Control Organization (CDSCO)

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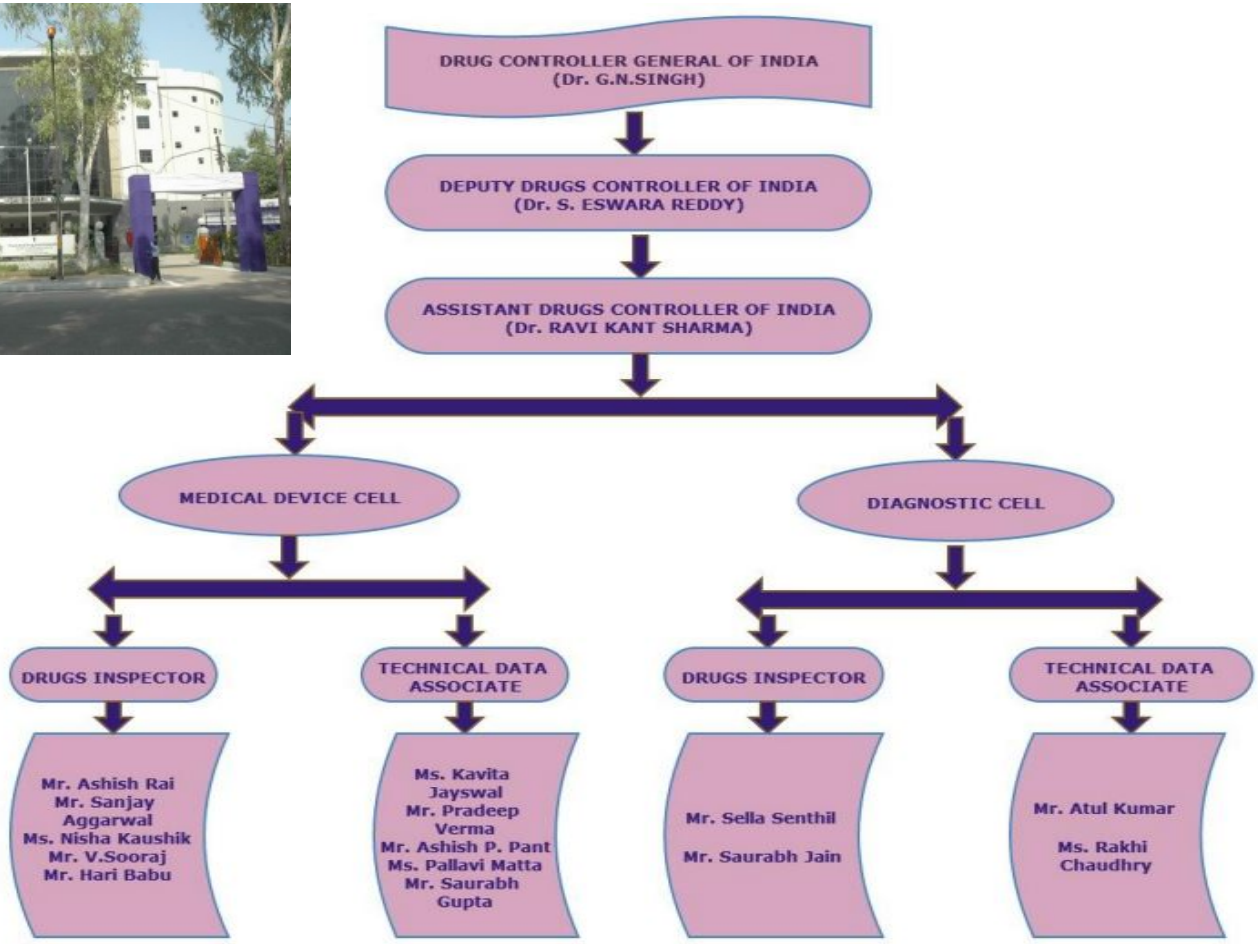
Indian Medical Device Regulatory Structure



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Regulation of Medical Devices

- Regulatory responsibilities of the Central Government (under the CDSCO)
  - Approval of new drugs and medical devices
  - Clinical Trials in the country
  - Drug/Medical Device standards
  - Control over the quality of imported drugs/medical devices
  - Coordinates the activities of State Drug Control Organizations
- Regulatory responsibilities of the State Governments (under State Drugs Control Organization) are more limited
- The Drug Controller General of India (DCGI) is the key official in the CDSCO

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Medical Device Regulations

- The definition of drugs in the Drugs and Cosmetics Act, 1940, ACT No. 23 of 1940 (April 10, 1940) was expanded to describe medical devices, *Chapter 1, Introductory, Section 3, Definitions, (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 in the Official Gazette, after consultation with the Board.*

- http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf; http://cdsco.nic.in/Drugs&CosmeticAct.pdf

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Attempts to Pass Comprehensive Medical Device Regulation

- In August 2013 the Drugs and Cosmetics Bill (2013) was proposed by the Ministry of Health
- The proposed bill from India's Ministry of Health (MOH) would:
  - Require the comprehensive regulation of all medical devices manufactured in or imported into India.
  - Create a new category of medical devices, regulated with a risk-based classification system.
  - Give India's Ministry of Health the power to create new rules regulating medical devices.
  - Establish the Medical Device Regulatory Authority (MDRA) as the regulatory and enforcement body for medical devices.

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India: Proposed Classification for Medical Devices

- Draft legislation also has a risk classification for medical devices, according to their intended use

Class	Risk Level	Device Examples
A	Low Risk	Thermometers / Tongue Depressors
B	Low Moderate Risk	Hypodermic Needles / Suction Equipment
C	Moderate High Risk	Lung Ventilator / Bone Fixation Plate
D	High Risk	Heart Valves / Implantable Defibrillator

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Former List of Regulated Medical Devices in India

- Disposable hypodermic syringes
- Disposable hypodermic needles
- Disposable perfusion sets
- Copper T Intra Uterine Devices
- Tubal ring
- Condoms
- Sterile disposable devices for single use
- Metered dose inhaler
- Blood/Blood component bags
- Cardiac stents
- Drug eluting stents
- Catheters
- Intra-ocular lenses
- IV cannulae
- Bone cement
- Heart valves
- Scalp vein sets
- Orthopaedic implants
- Internal prosthetic replacements (includes cardiac patches, occluders)
- Spinal Needles
- Insulin Syringes
- Three Way Stop Cock as an accessory of IV Cannula/ Catheter/Perfusion Set
- Endotracheal tubes
- Introducer Sheath
- Annuloplasty Ring
- Cardiac Patch
- Cochlear Implant
- Extension Tube
- Close Wound Drainage Set
- Tracheotomy Tube with / without Cuff
- AV Fistula Needle
- Extension Line as a accessory of Infusion Set
- ANGO kit/PTCA/Cath Lab Kit
- Heart Lung Pack
- Measure Volume Set
- Flow Regulator as a accessory of Infusion Set
- Hemodialysis Tubing Set / Blood Tubing Set/Arterial Venous Tubing Set
- Dialysis Catheter

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Current List of *Notified* Medical Device *Families* Requiring Registration in India

S.No	Name of the Device	Notification Number	Date of Notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	3-17-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	3-17-1989
3	Disposable Perfusion Sets	GSR 365 (E)	3-17-1989
4	In vitro Diagnostic Devices for HIV, HBsAG and HCV	GSR 601 (E)	8-27-2002
5	Cardiac Stents	S.O. 1468 (E)	10-6-2005
6	Drug Eluting Stents	S.O. 1468 (E)	10-6-2005
7	Catheters	S.O. 1468 (E)	10-6-2005
8	Intra Ocular lenses	S.O. 1468 (E)	10-6-2005
9	IV Cannula	S.O. 1468 (E)	10-6-2005
10	Bone Cements	S.O. 1468 (E)	10-6-2005
11	Heart Valves	S.O. 1468 (E)	10-6-2005
12	Scalp Vein Set	S.O, 1468 (E)	10-6-2005
13	Orthopedic Implants	S.O. 1468 (E)	10-6-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	10-6-2005

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Current List of *Notified* Medical Device *Families* Requiring Registration in India

- The following products are also regulated as 'Drugs' under the Drugs & Cosmetics Act
  1. Blood Grouping Sera
  2. Ligatures, Sutures and Staplers
  3. Intra Uterine Devices (Cu-T)
  4. Condoms
  5. Tubal Rings
  6. Surgical Dressings
  7. Umbilical Tapes
  8. Blood/Blood Component Bags

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IVD Regulations in India

- The *in vitro* diagnostic kits are categorized as Notified Diagnostic Kits and Non-notified Diagnostic Kits.
- The general guidance documents are offered for *in vitro* diagnostics on the CDSCO website
  - *www. cdsco.nic.in/draft_guidance.htm*

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Current Medical Device Registration Process

Notified product families require registration with DCGI

Medical Devices without predicate

New Device first requires Form 45, then apply for Form 40

For Form 45 follow the Form 44 route

Might require local clinical trial for 200 patients/PMS for a bigger group (even 1000 patients is common)

Require own office/ Authorized Indian Agent

Complete the dossier D(I) &D(II)

Pay the review fees in TR6 challan

Compile the application as per checklist and submit to DCGI

Obtain registration certificate (RC) for your product.

Medical Devices with predicate

Device registered Form 40 route

Clinical trial data/ device performance report from country origin; US FDA, EU CE, Australian, Canadian, and Japanese approvals will be sufficient

Product Registration Process

- Companies must register *regulated* medical devices in medical device families with the CDSCO before they can be introduced into the Indian market.
- DCGI released a guideline document with general instructions on common submission format for the registration of notified medical devices for obtaining marketing authorization.

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Product Registration Process

- Only a registered manufacturer/Indian entity of a foreign manufacturer or an Indian agent can represent a medical device product with the DCGI
- To import products into the Indian market, a foreign manufacturer must appoint an Indian agent

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Product Registration Process

- For products made in India, a manufacturing authorization Form 28 has to be approved by the government
- To import a foreign manufactured product, an application has to be made on Form 40
  - In general, only GHTF approved foreign devices that have a free sale certificate can register using Form 40
- A pre-submission check list for various submissions was released by DCGI in 2012-2013:
  - http://www.cdsco.nic.in/Forms/list.aspx?lid=1864

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Product Registration Process for Foreign Manufacturers

- Verify whether your product requires registration
- Appoint an Indian agent
- Prepare the Form 40 Application
- Pay the required government fees (TR6 Challan)
- Submit your application to the DCGI
- The product registration of medical devices can take 6-18 months if there are no clinical trials

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Documents Required For Submission

The following documents are required for submission for registration of medical devices in India:

- Covering Letter
- Authorization Letter
- Completed Form 40 for the issue of Registration Certificate
- Power of Attorney
- Completed Schedule D(I) and D(II)

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Documents Required For Submission

- Plant Master File
- Wholesale License (20B&21B)
- Free Sale Certificate/Certificate of Marketability
- Manufacturing License/Plant Registration Certificate
- CE Full Quality Assurance and ISO 13485 Certificate for a foreign manufacturing site
- CE Design Certificate for the medical device
- Declaration of Conformity for the medical device
- Latest Inspection/Audit Report
- Receipt of application fee

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Additional Documents Required For IVD Product Registration Submission

- Performance Evaluation Report from the National Institute of Biologicals.
- Detailed evaluation report conducted by the National Control Authority of the country of origin
- Product Insert (English version or authenticated translated copy)
- Published articles, if any, of each diagnostic kit/reagent proposed to be registered

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Product Registration: Form 40 (application)

FORM 40

(See rule 24-A)

Application for issue of Registration Certificate for port of drugs into India under the Drugs and Cosmetics Rules 1945

I/We*_____ (Name, full address with telephone, fax and E-mail address) hereby apply for the grant of Registrati Certificate for the manufacturer, M/s. _____ (full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises M/s_____(full address with telephone, fax and E-mail address), and manufactured drugs meant for import into India.

1. Names of drugs for registration.

S. No.	Name of Medical Devices (Including model No's, if applicable)	Indication and/or Intended Use

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Product Registration: Form 41 (approval)

[1][FORM 41

(*See* rule 27 A)

Registration Certificate

Registration Certificate to be issued for import of drugs into India under Drugs and Cosmetics Rules, 1945

Registration Certificate No._____ Date_____

M/s _____ (Name and full address of registered office) having factory premises at full address) has been registered under rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of drugs which may be imported under this Registration Certificate:

[2] * * *

[2] * * *

[2] * * *

3. This Registration Certificate shall be in force from _____ to_____unless it is sooner suspended or cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/s (name and full address)_____ who will be responsible for the business activities of the manufacturer, in India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Act and the rules, from time to time.

Place:_____

Date: _____

Licensing Authority

Seal / Stamp

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Product Registration: Schedule D(I) Plant Master File

SCHEDULE D(I)

(See rule 21 (d) and rule 24 A)

Information and undertaking required to be submitted by the manufacturer or his authorized agent with the Application Form for a Regis ation Certificate. The format shall be properly filled in for each applicatio in Form 40.

1. *Particulars of the manufacturer and manufacturing premises*

1.1 Name and address of the manufacturing premises (Telephone No., Fax No., E-mail address) to be registered.

1.2 Name(s) and address(es) of the Proprietor /Partners / irectors.

1.3 Name and address of the authorized Agent in India, responsible for the business of the manufacturer.

1.4 A brief profile of the manufacturer's business activity, in domestic as well as global market.

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Product Registration: Schedule D(II) Device Master File

Schedule DII (Device Master File)

Note: The manufacturer shall submit the duly signed and notarized information pertaining to Medical Device in the following format. I information/reports/data should be in English only. It is expected that the information submitted in the form of hard copy shall also be submitted in the form of so copy.

The dossier shall have an index listing the details of the documents produced as requested hereunder and shall reflect the page numbers.

1.0 EXECUTIVE SUMMARY (Not more than three A4 size pages):

An executive summary shall be provided by the manufact er and shall contain:

1.1 Introductory descriptive information on the medical device, the intended use and indication for use, Class of Device, novel features of the device (if any), Shelf Life of the Device and a synopsis on the content of the dossier (not more than 500 words).

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Registration Fees

- Registration fees

Type of registration	Fees (US$)
Registration of each manufacturing facility	1,500
Registration for a single medical device	1,000
Additional fee for each additional medical device proposed to be registered	1,000

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"New" Product Registration: Form 44

- Form 44 is required for when the product is judged to be a "new" medical device and for clinical trials

[1][FORM 44

(*See* rules 122A, 122B, 122D and 122 DA)

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

- Your new product approval is provided (by the CDSCO) on Form 45

FORM 45

(*See* rules 122 A, 122 D and 122 DA)

Permission to import Finished Formulation of the New Drug.

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Conducting Clinical Trials of Medical Devices

- Generally, clinical trials are only necessary for *new* medical devices
- Required documents for submission to conduct clinical trials of medical devices in India include:
  - Covering Letter
  - Completed Application Form 44
  - Global Regulatory Status of the medical device
  - Investigator's Undertakings
  - Ethics committee approvals
  - Informed Consent Form
  - Trial Protocol

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Conducting Clinical Trials of Medical Devices -- Updates

- The Medical Device Advisory Committee (part of the CDSCO) is the key approval committee for medical device clinical trials.
  - http://www.cdsco.nic.in/Forms/list.aspx?lid=1760
- However, new regulations over the past two years have significantly reduced the number of clinical trials in India and significantly increased timelines to get your product onto the market.
- Strict rules on liability for death or injury to drug trial volunteers have also been instituted.
- Compliance with good clinical practices (GCP) and adverse events reporting regulations were also included.
- Organizations conducting pharmaceutical trials must set up audio and video recording of the entire trial process.
- All stakeholders involved in a trial – such as ethics committees – must also be registered and accredited.

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Product Re-Registration

- The Registration Certificate (Form 41) is valid for 3 years from the date of issue.

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Medical Device Re-Registration Challenges

Notified Devices require registration with DCGI

Medical Devices with Form 45 approvals

Has to follow PSUR/ PMS requirements under schedule "Y"

Semi-annual device performance reports have to be submitted to DCGI for a period of two years

Require own office/ Authorized Indian Agent to re-register

To continue the product stock on the market, start the process 9 months before

D(II) has to include the Indian PMS data, too

Do you have the PMS right information to include in this section? Did you collate all the complaints from your various distributors?

Medical Devices with RC on Form 41

Device RC Form 41 issued by DCGI

Appoint Distributors all India/ Regional/ Multiple Distribution channels

Are your distributors knowledgeable on regulatory requirements related to PMS?

Product Re-registration: Schedule D(II) / PMS Data Required

1.7 Safety and performance related information on the device:

a. Summary of reportable events and field safety corrective action from the date of introduction

For Adverse event

Adverse Event	Frequency of Occurrence during the period(Number of Report/Total Units sold)

For Field Safety Corrective Action (FSCA)

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

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Product Re-registration: Schedule D(II) / PMS Data Required

7.10 Post Marketing Surveillance Data (Vigilance Reporting)

The dossier should contain the Post Marketing Surveillance/ Vigilance Reporting procedures and Data collected by the manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

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Indian Distributors Do *Not* Want to Keep PMS (Data Required)

- Distributors sell – that's how they make money
- If the doctor says there is a problem – unlikely to buy again or just replace device for free. Not keep PMS data.

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Re-registration Caution / PMS Data Required

- Doctors can directly report adverse events to the DCGI and not tell your distributor
- These rules are now being scrutinized more carefully

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Re-registration in India / PMS Data Required

- More and more re-registrations will require good PMS data
  - PBM has just set up a call center to collect PMS data in India

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Medical Device Re-registration in India – PMS Data Required

- Recent client applied for re-registration
- CDSCO asked for PMS data
  1. Details of the product sales and incidents that occurred in India as a result of your product sales over the last 3 years
  2. Recall status
  3. Root cause of any events or complaints
  4. CAPA by manufacturers for these complaints

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Re-registration Caution
Sample Reply Letter from the CDSCO

Date: May 7, 2014
File No: 1234
To: Western Company's India Agent
Subject: Registration of the manufacturing site and the proposed device of ABC Manufacturer

Dear Sir/Madam,
Please refer to your application XXX/XX/XX/2014/01. The case has been examined in the light of documents you submitted. We request that you submit the following documents/clarification to this office in order for us to take further action in this matter:

1. Original labels and package inserts of the Product
2. Duly notarized copy of conformity of the Product
3. A complete summary of the PMS data during the validity of the registration certificate as well as a summary of the procedures in place for PMS (to date, you have only submitted a declaration stating that there had been no complaint resulting in regulatory action or recall).

Yours faithfully,
Deputy Drugs Controller

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U.S./EU Post Marketing Requirements

- U.S./EU Post market data needs to be assembled globally

- If you can *not* provide this PMS data from India, you will likely get a 483 – which could lead to closing of your manufacturing plant, reduce sales and create an administrative nightmare

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Medical Device Import Registration

Notified Devices require registration with DCGI

Medical Devices without predicate

New Device RC Form 45 issued by DCGI is valid for 3 years

Medical Devices with predicate

Device RC Form 41 issued by DCGI is valid for 3 years

India Agent/Distributor can apply for Form 10

Complete Forms 8 & 9

Pay the review fees in TR6 challan

Obtain import license (Form 10) for your product

Appoint Distributors all India/ Regional/ Multiple Distribution channels

Only the India Agent/ RC holder can apply for Import License and obtain approval on Form 10

Each distributor can apply for Import Licenses and obtain multiple Form 10s independently

Obtaining an Import License

- The importer can apply for an import license from the DCGI.
- The following documents are required for submission for Import License (Form 10) for medical devices in India:
  - Covering Letter
  - Authorization Letter
  - Completed Form 8 and Form 9
  - Wholesale License
  - Registration Certificate (Form 41) for the medical device
  - For license renewal, a copy of existing Import License (Form 10)
  - Required fees

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Import License: Form 8

FORM 8
(See rule 24)
Application for licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

I/We*..... (Name, full address with telephone, fax and E-mail address) hereby apply for a licence to import drugs specified below manufactured by M/s..... .. (Name, full address with telephone, fax and E-mail address).

2. Names of the Medical Device (s) to be imported:
(1)
(2)
(As mentioned in Form 41)

3. I/We* ..... enclose herewith an undertaking in Form 9 dated ..... signed by the manufacturer as required by rule 24 of the Drugs and Cosmetics Rules, 1945.

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Import License: Form 9

FORM 9
(See rule 24)
Form of undertaking to accompany an application for an import licence

Whereas ..... of..... Intends to apply for a licence under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we.....of.....hereby give this undertaking that for the duration of the said licence—

(1) The said applicant shall be our agent for the import of drugs into India;

(2) We shall comply with the conditions imposed on a l ence by 1[rules 74 and 78] of the Drugs and Cosmetics Rules, 1945;

(3) We declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufactur will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;

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Obtaining an Import License / Form 10

- The Import License (Form 10) is valid for 3 years from the date of issue.
- Application for the renewal import license must be submitted no earlier than 3 months from the license expiration date.

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Import License: Form 10

[1][FORM 10

(*See* rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic Rules, 1945

Licence Number..... Date... ……..

..... (Name and full address of the importer) is hereby licensed to import into India during the period for which the licence is in force, the drugs specified below, manufactured by M/s..... (name and full address) and any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from ..... to ..... unless it is sooner suspended or cancelled under the said rules.

3. Names of drugs to be imported.

Place : ……..

Date : ……. *Licensing Authority*

Seal/Stamp

* *Delete whichever is not applicable.*

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Import License Fees

- The following are the fees prescribed in the DCA

Type of import license	Fees (Rupees)
Import License for one medical device	1,000
For each additional medical device to be imported	100

** 60 Indian Rupees = US $1*

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Expediting Import License Approval

- Selection of agent/importer is very important.
- Professional regulatory advice should also be taken.
- Preferably no correspondence between manufacturer and DCGI before submitting formal applications; clarifications at this stage should always be verbal.

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Expediting Import License Approval

- **For new products**, it is better to not be the first applicant
- **For fast tracking**, an endorsement letter can be obtained

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Agent/Importer

- If you do NOT have your own subsidiary, branch office or joint venture, it is critical to appoint a local agent and/or importer.
- Who can be an agent? Importer or an independent third party company in India
- The importer is the holder of the import license and must have:
  - license to stock and sell drugs, and
  - license to manufacture if there is any re-processing or pre-packing involved.

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Agent/Importer

- Agent and importer can be the same, or separate, if importer is not to have access to confidential material.
- The agent and/or importer is responsible for the manufacturer's business in India.

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Labeling and Packing

- As of now, labeling is in English
- No medical device can be sold in India without appropriate labeling
- Label must be in indelible ink
- Where required, the date of expiration of potency should be mentioned, and the period between date of manufacture and expiration should not exceed the specified period
- Label must show the maximum retail price of the product inclusive of all taxes

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Labeling and Packing

- If a medical device has to be used under medical supervision, that must be mentioned; similarly, if it is for external use only, that should also be mentioned
- Pack sizes have been recommended for certain drugs/medical devices
- The label should not contain any claims that the drug/medical device will cure certain specified diseases
- In addition, under the Standard of Weights and Measures Act (SWM), all imported packages must bear the name and address of the importer

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Labeling and Packing

- In addition, there are specific labeling requirements for the following devices:
  - Non-sterile surgical ligature and suture
  - Cloth bandages
  - Condoms

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Outer Carton Label

Rx

Brand Name: Kneeplus

Orthopedic knee implant

Directions for Use: Please refer to the insert

Dosage: As directed by the Physician or Surgeon.

Do not use the product if package is damaged or it contains any visible particulate matters.

Storage: Store below ------°C,
Protected from light.
Do not freeze.

Keep out of reach of children.

Contents: 1. plate
2. screw-2

QUANTITY:

For further details refer to the package insert.

NON-STERILE

Legal Manufacturer
Kneeplex

Actual Manufacturing site Address

Imported by:
<ABC importer>

Marketed by:
<XYZ distributor>

Import Licence No.: IE code

B.No:
Mfg. date:
Expiry date:

M.R.P. Rs :

For complaints: Contact <phone number>
Email: abc@bcd.com

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Kit/Package Label (Inside)

Rx

Brand Name: Kneeplus

Orthopedic knee implant

Directions for Use: Please refer the insert

Dosage: As directed by the Physician or Surgeon.

Do not use the product if package is damaged or it contains any visible particulate matters.

Storage: Store below ------°C,
Protected from light.
Do not freeze.

Keep out of reach of children.

Contents: 1. plate
2. screw-2

QUANTITY:

For further details refer to the package insert.

NON-STERILE

Legal Manufacturer
Kneeplex

Actual Manufacturing site Address

Imported by:
<ABC importer>

Marketed by:
<XYZ distributor>

Import Licence No.: IE code

B.No:
Mfg. date:
Expiry date:

M.R.P. Rs :

For complaints: Contact <phone number>
Email: abc@bcd.com

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Recent Changes

- New labelling requirements under Standard of Weights and Measures Act (SWM) require a 1-800 – or toll free telephone number for complaint reporting
- Form 40, Form 41 have a reporting requirement
- Section 1.7 Safety and performance related information on the device
- 7.10 Post-market surveillance data (vigilance report) are considered seriously during the review process

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Quality Assurance/Control

- Quality assurance systems should ensure compliance with GMP, GLP, GCP
- Self-inspection and Quality audit
- Quality Control System

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Auditing/Inspection of Foreign Manufacturing Facilities

- Several years ago, the CDSCO started auditing and inspection of manufacturing facilities in foreign countries.
- This was to ensure the quality of drugs and medical devices imported into India.

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Nizamia Hospital

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Saifee Hospital

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Manufacturing License For Medical Devices

- All manufacturing of regulated medical devices requires a license under the DCA
- State Government Drug Controllers can license most products
- A license is given after application and inspection for compliance by the authorities
- A license is given for each factory and for the medical device made therein
- Applicant must comply with the requirements of the current Schedule M (GMP)

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Manufacturing License For Medical Devices

- Details of company and application for license is made to the State FDA with a copy to the DCGI
- For medical devices that are new or do not have any benchmark certification, expert committees will be set up to examine the information provided
- An application for Manufacturing License (Form 28) for medical devices has to be made to the following bodies:
  - The State Drugs Licensing Authority
  - The CDSCO zonal/sub-zonal office
  - The Drugs Controller General of India, CDSCO HQ

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Manufacturing License For Medical Devices

These documents are required for submission for a medical device Manufacturing License (Form 28):

- Covering Letter
- Authorization Letter
- Completed Form 27 for Manufacturing License
- Constitution details
- Approved Manufacturing Premises Plan/Layout
- Full particulars of competent and full-time technical staff for the manufacturing and testing of medical devices
- Site Master File
- Specific manufacturing requirements
- Device Master File

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India Medical Device Regulatory

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