Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

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The Indian Medical Device Industry

Regulatory, Legal and Tax Overview

April 2016

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Nishith Desai, Founder of Nishith Desai Associates, has been voted 'External Counsel of the Year 2009' by Asian Counsel and Pacific Business Press and the 'Most in Demand Practitioners' by Chambers Asia 2009. He has also been ranked No. 28 in a global Top 50 "Gold List" by Tax Business, a UK-based journal for the international tax community. He is listed in the Lex Witness 'Hall of fame: Top 50' individuals who have helped shape the legal landscape of modern India. He is also the recipient of Prof. Yunus 'Social Business Pioneer of India' – 2010 award.

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Executive Summary

The Indian medical device sector is worth approximately USD 5.5 Billion and is growing at 15% CAGR.[1] The medical device market is dominated by imported products, which comprise of around 75% of total sales. The domestic companies are largely involved in manufacturing low-end products for local and as well as international consumption. Lately, many multinational companies have established local presence by acquiring established domestic companies or starting a new business.

There are few key factors about operating in India that every serious player should be aware of. Today, India's political and economic climate is welcoming foreign direct investment with open hands, but this wasn't the case some time back. Even now, there continues to exist a strong lobby within the corridors of power that is against the notion of foreign control of domestic companies in the health care sector. There is a need for clarity on the limit of permitted foreign direct investment without government permission in medical device sector as the sector is often linked with the uber-sensitive pharmaceutical sector. The Indian consumer mindset and local business practices are unique, and must be carefully studied while developing a business model. Certain laws, such as the foreign exchange regulations and the tax statute must also be assessed in-depth because they affect the ability of the investor to invest and draw out returns, and determine the degree of profitability.

The regulatory framework in India applicable to medical devices is sadly inadequate. At present, only 14 types of medical devices are regulated. The rest are unregulated. Some players enjoy absence of regulation while others frown upon it. Various associations in the medical devices sector have lobbied hard for introduction of a comprehensive regulatory regime and the government has proposed a few changes. However, the proposals haven't yet seen the light of the day. Another peculiar feature of regulation in India is prohibition on advertisement or promotion of medical devices claiming diagnosis/cure/mitigation of certain notified diseases or ailments.

The Indian legal regime, on the other hand, is robust and promotes innovation and commerce. Being a signatory to the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), India todays boast of strong patent, trade mark and copyright protection within its territory. India has also introduced a competition law regime with a view to ensure fair playing field to all interested in India's domestic market.

The Indian Government has introduced various fiscal measures to promote research, development, manufacturing and import of medical devices. There is no import duty on certain medical equipment. Similarly, a number of lifesaving medical equipment are exempt from payment of excise duty. Interestingly, the rate of customs duty on finished imported medical devices is less than the rate of excise duty paid for manufacturing the same medical device domestically. Some attribute this factor to the large market currently held by imported medical devices. The Indian government has incentivized scientific research and development by providing weighted deduction.

1. Medical device industry: Realizing the "Make in India" opportunity, a report by FICCI

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Those involved in medical devices sector confront issues and concerns peculiar to the sector. Recently, the issue of physician owned distributorships has gained importance. Under some situations, dealing with a physician owned distributorships may amount to an act of corruption. Clinical trial remains a major grey area because of inadequate regulatory framework. The Government has recently clarified that medical devices with universal labeling (i.e. non-India specific labeling) will not be permitted to enter the territory of India from September of 2014.

Thus, at present, the Indian medical device market presents a challenging yet exciting opportunity to foreign and domestic players alike. It is hoped that this research paper will act as a guide to those interested to be a part of it.

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1. Introduction

The approximate USD 5.5 Billion worth Indian medical device sector is Asia's fourth largest market, and presents an exciting business landscape and opportunities for both multi-national and domestic players. Till the early 1990s, the medical device sector was significantly dominated by domestic players. But after India opened up its markets in 1991, tables have turned. The technological advancement and expertise that the global market leaders offered has proved to be an advantage. Today, India's medical device sector is dominated by multi-national companies, which is evident from the fact that about 75% of the sales are generated by imported medical devices. The domestic players, on the other hand, were quick to adapt the winds of change and started to focus on low cost devices. It will come as a surprise to many that the domestic players in India export more than 60 percent of their output as Indian markets are dominated by such imported medical devices. Over the years, many multi-nationals have set up operations in India. However, the nature of majority of the operations is to only distribute imported devices and provide support function. Few multi-nationals have started domestic production too. Some multi-nationals have also entered India by acquiring domestic manufacturers. For example, in 2008, Netherland-based Royal Philips Electronics, a leading manufacturer of general X-Ray and Alpha X-Ray Technologies, acquired Medtronics, a leading manufacturer of Cardiovascular X-Ray systems.

The sector is at present growing at around 15% Compound Annual Growth Rate (**"CAGR"**) for a plethora of reasons. A significant percentage of purchasers of medical devices are private medical institutions and hospitals. Due to increased competition in Tier I cities, private enterprises have started to focus on Tier II and Tier III cities, a market which is until now untapped in India. As private enterprises expand in lesser explored markets, the demand for medical devices will expand proportionally. Other reasons for strong growth prospects of the industry are:

- Economic growth leading to higher disposable incomes
- Increased Public Spending in Healthcare
- Increased Penetration of Health Insurance
- Improving Medical infrastructure
- Increasing affordability due to growing income
- Increasing number of ailments
- Increasing demand due to "Medical tourism"

The sector is also witnessing strong Foreign Direct Investments (**"FDI"**) inflows, which reflects the confidence of global players in the Indian market. As per official data, the medical and surgical equipment sector received a total of INR 5558 Crore (approx. USD 835 Million) between 2000 and 2015. In 2013 alone, the FDI inflow was almost INR 920 Crore (approx. USD 138 Million). In 2015, this number jumped to a new high of INR 1019 Crore (approx. USD 153 Million). [2]

The major players in Indian market are (in no particular order): Hindustan Syringes & Medical Devices, Opto Circuits (India), Wipro GE Healthcare, 3 M, India Medtronic, Johnson & Johnson, Becton Dickinson, Abbott Vascular, Bausch & Lomb, Baxter, Zimmer India, Edwards Life Sciences, St. Jude Medical, Stryker, Baxter, Boston Scientific, BPL Healthcare India, Sushrut Surgicals, Trivitron Diagnostics, Accurex Biomedical, Biopore Surgicals, Endomed Technologies, HD Medical Services (India), Eastern Medikit, Harsoria health care, Nidhi Meditech System, Philips Medical, Wipro Technologies, HCL Technologies and Texas Instruments.

Some of the major industry associations are: Association of Indian Medical Device Industry and Association of Diagnostics Manufacturers

2. http://dipp.nic.in/English/Publications/SIA_Newsletter/2016/jan2016/index.htm

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of India, All India Plastics Manufacturers' Association, Medical Disposables Manufacturers Association, Society of Biomaterials & Artificial Organs, National Biomedical Engineering Society and Medical Surgical and Healthcare Industry Trade Association. One peculiar feature of the Indian medical device sector is that it is largely unregulated. The Indian government has regulated only a few types of medical devices. All other types of medical devices are unregulated, meaning there is no government oversight on its manufacture, import, distribution and sale. The sparse regulation is attributable to a legislative void because of absence of a medical device specific legislation in India. The medical device lobby in India has proactively pushed for introduction of medical device specific legislation with an intention to bring uniformity in device standards and certainty of regulation.

The multi nationals looking to invest in the Indian medical device sector must strategize their entry on the basis of certain key factors which will influence profitability of the investment. These key factors are listed and discussed next.

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2. India Entry Strategies

Multinational medical device companies or investors seeking to do business with Indian medical device companies need to appraise and structure their activities on three pillars:

Strategy	Law	Tax
Observing the economic and political environment in India from the perspective of the investment	*Exchange Control Laws:* Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same	*Domestic Taxation Laws:* The Income Tax Act, 1961; indirect tax laws including laws relating to value added tax, service tax, customs, excise
Understanding the ability of the multinational company or an investor to carry out operations in India, the location of its customers, the quality and location of its workforce	*Corporate Laws:* Primarily the Companies Act, 1956, the Companies Act, 2013 and the regulations laid down by the Securities and Exchanges Board of India (**"SEBI"**)	*International Tax Treaties:* Treaties with favorable jurisdictions such as Mauritius, Cyprus, Singapore and the Netherlands
To strategize the business model by identifying the correct modality to do business in India	*Sector Specific Laws:* Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945, The Patents Act, 1970 and other legislations, regulations and guidelines that affect the medical devices industry	

To be aware of the legal framework is another must. Specifically, investors must keep an eye on the exchange control laws as they govern how profits made by the company can be realized out of India. Many a times, if the investment is structured through favorable tax jurisdictions, it may lead to significant tax-savings. Lastly, if a multi-national company is operating a wholly owned subsidiary in India, it must be make sure that the subsidiary is compliant with the regulatory framework and other product liability related laws to avoid any unpleasant legal proceedings.

Doing business in India is as big a challenge as it is an opportunity. The sensitive healthcare sector in India has long been conservative about foreign investment over concerns of foreign influence over health priorities of domestic manufacturers. However, in recent times, there is growing governmental and popular support for foreign investment in all sectors, including health. It is, therefore, significant to observe the political and economic environment of India. It is equally important to understand the business culture and consumer mindset prevalent in India. Companies that are quick to adapt to it turn out to be more profitable.

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3. Investment Climate in India

By and large FDI is now permitted in almost all the sectors in India without obtaining prior regulatory approvals (*i.e.* under the **"automatic route"**) barring some exceptional cases like defense, housing and real estate, print media, *etc.* (referred to as the **"negative list"**). If the FDI is not in accordance with the prescribed guidelines or if the activity falls under the negative list, prior approval has to be obtained from the Foreign Investment Promotion Board (**"FIPB"**) (**"approval route"**).

Foreign direct investment is permitted to the extent of 100% under the automatic route. For the limited purpose of FDI Policy, Medical device is defined as follows;

Medical device means;

i. any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of-

   a. diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

   b. diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap;

   c. investigation, replacement or modification or support of the anatomy or of a physiological process;

   d. supporting or sustaining life;

   e. disinfection of medical devices;

   f. control of conception,

   and which does not achieve its primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means;

ii. an accessory to such an instrument, apparatus, appliance, material or other article;

iii. a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body or animals.[3]

However the definition above would be subject to the amendment in Drugs and Cosmetics Act. for manufacturing of medical devices.

3. Department of Industrial Policy and Promotion, Ministry of Commerce and Industry,Government of India Consolidated FDI Policy, (Effective from May 12, 2015)

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4. India's Post-Trips Intellectual Property Environment

In March 2005, new patent laws were passed in India to comply with World Trade Organization (WTO) regulations and, specifically, the Trade Related Aspects of Intellectual Property Rights Agreement (**"TRIPS"**). Prior to the adoption of TRIPS, protection of intellectual property rights (**"IPRs"**) in India were of concern to global and medical device companies seeking to enter India. Post-TRIPS, India has well-established statutory, administrative, and judicial frameworks to safeguard IPRs. A patented invention (including products) is now given 20 years of protection in India. Well-known international trademarks such as Volvo and Whirlpool have been protected in India through judicial decisions even when they were not registered in India. Computer software companies have successfully curtailed piracy through court orders. Computer databases and software programs, which are widely used by the medical devices industry, have been protected under copyright. Computer programs having technical application to industry and computer programs in combination with hardware can be now be patented in India. Though trade secrets and know-how are not protected by any legislation, they are protected under the common law and through contractual obligations. The courts, on the ground of breach of confidentiality, accord protection to confidential information and trade secrets.

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5. Legal And Regulatory Regime

The medical devices industry in India is largely unregulated because of absence of a medical device specific legislation specifying standards of safety and quality for most of the medical devices. There are certain medical devices which have been regulated by creating a statutory fiction and deeming these medical devices as "drugs". By virtue of this fiction, these few medical devices get regulated by the Drugs and Cosmetics Act, 1940 (**"Act"**) and the rules framed thereunder viz. Drugs and Cosmetics Rules, 1945 (**"Rules"**). A list of these medical devices is described in **APPENDIX 1**. They are referred to as **"Notified Medical Devices"**. It has been clarified by the authorities vide notification that any device that does not appear in the said list of Notified Medical Devices, does not require any registration certificate or other approvals from the authority.

The Act and Rules seek to:

- Regulate the import, manufacture, distribution and sale of Notified Medical Devices.
- Ensure the availability of standard quality Notified Medical Devices to the consumer.

I. Authorities

The Central Government and the State Governments are responsible for the enforcement of the Act. The Central Drugs Standard Control Organization (CDSCO), headed by the DCGI is primarily responsible for coordinating the activities of the State Drugs Licensing Authorities, formulating policies, and ensuring uniform implementation of the Act throughout India. The DCGI is responsible for handling matters of product approval and standards, clinical trials, introduction of new medical devices, and import licenses for new Notified Medical Devices as indicated above.

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Organisation Chart
Central Drugs Standard Control Organisation

Drugs Controller General (I)
(Dr.G. N. Singh)

Head Quarter (New Delhi)	Zonal Offices (6)	Sub-Zonal Offices (5)	Port/Airport Offices (13)	Laboratories (6)
Head Quarter (New Delhi)	**Zonal Offices** North Zone:Ghaziabad South Zone: Chennai East Zone: Kolkata West Zone: Mumbai Hyderabad Zone Ahmedabad Zone	**Sub-Zonal Offices** Banglore Chandigarh Goa Jammu Indore	**Port Offices** Ahmedabad Chennai Port Chennai Airport Banglore Hyderabad Goa Kochi Delhi kolkata Kolkata Air Cargo Mumbai Air Cargo Mumbai, Navasheva Mumbai Custom House	**Laboratories** CDL, Kolkata CDTL, Mumbai CDTL, Chennai RDTL, Guwahati RDTL, Chandigarh CDL, Kasauli *IVRI, Izatnagar *NIB, Noida *IPC, Ghaziabad
Staff DDC(I) ADCIDI TDAs Supporting Staff	**Staff** DDC(I) ADCI DI TDAs Supporting Staff	**Staff** ADCI DI TDAs Supporting Staff	**Staff** ADCI DI TDAs Supporting Staff	**Staff** Director Dy. Director Sr. Scientific Officer I Sr. Scientific officer II Research Officer Sr.Scientist Assistant Jr. Scientist Assistant Supporting Staff

Abbreviations: CDSCO- Central Drugs Standard Control Organisation; CDL- Central Drug Laboratories; CDTIL- Central Drug Testing laboratories; RDTL- Regional Drug Testing laboratories; IVRI- Indian Veterinary Research Institute; NIB- National Institute of Biologicals; IPC- Indian Pharmacopoeia commission; DDC(I) - Deputy Drugs Controller (I); ADC(I)- Assitant Drugs Controller(I); DIs- Drugs Inspectors; TDAs- Technical Data Associates

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II. Licenses Required For Import, Sale, Manufacture and Loan of Medical Devices Under the Rules

The regulation of Notified Medical Devices is overseen by both, the central government and the state governments. Under the applicable regulatory framework, the functions of manufacture, import, distribution and sale of medical devices require licenses or permissions, as the case may be. In specific instances such as manufacture or import of new Notified Medical Devices (discussed later), both, a permission from the central drug licensing authority and a license from the state drug licensing authority is required. The required licenses and permissions are described more specifically in the table below.

The Rules have prescribed the standard format of the application forms for relevant licenses for the benefit of the applicants. It has also prescribed the standard form (template) of the licenses that may be issued for the benefit of the regulatory authorities and the applicants.

License for or Registration Certificate	Form (template) of the License	Application form	Relevant Rule	Licensing Authority	Timelines (from the date of application)
Certificate of registration of the foreign manufacturer and the medical devices to be imported (Registration Certificate)	Form 41	Form 40	Rule 24-A	Drugs Controller General of India (**"DCGI"**)	9 months
Import of Notified Medical Devices	Form 10	Form 8	Rule 21	DCGI	3 months once Registration Certificate I s granted
Import of Notified Medical Devices for examination, test or analysis	Form 11	Form 12	Rule 33	DCGI	No time period prescribed
Permission to import new Notified Medical Device for clinical trial or marketing	Form 45	Form 44	Rule 122-A	DCGI	No time period prescribed
Permission to conduct clinical trial using new Notified Medical Device	Form 45	Form 44	Rule 122-DA	DCGI	Six months
Permission to manufacture/import new Notified Medical Device after satisfactory clinical trials	Form 45	Form 44	Rule		No time period prescribed
Retail sale of Notified Medical Devices	Form 21	Form 19	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
Whole sale of Notified Medical Devices	Form 21-B	Form 19	Rule 61(2)	(Same)	No time period prescribed (usually between three to six months)

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License to manufacture Notified Medical Devices	Form 28	Form 27	Rule 76	For Notified certain specified Medical Devices[4] – the DCGI. For other Notified Medical Devices – the State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture a Notified Medical Device for the purpose of examination, test or analysis when no manufacturing license under Form 28 is available.	Form 29	Form 30	Rule 89	(Same as above)	No time period prescribed (usually between three to six months)
Loan License (manufacture in facility owned by third party)	Form 28-A	Form 27-A	76-A	(Same as above)	No time period prescribed (usually between three to six months)

III. Manufacturing a Notified Medical Device in India

A separate license is required for each manufacturing location and for each Notified Medical Device at such manufacturing location.

Under the Act, "manufacturing" includes any process (or part) for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. However, "manufacturing" does not include dispensing or packing at the retail sale level.

IV. Importing a Notified Medical Device into India

Importing a medical device into India requires satisfaction of few additional legal requirements

than those indicated above. The import of all products in India, including medical devices, is governed under the provisions of the Export and Import Policy. Before importing device into India, the importer is required to obtain Importer and Exporter Code (**"IEC"**) Number from the office of the Director General of Foreign Trade (**"DGFT"**). The IEC Number would be required to be mentioned in the documents filed with Customs for clearance of imported goods. For obtaining the IEC Number, an application

in the prescribed form has to be submitted to the office of the jurisdictional Joint Director of Foreign Trade, wherein details of Bank Account Number and Permanent Account Number have to be furnished

Under the Act, the activity of import of Notified Medical Devices into India requires an import license from the office of the Drugs Controller General of India. In order to get an import license, there is a mandatory requirement of registration of the medical devices sought to be imported, the name of the manufacturer and its manufacturing premises with the office of the DCGI.

The registration is certified by grant of a registration certificate. An application for grant of a registration certificate may be made by the foreign manufacturer itself if it has a valid wholesale license for sale or distribution of Notified Medical Devices under the Rules or its authorized agent in India, either having a valid license under the Rules to manufacture for sale of a Notified Medical Device or having a valid wholesale license for sale or distribution of Notified Medical Devices in India. Many a times,

4. Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannulae, Bone Cements, Heart Valves, Scalp Vein Set, Orthopedic Implants, Internal Prosthetic replacements.

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foreign manufacturers do not have an Indian subsidiary which has a wholesale license for sale or distribution of Notified Medical Devices. Hence, the manufacturers choose to appoint a third party as an authorized agent to make the application for grant of registration certificate. The authorization by a manufacturer to its agent in India must be documented by a power of attorney.

Other documentation related requirements for import:

- Free Sale Certificate in country of origin issued by the Ministry of Health/National Regulatory Authority is a pre-requisite; or
- Regulatory status of a medical device:
  - » In case of medical devices manufactured in USA, USFDA approval for manufacture and free sale
  - » As regards medical devices manufactured in Australia, Japan and Canada, approval for manufacture and free sale
  - » In case of medical devices manufactured in European Countries, CE certification along with approval for manufacture and Free Sale Certificate
  - » Other countries: approval for manufacture and free sale in the respective country of origin alongwith approval from any one of the following viz. USFDA/TGA Australia/Health Canada/ Ministry of Health, Labour and Welfare Japan or CE Certification is to be submitted.

V. Manufacture/Import of New Notified Medical Device

A "new" medical device is a medical device which falls into the Notified Medical Device category, but which does not have a predicate Notified Medical Device registered (for import) / approved (for manufacture) in India. A "predicate" Notified Medical Device is one which is registered / approved in India and has the same indications/ intended use, material of construction and design characteristics as the device which is proposed for registration in India. Notified Medical Devices for which predicate devices are not registered in India are classified as "new" medical devices. These medical devices are referred to the Medical Device Advisory Committees (MDAC) to comment on safety, effectiveness, essentiality and desirability of proposed New Devices before the new medical device may be registered/approved. The importer/manufacturer of such new medical device may be required to furnish clinical data to satisfy the MDAC. It is noteworthy that if the new medical device is not marketed in any of the following markets *viz.* USA, Europe, Japan, Canada or Australia, then the marketing permission of such a device would depend on results of the local clinical trials conducted in India.

VI. Clinical Trials

The applicable regulatory framework for clinical trials is drug-trial specific. There is no medical device specific regulatory framework for clinical trials in India. The DCGI, who regulates clinical trials, is aware of this fact and has therefore, allowed for some tweaking in the drug-specific clinical trial regulatory framework to suit medical devices. For example, the DCGI has exempt Phase I clinical trials of medical devices. A number of manufacturers of Notified Medial Devices are interested in carrying out post-marketing observational study of medical devices. The core difference between an observational study and a clinical trial is the degree of interference of the manufacturer in both the scientific studies. In observational studies, the manufacturer does not interfere in the use of the device by the subject but in a clinical trial, the manufacturer sets out the way (design) in which the device would be used. There is no requirement to obtain any permission for an observational study, but permission would be required to carry out a post-marketing clinical trial.

India witnessed significant increase in the conduct of clinical trials due to the advantages India was

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offering some time ago such as speedier clinical trials, large treatment population sharing diseases with the West, trained medical experts, insignificant language barrier and cost. However, the clinical trials are on decline for two years due to regulatory issues. The sector has witnessed intense media scrutiny in recent times owing to allegations made by some non-governmental organizations that the present regulatory framework provides inadequate protection to clinical trial subjects. The Supreme Court of India has issued certain guidelines to increase administrative oversight and to strengthen protection of interests of clinical trial subjects. However, the turn of events has led to over-scrutinization and administrative delays. In January 2013, India formalized compensation rules which obligate the sponsor or sponsors representative in India to pay for clinical trial related injury or death and for medical management of trial subjects.

VII. Product Standards

No Notified Medical Device can be imported, manufactured, stocked, sold or distributed unless it meets the quality and other standards defined in the Act and Rules. For instance, Schedule R-1 of the Rules has prescribed standards for the following– Sterile Disposable Hypodermic Syringes, Sterile Disposable Hypodermic Needles and Sterile Disposable Perfusion Sets. Similarly, Schedule M-III of the Rules lays down a 'Quality Management System' (**"QMS"**) that is to be followed during the manufacture of medical devices and in-vitro diagnostics.

It is noteworthy that the Central Government has the power to prohibit the import, manufacture or sale of any Notified Medical Device. The Central Government considers banning those medical devices which are removed from the markets of two or more countries where they were being marketed.

VIII. Labeling

Before a Notified Medical Device is sold or distributed in India, it must be labeled according to specifications outlined in the Rules as well as The Legal Metrology (Packaged Commodities) Rules, 2011.

In relation to Notified Medical Devices, the Rules prescribes the contents of the label such as name of the medical device, the details necessary for the user to identify the device, statement as to the net contents (in terms of weight or measure), license number, dates of manufacture, expiry, applicable storing and handling conditions, warnings and precautions, the name and address of the manufacturer and the address of the premises where the Notified Medical Device has been manufactured, the batch number, as well as the manufacturing license number under which it is manufactured (if manufactured in India or elsewhere). Imported products must display the expiration date in addition to the import license number. Medical devices that are manufactured for export to other countries are exempted from certain labeling requirements and are instead required to adopt the requirements of the law to which the device is being exported.

The Legal Metrology (Packaged Commodities) Rules, 2011, which are applicable to all medical devices, have identical requirements. One important additional requirement prescribed by the said rules is to publish the name, address, telephone number, e-mail of the person or office to contact in case of consumer complaints.

All labels may be printed in English.

IX. Good Manufacturing Practices (GMP)

Schedule M -III of the Rules prescribes a QMS for manufacture of Notified Medical Devices and in-vitro diagnostics in India. Every company manufacturing Notified Medical Devices in India has to comply with the QMS provisions of Schedule M-III as a condition of its manufacturing license, else it may lead to cancellation or suspension of the manufacturing license.

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X. Penalties

The Ministry of Health and Family Welfare, Government of India (**"Ministry"**) in the year 2009 notified an amendment to the Act that attempts to strengthen the existing law against the menace of spurious and counterfeit medical devices in India.

This amendment has changed certain provisions of the Act that specifically relate to the offences of manufacture and trade of spurious Notified Medical Devices.

The penalties under the Act were found to be inadequate to act as a deterrent for persons involved in offences. The penalties have been significantly enhanced through the amendment for manufacture, sale, distribution, stocking or exhibiting or offering for sale or distribution of spurious or counterfeit Notified Medical Devices to INR 1,000,000 (appx. USD 16,667) or 3 times the value of the notified medical device confiscated, whichever is higher and imprisonment of not less than 10 years which may extend up to life, for spurious or counterfeit notified medical device leading to death or grievous hurt. The entire amount of fine that is realized from the person convicted for the offence is now paid by way of compensation, to the person who is the victim of spurious or counterfeit Notified Medical Devices. If the victim has died due the effect of the spurious or counterfeit Notified Medical Devices, the relative of the victim is entitled to receive the same amount by way of compensation.

In case the spurious or counterfeit notified medical device does not lead to death or grievous hurt, then the penalty is a fine of up to INR 300,000 (appx. USD 5000) or 3 times the value of the notified medical device confiscated, whichever is higher and imprisonment of not less than 7 years which may extend up to life.

The Ministry also has set up a "whistle blower" policy that aims to reward citizens, who provide information on the trade and source of spurious Notified Medical Devices.

XI. Export – Import Restrictions

Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992 along with the Customs Act, 1962 and the Export-Import Policy (EXIM Policy), issued by the Ministry of Commerce and Industry of the Government of India. The current EXIM policy also known as New Foreign Trade Policy covers the period 2009 – 2014. The purpose of the EXIM policy is to develop export potential, improve export performance, encourage foreign trade and create a favorable balance of payments positions.

XII. Advertising and Sales Promotion

Advertising medical devices is strictly regulated. The Rules prohibits labeling of Notified Medical Devices in a manner that may convey to the intending user that the enclosed device may be used for prevention or cure of certain ailments and diseases specified in Schedule J of the Rules. Some examples of such diseases and ailments are: Blindness, Bronchial Asthma, Cataract, Growth of New Hair, Deafness, Genetic Disorders, Improvement in vision, Myocardial Infarction *etc.*

Please note that while the restriction on labeling applies only to Notified Medical Devices, some of the restriction on advertisement is general in nature and are applicable to all medical devices. These are dealt in detail under the sub-heading of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1944.

XIII. Drugs And Magic Remedies (Objectionable Advertisement) Act, 1954

This legislation earlier applied only to drugs, but its application has been extended to medical devices by the Indian Courts. The Act prohibits advertise-

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ments about diagnosis, cure, mitigation or prevention of 54 diseases and listed disorders such as cancer, diabetes, epilepsy, leucoderma, paralysis, sexual impotence etc. The billboards in Delhi, the local train railway compartments in Bombay, advertisement pages of newspapers and glossy, and now the electronic media, are, however, in constant breach of the Act.[5]

XIV. The Competition Act, 2002

The growth of medical devices industry, though protected under several IP laws, raises competition law issues (anti-trust). The need to provide protection to medical device companies for their innovation is well recognized under the Competition Act, 2002 (**"Competition Act"**) however the same is restricted by providing specific inclusions under Section 3(5) of the Competition Act. Horizontal agreements in the medical devices sector would involve agreements entered at same level between medical device manufacturers to restrict supply/fix prices whereas vertical agreements are entered between players at different levels in the supply chain being manufacturers and hospitals in the form of tie-in arrangements.

Cartels by industry associations have been widespread across jurisdictions to set standard prices for both stockists and retailers but the same has often led to restricting prices. Although the provisions of the Act recognize protection granted under IP legislations, yet associations formed to exchange data and information serving purposes other than protection of the right holders could invite possible competition law violations.

Mergers and Takeovers in the medical devices sector have also grown considerably in the past few years. The Competition Act prescribes the thresholds under which combinations shall be examined and states that any combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India shall be void.

5. http://www.nihfw.org/ndc-nihfw/html/Legislations/TheDrugsAndMagicRemedies.htm (as visited on May 8, 2009).

XV. Patent Protection

The patent regime in India is governed by the Patents Act of 1970 (**"Patents Act"**) and is supported by the Patents Rule, 2003, (**"Patents Rules"**). The Indian Patents Act provides for patenting of both, products and well as processes for a span of 20 years.

A. Patentability of medical devices

The term *Invention* is defined under the Patents Act as "a new product or process involving an inventive step[6] and capable of industrial application.[7]" The Patents Act carves out an exception for medical, surgical, curative, etc., processes or other treatments for humans and animals and does not regard them as "inventions", thereby rendering these processes and treatments incapable of being patented. However, the carve out does not extend to medical devices. Thus, invention of a medical device (or process) is granted patent in India.

The patent rights with respect to any invention are created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Patent Rules. India follows a declarative system with respect to patent rights. Patents are granted on a "first to file" basis. The patent application can be made by either (i) the inventor or (ii) the assignee [8] or (iii) legal representatives [9] of the inventor.

B. Convention Application

India, a member of the Paris Convention, has published a list of convention countries under Section 133 of the

6. *Section 2(1) (ja) of the Patents Act: "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

7. *Section 2(1)(ac) of the Patents Act: "capable of industrial application in relation to an invention means that the invention is capable of being made or used in an industry."*

8. *Section 2(1) (ab) of the Patents Act: "Assignee includes an assignee of the assignee and the legal representative of the deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person".*

9. *Section 2(1) (k) of the Patents Act: "Legal representative means a person who in law represents the estate of a deceased person."*

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Patents Act. The convention application has to be filed within one year from the date of priority and has to specify the date on which and the convention country in which the application for protection (first application) was made. A priority document must be filed with the application. Since India is a member of the Patent Co-operation Treaty, a National Phase Application can also be filed in India, within 31 months from the priority date.
Some of the salient features are as follows:

- The term of the patent is 20 years from the date of priority;
- In infringement suits in relation to 'process' patents, the 'burden of proof' is reversed.

C. Infringement

If a patented invention is made, constructed, used sold or imported 'solely' for uses reasonably related to the development and submission of information required under any law (Indian or foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the 'Bolar provision, allows manufacturers to begin the research and development process in a timely manner in order to ensure that affordable equivalent generic medicines can be brought to market immediately upon the expiry of the product patent.

D. Parallel Imports

Import of patented products in India from a person authorized by the patentee to sell or distribute the product does not amount to an infringement.

E. Enforcement

India has historically been viewed by the global community as a 'poor patent enforcement' territory. Two provisions have been introduced that are likely to improve the patent enforcement mechanism. The first provision, compliant with Article 34 of TRIPS, is Section 104A, which is a "reversal of burden of proof" provision applicable to process patents. Section 104A is an exception to the normal rule which requires that a patent holder who alleges infringement should provide proof to any claims or allegations made. As per Section 104A, in any 'process patent' infringement suits, the defendant will have to prove that he has used a process different than the 'patented process' in order to arrive at an identical product produced by a 'patented process'. Second, an amendment to Section 108 of the Act will enable the court to order seizure, forfeiture or destruction of infringing goods and also materials and implements, used for creation of infringing goods.

F. Rights prior to the Grant

From the date of publication of the application until the date of the grant of a patent, the applicant has the like privileges and rights as if a patent for the invention has been granted on the date of publication of the application. However, applicant is not entitled to institute any proceedings for infringement until the patent has been granted.

G. Secrecy Provisions [10]

Any person resident in India is not allowed to apply for grant of patent for any invention unless either of the following two conditions is satisfied:

- Obtaining written permission of the Controller of Patents. The Controller is required to obtain consent of the Central Government before granting such permission for invention relevant for defense purpose / atomic energy. The application is to be disposed of within 3 months. OR
- Patent application for the same invention has been first filed in India at least six weeks before the application outside India and there is no direction passed under Section 35 for prohibiting /restricting publication/ communication of information relating to invention.

This section is not applicable to an invention for which an application for protection has first been filed in a

10. Sections 35 to 43 of the Patents Act; Can you keep a secret? <eco-times/2005/Can-you-keep-a-secret-Feb-14-2005.htm>, February 13, 2005

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country outside India by a person resident outside India. However, this provision will apply if the first filing is intended to be made in US, since US applications are required to be filed by the inventors and not assignees of the inventors.

XVI. Data Exclusivity

When the Indian Government began the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, multinational companies approached the Government with a recommendation to introduce a data exclusivity provision consistent with Article 39.3 of TRIPS. However, the Government had refused to accede to such a request.

Satwant Reddy committee that was formed to study and recommend on Data Exclusivity submitted its report in 2008. Recent reports suggest that the Government has accepted the recommendations on data exclusivity and may offer 'protection against disclosure' to the pharma/ medical device companies. However, the Government may take some more time to announce its decision on 'Protection against unfair commercial use' as the Union ministry of health and the Department Of Pharmaceuticals wants further discussions with stakeholders.

XVII. Trademarks

In India, trademarks are protected both under statutory and common law. The Trade and Merchandise Marks Act, 1940 was India's first legislation with respect to trademarks and was later replaced by the Trade and Merchandise Marks Act, 1958 (TM Act, 1958). The TM Act was further updated in 1999 to comply with TRIPS and is now known as The Trade Marks Act, 1999 (**"TM Act 1999"**). The TM Act 1999 allows for the registration of service marks and three-dimensional marks. India follows the Nice Classification of goods and services, which is incorporated in the Schedule to the Rules under the TM Act, 1999. Medical devices are covered under Class-10.

Class 44 covers the services for Medical services, veterinary services and cosmetics; and Class 42 covers Scientific and technological services and research and design relating thereto [11]

Class 44: Medical services; veterinary services; hygienic and beauty care for human beings or animals; agriculture, horticulture and forestry services

Class 42: Scientific and technological services and research and design relating thereto; industrial analysis and research services; design and development of computer hardware and software.

The TM Act 1999 provides a procedure to search trademarks. It is a prudent practice that often prevents potential litigation or opposition to conduct the search for conflicting trademarks (whether registered or pending) before using or applying for any trademark.

Any registered trademark must fulfill certain conditions. The TM Act 1999 has set forth absolute and relative grounds of refusal of trademark registration. These grounds are akin to the provisions of the UK Trade Mark Act of 1994. The trademark can be registered even if the mark is proposed to be used in India i.e. even if prior to the date of application no goods have been sold under the applied trademark. The term of registration and renewal is 10 years. Foreign companies can license trademarks in India under the appropriate license / Registered User Agreement.

The concept of "well-known trademark" has been recognized under the TM Act 1999. A well-known trademark prohibits registration of a mark which is merely a reproduction or imitation of a well-known mark - even if used in connection with different goods or services.

A trademark can be used without registration and can be protected under common law but not under the statutory law. Recently Indian courts have held that copying international names (even if the product is not made in India) is not permissible. Several international companies are engaged in trademark litigation in India, including IBM, Apple, Microsoft, Dunhill, Whirlpool, Sony and Cartier.

11. http://support.dialog.com/techdocs/international_class_codes_tmarks.pdf

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XVIII. Proposed Legislations to Regulate Medical Device Sector

There have been numerous proposals to introduce a comprehensive regulatory regime that would be applicable all medical devices. A comprehensive regulatory regime will be welcomed by the serious players as well as the consumers as it brings regulatory certainty. Below, we have drawn a comparison between two proposals which were circulated to the public for comments but could not be made into law. The Medical Devices Regulation Bill, 2006 was the first proposal that intended to overhaul the regulatory framework for medical devices in India. It proposed to adopt a broad and modern definition of medical devices and set up a separate regulatory authority to oversee regulatory affairs of the medical device industry. The proposal was, unfortunately, shelved. In 2013, another proposal in the form of a Bill of Drugs and Cosmetics (Amendment) Act, 2013 was made. This proposal was less ambitious as it did not propose setting up a separate regulatory authority, but was step in the right direction as it adopted the wide and modern definition proposed earlier, but with notable additions such as medical device software.[12]

Although this bill is still pending before the Parliament, the CDSCO has already released the draft Drugs and Cosmetics (Amendment) Bill, 2015 for public comment. By studying the table, one can get a flavor of the future regulatory regime. Industry associations in India have been lobbying hard for a new regulatory regime, and with a new government in place, introduction of such a regime seems more likely than ever before.

12. '**Medical device**' means any instrument, apparatus, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

i. intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

And

ii. which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

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Sr. No.	Medical Devices Regulation Bill, 2006	Drugs and Cosmetics (Amendment) Act, 2013
1.	Proposal to establish a separate regulatory authority called Medical Devices Regulatory Authority	Proposal to establish a new authority called Central Drug Authority that will regulate Medical Devices in addition to Drugs Cosmetics. This is very similar to the present regulatory regime.
2.	Definition of manufacture broad	Definition of manufacture broad, but does not include customization for individual patients
3.	Definition does not expressly include software	Definition includes software
4.	No industry representation on the advisory board of the regulatory authority. Industry representation in 'technical committees' which provides recommendations for setting standards and guidelines. Recommendations of the technical committees are not binding.	Industry representation on the board of the regulatory authority. Recommendations of the advisory board are binding on the regulatory authority.
5.	No power to regulatory authority to ban medical device in public interest	Power to Central Government to ban medical device in public interest
6.	Proposed risk-based classification of medical devices. Low risk devices to be marketed with self-certification. High risk devices to be marketed after obtaining conformity assessment	No risk-based classification proposed
7.	Proposed registration of both domestic and foreign medical device manufacturers, including products manufactured or imported.	No new registration requirement. Under existing law, foreign manufacturers and imported products are required to be registered with regulatory authority.
8.	Recognition to use of refurbished medical device	No such express recognition. The draft amendment, however, proposes to add refurbishing within the ambit of 'manufacture'
9.	Proposal for establishment of Appellate Tribunal comprising of experts to hear appeals from the decisions of the regulatory authority	No separate appellate tribunal. Under existing regime, all appeals are heard by the Minister/Secretary of the Central Government/ State Government. The Minister/Secretary is most often not an expert on the subject.

Between the Medical Devices Regulation Bill, 2006 and Drugs and Cosmetics (Amendment) Act, 2013, the former has a significantly greater potential of bringing the much needed regulatory overhaul. Therefore, we have discussed the Bill in some detail below:

- **Establishment of Medical Device Regulatory Authority Of India (MDRA):** The Bill proposes to create a separate regulatory authority called the Medical Device Regulatory Authority of India which will be responsible for overlooking the creation, implementation and enforcement of various standards, guidelines and rules.

- **Classification of medical devices:** As there are a variety of medical devices, the Bill recognized classification of medical devices is a pre-requi site so as to ensure that the level of regulation can be proportional to the level of risk associated with them. In this respect, 4 risk classes have been provided ranging from lowest to highest risk levels.

- **Medical device standards:** The Bill places responsibility on MDRA to specify standards that form the basis for the conformity assessment of the medical devices. The MRDA may select standards notified by the Bureau of Indian Standards or other international standards making bodies ISO, etc. or other standards in the Indian Pharmacopoeia and other international Pharmacopoeia monographs based on their suitability and on the recommendations of the Advisory Committee or Technical panel.

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- **Conformity assessment and placing on the market:** The Bill proposes that no medical device can be placed on the market without conformity assessment. For the medical devices classified in the lowest risk category, the conformity assessment can be done by the manufacturer through self-certification. However, for other categories, the conformity assessment will have to be done by MDRA or agencies appointed by it.

- **Import of medical devices:** The Bill proposes that any medical device imported into India will also have to meet the requirements of the essential principles of safety and performance as stipulated by MDRA. The conformity assessment will be the responsibility of the foreign manufacturer or his representative.

- **Refurbished and date expired medical devices:** The Bill proposes to govern use of refurbished and date expired medical devices. It envisages that MDRA will make and publish regulations governing the condition of use of refurbished and date expired medical devices whether imported or otherwise, to ensure that the safety of the patient and or user and other persons is not compromised.

- **Vigilance by MDRA:** The Bill proposes that MDRA will prescribe the procedures and methods to obtain information from the manufacturer/ hospitals, healthcare delivery professionals and users on any adverse events/incidents related to the use of medical devices and take appropriate precautionary/preventive measures to minimize the risks and hazards associated with its use.

- **Enforcement:** The Bill envisages that MDRA will have the primarily responsibility for the enforcement of the rules and will monitor, verify and ensure that medical device manufacturers fulfill the relevant requirements, at all stages of medical device business.

- **Medical Device Safety Appellate Tribunal:** The Bill proposes establishment of an exclusive appellate forum called Medical Device Safety Appellate Tribunal to hear appeals from the orders of the MDRI. The constitution of the appellate tribunal will be decided by the Central Government, but it will certain have High Court Judges on it.

- **Offences and penalties:** The Bill also provides for offences and penalties that may be applicable to cases where medical devices have not conformed to the Bill, misbranding of a medical device, tampering of the medical device, providing false information, or interfering with seized items, obstructing an MRDA officer, failure to comply with the directions of the MRDA, etc. The maximum imprisonment is one year and the maximum penalty is INR 5 lakh (approximately USD 8300).

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6. Taxation Regime

I. Direct Taxes

A. General overview

Taxation of income in India is governed by the provisions of the Income Tax Act, 1961 (**"ITA"**) as amended annually by the Finance Acts. Under the ITA, residents are subject to tax in India on their worldwide income, whereas non-residents are taxed only on Indian source income i.e. income that accrues or arises in India, is deemed to accrue or arise in India or which is received or is deemed to be received in India. Section 9 of the ITA deems certain income of non-residents to be Indian source income. Under section 9(1), "capital gains" are considered to have their source in India and are taxable in India if they arise directly or indirectly, through the transfer of a capital asset situated in India. Similarly, the "business income" of a non-resident is taxable in India only if it accrues or arises, directly or indirectly, through or from any business connection in India.

The Indian tax rates applicable to non-residents could be up to 40% (all tax rates provided herein are exclusive of surcharge and cess discussed below) on taxable business income and capital gains.

Section 90(2) of the ITA is a beneficial provision which states that, where the taxpayer is situated in a country with which India has a double tax avoidance agreement (**"Indian Tax Treaty"**), the provisions of the ITA apply only to the extent that they are more beneficial to the taxpayer. Rules under Indian Tax Treaties are generally more beneficial to the taxpayer than those under domestic law (ITA) and hence it is typically advantageous for a non-resident taxpayer to structure his investments or business through a jurisdiction which has signed an Indian Tax Treaty.

In recent times, the Indian income tax authorities have been adopting an aggressive approach to transactions where any form of exemption from taxation is sought by the taxpayer. Their approach is even more hostile when the transaction in question has an offshore element to it. Hence, it is has become critical to ensure that offshore transactions are structured in a manner such that legitimate tax exemptions are not challenged by the tax department.

Before delving into specific tax issues concerning contract research and manufacturing, set out below is a snap shot of the taxation regime in India. All tax rates mentioned herein are exclusive of surcharge on tax (for companies with total income exceeding INR 10 million but less than 100 million) which is presently at 7% for domestic companies and 2% for foreign companies and an education cess on tax which is presently at 2%.

i. Taxes Applicable to companies

Under the ITA, the corporate income tax rate is 30% for an Indian company and 40% for a foreign company (where such income is taxable in India).

Further, dividend paid by Indian companies is exempt from income tax in the hands of all shareholders, irrespective of their residential status. However, the company distributing the dividends is required to pay a dividend distribution tax of 15%.

ii. Minimum Alternate Tax

Prior to the introduction of the Finance Bill 2016, If the tax payable by any company, including a foreign company taxable in India, was less than 18.5% of its book profits, it was required to payMinimum Alternate Tax under the ITA which was deemed to be 18.5% of such book profits.

However, the Finance Bill, 2016 (**"Bill"**), has amended the position of law to state that Minimum Alternative Tax shall not be applicable to a foreign company if the company does not have a permanent establishment under the relevant DTAA or a place of business in India. The Bill proposes to amend the law with retrospective effect from 01.04.2001.

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Under the Minimum Alternative Tax regime, the carry over and set-off is allowed only up to ten assessment years immediately succeeding the assessment year in which such tax credit becomes allowable and is governed by the following basic principles:

i. The amount of tax credit that is allowed shall be the difference of the Minimum Alternate Tax paid and the amount of tax payable by the taxpayer on his total income as per the other provisions of the ITA.

ii. Set off in a future assessment year in respect of brought forward tax credit is allowed only to the extent of the difference between the tax payable by the taxpayer on his total income and the tax that would have been payable under the Minimum Alternate Tax provisions.

iii. Interest

Interest received by a non-resident from Indian on foreign currency denominated loans is generally taxable at the rate of 20% as per the provisions of the ITA (though it may be reduced to 10/15% under some of the Indian Tax Treaties) and is required to be withheld at source by the resident payer. Further, interest is a tax-deductible expense for the Indian payer company, provided the applicable tax has been withheld before making the payments to the non-resident.

iv. Royalties / fees for technical services

Payments towards royalty and Fees for Technical Services (FTS) currently attract a withholding tax at the rate of 25% as per the provisions of the ITA on gross as proposed in budget 2013. However, subsequent by Finance Act, 2015 has reduced the rate to rate of withholding tax to 10%. Further, where royalties or FTS is paid to a foreign company and is effectively connected to a PE of the foreign company in India, then such payments would be taxed as business profits on "net income" basis.

v. Capital Gains

Under the ITA, capital gains earned upon the transfer of capital assets are classified into short-term capital gains and long-term capital gains depending on the period of holding. Shares of a company, securities listed on a recognized Indian stock exchange if held for more than 12 months are treated as long-term capital assets and if held for 12 months or less are treated as short-term capital gains. These gains are taxed as follows:

- Long-term capital gains arising on transfer of listed equity shares (including units of an equity oriented mutual fund) on a recognized stock exchange in India will be exempt from tax in India.
- Short-term capital gains arising on transfer of listed equity shares (including units of an equity oriented mutual fund) on a recognized stock exchange in India will be taxed at the rate of 15%.
- Capital gains realised on sale of listed equity shares not executed on a recognised stock exchange in India would be taxed at the rate of 10% for long-term gains and as normal income in case of short-term gains.
- Capital gains realised on sale of unlisted Indian securities would be taxed at the rate of 10% for long-term gains and as normal income in case of short-term gains.

The exemption on long term capital gains and reduction of rate for short term capital gains on the sale/transfer of the equity shares on a recognised stock exchange in India is only allowed where the applicable Securities Transaction Tax has been paid on the transaction.

B. Incentives Under the ITA

The Government of India has taken various policy initiatives in order to strengthen scientific research and development in the various sectors, including the pharmaceutical sector. The term "scientific research"

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has been defined in the ITA to include activities for the extension of knowledge in the fields of natural or applied science. Scientific research can be carried out either in-house or by contributing to outside agencies engaged in scientific research.

Typically, in the pharmaceutical industry, fiscal incentives are awarded to research and development units towards the development of new drug molecules, clinical research, new drug delivery systems, new research and development set ups and infrastructure provision.

i. In-House Research and Development

Companies engaged in the business of biotechnology or in the business of manufacture or production of any drugs, pharmaceuticals, chemicals, etc. and who have incurred any expenditure on scientific research (not being expenditure in the nature of cost of any land or building) on in-house research and development facility as approved by the Department of Scientific and Industrial Research, are allowed a deduction of 200 percent of such expenditure. Expenditure on scientific research includes expenditure incurred on clinical drug trial, obtaining approval from any regulatory authority under any Central, State or Provincial Act and filing an application for a patent under the Patents Act, 1970. However, the Finance Bill 2016 proposes to restrict the rate of deduction to 150 percent with effect from 01.04.2017 to 31.03.2020. Further, the deduction shall be restricted to 100 percent from 01.04.2020 onwards.

It should be borne in mind here that no company would be entitled to the aforementioned deduction unless it enters into an agreement with the Department of Scientific and Industrial Research for co-operation in such research and development facility and for audit of the accounts maintained for that research and development facility.

Currently, this deduction is available for expenses incurred prior to March 31, 2017.

ii. Contributions made to other Institutions for Scientific Research

The ITA provides for a deduction of 200 percent of sums paid to any scientific research association (having as its object the undertaking of scientific research), or to any university, college or other institution, for the purpose of scientific research approved by the concerned authority. Similar to the position in respect of an in-house research and development, the Finance Bill 2016 proposes to restrict the rate of deduction to 150 percent with effect from 01.04.2017 to 31.03.2020. Further, the deduction shall be restricted to 100 percent from 01.04.2020 onwards.

iii. Capital Expenditure

Under Section 35(1)(iv) read with Section 35(2) of the ITA, the whole of any expenditure on scientific research (other than expenditure on acquisition of any land) being capital in nature, incurred after 31 March 1967 is allowed as a deduction. Further, under Explanation 1 to Section 35(2) of the ITA, the aggregate capital expenditure on scientific research incurred three years immediately prior to the commencement of business is allowed as a deduction in the year in which the business is commenced.

iv. Incentive Provided to Venture Capital Funds Investing in the Pharmaceutical Sector

In order to provide an impetus to venture capital investment in the pharmaceutical sector, the ITA has granted certain tax benefits to venture capital funds registered with the Securities and Exchange Board of India that invest into certain pharmaceutical businesses. Under section 10(23FB) of the ITA, income of a venture capital fund which arises as a result of investments

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into companies engaged in, inter alia, "bio-technology" and "research and development of new chemical entities in the pharmaceuticals sector", is exempt from tax and such income is taxable only in the hands of the investors of the venture capital fund at the time of distribution of the income.

C. Potential Permanent Establishment Issues in Contract Research and Manufacturing

Where a foreign enterprise proposes to outsource research and manufacturing functions to an Indian CRO / CMO, the outsourcing arrangement would have to be carefully structured in order to mitigate the risk of the Indian CRO / CMO being regarded as the Permanent Establishment of the foreign enterprise. The risk is significantly greater where significant manufacturing functions are outsourced by the foreign enterprise to an Indian CMO. The issue of creation of an Indian Permanent Establishment of the foreign enterprise is a significant one given that, if such Permanent Establishment is created, the business income (attributable to the Permanent Establishment) of the foreign enterprise, which may otherwise not be taxed in India, would be subjected to taxation at the rate of 40%.

Under the ITA, business income of a non-resident is taxable in India (at the rate of 40%) if it accrues or arises, directly or indirectly, through or from any 'business connection' in India. Similarly, under the Indian Tax Treaties, typically, the business income of a non-resident is taxable only to the extent that it is attributable to a Permanent Establishment (**"PE"**) of such non-resident in India. The concept of PE under typical Indian Tax Treaties is expressed as an exhaustive list of factors, as opposed to the "business connection" rule contained in the ITA, which has no exhaustive definition in the ITA and which has been afforded a wide interpretation by Indian courts in the past. Therefore, there may be situations where a non-resident is considered to have a business connection in India, but no PE. As mentioned earlier, since it is open for the non-resident taxpayer to choose to be treated under the more beneficial regime, a non-resident may rely on the PE rule under the applicable Indian Tax Treaty rather than the business connection rule in the ITA.

The term PE has been succinctly defined by the Andhra Pradesh High Court in the case of CIT v. Visakhapatnam Port Trust[13], as follows:

"In our opinion, the words permanent establishment postulate the existence of a substantial element of an enduring or permanent nature of a foreign enterprise in another country which can be attributed to a fixed place of business in that country. It should be of such a nature that it would amount to a virtual projection of the foreign enterprise of one country into the soil of another country."

The Indian Tax Treaties typically lay down certain criteria to determine whether a foreign enterprise earning business income from India would be construed to have a PE in India. Some of these tests are discussed below, especially in the context of contract research and manufacturing.

i. Fixed Place of Business PE

A foreign enterprise is deemed to have a PE in India if the business of foreign enterprise is, wholly or partly, carried on through a fixed place of business in India.

The principle of fixed place of business PE is particularly relevant in the context of contract research and manufacturing. As demonstrated below, unless such arrangements are structured carefully, there may be circumstances which may lead to the inference that the business of the foreign enterprise, which outsources the research and manufacturing functions to an Indian CRO / CMO, is being carried on through a fixed place of business in India.

In a typical contract research and manufacturing model, it is common for the foreign enterprise to frequently send personnel to the offices of the Indian CRO / CMO to provide training services. Often, the foreign enterprise also sends it personnel to the offices

13. 1983 144 ITR 146 AP

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of the Indian CRO / CMO to supervise and inspect the activities carried on by the Indian CRO / CMO, in order to ensure that such activities adhere to the prescribed standards. In both these instances, if these personnel, being employees of the foreign enterprise, have some premises (often even a desk or an office is regarded as premises) allotted to them for a reasonably long period of time within the Indian CRO / CMO, such premises, though not owned or rented by the foreign enterprise, is likely to be considered to be a "fixed place of the foreign enterprise". In such a scenario, it may be claimed the Indian tax authorities that the foreign enterprise is carrying on its business through a fixed place and hence a PE of the foreign entity exists in India. Therefore, in any arrangement to outsource research and manufacturing to an Indian CRO / CMO, it is critical to ensure that the outsourcing arrangement is structured in manner that mitigates the risk of the foreign entity having a PE in India.

ii. Service PE

Further, under some Indian Tax Treaties, a foreign enterprise may be considered to have a PE in India due to the presence of its personnel in India, who render services beyond a specified time period or to a related enterprise. For instance, under the India-US tax treaty, a PE is said to be constituted where there is:

"(l) the furnishing of services, other than included services as defined in article 12 (royalties and fees for included services), within a Contracting State by an enterprise through employees or other personnel, but only if:

i. activities of that nature continue within that State for a period or periods aggregating to more than 90 days within any twelve-month period; or

ii. the services are performed within that State for a related enterprise (within the meaning of paragraph 1 of article 9 (associated enterprises)." In the example discussed earlier, if the training and inspection personnel sent by the foreign enterprise to the offices of the Indian CRO / CMO are deemed to be "furnishing services" beyond the prescribed limit of 90 days, it is likely that the tax authorities may argue that the presence of such personnel constitutes a PE of the foreign enterprise in India.

iii. Agency PE

Indian Tax Treaties typically contain a provision whereby an Indian entity may be treated as a PE of a foreign enterprise if the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise. Moreover, some Indian Tax Treaties, such as the India-US tax treaty, also contain an additional provision whereby an Indian entity may be regarded as a PE of the foreign enterprise, if the Indian entity maintains a stock of goods from which it regularly delivers such goods on behalf of the foreign enterprise and contributes to the sale of such goods. An agent of independent nature is considered as an exception to the Agency PE rule.

In the context of contract manufacturing, it may be contemplated in the arrangement that the Indian CMO would maintain and deliver the final pharmaceutical product on behalf of the foreign enterprise. In such cases, if the contract is not structured cautiously, the Indian CMO may be regarded as a PE of the foreign enterprise under the Agency PE clause in the applicable Indian Tax Treaty. The Indian CRO / CMO may also run the risk of being regarded as the PE of the foreign enterprise where the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise.

Although such rights are not ordinarily granted by the foreign enterprise to the Indian CRO / CMO, care should be taken to ensure that the Indian CRO / CMO does not have the right to even represent the foreign entity in any negotiations since, in the past, the exercise of such right has been held to constitute a PE of the foreign entity in India.

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In cases of outsourcing by a foreign enterprise to its Indian subsidiary, a question arises as to whether there is added PE risk for the foreign enterprise as a result of the parent subsidiary relationship of the two entities. The answer to this lies in the Indian Tax Treaties itself. The principle which is embodied in typical Indian Tax Treaties is that the existence of a subsidiary company does not, by itself, constitute that subsidiary company a PE of its parent company. This follows from the principle that, for the purpose of taxation, such a subsidiary company constitutes an independent legal entity. Thus, where a foreign enterprise outsources its research and manufacturing functions to an Indian CRO / CMO, the fact that the Indian CRO / CMO is the subsidiary of the foreign enterprise, should not, by itself, constitute that Indian CRO / CMO to be a PE of the foreign enterprise.

As is clear from the discussion above, the issue as to whether any activity of a foreign entity in India results in a PE of that foreign entity in India depends on the facts and circumstances of each case. In the context of contract research and manufacturing, the answer lies in the manner in which the outsourcing arrangement is structured and the activity of the Indian CRO / CMO is managed and operated.

D. Issue of taxation as an Association of Persons

Depending on the manner in which it is structured, a contract research and manufacturing arrangement could run the risk of being taxed under the ITA as a separately taxable unit called an association of person (**"AOP"**). This is a significant issue for the foreign enterprise which outsources these functions, given that, if such arrangement is treated as an AOP, the profits of the foreign enterprise attributable to such AOP, which otherwise would not have been subjected to tax in India (in the absence of a PE of the foreign enterprise in India), would be taxable at the maximum marginal rate of 40%.

Although there is no definition of AOP under the ITA, there have been a number of cases in which this issue has been discussed. In the case of Commissioner of Income Tax v. Indira Balkrishna[14], the Supreme Court has explained the concept of AOP as "an association of persons must be one in which two or more persons join in a common purpose or a common action, and as the words occur in a section which imposes a tax on income, the association must be one the object of which is to produce income, profits or gains."

Further, in the case of Deccan Wine and General Stores[15], the Andhra Pradesh High Court further examined this concept and observed that "it is, therefore, clear that an association of persons does not mean any and every combination of persons. It is only when they associate themselves in an income-producing activity that they become an association of persons. They must combine to engage in such an activity; the engagement must be pursuant to the combined will of the persons constituting the association; there must be a meeting of the minds, so to speak. In a nutshell, there must be a common design to produce income. If there is no common design, there is no association. Common interest is not enough. Production of income is not enough."

Although there is lack of clarity in the Indian law on the concept of an AOP, broadly the essentialconditions for constituting an AOP may be said to be:

- Two or more persons
- Voluntary Combinations
- A common purpose or common action with object to produce profit or gains.
- Combination in Joint Enterprise
- Some kind of scheme for common management.

The risk of a contract research and manufacturing arrangement being regarded as an AOP is particularly greater in cases where the Indian CRO / CMO co-develops the drug with its foreign partner based on a revenue sharing model. Such special arrangements, if not structured appropriately, could lend weight to the characterization of the arrangement as

14. [1960] 39 ITR 546 (SC)
15. ([1977] 106 ITR 111 (AP)

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an AOP, namely, two persons joining in a common purpose or a common action the object of which is to produce income, profits or gains. Thus, in order to avoid such characterization, it becomes important to clearly demonstrate in the contract that the intention is not to carry out any business in common and that the Indian CRO / CMO will only execute a part of the job (i.e. research and manufacturing) according to its technical skill and capability. To the extent possible, the contract should convey that the work and income arising from the foreign enterprise's contribution is quite distinct and independent of the Indian CRO / CMO's work and income. Hence, it must be ensured that the arrangement is structured in a manner so as to mitigate any risk of it being regarded as a single assessable unit and liable to tax as an AOP.

E. Structuring Investment into India – Use of Intermediate Jurisdictions

Foreign entities that are looking at incorporating subsidiaries in India for outsourcing research and manufacturing functions can achieve tax efficiency by use of a tax neutral intermediate jurisdiction which has signed an Indian Tax Treaty (**"Treaty Jurisdiction"**) rather than directly investing into the Indian company. The foreign entity can achieve tax efficiency by incorporating a company (or any other entity which is eligible to benefits of the relevant Indian Tax Treaty) in the Treaty Jurisdiction which would, in turn, invest into the underlying Indian company.

The choice of an appropriate Treaty Jurisdiction, apart from tax neutrality and a good treaty network, would depend on factors such as political stability, ease of administration, availability of reliable administrators, favourable exchange controls and legal system, certainty in tax and legal framework and ease of winding up operations.

Indian Tax Treaties aim to prevent double taxation of income and capital gains for a person or entity resident in another jurisdiction. For instance, under the India Mauritius DTAA, capital gains earned on sale of Indian securities by a Mauritius company would be taxable only in Mauritius. Further, currently the Mauritius domestic tax laws provide an exemption on most categories of capital gains. By investing through such a jurisdiction, a foreign investor need only pay capital gains tax in its home jurisdiction. Further, in selecting an appropriate Treaty Jurisdiction, it is important for a foreign investor to select a jurisdiction that gives it the specific benefits it requires. For instance, while investing in debt and extracting returns in the form of interest, Cyprus proves to be better placed than Mauritius, even though the latter is widely used by investors making investments into India.

F. Indian Transfer Pricing Issues in Contract Research and Manufacturing Services

Where entities are looking to outsource research and manufacturing functions to an associated enterprise, such as in cases of captive outsourcing, the fees payable to the service provider should take into account transfer pricing issues.

In India, transfer pricing regulations (**"TP Regulations"**) were introduced on April 1, 2001. The Indian Income Tax Act, 1961 lays down provisions that deal with the computation of income arising from "international transactions" between "associated enterprises". The basic rule enshrined in the TP Regulations is that any income arising from an "international transaction" shall be computed having regard to the arm's length price (discussed below). The TP Regulations define "associated enterprise" to include any enterprise that participates directly or indirectly or through one or more intermediaries in the management or control or capital of another enterprise. Enterprises may also be regarded as "associated" as a result of circumstances such as interdependence by virtue of borrowings, guarantees, licensing of trademarks, purchase, sales or where enterprises have "mutual interest" as may be prescribed by the revenue authorities. Here, "enterprise" is defined broadly and covers any entity (including a permanent establish-

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ment) which is or proposes to be engaged in any activity relating to the provision of goods / services of any kind, investment activity, dealing in securities and extending loans. The term "international transaction" has been defined as a transaction between two or more associated enterprises, either or both of which are non-residents. As mentioned earlier, the basic principle is that any income arising from such an "international transaction" shall be computed having regard to the "arm's length price".

i. Arm's Length Price

Arm's length price is the price which is applied or proposed to be applied in a transaction between persons other than associated enterprises, in uncontrolled conditions. The OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, 2010 (**"Guidelines"**) provide that the application of the arm's length principle is generally based on a comparison of all the relevant conditions in a controlled transaction with the conditions in an uncontrolled transaction. Under the Guidelines, comparability is achieved when there are no differences in the conditions that could materially affect the price or when reasonably accurate adjustments can be made to eliminate the effects of any such differences. The analysis of the controlled transactions with uncontrolled transactions is the very basis of ascertaining whether the controlled transactions adhere to the arm's length standard.

The arm's length price in relation to an international transaction is to be determined by any of the following methods depending on which is the most appropriate given the business of the enterprises:

- Comparable uncontrolled price method;
- Resale price method;
- Cost plus method;
- Profit split method;
- Transactional net margin method;
- Such other method that may be prescribed by the Central Board of Direct Taxes (till date, no other method that may be considered appropriate in determining the arm's length price has been prescribed).

The pharmaceutical industry in India has time and again faced issues with respect to arriving at a comparable arm's length price for the purpose of transfer pricing. The industry faced a significant setback earlier this year, when the Mumbai Income Tax Appellate Tribunal (**"Tax Tribunal"**), hearing an appeal by Serdia Pharmaceuticals India Private Limited (**"Serdia"**) [Serdia Pharmaceuticals (India) Private Limited v. ACIT, ITA Nos: 2469/ Mum/ 07 and 2531/ Mum/ 08], held that the arm's length price for importing active pharmaceutical ingredients (**"API"**) from related enterprises should be determined on the basis of price at which locally manufactured generic API are sold in the domestic market. Serdia, a pharmaceutical company, imported API from its related entities in France and Egypt for the purpose of manufacturing certain drugs. In order to arrive at the correct arm's length price of the API which was imported into India, the tax payer had adopted 'Transactional Net Margin Method' (**"TNMM"**). However, the Income Tax Department contended that the APIs purchased were at prices that were higher than that paid for similar APIs by other companies in India and that the Comparable Uncontrolled Price (**"CUP"**) was the most appropriate method to be adopted. On the basis of the domestically available data, the tax department claimed that the arm's length price for the API should have been significantly lesser than that at which Serdia had imported these API. The Tax Tribunal ruled in favour of the tax department and held that the tax department was justified in applying CUP Method without specifying the reasons for rejection of TNMM method. The Tax Tribunal did not accept Serdia's justification of the high import price, namely, that the APIs were manufactured on equipment standards set by the World Health Organisation, the British Good Manufacturing Practices (GMP) and as per HSE or health, safety and environment standards. The Tax Tribunal observed that the high quality standards employed in manufacturing process conferred merely a certain degree of comfort pertaining

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to the minimum level of impurities and this did not necessarily affect its comparability with the same API manufactured by generic drug companies.

The Tax Tribunal's ruling in the Serdia case has adversely impacted pharmaceutical multinationals that are doing business in India. It has been seen that, post the Serdia ruling, the income tax department has been aggressively pursuing multinational pharmaceutical companies which are procuring APIs from their respective parent companies.

Another challenge faced by Indian pharmaceutical companies with respect to transfer pricing is that the TP Regulations do not specifically deal with intangibles, or provide a basis of computing the arm's length price, while dealing with the same. As opposed to transactions involving tangibles, where a pricing situation in controlled transaction can be compared with that of an uncontrolled transaction (provided all other conditions are similar or identical), in case of intangibles/intellectual property it is very difficult to identify comparable given the unique nature of the intellectual property involved. Hence, it becomes difficult to find a comparable based on which the arm's length price may be ascertained.

The Indian contract research and manufacturing industry too has had its fair share of problems with the tax department as far as transfer pricing is concerned. This is once again attributable to the lack of comparable for arriving at an appropriate arm's length price. The databases that provide comparable information are lacking in so far as they fail to provide information relating to companies engaged in pure contract research activities. Typically, the information offered by these databases relate to companies that work on different models, such as, co-development of a drug by the Indian CMO in partnership with its foreign associate based on a revenue sharing arrangement. Hence it becomes extremely difficult for Indian CROs / CMOs to arrive at a suitable arm's length price. As a result, the Indian tax department has time and again created issues for Indian CRO / CMOs by insisting on a significantly higher mark-up. It is important to note that TP Regulations also require persons entering into international transactions to maintain prescribed documents and information, and to obtain and furnish to the revenue authorities an accountant's report containing prescribed details regarding the international transactions. Stringent penalties have been prescribed for non-compliance with the procedural requirements and for understatement of profits.

ii. Safe Harbor Rules

To address litigation and uncertainty concerns raised by the industry and professionals, the Central Board of Direct Taxes has recently notified certain transfer pricing safe harbors. Under this regime, tax authorities will accept the transfer price set by the taxpayer if the taxpayer and transaction meet eligibility criteria specified in the rules. Key features of these rules are:

- The rules will be applicable for 5 years beginning assessment year 2013-14. A taxpayer can opt for the safe harbour regime for a period of his choice but not exceeding 5 assessment years. Once opted for, the mutual agreement procedure would not be available.
- Safe harbour margins have been prescribed for provision of: (i) IT and IteS services; (ii) Knowledge Process Outsourcing services; (iii) contract R&D services related to generic pharmaceutical drugs and to software development; (iv) specified corporate guarantees; (v) intra-group loan to a non-resident wholly owned subsidiary; (vi) manufacture and export of core and non-core auto components.
- The prescribed safe harbour margin in case of for Contract R&D services, with insignificant risks, wholly or partly relating to generic pharmaceutical drugs is an operating profit margin to operating expense - 29% or more

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G. Disallowance of Deduction of Expenses Incurred in Unethical Promotion

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibit the medical practitioners and their professional associations from taking any Gift, Travel facility, Hospitality, Cash or monetary grant from the pharmaceutical and allied health sector Industries. The Central Board of Direct Taxes has issued instructions[16] to the revenue department that the claim of any expense incurred in providing above mentioned or similar freebees in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible as expense because it is an expense prohibited by the law.

II. Indirect Taxes

India has a well-developed tax structure with clearly demarcated authority between Central and State Government and local bodies. The Indian Central Government levies taxes on income (except tax on agriculture income, which the State Government can levy), custom duties, central excise and service tax. On the other hand, Value Added Tax (Sales tax in states where VAT is not yet in force), stamp duty, land revenue and tax on professions are levied by the State Government.

Although the cost of labour and production in India is significantly lower than other countries, the ultimate price of the goods is on the higher side on account of a multi-layer and multi-stage levy of indirect taxes. As a result, traditionally the growth of Indian industry, including the pharmaceutical industry, has been stunted. Further, the greater concern is that the appreciation in the cost of goods, as a result of levy of such taxes, is indirectly passed on to the end customer, namely, the common man, who bears the brunt especially in case of essential products such as pharmaceuticals. The reason for the significant increase in the price of goods post taxation is more on account of the multi-layer and multi-stage indirect taxation framework. It is for this reason that efforts are being made to replace the existing indirect tax system (which provides for a multi-layer and multi-stage levy for goods and services) with a unified Goods and Services Tax (**"GST"**) system.

A. Service Tax

Service tax was introduced vide Chapter V to the Finance Act, 1994 and further widened in scope by the subsequent Finance Acts. The Finance Act 2012 has brought about substantial changes in the provisions of Finance Act 1994 dealing with levy and collection of service tax. Section 66B of the Finance Act 1994 specifies the charge of service tax which is essentially that the service tax shall be levied on all services provided or agreed to be provided in a taxable territory, other than services specified in the negative list or otherwise exempt under notification. Currently, service tax is levied at the rate of 14% on gross basis on the specified taxable services.

Service tax from April 1, 2011 is payable on accrual basis instead of realization of value of taxable service. Some of the taxable services are management consulting services, consultancy or technical services by a consulting engineer, business auxiliary services, intellectual property services, etc.

Until July 10, 2014, services provided by way of technical testing or analysis of newly developed drugs, including vaccines and herbal remedies, on human participants by a clinical research organization approved to conduct clinical trials by the Drug Controller General of India, were exempt from service tax. However, this exemption is no longer available. Export of services is not subject to service tax in India while in case of import of service, the recipient is liable to pay service tax. In order to qualify as an export under the Export of Service Rules 2005, inter alia the service must be rendered from India but

16. Circular No. 5/2012 [F. No. 225/142/2012-ITA.II], dated 1-8-2012.

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consumed outside India and the consideration must be paid in convertible foreign exchange. Additional conditions are imposed depending upon the type of service provided.

B. Customs Duty

Customs duties are levied whenever there is trafficking of goods through an Indian customs barrier i.e. levied both for the export and import of goods. Export duties are competitively fixed so as to give advantage to the exporters. Consequently a large share of customs revenue is contributed by import duty. Customs duty primarily has a 'Basic Customs Duty' for all goods imported into India and the rates of duty for classes of goods are mentioned in the Customs Tariff Act, 1975 (the **"Tariff Act"**), which is based on the internationally accepted Harmonized System of Nomenclature (**"HSN"**). The general rules of interpretation with respect to tariff are mentioned in the Tariff Act. The rates are applied to the transaction value of goods (for transactions between unrelated parties) as provided under the Customs Act, 1962 (the **"Customs Act"**) or by notification in the official gazette. A further duty, known as Additional Customs Duty or the Countervailing Duty (**"CVD"**) is imposed to countervail the appreciation of end price due to the excise duty imposed on similar goods produced indigenously. To bring the price of the imported goods to the level of locally produced goods which have already suffered a duty for manufacture in India (excise duty), the CVD is imposed at the same rate as excise duty on indigenous goods. In addition to the above, there are also Additional Duties in lieu of State and local taxes (**"ACD"**) which are also imposed as a countervailing duty against sales tax and value added tax imposed by States. The ACD is currently levied at the rate of 4 per cent.

Further, the Central Government, if satisfied that circumstances exist which render it necessary to take immediate action to provide for the protection of the interests of any industry, from a sudden upsurge in the import of goods of a particular class or classes, may provide for a Safeguard Duty. Safeguard Duty is levied on such goods as a temporary measure and the intention for the same is protection of a particular industry from the sudden rise in import. In the Indian pharmaceutical Industry, given that a large number of companies are involved in the import and subsequent resale of unpackaged pharmaceutical products, such import is subject to a levy of a special duty termed as Special Additional Duty (SAD).

An exemption has been provided to pre-packaged goods where the sale price has been declared on the package. The SAD paid is only available as a refund if it is proved that state level VAT is paid on the subsequent sales of the imported products. The issue often faced by companies is that the process of obtaining refunds of SAD is tedious and time consuming and the time limit for filing the refund is stipulated as one year, which often leads to a failure in obtaining rightful refunds.

Under Section 9A of the Tariff Act, the Central Government can impose an Antidumping Duty on imported articles, if it is exported to India at a value less than the normal value of that article in other jurisdictions. Such duty is not to exceed the margin of dumping with respect to that article. The law in India with respect to anti-dumping is based on the 'Agreement on Anti-Dumping' pursuant to Article VI of the General Agreement on Tariffs and Trade, 1994.

C. Sales Tax and Value Added Tax

Central Sales Tax (**"CST"**) is imposed on the sale of goods in the course of inter-state trade or commerce. Sales of goods are deemed to take place in the course of inter-state trade if they result in the movement of goods from one state to another, or if such sales are effected by the transfer of documents of title to the goods during their movement from one state to another. No CST is levied on direct imports or exports or the purchase or sale effected in the course of imports or exports. The process of phasing out CST commenced with a reduction in the CST rate from 4 per cent earlier to 2 percent on April 1, 2008.

Value Added Tax (**"VAT"**) is levied on the sale of goods within a particular state at the two main VAT rates of 4 per cent and 12.5 per cent. VAT is

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a state specific levy and most states in India have introduced specific legislations for VAT based on the Model VAT legislation circulated by the Empowered Committee of State Finance Ministers. Further, under the VAT regime, a system of tax credits on input goods procured by the dealer is also available, to avoid the cascading effect of taxes that was prevalent under the erstwhile sales tax regime.

D. CENVAT

Cenvat is a duty of excise which is levied on all goods that are produced or manufactured in India, marketable, movable and covered by the excise legislation. The peak duty rate was reduced from 16 per cent to 14 per cent by the Finance Act, 2008 and was further reduced to 8 per cent, although there are other rates ranging upwards, or based on an ad valorem/quantity rate.

In order to avoid the cascading of excise duty and double taxation, the CENVAT scheme has been framed under the Central Excise Act and the CENVAT Credit Rules. Under the CENVAT Credit Rules, a manufacturer of excisable goods can avail of credit of duty paid on certain inputs and capital goods barring certain inputs used in the specified manufacture of certain products. The credit can be utilized towards the duty payable on removal of the final product. It must also be noted that the CENVAT scheme also takes into account credits with respect to any service tax paid by the manufacturer on input services received.

In the pharmaceutical industry the excise duty rate on inputs has always been higher than the excise duty rate applicable to the finished products. While the generic excise duty rate on the inputs (Active Pharmaceutical Ingredients or APIs) is currently at 10.3 %, the generic excise duty rate on finished formulations is 4.12 %. The net result has been that the CENVAT Credit has accumulated in the books of the drug manufacturer who is unable to use it efficiently. The manufacturers catering to the domestic market have borne the brunt of this issue since neither can they set off the entire CENVAT Credit nor can they claim refund for the same, unlike their counterparts who export pharmaceutical products and are eligible to refund of the unutilized CENVAT Credit. One can only hope that, in the days to come, the Indian Government will either align the excise duty rates of APIs (inputs) with that of the finished formulations or provide for a refund mechanism for the unutilized CENVAT Credit.

Another issue commonly faced by pharmaceutical companies is the low abatement percentage for pharmaceutical products. The assessable value for the purpose of levy of excise duty for pharmaceutical products is calculated by providing certain abatement from the Maximum Retail Price (**"MRP"**) of the product. At present, an abatement of 35% of MRP is permitted for pharmaceutical products. The pharmaceutical industry has claimed that the abatement is not sufficient given that the industry faces trade margins, R&D costs and other costs specifically associated with the pharmaceutical industry.

E. Research and Development Cess

All payments made towards the import of technology are subject to a cess of 5% under the Research and Development Cess Act, 1986. Technology includes any special or technical knowledge or any special service required for any purpose whatsoever by an industrial concern under any foreign collaboration, and includes designs, drawings, publications and technical personnel.

F. Synopsis of Benefits available to units setup in Special Economic Zones

The following benefits are available to units located in Special Economic Zones (**"SEZ units"**) in India:

- During the financial year beginning April 1, 2005 SEZ units will get the following exemptions:
  - 100% exemption of profits and gains from business for the first 5 years;

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» 50% exemption on profits and gains from business for the next 5 years;

» 50% exemption to the extent that such amounts are re-invested in the SEZ Special Reserve Account;

- Exemption from capital gains arising on transfer of capital assets in case of shifting of industrial undertaking from urban areas to any SEZ, provided that, 1 year before, or 3 years after the transfer (i) machinery / plant was purchased for the business of the industrial undertaking in the SEZ, (ii) building or land was acquired or building was constructed in the SEZ, (iii) the original asset was shifted and the establishment was transferred to the SEZ and (iv) the assessee incurred such other expenses as are notified by the Central Government;
- 100 per cent customs duty exemption on the import of goods or services into the SEZ.However, any goods removed from the SEZ into a domestic tariff area will be subject to customs duty.
- 100 per cent excise duty exemption on goods brought from a domestic tariff area into the SEZ.
- 100 per cent service tax exemption.
- 100 per cent exemption from securities transaction tax.
- Exemption from the levy of taxes on the sale or purchase of goods other than newspapers under the Central Sales Tax Act, 1956 if such goods are meant to carry on the authorized operations by the Developer or entrepreneur.
- However, the Finance Bill, 2016 proposes to phase out certain benefits available to SEZ units by stating that no deduction shall be available to units commencing manufacture or production of an article or thing or start providing on or after April 01,2020.

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7. Issues and Concerns

Those involved in business of medical devices in India face similar issues or concerns over a span of time because of some shortcoming in the law or lack of awareness of applicable legal and regulatory regime. Below, we have listed few common issues and concerns faced by the medical device industry.

I. Physician Owned Distributorships

Lately, in certain cities in India, the distribution arrangement which manufacturers and importers of medical devices have entered into is such where the distribution agency is owned or managed by individuals having direct or indirect financial interest over certain hospitals or institutions who use the medical devices for patients (**"Customers"**). Similarly, some physicians too, who prescribe medical devices are known to have a direct or indirect financial interest or control in the distribution agency.

The legality of such a business arrangement is questionable.

The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (**"MCI Code"**) prescribes the code of medical ethics for the medical practitioners and, *inter alia*, covers under its ambit the requirements for the medical practitioners which regulate their relationships with pharmaceutical and medical device companies. The MCI Code has laid down that certain acts, if undertaken by the medical practitioners, may be construed as unethical and amounting to misconduct, rendering him/her liable for disciplinary action which may extend to debarment from the practice of medicine.

Under Regulation 1.8, it is provided that *"The personal financial interests of a physician should not conflict with the medical interests of patients."* Therefore, where the professional judgment of a physician towards services rendered to a patient is influenced by a financial interest, it could lead to a violation of the above Regulation. However, note that the MCI Code is applicable only to medical practitioners (prescribing physicians). No legal liability vests on a medical device company.

Doing business with physician owned distributorships may also be considered a "corrupt" act, leading to penalty under various anti-corruption legislations applicable to India and to the parent company in its jurisdiction (like Foreign Corrupt Practice Act in the US). The Prevention of Corruption Act, 1988 (**"PCA"**), deals with largely the liability of public servants arising from their act of accepting or obtaining or agreeing to accept or attempting to obtain from any person, for himself or for any other person any gratification/things of value as well as the liability arising from the act for abetment in such events.

Medical Practitioners appointed / hired by the Government / Government-aided hospitals and institutions as employees and who are in the service of or remunerated (by way of fees or commission) by such Government / Government-aided hospitals and institutions will be deemed to be 'public servants' for the purposes of the provisions of the PCA.

The following actions of a Public Servant are punishable:

i. Accepting any gratification other than legal remuneration;

ii. Taking gratification, in order, by corrupt or illegal means, to influence a Public Servant to forbear to do any official act, or in the exercise of their official functions to show favor or disfavor to any person, or to render or attempt to render any service or disservice to any person with the Government;

iii. Obtaining valuable things, without consideration or for a consideration which the Public Servant knows to be inadequate from persons concerned in proceeding or business transacted by them or about to be transacted by them, or

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having any connection with their official functions or of any Public Servant to whom they are subordinate, or from any person whom they know to be interested in or related to the person so concerned.

A. Liability for abetment

The PCA aims to control the source of bribery or corruption through the principle of *"abetment"*. Thus, in addition to punishing the Public Servant who receives a bribe, PCA also punishes the party abetting offences, whether or not the offence is committed as a consequence of abetment. Therefore, a person offering the bribe is also an offender under PCA. Further, the principle of abetment is also provided under the Indian Penal Code .[17]

Whoever abets any offences / actions of the Public Servants as set out above, is punishable with imprisonment for a minimum term of six months extending up to five years along with fine irrespective of the fact as to whether or not that offence is committed in consequence of their abetment.

A prescribing physician who is employed in a Government / Government aided hospital or institution is a "Public Servant" for the purpose of PCA. Depending upon the facts and circumstances, it will have to be evaluated whether supplying medical devices to a distribution agency owned directly or indirectly by such a physician will trigger the provisions of PCA which may lead to liability for the medical device company.

II. Clinical Trials of Medical Devices

A manufacturer of medical devices, whether produced locally or imported in India, may feel the need to carry out clinical trial in India. The purpose of the trial may be to determine safety of the device or simply to conduct post-marketing evaluation of the device. If the device is a Notified Medical Device, then the medical device manufacturer may rely on the regulatory framework prescribed under the Act. However, if the device is not a Notified Medical Device, then the device is not covered by the Act and the manufacturer need not conduct the clinical trial as per the requirements of the Act and the Rules.

There are two peculiar problems which manufacturers have faced in recent times. First, there is no other guidance document to rely on. The Indian Good Clinical Practices guidelines were drafted from the point of view of a drug trial. Therefore, placing reliance on the guidelines may not be feasible. In absence of any guidelines, the manufacturers often find themselves at the mercy of Institutional Ethics Committees who dictate terms.

Second, the DCGI has reportedly requested medical manufacturers who were conducting clinical trials of non-Notified Medical Devices to follow the Act and Rules. Adherence to Act and Rules may lead to significant increase in the trial budget. The Act and Rules require audio-visual recording of the entire informed consent process as well as storage of the video. Further, the Rules have formalized a system of compensation for trial related injury or death. The system is onerous for the Sponsor because it does not allow the Sponsor to present its case before a decision on compensation is taken. The Act and Rules also contain stringent timelines for submission of reports on serious adverse events.

17. Under the Indian Penal Code, bribery is an offence, whereby accepting or giving gratification for exercising or inducing the exercise of any electoral right is an offence, and both the acceptor and the giver of such bribe are liable to be punished under the code. Also, an act would be considered as an offence even if committed partially.[1] Further, abetment would also be considered as an offence, when a person offering a bribe, whether received or rejected, is held liable.

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It is recommended that any medical device company who wishes to conduct clinical trial of non-notified medical devices should intimate the office of the DCGI regarding the trial in order to be able to budget the trial and avoid future regulatory surprises.

III. Labeling of Imported Medical Device

It is a common global practice to re-label imported medical devices after they have arrived in the country of Import. In India, the re-labeling is carried out at customs warehouses, or any other place, which is approved by the CDSCO.

However, a change in the status quo is in the pipeline. It is now expected by the customs authority that the medical devices entering Indian customs should already be labeled as per Indian laws. Thus, re-labeling of medical devices after importing it in India will not be possible in future. This requirement will become mandatory from September 28, 2014.

The requirement may lead to cost escalations and change in business plans because earlier re-labeling was carried out by the importers in India but eventually will have to be carried out by the manufacturers themselves.

IV. Issues Connected to Appointment of Authorized Agent Through Power of Attorney

As noted in the regulatory section, all foreign manufacturers and medical devices sought to be imported into India are required to be registered with the DCGI. An application for grant of a registration certificate may be made by:

i. the manufacturer himself if it has a valid wholesale license for sale or distribution of drugs under the Rules; or

ii. his authorized agent in India, either having a valid license under the Rules to manufacture for sale of a drug or having a valid wholesale license for sale or distribution of drugs in India.

The foreign manufacturers usually do not have a local subsidiary or affiliate in India which has a wholesale license for sale or distribution of medical devices. Hence, the foreign manufacturers most often choose to appoint a third party as an authorized agent to make the application for grant of registration certificate.

The law requires that the authorization by a manufacturer to his agent in India must be documented by a power of attorney. The power of attorney declares the concerned applicant (third party) to be the authorized agent of the foreign manufacturer for the purpose of fulfilling the requirements imposed on the manufacturer in connection to registration certificate and import license. Under the power of attorney, the manufacturer undertakes to comply with any instruction or directions of DCGI for the purpose of registration and import of medical devices into India.

The Power of Attorney is signed by both, the foreign manufacturer and the authorized agent and authenticated by appropriate government bodies. Thus, the authorized agent is obligated to comply with requirements imposed on the foreign manufacturer of imported medical devices as applicable under the Act and Rules, including the obligations which the manufacturer has decided to undertake upon itself through the undertaking under Schedule D-I. The Registration Certificate, too, expressly states that the concerned party, who is the authorized agent of the manufacturer in India, will be responsible for the business activities of the manufacturer in India in all respects.

Owing to the fact that the Authorized Agent has taken up responsibility of business activities of the foreign manufacturer in India, it starts to insist on being the sole importer of the medical devices. There have been instances where the Authorized Agent has claimed exclusive right to import products in India based on the power of attorney. This may not be acceptable to most of the foreign manufacturers.

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In order to avoid future disputes, manufacturers should be considering introducing protective terms in the power of attorney.

V. Change of Name, Registered Address or Acquisition of License/ Registration Holder Company

In case of any change of the name of license/registration holder, change in registered address or change in constitution (i.e. change in controlling shareholding in case of companies with shares capital and change of partners in case of partnerships) renders the existing license or registrations invalid after three months of the date of the occurrence of the event. It is expected that the license/registration holder must immediately intimate the concerned licensing authority about the change. Further, it is in the interest of license/registration holder that a fresh application for issue of the license/registration is made as soon as possible. It is likely that after the fresh application is made, the concerned licensing authority may take more than three months to issue the license/registration. In such a case, the license/registration holder may continue to operate on the basis of the old license/registration until the new license/ registration is issued, provided there was no undue delay for making the fresh application.

VI. Government Control Over Prices of Medical Devices

The State Drug Licensing Authority in the State of Maharashtra, called as Food and Drug Administration (**"FDA"**), recently issued a letter to the DCGI and the National Pharmaceutical Pricing Authority making a case for bringing medical devices under price control. The assertion of the FDA was that medical devices in India are being sold at a huge margin. We have summarized the price control framework in India and analyzed the likelihood of price control over medical devices below.

In India, a legislation called Essential Commodities Act, 1955 (**"ECA"**) is invoked when the prices of a commodity or a class of commodities are sought to be controlled. The ECA gives power the Central Government to control production, supply, distribution etc. of essential commodities for maintaining or increasing supplies and for securing their equitable distribution and availability under fair prices. Under the ECA, if a commodity or a class of commodities, for example, medical devices, is notified as an "essential commodity" in the Official Gazette of India, then the Central Government can, amongst other things, fix prices of the medical devices. However, medical devices have not yet been notified as essential commodity. To control prices of medical devices, the Central Government will have to first notify 'medical devices' as an essential commodity.

Interestingly, 'drugs' as a class of commodities have been notified as 'essential commodities'. Thus, the Central Government has the powers to fix prices of drugs. In fact, in furtherance of the said notification, the Central Government has issued an order called The Drug Price Control Order, 2013 (**"DPCO"**) which provides a framework for controlling the prices of drugs. The main objective of the DPCO is to ensure the availability of essential, lifesaving and prophylactic medicines specified in National List of Essential Medicines, 2011 (**"NLEM"**) at affordable prices,. The government agency under DPCO which is responsible for controlling the price of drugs is called the National Pharmaceutical Pricing Authority (**"NPPA"**). The DPCO also provides for controlling the prices of non-NLEM drugs in two situations:

a. If the price of any non-NLEM drug increases by more than 10% of maximum retail price within a span of 12 months, then the DPCO gives NPPA the power to reduce the price to the level of 10% of maximum retail price for the next twelve months.

b. By discretion of NPPA, in public interest and under extra-ordinary circumstances.

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The catch here is that the definition of "drugs" under ECA refers to the definition of "drugs" under the Drugs and Cosmetics Act, 1940 (Act). The definition of "drugs" under the Act includes medical devices that have been notified by the Central Government (See Appendix 1). Thus, technically, all Notified Medical Devices may be brought under price control if any of the two situations referred to above in (a) and (b) arise. However, all medical devices other than Notified Medical Devices cannot be brought under price control unless "medical devices" as a class is notified by the Central Government to be an "essential commodity", as discussed above.

VII. Certain Recent Regulatory Changes

The manufacturers of medical devices listed in Schedule C and C1 of the **"D&C Rules"**, namely sterilized surgical ligature, sterilized surgical suture, sterile disposable devices for single use only and in-vitro diagnostic devices for HIV, HbsAg and HCV, and those notified by Ministry of Health and Family Welfare (See **Annexure-A**) are now set to face stricter regulations. Through the Drugs and Cosmetics (Fourth Amendment) Rules, 2014 notified on September 24, 2014, the Ministry of Health has introduced certain changes to the existing regulatory framework applicable to medical devices under the D&C Rules. We have summarized the major changes below:

A. Whole-Time Employee to Supervise Manufacture is Now Required to Have Significant Experience

The Health Ministry has made it mandatory for the manufacturers of medical devices listed in Schedule C and C1 to employ only those manufacturing supervisors who have considerable experience. Under the old rule, there was no minimum experience prescribed. The below table provides for the new minimum experience requirements.

Sr. No.	Qualification	Minimum experience requirement
1.	Graduate in Pharmacy or Engineering (in appropriate branch)	At least eighteen months practical experience in the manufacturing or testing of devices to which this licence applies after his or her graduation.
2.	Graduate in science, with Physics or Chemistry or Microbiology as one of the subject	At least three years practical experience in the manufacturing or testing of devices to which this licence applies after his or her graduation.
3.	Diploma in Pharmacy or Engineering (in appropriate branch)	At least four years practical experience in the manufacturing or testing of devices to which this licence applies after his or her diploma.

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B. Manufacturing Supervisors May Now Have Foreign Qualification

The Health Ministry has relaxed the requirement under the D&C Rules to hire manufacturing supervisors with only domestic qualifications for manufacture of medical devices listed in Schedule C and C1. A person with foreign qualification, the quality and content of training of which are comparable with those specified in Table under Sr. No. (1), clause (2) and (3) above and who is permitted to work as competent technical staff by the Central Government, may be hired as a manufacturing supervisor. The D&C Rules make it mandatory to manufacture under the active direction and personal supervision of a competent technical staff who is a whole-time employee.

C. New Labeling Requirements

Under the old rule, the manufacturers of medical devices were required to comply mainly with the labeling specifications laid down by the Bureau of Indian Standards (BIS), in addition to any other requirement prescribed under the D&C Rules. The BIS notified a few domestic standards but relied majorly on International Standard Organization (ISO) standards and European Standards (EN). BIS was also not able to keep pace with the developments under the international standards. The Health Ministry has now decided to completely move away from reliance on BIS and has notified an exhaustive list of labeling particulars to be printed on the label or the sticker. The full list is present in **Annexure-B**.

Medical devices that are exported need not comply with the full labeling particulars and requirements specified in Annexure-A. A separate list of labeling particulars has been notified and is reproduced herein **Annexure-C**.

D. Shelf-Life of Medical Devices Prescribed

While no shelf life for medical devices was prescribed, it has now been made clear that the shelf life of such medical devices will not exceed 60 months from the date of manufacture.

E. Import and Manufacture of Custom Made Medical Devices Recognized and Exempted From Regulatory Framework

The Ministry of Health has recognized application of custom made medical devices which are made according to the written prescription of duly qualified medical practitioner, under his responsibility, in accordance with specific design characteristics and intended for sole use of a particular patient. Such custom made devices, when imported or manufactured bearing the label "custom made device", will be exempt from the regulatory framework applicable to medical devices, for instance, from requirement to obtain a license to manufacture, license for sale, requirement to obtain and produce prescription of a registered medical practitioner for purchase of medical device *etc.*

F. Standards Of Medical Devices Clarified

The Ministry of Health has expanded the list of standards that are required to be met by medical devices. Earlier, standards were prescribed only for sterile disposable perfusion sets for single use only, sterile disposable hypodermic syringes for single use only and sterile disposable hypodermic needles for single use only. No standards were prescribed for other devices. This led to confusion over the standards to be met by manufacturers of other medical

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devices. The issue has been addressed by Ministry of Health now. Henceforth, all medical devices will have to conform to the Indian Standards laid down from time to time by the BIS. If there are no standards laid down by BIS, then the medical devices will have to conform to the International Standards, like International Organisation for Standardisation, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. Where national or international standards are not available, the medical devices will have to conform to the manufacturer's validated standards.

The Quality Council of India, which is the apex facilitation and accreditation body in India, along with the Association of Indian Medical Device Industry, has now introduced an 'Indian Certification for Medical Devices Scheme' (ICMED) in order to help Indian companies cut costs and reduce time spent in obtaining globally accepted certification for their medical devices. The ICMED is an indigenous quality assurance system for Indian manufactured medical devices which can be adopted by the companies on a purely voluntary basis. It provides 3 voluntary certification criteria that are based on related ISO standards.

G. Drugs Controller General of India Clarifies that Non- Notified Medical Devices are Not Covered by Regulatory Framework of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945

With a view to rest speculations and doubts about selective applicability of regulatory framework under Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic Rules, 1945 to certain medical devices, the apex medical device regulator in India, the Drugs Controller General of India, has clarified through an office order dated July 09, 2014[18] that the regulatory framework will be applicable to only those medical devices which have been notified by the Ministry of Health and Family Welfare. The Order further states that all non-notified devices do not require any registration, license, permission or NOC for their import, manufacture, sale and distribution under D&C Act and D&C Rules. A list of these notified medical devices is reproduced in **Annexure-D**.

H. Draft Rules for Delinking Medical Device Sector from the Pharmaceutical Sector Introduced

The CDSCO has released draft rules for public comment in relation to an amendment to Schedule M-III of the Drugs and Cosmetic Rules, 1945. Previously, Schedule M-III provided requirements for factory premises which were manufacturing medical devices, but only covered three of the notified devices – disposable perfusion and blood collection sets, disposable hypodermic syringes and disposable hypodermic needles. The other notified medical devices, which fell within the ambit of the definition of a 'drug' under the Act, was governed generally under the provisions of the Act and Rules. The amendment to Schedule M-III proposes to exclusively regulate medical devices, while Schedule M would exclusively regulate pharmaceutical products. Schedule M-III would now contain a "Quality Management System" requirement for notified medical devices and in-vitro diagnostics. The draft rules are expected to come into force soon, and would be a welcome change for the medical device industry.

18. http://www.cdsco.nic.in/writereaddata/Office%20Order%20dated%2009_07_2014%20(1).pdf

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8. Conclusion

The Indian medical device sector continues its upward march of growth and is strongly supported by India's robust legal framework.
The regulatory framework, though, is under-developed and poses a challenge. A new regulatory regime is the need of the hour. The new government at center has shown promise and it is likely that a new law that will overhaul the regulatory framework applicable to medical devices may soon see the light of the day.

The market, which was until now dominated by imported medical devices, may face fierce competition from domestically manufactured devices as many multi-nationals, too, have started shop locally. Thus, the sector presents an exciting investment opportunity to the players within India as well as outside

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Annexure A

List of Notified Medical Devices

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. In vitro Diagnostic Devices for HIV, HBsAg and HCV
5. Cardiac Stents
6. Drug Eluting Stents
7. Catheters
8. Intra Ocular Lenses
9. I.V. Cannulae
10. Bone Cements
11. Heart Valves.
12. Scalp Vein Set
13. Orthopedic Implants.
14. Internal Prosthetic replacements

It is noteworthy that in addition to the above medical devices, the following substances are also regulated as 'Drugs' under Drugs & Cosmetics Act, 1940 & Rules, 1945 there under:-

1. Blood Grouping Sera
2. Skin 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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Annexure B

Labeling Requirements for medical devices

a. Proper name of the medical device;

b. The details necessary for the user to identify the device and its use;

c. The name of the manufacturer and address of the manufacturing premises where the device has been manufactured;

d. The correct statement of the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package shall be expressed in metric system;

e. Date of manufacture and date of expiry;

f. Indication that the device contains medicinal or biological substances, where necessary;

g. Batch number or lot number;

h. Special storage and handling conditions, where required;

i. Indication if the product is a sterile product, its sterile state and sterilization method;

j. Warnings or precautions where required;

k. To label the device, if the device is intended for single use;

l. To overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;

m. To overprint on the label of the device, the words "Physician's Sample--Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample;

n. To provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L.";

o. In case of imported devices, the import licence number, name and address of the importer and address of the actual manufacturing premises, date of manufacture,
(if not already printed at the time of import).
The label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for standardisation (ISO) may be used in lieu of text and the device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, for example, for a newly introduced symbol; an explanation shall be provided in the instructions for use.'.

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Annexure C

Labeling requirements for medical devices intended for export

a. name of the Device;

b. distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";

c. date of expiry, if any;

d. name and address of the manufacturer and address of actual premises where the device has been manufactured

e. manufacturing Licence No. preceded by the letters "M.L. No." or "Manufacturing Licence No.";

f. internationally recognised symbols in lieu of text, wherever required

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Annexure D

List of Notified Medical Devices

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. In vitro Diagnostic Devices for HIV, HBsAg and HCV
5. Cardiac Stents
6. Drug Eluting Stents
7. Catheters
8. Intra Ocular Lenses
9. I.V. Cannulae
10. Bone Cements
11. Heart Valves.
12. Scalp Vein Set
13. Orthopedic Implants.
14. Internal Prosthetic replacements

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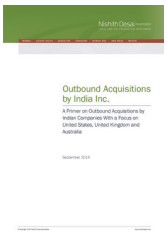

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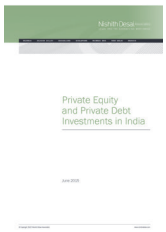

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