REVIEW ARTICLE

Regulatory guidelines for medical devices in India: An overview

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The objective of the present study offers an overview of regulatory guidelines for medical devices in India. Medical devices are now a pervasive part of modern medical care. They are in many cases associated with quality of care. In some cases, the use of devices has certainly improved quality. In other cases, devices have been associated with many problems. The approach to quality of devices has depended largely on regulation**.** Recently introduced guidelines and the amendment in the law will provide adequate guidance for both the manufacturers and competent authorities to manage cases efficiently and appropriately. While these regulations and reforms promise to clarify, unify, and expedite the process of manufacturing and importing medical devices into India, they also pose their own challenges and complications. Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand their business in India's medical markets. It is hoped that the guidelines are implemented and regulated properly with effective outcome. This article highlights current regulations pertaining to applications for medical device registration certificates, medical device clinical trials, and medical device manufacturing/importation licenses.

Key words: *Adverse event, conformity assessment, device regulation, medical devices, notified bodies*

INTRODUCTION

Demonstrates that Medical devices have been used to treat and diagnose disease since antiquity. There is evidence of trephination having been performed in Neolithic times and instruments have been excavated in Jericho from 2000 BC. Today devices are widely used in all branches of medicine, surgery, and community care.[1] The device industry is a major one, with worldwide sales of more than £110 billion per year.[2]

A medical device is defined according to Schedule M-III creates a specific definition of medical devices as separate from drugs. Unlike a drug, a medical device is defined as a medical tool "which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means." Medicinal products covered by the Drugs and Cosmetics Act (DCA) will not fall under Schedule M-III.[3] If there is any uncertainty about whether the product falls under the drug or medical device category of the DCA under this schedule, regulators will consider the principal mode of action of the product.

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Classification of medical devices under Schedule M-III, medical devices will be divided into four classes according to their risk level: A, B, C, and D. Class A will include low-risk devices such as thermometers and tongue depressors. Low- to moderate-risk devices such as hypodermic needles will fall under Class B. Class C will cover moderate-to high-risk devices such as lung ventilators and bone fixation plates; and high-risk devices heart valves and implantable defibrillators, for example will comprise Class D.[3] The regulatory procedures for medical devices will vary according to their class. In general, higher-risk devices will require more regulations and a more stringent conformity assessment process. The regulatory procedure for medical devices varies according to their class. The objective of the present study is to provide an overview of Regulatory guidelines for medical devices are importing, registering, and licensing and clinical trials in India. These new Central Drug Standard Control Organization (CDSCO) documents may be used as a basis for any future comprehensive changes in medical device regulations in the country.

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IMPORTANCE OF MEDICAL DEVICES

The era of newer development and technology has decreased the morbidity and mortality of life. The medical development in terms of drugs and devices has brought about the robust change in the life of the people (as offered by the cosmetic treatment, dentist, face and cardiology devices).[4] The usefulness of a test for slime production as a marker for clinically significant infections with Pseudomonas (Ps) aeruginosa of patients used a medical devices. Results suggested that Slime-mediated adherence may be a critical factor in the pathogenesis of pseudomonas.[5] Ananthan G reported that the range of MICs (Minimum Inhibitory Concentration) and MBCs (Minimum Bactericidal Concentration) was high in ethyl acetate extract and it was low in the methanol extract. This result suggests that P. Arabica can be used as effective inhibitor of urinary tract infection pathogens making them applicable to medical devices.[6]

Medical devices have extended the ability of physicians to diagnose and treat diseases, making great contributions to health and quality of life. Implementing a full regulatory programme can be very demanding on resources, especially for a developing nation. A good approach to setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on medical device. Registration ensures that the government can (i) have a record/listing of the vendor; (ii) lay emphasis on after-sale obligations; (iii) enforce orders on defaulters like suspension of licenses, and (iv) have a renewal system in place for registration thereby maintaining updated information.[6] Better society requires best knowledge management practices and use of latest devices and technologies.[7]

Despite the global economic downturn, the Indian medical device market is growing at an impressive rate. India has a relatively young population of more than 1.1 billion, and its economy has fared relatively well through the global economic crisis. Prime Minister Manmohan Singh projected a 6% to 7% growth rate in the fiscal year beginning on April 1, 2009, with a return of a 9% growth rate within the next 2 years.

Although few reliable statistics are available, we estimate India's medical device market to be worth about $2.5 billion. Furthermore, about 75% of the device market comes from imports. The current annual growth rate for the medical device sector is about 6%, with projected growth rates of 12% to 16% through 2010. The driving forces of this remarkable growth include an increasingly affluent population that is demanding better healthcare, increased public and private investment in healthcare, and the rapid proliferation of public and private health insurance.[8]

In order for foreign companies to enter and take full advantage of these opportunities, it is critical to understand the relatively complex regulations for medical devices in India.[8] Currently, medical devices are regulated as drugs by the drug controller general of India (DCGI) of the Central Drugs Standard Control Organization (CDSCO). The lack of a drug/device distinction has created difficulties for foreign companies in the medical device market. There is no single list (you must merge several lists) of regulated devices with different regulations for different devices, and some devices are not regulated at all. In certain cases, product registration and manufacturing standards intended for drugs are applied to the manufacture of devices.[9]

India, however, is attempting to address these problems with a new set of guidelines for regulating medical devices and several broader reforms pending within the Indian government. While these regulations and reforms promise to clarify, unify, and expedite the process of manufacturing and importing medical devices into India, they also pose their own challenges and complications. Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand their business in India's medical markets.[10]

The central licensing approval authority (CLAA). The CLAA, a branch of the CDSCO, will serve as the main regulatory body for medical devices. The CLAA will classify medical devices, and any manufacturer seeking a less stringent classification must send justification to the CLAA.[11] In consultation with an expert panel on medical devices, the CLAA also will set and enforce safety standards, appoint notified bodies to oversee conformity assessment, conduct post-market surveillance, and issue warnings and recalls for adverse events.

All medical devices will undergo conformity assessment procedures to ensure compliance with quality and safety standards before they are allowed on the Indian market. The CLAA will adopt as regulatory standards the Bureau of Indian Statistics (BIS) and International Organization for Standardization (ISO) specifications for quality management systems. To meet these standards, medical devices must be designed and manufactured in a way that achieves their intended purpose and does not compromise patient health or safety.[12]

For Class A devices, manufacturers may perform their own conformity assessment procedures. However, for Class B, C and D devices, the CLAA, in consultation with the BIS, will publish a list of notified bodies authorized to perform conformity assessment. Medical device manufacturers must submit an application for assessment to one of these notified bodies. The necessary application materials will include technical documentation, corrective and preventative action procedures, as well as information about the organization and goals of the business. In the case of Class C and D devices, further information and clinical investigation may be required.[13]

After receiving all of the application materials, the notified body will examine and assess whether the device conforms to BIS and ISO standards. Notified bodies also Hill conduct unannounced audits of manufacturing facilities to ensure that actual manufacturing practices match those described in the documentation.

Medical devices that conform to proper standards must bear the Indian Conformity Assessment Certificate mark, which will allow them to be placed on the market and to move freely throughout India.[13]

All medical devices imported into India are covered by Schedule M-III and will be subject to its guidelines. When applying for conformity assessment, manufacturers of imported devices must provide the name and address of the authorized agent or representative in India. The name and address of this authorized person or organization must also appear on the label or packaging of all imported devices marketed in India.

Imported medical devices that already have been approved in the United States and/or European Union, or that have been deemed equivalent to a CE Mark and FDA-approved device, will be allowed on the Indian market without undergoing separate conformity assessment procedures.[14]

Overall, these regulations should benefit foreign companies in the medical device sector. They will expand the number of regulated medical devices and help untangle the regulation of devices from the regulation of drugs, greatly clarifying the regulatory process. However, many in the medical devices industry both foreign and domestic are pushing for even broader reforms that would create an independent authority to regulate medical devices. Several such proposals are pending within the Indian government.

IMPORT AND REGISTRATION

Presently, the Indian market for medical devices is largely unregulated. Medical devices are freely imported into India. The purchaser (whether it is a government hospital, a private hospital or a doctor) evaluates the quality of the product being purchased. Normally, the FDA and Conformité Européene (CE) approved products are preferred because of their better quality and performance.[15] But, India being a price sensitive market, low-priced medical devices finds a big market. To ensure the quality of healthcare service, the Government of India (GOI) is in the process of developing regulations for medical devices. The authority regulating medical devices in India are the CDSCO in the Ministry of Health. The regulatory procedure will be clear only after the government notifies the regulations and the CDSCO provides the import guidelines. This paper presents the registration requirement and the standard procedure to import medical devices into India. It provides an overview of the Indian Government's plan to regulate medical devices. The information shall include the following details:-

IMPORT OF MEDICAL DEVICES

For the purpose of import of Devices specified above, the procedure for registration and import license as prescribed under the Drugs and Cosmetics Rules shall be followed:

1. A period of 60 days would be provided for the importers to make application for import and registration from the date of publication of these guidelines.
2. In case of devices which have not been imported in the country before the date of notification no import would be permitted without the approval of the competent authority.
3. For the time being and for a period up to 6 months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use will be permitted to be sold. In case of stents or drug eluting stents the import will not be permitted if the applicant has sold less than One thousand stents of the particular specification prior to the date of issue of these guidelines. Separate committees consisting of subject experts and representative of DCG (I) office would be setup for their expert advice for evaluation of specific categories of devices. The expert committees would formulate their own benchmarks and procedures for evaluations and the standards to which such devices should conform.

Guidance document for import license in "Form 10" includes the following:

1. Covering letter
2. Authorization letter
3. Form 8 (Application for license to import drugs (excluding those specified in Schedule X)
4. Form 9 (Form of undertaking to accompany an application for an import licence)
5. Requisite fees & TR_6 Challan
6. Whole sale license/manufacturing license
7. Registration certificate in form 41 (by CDSCO)
8. Copy of import license in fORM 10
9. Required documents as per registration certificate in form 41 issued by the CDSCO.

REGISTRATION OF MEDICAL DEVICES FOR IMPORT

1. Application for registration certificate in respect of the premises and the devices manufactured by the manufacturer and meant for import into India is required to be made by the manufacturer or importer or his agent in India, in form 40 and in form and manner as under Rule 24A of the drugs and cosmetics rules. The application addressed to the drugs controller general (India) shall be deposited at the resource centre,

CDSCO, CGHS Dispensary Building, Sadiq Nagar, and New Delhi-110049.[16]

2. A fee of US$ 1500 or its equivalent shall be paid along with the application as registration fee for the premises where the devices, intended to be imported are being manufactured by the manufacturer.
3. A fee of US$ 1000 or its equivalent shall be paid for registration of single medical device (which may include variation in sizes or shape without any change in the material or method of use) and an additional fee US$ 1000 for each additional device shall be paid.
4. The fee shall be paid through a challan in the Bank of Baroda as prescribed under the said Rules.
5. The information's and undertakings required to be furnished under Schedule DI and DII may be modified to suit the requirements of devices in place of normal pharmacological products. The information shall include the following details.

Applicant details

1. Applicant's company name, address and contact number.
2. Name and address of foreign manufacturer (Manufacturing premises).
3. Copy of the Plant Master File.
4. Name and address of the local authorized representative.
5. Name and address of the importer.
6. Local manufacturer, if any processing is being done in the country.

Product information

1. Proprietary/Brand name.
2. Brief description of the device.
3. Category of device.
4. Intended use and method of use.
5. Medicals specialty in which the device is used.
6. Qualitative and quantitative particulars of the constituents.
7. Brief description of the method of the manufacture and specification of the materials used.
8. Contraindications, warnings, precautions potential adverse events, and alternate therapy, wherever applicable.
9. List of accessories and other devices or equipment to be used in combination with the device. Other descriptive information, including accessories packaged with the product.
10. Variations in shape, style, or size of the device, if applicable.
11. Labeling details conforming to drugs and cosmetics rules, 1945.
12. Physician manual and promotional literature (Literature insert) in English.
13. Packaging description including pack sizes.
14. Recommended storage conditions.
15. Summary indications of any reported problems.
16. Details of standards to which the device conform along with the copy of the standard.

Regulatory status

1. Approval of the product from any other regulatory agency (Separate evidence for the approval from the each agency) US FDA clearance/approval.
2. EU medical device directive (CE Certificate).
3. Australia/Canada/Japan approval.
4. Approval in any other country.
   - Copy of ISO/EN Certification if any for the manufacturing facility.
   - List of countries where the device is being sold.
   - List of countries where device is withdrawn from sale with reasons, if any.

Master file (details of good manufacturing practices employed by the manufacturer to ensure quality of the device)

1. Component/Material used.
2. Device Master File.
3. Manufacturing process/Flow Chart.
4. Quality Assurance procedures/process controls.
5. Final product testing or design inputs/outputs verification, if applicable.
6. Functionality Test protocol and report, if applicable.
7. Risk assessment as per ISO 14971.
8. Sterilization process and validation/verification.
9. Stability data or statement of established stability of material used as applicable.
10. Shelf life of the device.
11. Biocompatibility and Toxicological data, wherever applicable.
12. Device GMP Certificate.

Devices containing medicinal product

1. If device incorporates a medicinal product, which is liable to act upon the body with action ancillary to that of the device, data on the safety, quality and usefulness of the medicinal substance used.
2. Data on compatibility with medicinal products, if device intended to deliver medicinal products.
3. Clinical data and published articles, if any.
4. Batch Release Certificate for products incorporating any medicinal substance or substances of animal origin.
5. For devices not approve for marketing in the country of origin, the applicant shall submit reports of clinical trials, details of sales, certificates of satisfactory use from the medical specialists about the use of the device, and details of product complaints, if any.

(Medical Devices with prior approval from any of the recognized regulatory authorities will be subjected to an abridged evaluation and only a summary of all the studies and information described above is to be submitted).

Post-Market surveillance

1. Procedures for distribution of records.
2. Complaint handling.
3. Adverse incident reporting.
4. Procedure for product recalls.

Undertaking of conformity with respect to product standards, safety, and effectiveness requirements and quality systems in the country of origin.

1. The Registration Certificate shall be issued in Form 41 of the said Rules.
2. The application for import license shall be made in Form 8 along with a fee of Rs. 1000/- in the Form and manner prescribed under the Drugs and Cosmetics Rules.

MANUFACTURE OF MEDICAL DEVICES IN THE COUNTRY

1. Application for the grant of license for manufacture of these notified sterile Devices in the country shall be made in Form 27 to the State Licensing Authority, accompanied by the requisite fee in the Form and manner as prescribed in the said Rules along with a copy to the office of DCG (I).[15]
2. A period of 60 days would be provided for making the application for manufacture from the date of publication of these guidelines.
3. In case of devices belonging to above said categories which have not been manufactured in the country before the date of notification, no manufacture would be permitted hence forth without the approval of the competent authority as per norms prescribed.
4. The applicant shall provide the following information along with the application for consideration of the licensing authority.

Manufacturing details

- Complete details about the names, addresses of the directors of the company, and addresses of the manufacturing premises and registered offices of the manufacturer.
- A brief project highlight indicating the plans of the company, devices to be manufacture their viability, and other relevant profiles.
- Copy of the site master file.
- A brief description of the manufacturing process of the devices to be manufactured.
- Details of the standards followed by the company for good manufacturing practices and product evaluation.
- Name, qualification and experience of technical staff under whose supervision the devices will be manufactured.
- Copies of ISO or any other certifications, if any, obtained by the firm for its manufacturing facility.

Product details

- Proprietary/Brand name.
- Brief description of the device.
- Category of device.
- Intended use and method of use.
- Medical specialty in which the device is used.
- Qualitative and quantitative particulars of the constituents.
- Specifications of the materials used.
- Testing facilities available in the manufacturing premises for testing.
- Standards and procedures for testing the device.
- Contraindications, warnings, precautions potential adverse events and alternate therapy, wherever applicable.
- List of accessories and other devices or equipment to be used in combination with the device. Other descriptive information, including accessories packaged with the product.
- Information on stability of the product.
- Details of clinical trials, (wherever applicable) carried out on the product.
- Variations in shape, style, or size of the device, if applicable.
- Labeling details conforming to Drugs and Cosmetics Rules, 1945.
- Physician manual and promotional literature (Literature insert) in English (if any).
- Packaging description including pack sizes.
- Recommended storage conditions.
- Summary indications of any reported problems.

5. For the purpose of evaluation of Medical Devices which are new or do not have any benchmark certification, Expert Committees shall be setup to examine in detail the information provided by the applicant for the assessment of the device.
6. The committees after completing their assessment forward the opinion regarding suitability of the device to the competent authority for the purpose of grant of permission for placing the device in the market.
7. The State Licensing Authority after Joint Inspection and verification would forward the license to CLAA for approval.
8. The license shall be issued in Form 28 of the said Rules after due approval of CLAA.

SALE OF MEDICAL DEVICES IN THE COUNTRY

Importers, stockiest, and retail sellers of Medical Devices shall obtain appropriate sale licenses from the State Licensing Authorities for these medical devices within a period of 3 months form the issue of these guidelines.

CLINICAL TRAILS

Clinical trials and clinical evaluation of medical devices in India are as per Global harmonization task force (GHTF) Guidance USA, Australia, Japan, Canada, and European Union. Industry has encouraged (GOI) to follow the GHTF Study Group 5 recommendations on clinical evaluation and investigations.[17] It will also provide a copy of ISO 14155 on clinical investigations and compare it to the International conference on harmonization (ICH) guidelines on pharmaceutical Good Clinical Practices for further

discussions and possible adoption. The document is intended to provide non-binding guidance for conducting clinical trial (s) of medical devices in India.

All the general principles of clinical trials described for drug trials should also be considered for trials of medical devices. As for the medicated devices, safety evaluation and pre-market efficacy of devices for 1-3 years with data on adverse reactions should be obtained before pre-market certification. The duration of the trial and extent of use may be decided in case-to-case basis by the appropriate authorities. However, the following important factors that are unique to medical devices should be taken into consideration while evaluating the related research projects:

1. Safety data of the medical device in animals should be obtained and likely risks posed by the device should be considered.
2. Clinical trials of medical devices are different from drug trials, as they cannot be conducted in healthy volunteers. Hence, Phase I trials are not necessary for trial on medicated devices.
3. Medical devices used within the body may have greater risk potential than those used on or outside the body, for example, orthopedic pins vs. crutches.
4. Medical devices not used regularly have less risk potential than those used regularly, for example, contact lens vs. intraocular lenses.
5. Safe procedures to introduce a medical device in the patient should also be followed as the procedure itself may cause harm to the patient.
6. Informed consent procedures should be followed as in drug trials. The patient information sheet should contain information on follow-up procedures to be adopted if the patient decides to withdraw from the trial.
7. Study design of the intra body devices like implants can be very challenging and should have adequate protective safeguards. The study should be long enough to detect if there are any late onset ADRs.
8. If full assessment of safety is not complete, the Phase III could extend to Phase I.

DOCUMENTS REQUIRED FOR CLINICAL TRIAL APPLICATION OF NOTIFIED MEDICAL DEVICES IN INDIA

(Note: Data on item number 5-10 is required, as applicable for the proposed study, if not available in the device master file and investigator's brochure)

1. Covering letter
2. Duly filled application in form 44: Application for grant of permission to import or manufacture a new drug or to undertake clinical trail
   i. Particulars of Subject Device:
      - Generic Name
      - Brand Name
      - Composition of device
      - Specifications/standard of device
      - Qualitative and quantitative particulars of Constituents
      - Information on sterility and stability of the Product
      - Labeling details
      - Variations in shape, style or size of the device, if applicable
      - Physician manual and promotional literature (Literature insert) in English (if any)
      - Packaging description including pack sizes
      - Risk classification (in country of origin as well as in 5GHTF Countries) (E.U., USA, Japan, Canada, Australia)
      - List of accessories or device to be used in conjunction with subject Medical Device
      - Indication w.r.t which clinical study is to be carried out
      - Name and address of the manufacturer/ contract manufacturer(s)
      - Regulatory status of the subject device (Particularly 5GHTF Countries i.e., E.U, USA, Japan, Canada, Australia
   ii. Technical data to be submitted along with the application for the subject medical device:
      - For all medical device
        a) Design Analysis Data
        b) Biocompatibility
      - For Moderate/ high risk medical devices:
        a) For Phase I study [feasibility/ first in man trails]: i.e., Animal Study data
        b) For Phase II/III Study [pivotal trails]
3. Requisite fee

As per the provisions of drugs and cosmetics act and therefore under in the Form of TR6 Challan issued by Bank Baroda. Fee can be submitted at notified branches of Bank of Baroda under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fines" adjustable to Pay and Account Officer, DGHS, New Delhi, in the form of a Treasury Challan. Performa for Treasury Challan (TR 6) is annexed at. TR6 Challan receipt (in original) needs to be submitted clearly specifying the fee deposited. The fee to be paid is as follows:

   i. Feasibility study (i.e. Safety and efficacy study); which is equivalent to Phase I trials in case of drugs: Rest 50,000/-
   ii. Pivotal Study (i.e. Confirmatory trials); which is equivalent to Phase II/III trials in the case of drugs: Rest 25,000/-
4. Delegation of responsibility
5. Protocol: Should include following points
   i. Title page
   ii. Table of contents:
      - Background and introduction
      - Study rationale
      - Study objective

- Study design
- Study population
- Subject eligibility
- Study assessment
- Study conduct
- Study end points
- Risk analysis
- Adverse event management
- Ethical consideration
- Study monitoring and supervision
- Investigational product management
- Data analysis
- Statistical considerations

6. Global regulatory status
   i. Clinical trial in each participating country:
      - Copies of regulatory approval letters, IRB/EC approvals, recruitment figures (Protocol specific) from participating countries (if available)
        a) Regulatory status of device and/or drugs in other Countries (if applicable):
      - Approved
      - Marketed (if marketed a copy of package insert)
      - Withdrawn, if any, with reasons
      - Free sale certificate or certificate of analysis, as appropriate

   ii. ISO Certificate and for CE certificate
7. Investigator's undertakings
8. Ethics committee approval letters
9. Informed consent form
10. Case record form
11. Patient record form
12. Relevant published literature
13. Investigator's brochure
14. Suspected unexpected serious adverse reaction (SUSAR) from other participating countries if any reported and summary of any reported problems.
15. Affidavit from the sponsor that the study has not been discontinued in any country and in case of discontinuation the reasons for such a discontinuation and that the applicant would further communicate to DCG (I) about the future discontinuation and Investigator's Brochure containing the summarized information is based on the facts. (On a plain paper duly notarized and apostil led).
16. Any other specific relevant information w.r.t. subject device.
17. Clinical study report structure, contents and format for clinical study report.

LICENSING

Guidance document Requirements for grant of license in Form-28 for manufacturing of medical device in India.[18] Application for the grant of license for manufacture of Medical Devices in India shall be made in Form 27:

1. The concerned state drugs licensing authority,
2. The concerned CDSCO Zonal/Sub-Zonal office and
3. The drugs controller general of india CDSCO (HQ).

Form 28: Fallowing documents are required to grant the license:

1. Covering letter
2. An authorization letter
3. A duly filled form 27
4. The requisite fee
5. Constitution details
6. Approved manufacturing premises plan/layout
7. Full particulars of competent and regular technical staff for manufacturing and testing of medical devices along with the copies of educational qualification, experience certificate, appointment letter, acceptance letter, etc.
8. Site master file
9. Specific requirements
10. Device master file
11. List of medical devices along with undertaking in prescribed pro-forma
12. ISO 13485:2003 certificate (if any)
13. Full quality assurance certificate (if any)
14. CE design certificate (if any)
15. Declaration of conformity (if any)
16. Any other approvals (e.g. US FDA).

CONCLUSION

Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand their business in India's medical markets. It is hoped that the guidelines are implemented and regulated properly with effective outcome. This article highlights current regulations pertaining to applications for medical device registration certificates, medical device clinical trials, and medical device manufacturing/importation licenses.

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