Medical Device Regulatory Profile for India

Market Overview

Many in the international investment community have identified healthcare in India as a major business opportunity as the sector expands to meet the needs of India's growing middle-class, a population of around 300 million with rising income, increasing expectations and greater access to healthcare services. Despite India's relatively low per capita expenditure on healthcare to date, India's market for medical devices is in the world's top twenty - in 2007 India's medical equipment market was estimated at about $1.56 billion. The market is expected to grow about 8 percent annually and approach $2.3 billion by 2012 [source: Espicom Business Intelligence]. Although India has a growing domestic medical device manufacturing sector the country still imports more than half of its healthcare equipment, in particular high technology products.

India has both government and private healthcare providers, however most growth in recent years has occurred in the private sector (which currently contributes about 80 percent to growth in the healthcare delivery market). Medical equipment distribution in India is through regional distributors who have networks of sub-distributors, and the use of a local, well-qualified distributor helps in establishing good relationships influencing buying decisions. Smaller medical electronics manufacturer may find it difficult to compete with the larger, branded medical electronics manufacturers unless the product has niche applications. Regardless of the electronics equipment being imported, a rigorous after-sales servicing plan is expected.

Background

The Government of India (GOI) is in the process of developing a regulatory regime designed to ensure the quality, safety and performance of medical devices. The GOI recognizes that an efficient regulatory system will help to improve India's healthcare sector and support the development of India's domestic industry. There has been forward movement in recent years toward a basic system of regulatory controls since the GOI first announced its intentions in 2005 and began issuing guidelines for product registration in early 2006. However, as would be expected in any major undertaking with competing interests and shifting landscapes, the process has experienced its share of false starts and has sometimes been contentious. Legislation is under consideration in the Parliament and officials in the Ministry of Health and Family Welfare (MoHFW) and Drugs Controller General of India (DCG(I)) now seem engaged, however much remains to be done before a workable regulatory system is established in India.

Early Guidelines

In 2005 the state regulatory authority (Drugs Controller) of Maharashtra found that drug eluting stents (DES) used in cardiac patients had not been approved by the DCG(I) and immediately banned the use of the product within the state. The High Court of Bombay subsequently intervened and directed the GOI to resolve the issue by expanding the scope of products under regulation.

In October 2005 the MoHFW issued Notification G.S.R. 627 (E) which contained a list of ten categories of products (regulated elsewhere as medical devices) that would henceforth be subject to licensing as drugs by the central government under existing regulations governing pharmaceuticals before they could be manufactured, sold, or distributed in India. The notification was adopted in March 2006, and applied to both Indian and foreign firms.

Notification 627 created some confusion in the early stages - it was not accompanied by implementing guidelines, which left companies to speculate how the regulations would be carried out. Some companies reportedly received oral assurances that the requirement would not be stringently enforced in the early stages, and acknowledgement that the content of the regulations lacked clarity and the GOI did not have the capacity to review the burgeoning number of device applications. Customs authorities in Mumbai, however, began holding up shipments of medical devices due to the ensuing uncertainty, prompting complaints from industry and an inquiry from the U.S. Embassy in Delhi.

After initial difficulties, however, the guidelines adopted in March 2006 seemed to work reasonably well given their purpose, the speed with which they were required to be implemented and the limited resources available to the DCG(I). The Central Drugs Standard Control Organization (CDSCO) allowed some flexibility in the guidelines as the GOI wanted to ensure the continued flow of safe and effective medical technology to patients in India. By mid 2008, however, industry again began to experience inconsistent application of the current guidelines causing renewed confusion and delays. These problems were sourced in part to multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within CDSCO. Companies importing medical devices that had not required a license since the guidelines were implemented were told licenses were necessary, and customs officials again stopped some imports of medical devices unless they had a “no objection certificate,” even if they were not covered by the guidelines. In addition, new guidelines on the CDSCO website seem to indicate that importers must register accessories, contradicting arrangements worked out for the March 2006 guidelines.

Pending Legislation

In 2007 legislation was drafted to advance India’s medical device and pharmaceutical regulations and the development of a centralized regulatory authority. Two independent bills were put

forward - one by the Department of Science and Technology (DST) that proposed a comprehensive regulatory framework specifically for medical devices, and the other by the Ministry of Health to establish a Central Drugs Authority (CDA) covering all regulated products. Both bills call for a regulatory regime that distinguishes between pharmaceuticals and medical devices and has adequate powers to ensure standards, efficacy, safety and availability of medical devices manufactured or marketed in the country.

The CDA legislation proposed that all the existing powers of the CDSCO at present would be brought under a newly created body. The CDA would be charged with regulation, licensing, surveillance and monitoring of medical products and the uniform implementation of laws pertaining to medical devices within the country. It would collect fees for permission to conduct clinical trials for drugs, devices and cosmetics. The CDA could convene committees or subcommittees it considered essential for the efficient discharge of its functions and exercise of its assigned powers. The DCG(I) would be the chief executive officer and legal representative of the CDA and would be responsible for the day-to-day administration of the authority. The CDA would classify devices, notify standards and guidelines from time to time, provide a mechanism for conformity assessment using direct or third party notified bodies and stipulate the procedure and guidelines for testing laboratories.

In 2008, however, an alternative approach was espoused by a Parliamentary Committee headed by Amar Singh. The Committee suggested that a separate chapter be added to the Amended Drugs and Cosmetics Bill of 2007 that would allow for a financially self-sustaining regulatory body that could handle administration of medical devices regulation without creating a big, new infrastructure or encroaching on many of the responsibilities of other existing bodies. The Committee's position stemmed from the belief that it was neither feasible nor desirable to disband all existing entities and create a centrist structure like the USFDA in India. While agreeing with many provisions of the CDA Bill, the Committee recommended against establishing the much publicized CDA at this stage and called instead for a "central drug administration".

In place of a CDA, the Committee essentially supported recommendations made by the Mashelkar Committee in 2003 to restructure, strengthen and modernize the existing CDSCO under the MoHFW. A newly-equipped and professionally managed CDSCO would oversee a centralized licensing system and maintained a network of offices at the zonal and sub-zonal levels. The panel felt that while the current system was inadequate, it was not necessary to go as far as proposals in pending legislation, and objected to the ongoing clash of views between the MoHFW and the DST on the issue of regulating medical devices. The move toward centralization of issue of manufacturing licenses would still be done in a phased manner - the Committee suggested a 10-year transition from the current state-level mechanism to a more centralized system (the CDA bill originally provided for five years). The Committee also recommended the creation of 10 divisions within the central drug administration, including a separate medical device division.

The Committee's report on the Drugs and Cosmetics (Amendment) Bill, 2007 came after more than a year of studies and consultation with industry and other interested parties. The report was tabled in the Rajya Sabha (upper house of the Indian Parliament), and in December 2008 the MOH was reportedly re-drafting the Bill to be in line with the Committee's recommendations. Significantly, according to press reports nineteen States, including Andhra Pradesh, Goa, Gujarat, Maharashtra and Tamil Nadu, supported this approach. [Source - Pharmabiz - Wednesday, December 03, 2008].

Very recently, DST has issued another draft Bill, The Medical Devices Safety Bill, 2008. It is an updated version of its earlier proposal.

In summary, legislation governing the regulation of medical devices is still in flux - including the drafting stages, legislation has now been under consideration for more than three years, during which time the MoHFW and the DST have been debating many issues with limited results. While the GOI seems be making a reasonable, good faith effort there remain significant uncertainties and concerns about the direction and pace of India's attempt to regulate medical technologies, as well as the structure of India's planned regulatory authority.

Participation by Industry

Both domestic and foreign medical device industry advocates have asked the GOI for the opportunity to be fully involved in the process, and the GOI has generally been receptive to participation by private sector stakeholders. Industry has urged the GOI to adopt a phased approach to implementation of new regulations and guidelines, and has provided a considerable amount of information to help inform GOI decisions.

The U.S. medical device trade association AdvaMed has worked with the local American Chamber of Commerce (AMCHAM), Confederation of Indian Industry (CII), and the Federation of Indian Chambers of Commerce and Industry (FICCI) to provide comments on the 2006 DCG(I) guidelines on ways to improve their effectiveness. Industry has encouraged, and the GOI has accepted, the principle that the regulatory framework for medical technology should be distinct from regulations for pharmaceuticals. Industry has also urged that GOI's regulatory scheme be based on harmonized international guidance and consistent with established regulatory systems of major trading partners. Finally, industry has urged the GOI to develop regulatory controls that are be proportionate and based on risk management principles.

Influences on Regulatory Structure Development

India has not modeled its regulatory system after the U.S. or EU systems per se, considering them too costly to apply in India and too stiff and complex for Indian industry to readily adopt. The GOI has, however, looked to elements of both systems to advance its regulatory regime. India respects many aspects of the USFDA (e.g. certain mechanisms of the USFDA's Center for Devices and Radiological Health (CDRH) are considered comprehensive and efficient), and

there is general agreement that a centralized body should assume many of the responsibilities held by CDRH without, however, assuming many of the U.S. system's labor- and resource-intensive elements. At present the GOI is leaning more toward a European-type approach to regulations. For reasons of cost and existing infrastructure, India is attracted to the flexibility of the EU's structure with its reliance on a de-centralized network of private sector conformity assessment bodies appointed by the Competent Authority of each member state.

Current Regulatory Structure and Related Considerations

The MoHFW, DCG(I), Bureau of Indian Standards (BIS) and Nuclear Medicine Board of the Bhabha Atomic Regulatory Commission (BARC) regulate different aspects of the healthcare sector. The authority principally responsible for regulating medical devices in India, however, is the Central Drugs Standard Control Organization (CDSCO) **http://cdsco.nic.in/** under MoHFW. Companies must register all products with the CDSCO before the company's products can be introduced into the Indian market. (Contact information below).

Gazette Notification S.O. 1468 (2005) (**http://www.cdsco.nic.in/html/Notification**/not1.pdf) applies to certain medical devices in India. The notification declares ten categories of sterile devices to be considered as drugs under Section 3 (b) (iv) of the Drug and Cosmetic Act (DCA) and, therefore, subject to registration. The ten devices are: cannulae, bone cements, heart valves, scalp vein set, orthopedic implants, and internal prosthetic replacement. This notification outlines the specific documents necessary to register a medical device with the CDSCO (see attachment).

In late 2008 the DCG(I) prepared an expanded list of medical devices which require registration. The list now includes over 160 medical devices. Industry has expressed concern that to date (December 08) no notification about the registration of these additional devices has been issued by DCG(I)/MoHFW but the Assistant Drugs Controller at Delhi port has stopped customs clearance of devices featured in that 'expanded list'.

Development of New Regulatory Scheme

As part of GOI's efforts to develop a regulatory system for medical devices, DCG(I) formed a small "core group" of CDSCO officials and industry representatives. In April 2008 a core group meeting was convened to discuss the planned medical device regulatory guidelines in light of comments submitted by stakeholders, submissions made, and further GOI review. Representatives from industry and GOI officials discussed a "road map" and recommendations prepared by industry. This road map included a current status review as well as guiding principles and a regulatory process implementation phases to make it an all inclusive process. A paper prepared by industry - "Proposals for Implementation" - was also presented and referred to support the road map presented. It was agreed that the recommendations made would be

reviewed by the DCG(I) office and they would revert to the Core Group. While not yet publicly accepted by GOI, those recommendations include1:

Definition of Medical Devices

India will move toward adoption of the Global Harmonization Task Force's (GHTF) definition and rules-based classification of medical devices.

Product Classification

Consistent with GHTF guidance and the EU medical device directives, devices are to be classified as Class A (devices involving lowest risk levels), Class B (low to moderate risks), Class C (moderate to high risks) and Class D (highest risks) for efficient monitoring and regulation. The conformity assessment requirements will be proportionate to device classification.

Use of Notified Bodies

India will consider the use of private third-party conformity assessment bodies (referred to as "Notified Bodies" and similar to Notified Bodies under the European Union medical device directives) to carry out conformity assessments. They would be assess medical device manufacturing sites on the basis of the ISO 13485 quality management system standard and submit their findings to the regulatory authority (CDSCO or CDA) to take a decision on granting a manufacturing license. This would apply to medical device classes Class IIa, IIb, and III.

Standards

India will move toward the use of international standard ISO 13485: 2003 quality management systems for medical devices, published by the Bureau of Indian Standards (BIS) as Indian national standard IS 15579: 2005. [Note: BIS has reportedly stated to industry that these standards are identical except for a national foreword and minor editorial changes, e.g., punctuation.] Unlike Europe or GHTF guidance, however, compliance with IS 15579 may be made mandatory. Additionally a list of EU harmonized product and process standards and list of BIS standards were exchanged, and industry will provide comments suggesting which out of these should be considered relevant.

Testing

The DCG(I) has reportedly identified two primary government-funded laboratories that are equipped and capable of testing Medical Devices. One laboratory will be used for physical

[1] It should be noted that these developments are the subject of active ongoing discussion between government, industry, and other interested parties. The future regulatory system and requirements outlined below is subject to change.

testing and the other for chemical and microbiological/biological testing procedures. The GOI indicated that the labs will be fully operational by 2009 to early 2010. Industry help will be sought during the start up operations and infrastructural requirements phases. The DCG(I) reportedly believes there should be some form of testing for some or all medical devices as part of pre-market conformity assessment. According to press reports, the GOI may soon make it mandatory for medical devices such as stents, catheters, orthopedic implants and heart valves to obtain quality certifications based on testing before they are sold in India. The role, if any, of such laboratories in pre-market conformity assessment and market surveillance has not yet been defined.

Clinical Trials and Clinical Evaluation of Medical Devices as per GHTF Guidance

The Expert Committee stated that clinical evaluation should be "thorough and objective", flexible, not unduly burdensome, and appropriate to the nature of the intended use and risks of the device in question. Industry has encouraged GOI to follow the GHTF Study Group 5 recommendations on clinical evaluation and investigations. 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.

Quality Management Systems

Officials in the CDSCO have expressed concerns that ISO 13485 may be insufficiently specific for manufacturers or for external auditors. Industry has sought to explain that this approach is necessary to accommodate the diversity in medical devices, technologies, and processes and that more detailed specific guidance is impractical. GHTF guidance documents may be used to supplement the standard.

Like the U.S. and EU systems, quality assurance, risk management, and quality management systems will be the responsibility of the manufacturer, who must obtain certification from a notified body for medium and higher risk class devices. The Notified Bodies would also conduct periodic surveillance audits of the manufacturer's facilities and systems. The cost of such certification and surveillance will be borne by manufacturers. At this time, however, many in the GOI feel that India is not fully ready for such a system because it would be viewed as cost-prohibitive by many smaller Indian manufacturers. According to the Expert Committee, "suitable changes" would need to be introduced to this model.

Post Marketing Surveillance

The DCG(I) has stated that adverse event and complaint reporting for medical devices is considered essential, and GHTF Study Group 2 guidance document "N 54"on Post Market Surveillance and Vigilance is under consideration for adoption.

In-vitro Diagnostics

Consistent with GHTF guidance and the practice in other developed regulatory systems, manufacturers and importers of in vitro diagnostic medical devices are pressing to have their products included in the scope of the new medical device system, rather than under the drugs schedules as at present.

Tariffs and Duties on Life Saving Products: In past years, most electronic medical equipment fell under the Open General License (OGL) program and was eligible for duty-free import under certain conditions (life saving, public hospitals, public research institutes, etc.) As an example, imports of cardiac care instruments, equipment, spare parts, components, and suppliers are listed under the "open general" category of import regulations that do not require government approval. Foreign medical electronic equipment must meet certain technical and safety standards, which are overseen by the Bureau of Indian Standards (BIS).

USDOC discussed the lifesaving designation for certain medical equipment and drugs with the Indian Government on May 30, 2008 in New Delhi, at a meeting of the Trade Policy Forum tariff and non-tariff barriers focus group. The Indian Government said that tariffs are applied based on Harmonized System classification. They said there could be a tariff line in which some were devices are classified as life saving and others not. They said they would need more details on technical aspects of the specific devices and drugs in question devices to explore the issue further

Counterfeit Medical Products

In 2008 the MoHFW has asked the DCG(I) to evaluate the scope of the problem of fake or poor quality medical products in India. In the opinion of the GOI, the perception of counterfeit products is greater than the actual incidence of counterfeits and occur mainly with lower value/lower tech devices (e.g., dressings, catheters) products than high-tech med devices (e.g., pacemakers).

The GOI declined the WHO's proposal to give a new definition to counterfeit drugs on the grounds that the new definition will act against the Indian drug industry, especially the generic drug manufacturers. WHO presently defines a counterfeit medicine as one "… which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

The GOI has stated that it has turned down this definition because the new definition considers apparent 'trademark violations' as 'counterfeiting' cases. The Indian drug manufacturers in India, especially the small scale sector, are concerned over this proposed definition as they fear that such a change of definition would harm the Indian generic drug makers as foreign drug firms

could stall exports of low-cost versions of patent expired medicines to key markets as “counterfeits”. Under the present definition a similar trademark that is being used by generic drug company will be liable for a trademark infringement. However if the new definition is accepted such a drug will be treated as ‘counterfeit’ in the international market. (Source: **www.pharmabiz.com**)

Taxes and Tariffs

Classification of products, including medical devices, under India's customs and excise tax schedules is generally aligned with the Harmonized System (HS) of tariff nomenclature. The GOI publishes tariff and other customs duty rates applicable to imports, but there is no official publication or searchable database setting forth applied tariff and other customs duty rates. To determine the applied tariff or other customs duty rate applicable to a particular product, importers must consult separate customs and excise tax schedules and cross-reference these schedules with any applicable customs or excise notification that may subject the product to higher or lower rates than set forth in the schedules (assuming the importer is able to determine that any such notification exists). Such a system lacks transparency and imposes significant burdens on importers.

Other Fees

A number of countries require manufacturers to pay “user fees” to gain regulatory approval for medical devices. DCG(I) implemented user fees for product registration under the 2006 Guidelines and accepted many industry recommendations on appropriate categories, or “families” of products. If, as expected, user fees are used under the new regulatory structure, industry would hope to work with the GOI on an appropriate arrangement and reasonable fees based on product families.

Application for Registration Certificate addressed to the Drug Controller General (India) and deposited at the Resource Center, CDSCO, CGHS Dispensary Building, Sadiq Nagar, New Delhi-110049; A registration fee of about $US 1500 for the premises where the devices intended to be imported; A registration fee of $US 1000 for a 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 of US$1000 for each additional device.

Intellectual Property Rights (IPR) Protection: Large-scale copyright piracy, especially in the software, optical media, and publishing industries, continues to be a major problem in India. The United States retained India on the "priority watch list" as part of the 2008 Special 301 review. IPR protection and enforcement has been the subject of ongoing discussion in the trade policy forum's innovation and creativity focus group.

India's criminal IPR enforcement regime, including border protection against counterfeit and pirated goods, needs to be bolstered. There have been few reported convictions for copyright infringement resulting from raids, including raids against repeat offenders. Backlogs in the court system and documentary and other procedural requirements have provided impediments to the prosecution of criminal counterfeiting and piracy. Obstruction of raids, leaks of confidential information, delays in criminal case preparation, and the lack of adequately trained officials have further hindered the criminal enforcement process.

Insurance

Health insurance in India covers a small share of the population – estimated to be less than 10 percent. In addition to group coverage under private insurance, there are several government programs – including Employee State Insurance Scheme (which involves the state governments) and the Central Government Health Scheme. NGOs also provide very modest coverage to various poverty groups. While growing, India's share of private health insurance coverage is low, even compared to countries generally considered as having public insurance systems. The result of low government or private insurance in India is that a high proportion of healthcare funding is directly from personal resources. Roughly 80 percent of healthcare costs in India are paid for from out-of-pocket expenditures.

Government-to-Government Interface

Through the U.S.-India High Technology Cooperation Group the U.S. Government and U.S. industry continue to encourage India to develop its medical device regulations by taking into account and participating in international harmonization efforts on medical device regulation. The USG has recommended a consultative approach where interested parties have a voice. India can obviously decide how best to make use of offers of assistance, and benefit from a better understanding of existing medical device regulatory systems in other large economies.

The GOI has acknowledged the need for closer cooperation with USFDA as India develops medical device regulatory processes. The MOH and DCG(I) have sought counsel and advice from the U.S., Canada, and the World Health Organization on regulations and has an agreement with Canada on vaccine regulations. Additionally, the DCG(I) has referenced the use of a "full time consultant" from the EU" (but has not identified the consultant or provided any specific details). Regulation of medical devices is one of six areas for U.S.-India collaborations with the DCG(I)'s office. The other areas are structure of a central drug authority (CDA), E-governance, Pharmaco-vigilance, clinical trials, and regulation of high technology products.

Generally speaking, the USG's approach has been similar to that of industry - to endorse transparent, proportionate, and predictable regulations, based on principles of good governance and risk management, covering the quality, safety and performance of products placed on the market in India and elsewhere, which will ensure patients have access to medical technology in a timely manner, without undue delays caused by unnecessary and burdensome regulation.

The USG has urged that the GOI use the principles of efficient regulations adopted by the Organization for Economic Cooperation and Development (OECD).

Name of the Nodal Organization & Contact Information

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
Nirman Bhavan, New Delhi -110011
Phone: 91-11-23061806
Fax: 91-11-23062648

Website of **Central Drugs Control Organization**
http://cdsco.nic.in/

Drugs & Cosmetic Act & Rules available in the link below
http://cdsco.nic.in/html/downloads.htm

More information or assistance in exploring business opportunities and establishing presence in the Indian market please contact the U.S. Commercial Service in India at:

U.S. Commercial Service
American Center
24 Kasturba Gandhi Marg
New Delhi
Phone: 91-11-23316841
Fax: 91-11-23315172
Email: New.Delhi.office.box@mail.doc.gov.

For additional information regarding market research specific to your products and services, ask about our Customized Market Research (CMR) program by contacting us at 1-800-USA-TRAD(E) or www.export.gov or www.buyusa.com. Both reports provide timely, customized, reliable answers to your inquiries about a market and its receptivity to your products and services.

ATTACHMENT 1

Document Requirements

Note: Due to rapidly changes conditions this list should be considered for general guidance purposes only. Companies should consult with in-country representation and the regulatory authority's website

- The following documents are necessary to complete the application:
- Applicant Details
- Applicant's company name, address and contract information
- Name and address of foreign manufacturer (manufacturing premises);
- Copy of Plant Master File;
- Name and address of the local authorized representative;
- Name and address of importer;
- Local manufacturer, if any processing is being done in the country;

Product Information

- 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;
- Brief description of the method of the manufacture and specification of the material used;
- 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;
- Variations in shape, style or size of the device, if applicable;
- Labeling details confirming to Drug and Cosmetic Rules, 1945;
- Physician manual and promotional literature in English;
- Packaging description including pack size;
- Recommended storage conditions;
- Summary indications of any reported problems;
- Details of standards to which the device confirm along with the copy of the standard;

Regulatory Status

- Approval of the product from any other regulatory agency (separate evidence for the approval from each agency):
- USFDA clearance/approval
- EU medical device directive (CE Certificate);

- Australia/Canada/Japan approval;
- Approval in any other country;
- Copy of ISO/EN Certification if any for the manufacturing facility;
- List of countries where the device is sold;
- List of countries where device is withdrawn from sale with reason, if any.
- Master File (Details of GMP employed by the manufacturer)

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