



India's Latest Medical Device Regulation Developments

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Introduction

India's [medical device market](#) is currently valued at approximately \$2.5 billion. The country ranks fourth in Asia for largest medical device markets (following Japan, China, and South Korea). Roughly 75% of the medical device market in India consists of imported products.

Despite this high percentage of imports, India does not comprehensively regulate many of the medical devices (both local and foreign). Currently, a number of specific medical devices are regulated as drugs and fall under India's Drugs and Cosmetics Act (DCA).

The Central Drugs Standard Control Organization (CDSCO) is the key medical regulatory organization in India. As the CDSCO is in charge of implementing and enforcing the DCA, it is the only government body that regulates medical devices in any way.

Since 2008, both the Indian Department of Science and Technology and the Ministry of Health have sought to completely restructure the regulations for medical devices.

- *Department of Science and Technology*: proposed creation of a Medical Devices Regulatory Authority that would operate similar to a division within the CDSCO.
- *Ministry of Health*: proposed revision of the DCA that would create a Central Drug Authority to function similarly to the U.S. FDA.

To date, neither of these attempts has been successful. In 2009, multiple reports suggested that the Department of Science and Technology had the more favorable suggestion. Based on more recent statements by legislators and other government officials, however, there seems to be stronger support for the Ministry of Health's proposal. Furthermore, India's Prime Minister's Office has reportedly given its sponsorship to the Ministry of Health's idea.

Despite these attempts by other organizations at reforming medical device control in India, the CDSCO is continuing to entrench its own medical device regulation standards. In June 2009, it seemed as if the CDSCO would begin its own form of [medical device regulations](#).

- *CDSCO*: released Schedule M-III, which provided an official definition for medical devices, outlined a four level medical device risk classification scheme, created a body within the CDSCO to regulate medical devices in India, and more.

This notice was approved by the Indian government, but in practice, most medical devices are not regulated.

Right now, it is still very unclear as to which of these three different medical device regulation proposals will become the official standard in India. In August 2010, though, four drafts of medical device guidelines that contain more specific details on how CDSCO's idea may be implemented were released on the CDSCO's website. These documents are related to applications for medical device registration certificates, medical device clinical trials, and medical device manufacturing/importation licenses. These new CDSCO documents may be used as a basis for any future comprehensive medical device regulations in the country.

The rest of this article offers an overview of the guidelines' contents.

Common Components

Each guidance document begins with a general introduction to the requirements for the application. For some of the items in an application, there is a summary of what the actual item is or suggestions on how to best complete certain sections. One can additionally find application fee information and blank versions of the necessary forms (some forms are referred to as "schedules" in India).

Also, all four of the application guidelines require a "covering letter" and a Challan. The covering letter is essentially a signed summary of the application's purpose and contents. A Challan is an accounting form that is submitted with any fees paid to the government.

Medical Device Registration Application Guidelines Draft

In the "Guidance Document on Common Submission Format for Registration of Medical Devices in India," there are general instructions on how to apply for a medical device registration certificate. Registration certificates are valid for up to three years after issuance in India. The guidance shows that 15 components are usually required. These include:

1. Covering Letter
2. Authorization Letter (for proof of a local agent)
3. Form 40 (a general medical device registration application form)
4. TR6 Challan
5. Power of Attorney (for proof of authorization from manufacturer to agent in India)
6. Schedule DI and Plant Master File (requires information on the manufacturer/manufacturing premises, details on the medical device, and more)
7. Schedule DII and Device Master File (requires information on the medical device intended use, indication for use, classification, novel features, sterilization, similar devices in India, domestic price of the device in country of origin, marketing history of the device, regulatory approvals/marketing clearances, labeling, risk analysis and control, biocompatibility, biological safety, clinical evidence, post marketing surveillance data, and more)
8. Wholesale License
9. Free Sale Certificate
10. Manufacturing License/Plant Registration Certificate
11. ISO 13485:2003 Certificate

12. Full Quality Assurance Certificate
13. CE Design Examination Certificate
14. Declaration of Conformity
15. Inspection/Audit Report

Medical Device Clinical Trials Application Guidelines Draft

“Requirements for Conducting Clinical Trial(s) of Medical Devices in India” similarly provides basic instructions on how to apply for clinical trials for medical devices. Most applicants will have to include 17 parts in the application:

1. Covering Letter
2. Form 44 (a general application to import or manufacture a new drug or conduct clinical trials – requires design analysis data, biocompatibility data, animal study data (if any), and more)
3. TR6 Challan
4. Delegation of Responsibility (a letter from sponsor stating responsibilities of the Primary Investigator)
5. Protocol (requires information on study design, study population, study eligibility, study assessment, study endpoints, risk analysis, adverse event management, ethical considerations, study monitoring and supervision, investigational product management, data analysis, statistical considerations, and more)
6. Global Regulatory Status of the Device
7. Investigator’s Undertaking
8. Ethics Committee Approval
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)
15. Affidavit from the sponsor
16. Any other specific relevant information
17. Clinical Study Report (if any)

Medical Device Manufacturing License Application Guidelines Draft

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 16 items are:

1. Covering Letter
2. Authorization Letter
3. Form 27 (a general application form for medical device manufacturing license application in India)
4. Challan
5. Constitution Details (documents related to the constitution of the firm, article of association, etc.)

6. Approved Manufacturing Premises Plan/Layout (a component of the Site Master File)
7. Full Particulars of Competent and Regular Technical Staff (requires information and documents about employees, such as educational qualifications, appointment letters, and more)
8. Site Master File (requires information on manufacturer/manufacturing site, personnel, equipment, sanitation, production, quality controls, storage, documentation, medical device complaints and field safety corrective action, self-inspection, contract activities, etc.)
9. Specific Requirements (requires information on moulding/assembly/packing areas and testing facilities)
10. Device Master File (requires information on medical device intended use, indication for use, classification, novel features, sterilization, similar devices in India, domestic price of the device in country of origin, marketing history of the device, regulatory approvals/marketing clearances, labeling, risk analysis and control, biocompatibility, biological safety, clinical evidence, post marketing surveillance data, and more)
11. Product Undertaking by Manufacturer (a required signed form)
12. ISO 13485:2003 Certificate
13. Full Quality Assurance Certificate
14. CE Design Examination Certificate
15. Declaration of Conformity
16. Any other approvals

Medical Device Import License Application Guidelines Draft

The latest document to be uploaded onto the CDSCO site is the “Guidance Document on Common Submission Format for Import Licence in Form 10 of Medical Devices in India.” It introduces the application documents for a medical device import license. Medical product import licenses are valid for three years after issuance in India. There are 8 parts to the application:

1. Covering Letter
2. Authorization Letter
3. Form 8 (a general application for medical product import license)
4. Form 9 (a “form of undertaking” that is included with any import license applications)
5. TR6 Challan
6. Wholesale License/Manufacturing License
7. Copy of Registration Certificate
8. Copy of Import License

Conclusion

India’s government has identified medical device regulation as a key issue that needs to be addressed. Although debate over *how* to regulate has thus far prevented the full acceptance of any one system, the CDSCO’s guidelines may be used as a resource for future laws. Foreign medical device companies currently exporting to India or companies hoping to enter India’s medical device market in the future should consider these applications’ required contents.