

The Indian Medical Device Industry

Regulatory, Legal and Tax Overview

August 2017

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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. Foreign Direct Investment in medical device manufacturing sector is now possible without any prior approval. The Indian legal regime is robust and promotes innovation and commerce. Being a signatory to the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), India today's boast of strong patent, trade mark and copyright protection within its territory. India has a competition law regime that ensures a 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. The Indian government has incentivized scientific research and development by providing weighted deduction.

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. A 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 regulatory framework in India applicable to medical devices borrows heavily from the regulatory framework applicable to drugs. At present, only 15 types of medical devices are regulated (unfortunately, as "drugs"). The rest are unregulated. After a lot of efforts of various stake holders, the government has notified the Medical Device Rules, 2017, which are to come into effect from the 1st of January, 2018 unless a different date is notified. These rules will regulate a much larger set of medical devices under a framework customized for medical devices. This should boost the confidence of all stakeholders, especially those who have been hesitant to enter into Indian market because of lack of regulation.

In 2017, the biggest challenges before the medical devices industry will be price control, the uncertainty about the effect of new Medical Device Rules, 2017 and adaptation to additional labelling requirements prescribed under the Legal Metrology (Packaged Commodity) Rules, 2011. All these themes are discussed in the paper in some detail.

Overall, it should come as surprise to no one that the Indian medical device industry presents an exciting opportunity to foreign and domestic players alike. It is hoped that this research paper will act as a guide to all stakeholders.

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

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 acquired Alpha X-Ray Technologies, 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 8344 Crore (approx. USD 1452 Million) between 2000 and 2016². 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).³

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 (now a part of Abbott), 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: Advanced Medical Technology Association

2. Department of Industrial Policy and Promotion; Cumulative FDI Flows into India; available at: http://dipp.nic.in/English/Publications/FDI_Statistics/2016/FDI_FactSheet_April_Sep_2016.pdf

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

(ADVAMED), Association of Indian Medical Device Industry (AIMED), NATHEALTH, Association of Diagnostics Manufacturers 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 Medical Device Rules, 2017, which is to come into effect from 2018, is expected to fill the legislative void that is currently present, due to the absence of a medical device specific legislation in India.

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.

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	<i>Exchange Control Laws:</i> Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same	<i>Domestic Taxation Laws:</i> 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	<i>Corporate Laws:</i> Primarily the Companies Act, 1956, the Companies Act, 2013 and the regulations laid down by the Securities and Exchanges Board of India (" SEBI ")	<i>International Tax Treaties:</i> 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	<i>Sector Specific Laws:</i> 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	

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.

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.

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**”).

FDI in manufacturing of medical devices 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.⁴

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

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

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.

5. Legal And Regulatory Regime

As referred to in the introduction, the medical devices industry in India is currently largely unregulated because of the absence of a medical device specific legislation specifying standards of safety and quality for most of the medical devices. However, this is set to change with the introduction of the Medical Device Rules, 2017, which is to come into effect from January 1st, 2018. Presently, 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 (“**D&C Rules**”). A list of these medical devices is described in **ANNEXURE A**. 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.

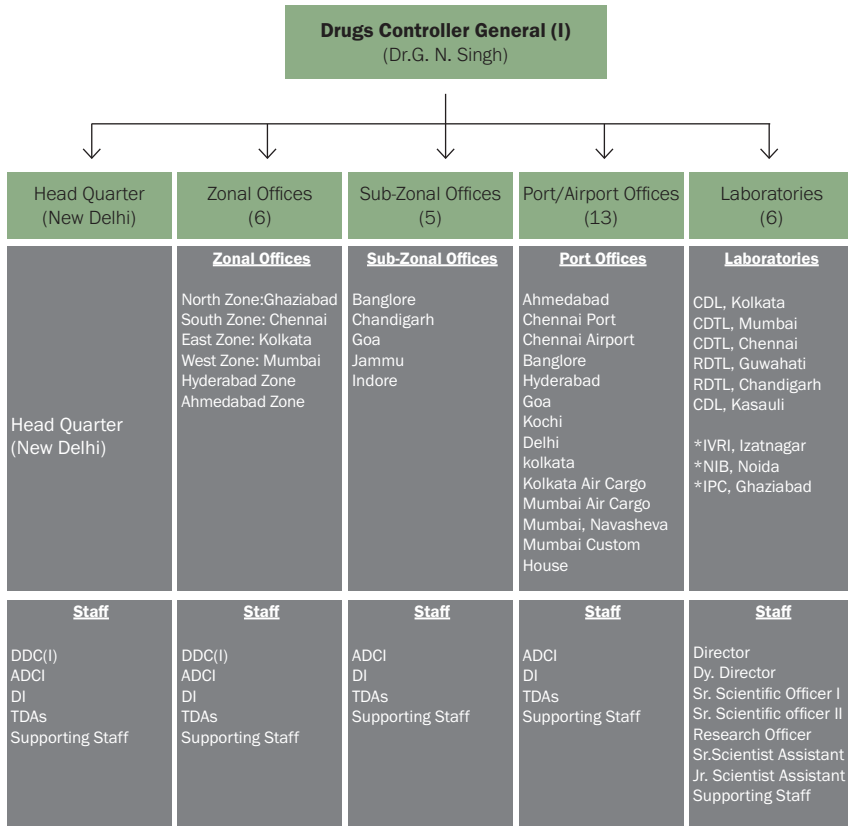
The Act and D&C Rules seek to:

- 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 Drugs Controller General of India (“**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.

Organisation Chart Central Drugs Standard Control Organisation



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); ADCI(I)- Assitant Drugs Controller(I); DIs- Drugs Inspectors; TDAs- Technical Data Associates

II. Licenses Required for Import, Sale, Manufacture and Loan of Medical Devices Under the D&C 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 D&C 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 is 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)
License to manufacture Notified Medical Devices	Form 28	Form 27	Rule 76	For Notified certain specified Medical Devices ⁵ – 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

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

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 D&C Rules or its authorized agent in India, either having a valid license under the D&C 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, 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 exempted Phase I clinical trials of medical devices. A number of manufacturers of Notified Medical 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 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 D&C Rules. For instance, Schedule R-1 of the D&C 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 D&C 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 D&C Rules.

The D&C 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 labeling requirements for medical devices under the D&C Rules have been described in **ANNEXURE B** and **ANNEXURE C**.

All labels may be printed in English

From January 1, 2018, Notified Medical Devices will also have to bear additional declarations and particulars on the label prescribed under the Legal Metrology (Packaged Commodity) Rules, 2011. This development is analyzed in some detail under Section XX below.

IX. Good Manufacturing Practices (Gmp)

Schedule M -III of the D&C 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.

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 to 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 the Foreign Trade Policy covers the period 2015 – 2020. 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 D&C 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 D&C 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, 1954.

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 advertisements about diagnosis, cure, mitigation or prevention of 54 diseases and listed disorders such as cancer, diabetes, epilepsy, leucoderma, paralysis, sexual impotence *etc.*

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.

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 step⁶ and capable of industrial application⁷.” 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 assignee⁸ or (iii) legal representatives⁹ 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 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 ena-

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.”

ble 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 Provisions¹⁰:

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 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

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

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.

XVIII. Government Control Over Prices of Medical Devices

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 power to fix prices of drugs. In fact, in furtherance of the said notification, the Central Government has issued an order called the Drug (Prices 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, 2015 (“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 other situations:

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

- 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 the NPPA, in public interest and under extra-ordinary circumstances.

The catch here is that the definition of “drugs” under ECA refers to the definition of “drugs” under the Act. The definition of “drugs” under the Act includes medical devices that have been notified by the Central Government (See Annexure D). Thus, the government is empowered to bring Notified Medical Devices under price control if any of the two situations referred to above 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.

In 2016, Coronary Stents, which fall under the class of Cardiac Stents amongst Notified Medical Devices, were added to NLEM. Accordingly, the price of bare metal stents, drug eluting stents (DES) (including metallic DES) and Bioresorbable Vascular Scaffold (BVS) / Biodegradable stents was fixed under DPCO to INR 7,260 (approximately 75 USD) and INR 29,600 (approximately 430 USD) per unit respectively. This effectively means that no patient (consumer) in India will have to pay more than the afore-stated amount for purchasing those stents in India. The importers and manufacturers will also have to structure their margins and business models to meet the fixed price.

The price fixation of Coronary Stents may appear at first glance to hurt the interests of the importers and manufacturers of Cardiac Stents and could make importers and manufacturers of other medical devices wary about a threat of potential price control. However, on a detailed analysis, a very different picture comes out:

1. The government decided to fix prices of Cardiac Stents only after an expert committee found them to be “essential” for the Indian population;

2. The government held several meetings with manufacturers, importers, distributors and hospitals and took into account their feedback;
3. The price data published by the government shows that the price control majorly cuts into the margins of the distributors and hospitals and may not hurt the margins of manufacturers and importers so much;
4. The reduction in cost of Cardiac Stents could lead to increase in demand in Tier II and Tier III cities of India where the population is cost-sensitive; and
5. The manufacturers and importers of Cardiac Stents have assured the government that they will continue production and supply at pre-price fixation levels; and
6. If a medical device is not a Notified Medical Device, it will not fall under price control.

Therefore, it may be wrong to give negative connotation to all acts of price fixation by the government. The government appears to have taken into account the interest of all stakeholders in the process of price fixation of Cardiac Stents.

It is possible for importers and manufacturers of Cardiac Stents and other Notified Medical Devices to remain profitable despite price control by restructuring their relationships with hospitals and absorbing the margins which was hitherto shared with distributors with the help of right documentation.

It is also possible for importers and manufacturers of Cardiac Stents and other Notified Medical Device to avail certain relaxations available in DPCO for patented devices and/or devices with specific therapeutic rationale. By using the relaxation, the manufacturers and importers of Cardiac Stents could limit the impact of price control.

XIX. Medical Device Rules 2017 – An Analysis

The Indian Government has finally introduced the Medical Device Rules, 2017 (“**2017 Rules**”). The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for the purpose of regulation. The 2017 Rules will come into effect on January 1, 2018 unless a later date is notified by the government.¹²

The key highlights of the 2017 Rules are:

A. Definition of Medical Devices

Under the 2017 Rules, medical devices mean:¹³

- a. Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the Act. Some categories of devices have already been notified by the government. A list of classes of currently notified medical devices is annexed as Annexure D.
- b. Specific substances intended to affect the structure or any function of the human body which are notified by the government. At present, the substances notified are mechanical contraceptives (eg. condoms, intra-uterine devices, tubal rings) and disinfectants.
- c. Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;
- d. Substances used for in vitro diagnosis
- e. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals.

12. Rule 1(2) of 2017 Rules.

13. Rule 3(zb) of 2017 Rules.

The most important take-away from the definition of medical devices is that only those products that are covered by the definition of medical devices will be regulated by the 2017 Rules.

Unfortunately, since the Act, in which the definition of ‘drug’ includes all the medical devices identified above, remains unamended, the Rules will continue to apply to all medical devices.

However, to avoid confusion, the 2017 Rules do clarify that in case of any contradiction between the provisions of 2017 Rules and the D&C Rules, the provisions of the 2017 Rules will have effect.¹⁴

B. Introduction of risk based classifications system

In tune with the global practice, the 2017 Rules will introduce a risk based classification system for regulation of medical devices. The classification would be as follows:

- a. Low (Class A)
- b. Low Moderate (Class B)
- c. Moderate High (Class C)
- d. High (Class D)

The method of classification is described in detail in the first schedule of the 2017 Rules (first schedule attached as **Annexure E**). It is important to note that unlike other countries which give liberty to manufacturers/importers to classify their product for the purpose of registration, the 2017 Rules do not provide this liberty and the manufacturers/importers will have to follow the classification decided by DCGI.¹⁵ This classification will be made available on a publicly accessible website on a later date.¹⁶ The classification, once done, appears to be non-appealable.

An example of the difference in regulation on the basis of risk-based classification is as follows:

14. Rule 96 of 2017 Rules.

15. Rule 4(3) of 2017 Rules.

16. Rule 4(4) of 2017 Rules.

The application for license to import Class A or Class B medical devices from Unregulated Jurisdictions (defined below) can be granted on the strength of a free sale certificate and either of published safety and performance data or clinical investigation in the country of origin. However, an application for import of Class C or Class D medical devices from Unregulated Jurisdictions can be granted only after its safety and effectiveness has been established through clinical investigation in India.

Unregulated Jurisdictions are jurisdictions other than Australia, Canada, Japan, European Union Countries, or the United States of America.

Similarly, for applications for grant of license to manufacture - Class A medical devices do not require prior audit by third party¹⁷ or official inspection; Class B medical devices require prior audit by third party¹⁸ but do not require official inspection, and; Class C or Class D medical devices require prior official inspection.¹⁹

Therefore, it is easy to make out Class A medical devices will enjoy least regulation and Class C or Class D medical devices will have to face most regulation.

The application for manufacture of Class A or Class B medical device will be assessed by the State licensing authority whereas the application for manufacture of Class C or Class D medical device will be assessed by DCGI.

C. Single window clearance

All applications for import, manufacture, sale or distribution and clinical investigation, whether to be assessed by the DCGI or State licensing authority, will have to be made through a single online portal of the central government. The details of the portal will be notified in the near future.

17. Rule 20(4)(i), of 2017 Rules

18. Rule 20(5) r/w Rule 20(6)(iii) of 2017 Rules

19. Rule 21(1) of 2017 Rules.

D. Product standards for medical devices

All medical devices will be expected to conform to the following standards, in the same order of relevance:²⁰

- a. A standard notified by central government for the medical device specifically or which has been laid down by the Bureau of Indian Standards (“BIS”); or
- b. Where (a) is absent, to a standard laid down by International Organisation for Standardisation (“ISO”) or the International Electro Technical Commission (“IEC”), or by any other pharmacopoeial standards; or
- c. Where both (a) and (b) are absent, to the validated manufacturer’s standards.

The clarity in products by 2017 Rules is a welcome step by the government. For much too long, the medical device manufacturers and importers suffered because of absence of clarity on product standards. The D&C Rules presently states that manufacturers or importers of notified medical devices are required to confirm to BIS standards or in absence of BIS standards, to international standards and such standards as may be specified.²¹ There was always a question on which standards would have to be followed when the BIS standards were not available. However, the introduction of 2017 Rules is expected to resolve this issues.

E. Certainty and rationalization of timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market/manufacture medical devices. Under the 2017 Rules, an applicant can be certain of the time within which its application will be decided and can also plan the time within which it can expect an audit or

20. Rule 7 of 2017 Rules

21. Schedule R-1 of Rules.

inspection to happen because timelines have been assigned to each regulatory function. Further, unlike the D&C Rules, the 2017 Rules do not give any scope to the regulators to extend the time-line for coming to a decision for any reason whatsoever. For instance, in case of license to manufacture Class C or Class D medical device, the scrutiny of the application is required to be submitted within forty five (45) days of the date of the application²², the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application²³, the report of the inspection has to be forwarded to the applicant²⁴, and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.²⁵

Similarly, a decision on application to import a medical device is required to be communicated within 9 months from the date of the application irrespective of whether the foreign manufacturing site is inspected or not.²⁶

The 2017 Rules have also introduced the concept of “deemed approval” in the event of non-communication of a decision, by the relevant authority, in application for approval to undertake major change in licensed particulars (the subject of major change in licensed particulars is discussed later in detail). If the appropriate licensing authority i.e. the DCGI or the State licensing authority is unable to communicate its decision on the aforesaid application within the stipulated timeline, i.e., forty five (45) days for manufacture, sixty (60) days for import, then such approvals shall be deemed to have been granted.²⁷

F. Perpetual licenses

The licenses granted under the 2017 Rules shall be perpetual, meaning they will continue to be

valid unless they are cancelled. In order to save a license from getting cancelled, the licensee is required to pay a prescribed license retention fee every five years. A delay of ninety (90) days past the five years is acceptable provided the licensee pays a prescribed late fee. However, if the licensee fails to deposit the license retention fee within the aforementioned time-limit, then the license is deemed to have been cancelled.

Once a license is cancelled, the licensee will have to apply afresh for the license.

Please note that while the license may be perpetual, if a licensed manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, it is obligated to inform the appropriate licensing authority.²⁸

G. Consolidation of registration certificate and import license into a single license

The 2017 Rules have done away with the requirement of a registration certificate for registration of the foreign manufacturer, its manufacturing site and the products. The only regulatory requirement to be able to import and market products in India is to appoint an authorized agent in India and apply for an import license through it. The immediate outcome of this change is that the hassle of making two separate applications (registration and import license) has vanished and the timeline for obtaining the import license (of nine months) has become certain.

Further, it will not be possible for two different importers to import different products manufactured at the same manufacturing site. Where an importer has been licensed to import certain products from a manufacturing site, all other products manufactured at the same site are mandatorily required to be licensed to the same importer.²⁹

22. Rule 21(4) of 2017 Rules

23. Rule 23(1) of 2017 Rules

24. Rule 24 of 2017 Rules

25. Rule 25 of 2017 Rules

26. Rule 36(1) of 2017 Rules

27. Rule 26(iii); Rule 38(vi) of 2017 Rules

28. Rule 26(xii) of 2017 Rules

29. Rule 34(4)(ii) of 2017 Rules

H. Certainty on consequence of change in particulars contained in the license

The 2017 Rules are clear about the consequences of change in the particulars of a license. Any major change requires a prior approval from the appropriate licensing authority (either DCGI or State licensing authority, as the case may be).³⁰ Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.³¹

What constitutes major change and minor change has also been specified.³² For instance, the change in name or address of the manufacturer (whether domestic or foreign) or importer is a major change. A change in design which does not affect quality in respect of its specifications, indication for use, performance and stability of the medical device is a minor change.

This clarificatory inclusion in the 2017 Rules is greatly welcomed.

At present, the D&C Rules do not specify what constitutes a major change or a minor change. That is not all. Whether a change in the manufacturing or in processing or in testing or in documentation is major or not is left to the discretion of the licensing authority and triggers the requirement to make a fresh application.³³ The challenges of making a fresh application are discussed later with the subject of change in constitution.

In fact, at present, it is known that the following changes will result in the requirement to obtain a fresh import license:³⁴

- a. Changes in name and/or address of Indian agent/ Importer or change in constitution

after issue of Registration Certificate/
Import License

- b. Change in the Indications and/ or Intended use
- c. Change in constitution

Under the 2017 Rules, the above changes (excepting change in constitution) do not require fresh application.

There is one more welcome change.

Under the D&C Rules, it is prescribed that the application for registration certificate for import of notified medical devices will be decided within nine months³⁵ and for import license the application is customarily decided within three months after grant of registration certificate. Thus, on an average, a total time of around one year is spent in obtaining the import license. Since it is a considerably long span of time, it is possible that certain changes may occur in the details that were submitted to the licensing authority at the time of making of the application. For instance, it is possible for business reasons that a different manufacturing site is sought to be registered. Ideally, since the application has not been decided, it should be possible for the applicant to revise the application. However, the current practice is that in case of such a change, even if the application has not been decided, a fresh application has to be made.³⁶ Apart from loss of money and resources, this results in loss of valuable time and sometime delays imminent and time-sensitive launch of products. This serious shortcoming appears to have been rectified in the 2017 Rules. Such a change now is required to be informed in writing to the licensing authority.³⁷ Due to this explicit requirement, it should not trigger requirement to make a fresh application.

30. Rule 26(iii); Rule 38(vi) of 2017 Rules

31. Rule 26(iv); Rule 38(vii) of 2017 Rules

32. Sixth Schedule of 2017 Rules

33. Schedule D(I), Para 3.5 of Rules.

34. See Import and Registration of Medical Devices FAQs published by CDSCO.

35. Rule 27A(1) Proviso of Rules.

36. FAQ No. 51 under Import and Registration of Medical Devices FAQs published by CDSCO.

37. Rule 34(2) Proviso. of 2017 Rules

I. Meaning of “change in constitution” finally explained and change in constitution rationalized

“Change in constitution” could easily be the most dreaded event under D&C Rules, even more than a “serious adverse event”. This is because no one seems to have any idea about what it means. Having said that, the D&C Rules require that upon its occurrence the license remains valid for three months only. The licensing authority itself has issued several clarifications, FAQs and guidelines over past seventy two (72) years but has not clarified what it means.

But worry no more. The 2017 Rules state that change in constitution of a licensee in relation to:³⁸

- i. *a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;*
- ii. *a company means-*
 - a. *its conversion from a private to a public company, or from a public to a private company; or*
 - b. *any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate;*

Therefore, it is now clear that at least after enforcement of 2017 Rules:

1. Change in directors will not result in change in constitution;
2. Change in shareholding by way of sale/ investment will not result in change in constitution; and

3. Change of parent shareholder due to restructuring exercise will not result in change in constitution.

Whether or not the above event constitutes a change in constitution of the licensee remains an enigma under the D&C Rules at present.

Let us understand what the practical challenge is if the license only remains valid for a period of three months due to change in constitution. It has already been discussed that it takes around a year to obtain an import license under the D&C Rules. It means that after change in constitution, an importer has only three months at present to import and stock products for domestic market to last for the time when it does not have an import license i.e. at least nine (9) months. This is almost impossible due to production, logistics, storage and commercial considerations. Thus, for many importers today, a change in constitution means halt of business for close to a year.

However, the government seems to have realized this pitfall and has made the process surrounding change in constitution a breeze under the 2017 Rules. Upon a change in constitution as defined before, a manufacturer licensee has forty five (45) days to inform the licensing authority and one hundred eighty (180) days to make a fresh application.³⁹ An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.⁴⁰ After making such an application, the existing license is deemed to be valid until the fresh application is decided by the licensing authority. Thus, there remains nothing to dread about change in constitution under the 2017 Rules.

J. License for sale of medical devices

The 2017 Rules do not have separate provisions for sale of medical devices. The provisions related to sale of drugs other than homeopathic

38. Rule 3(j) of 2017 Rules

39. Rule 27 of 2017 Rules

40. Rule 39 of 2017 Rules

medicines under the D&C Rules will apply to medical devices as if it was inserted within the 2017 Rules.⁴¹ All licenses for sale of drugs other than homeopathic medicines issued prior to commencement of 2017 Rules shall be deemed to be valid for sale of medical devices as well.⁴²

The 2017 Rules do, however, address a practical difficulty faced by many distributors in India. Implantable medical devices cannot be self-administered and therefore are seldom bought at retail. They are stocked by hospitals for clinical use as and when required. The hospitals sell the medical device to the patient directly on a unit basis or as part of treatment package. However, considering the medical devices are expensive and its demand is difficult to predict, hospitals are hesitant to purchase medical devices in large quantities. At the same time, some of the medical devices are critical and may be required on short notice, therefore it is in hospital's and patients' interest that the hospital maintains a large stock of medical devices. As a solution to this dilemma, the distributors transfer a sizeable stock of the medical devices to the hospital through a stock transfer. A stock transfer is not a sale, it is merely transfer of stock. As and when the hospital requires a medical devices, it uses it from the stock. The distributor then charges the hospital on the basis of its use. All the unused stock is later re-transferred to the distributor. The proof of stock-transfer of medical devices by distributor to the hospital is a delivery note.

The D&C Rules requires that any sale or distribution should be recorded by the distributor. A stock transfer is not a sale or distribution, therefore it is not recorded by the distributor. However, the presence of stock at the hospital may be interpreted as an act of distribution. This can lead to unnecessary investigation against the distributors by the licensing authority.

In order to resolve this complication, the 2017 Rules have permitted supply of implantable medical devices against a delivery note (challan).⁴³

K. Mandatory recalls on knowledge of risk to safety

The 2017 Rules make it mandatory⁴⁴ for manufacturers and importers to immediately initiate recall in case it has reasons to believe that a medical device is likely to pose risk to the health of a user or patient during its use and therefore may be unsafe. The recall should aim to withdraw the medical device in question from both the market as well as patients, indicating reasons for its withdrawal. The manufacturer and importer initiating recall is required to inform the licensing authority about the details of the recall.

In contrast, the D&C Rules do not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to user or patients.⁴⁵ There is also no explicit requirement to report the facts leading to a recall, unless the medical device is "new" and is required to submit periodic safety update reports and have a system of pharmacovigilance in place.⁴⁶

L. New thresholds for residual shelf life of imported products

The D&C Rules prescribe that all imported products should have a minimum residual shelf life of sixty (60) percent on the date of import unless specific permission is obtained to the contrary.⁴⁷ This becomes an issue for importers of medical devices which have a short claimed shelf life.

The 2017 Rules have addressed the issue by relaxing the residual shelf life requirement for

41. Rule 87(1) of 2017 Rules

42. Rule 87(2) of 2017 Rules

43. Rule 88(1) of 2017 Rules

44. Rule 89(1) of 2017 Rules

45. Rule 26(v); Rule 74(f); Rule 78(i) of Rules

46. Schedule Y, Para 3(4) of Rules.

47. Rule 31 Proviso of Rules.

medical devices with short shelf life.⁴⁸ Any medical device, whose total shelf life claim is

- a. less than ninety (90) days, will be allowed to be imported if it has more than forty (40) per cent residual shelf-life on the date of import
- b. between ninety (90) days and one (1) year, will be allowed to be imported if it has more than fifty (50) per cent residual shelf-life on the date of import
- c. is more than one (1) year, will be allowed to be imported by the licensing authority if it has more than sixty (60) per cent residual shelf-life on the date of import.

M. New regulatory framework for clinical investigation of medical device

The 2017 Rules will introduce a new regulatory framework for clinical investigation of medical devices. Some of the interesting provisions of this framework are:

- a. A fixed timeline of ninety (90) days has been prescribed for the licensing authority to arrive at a decision on application for permission to conduct clinical trial;
- b. After obtaining permission to conduct clinical trial, the first subject is required to be enrolled within one year;
- c. New concepts of Pilot Study (i.e. exploratory study) and Pivotal Study (i.e. confirmatory study) have been introduced with respect to approval of investigation medical device;
- d. New concept of “substantial equivalence” to predicate devices has been introduced with respect to approval of medical devices other than investigational medical devices;
- e. The clinical performance evaluation of In Vitro Diagnostic Devices is now part of the regulatory framework;

- f. Any institute, organization, hospital run or funded by the Central Government or the State Government is exempted from payment of fees for conduct of clinical investigation; and
- g. Academic clinical trials do not require prior approval of the licensing authority for its initiation if the data generated during the study will not be used for obtaining manufacturing or import license.

These changes should bring lot of comfort to stakeholders in the clinical investigation of medical devices.

N. Debarment on account of supply of misleading information

The 2017 Rules frown upon submission of misleading information along with an application for grant of any license. It prescribes that any applicant found guilty of submitting misleading, or fake, or fabricated documents, may be debarred by the appropriate licensing authority for such period as it may deem fit.⁴⁹ In other words, if any misleading or false information is found to have been submitted to the licensing authority, then it can debar the applicant from doing business in India.

The provision appears to be based on the jurisprudence of strict liability. It does not matter whether the applicant knew or intended to submit misleading or false information. This should act as a wake-up call to importers, manufacturers, distributors and researchers to ensure that all information that is finally submitted by it (or on its behalf) is verified prior to submission.

O. Medical Devices Rules, 2017 to be placed before Parliament

The Medical Device Rules, 2017 have been notified under the Act. The Act requires that

⁴⁸. Rule 47 of 2017 Rules

⁴⁹. Rule 93(1) of 2017 Rules

every rule made under it is laid down before each House of Parliament, for a total period of thirty days. If both Houses agree to make any modification in the rules or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be.

Thus, the 2017 Rules will soon be placed before the Indian Parliament. It will be interesting to see whether the Indian Parliament effects any modification to the 2017 Rules or rejects it completely. However, given the political and economic scenario, either event seems unlikely.

P. Next steps for existing importers, manufacturers and distributors

After the commencement of 2017 Rules, all licenses and registrations for medical devices issued under the D&C Rules that are valid on the date of commencement, shall be valid at least until July 31, 2018 or until the expiry date of the license or registration, whichever is later (“**Grace Period**”). Upon expiry of the Grace Period, all existing licensees will require a license issued under the 2017 Rules. Therefore, there is no need to rush to adopt to the 2017 Rules. However, it is important to start preparing for the new regulatory regime under 2017 Rules.

It is not clear whether existing licensees could voluntarily surrender their licenses before the expiry of the Grace Period in order to obtain a license under the 2017 Rules. However, such a step by licensees is not advisable. This is because the license fees paid to obtain the license under D&C Rules is far cheaper than the license fees prescribed in 2017 Rules. By opting to surrender the license, the licensee would effectively end up forfeiting the license fees already paid and incur expense of higher license fees. In case the decision to surrender is being contemplated

for taking benefit of the beneficial provisions of 2017 Rules (eg. change in constitution), then such rationale needs to be re-evaluated because the 2017 Rules clarify that the existing license under the Grace Period shall be deemed to be valid under the corresponding provision of 2017 Rules. Therefore, all existing licensees should be able to derive the benefit of 2017 Rules during the Grace Period despite transacting on a license issued under the D&C Rules.

Q. An opportunity lost

Though the 2017 Rules have introduced a number of business friendly provisions, one cannot help but regret that it was an opportunity lost to bring more change. The fact of the matter is that even after commencement of the 2017 Rules, medical devices will continue to be deemed to be drugs, since the definition of medical devices is tied to the definition of drugs under Act. This has repercussions under other laws, most important of which is the price control legislation – the Drugs (Price Control) Order, 2013 issued under the Essential Commodities Act, 1955. The Essential Commodity Act, 1955 has notified drugs as defined under Act as essential commodity. Due to the reference to this definition, medical devices which are deemed to be drugs, are also currently subject to limited price control. Had the government separated the definition of medical devices from the definition of drug, the tragedy that inadvertent and unintended price control of medical devices is today would have been avoided.

Having said that, there is no doubt that the fact of notification of the 2017 Rules and the very real possibility of it coming into effect in 2018 needs to be celebrated!

R. Draft classification of medical devices published

The government has published a draft classification for medical devices under 2017 Rules. The draft classification is available here:

http://www.cdsc0.nic.in/writereaddata/notice%2029_6_2017.pdf

All medical devices (whether notified earlier or not) have been classified as per their risk profile in Class A, B, C or D. The importers, manufacturers and other stakeholders in the medical device industry are expected to take notice of the draft classification and prepare themselves for the new requirements prescribed by the 2017 Rules by the time they come into effect (i.e. January 1, 2018).

XX. Notified Medical Devices in India to Lose Exemption from Labelling Requirements from January 1, 2018

On June 23 2017, the Government of India notified an amendment to a law that regulates contents of labels of all pre-packaged goods sold in India. The amendment takes effect from January 1, 2018. The most significant aspect of the amendment is that the application of this law has been extended to all Notified Medical Devices, which presently enjoy exemption. The label of all Notified Medical Devices sold in India will have to bear certain additional declarations and particulars, failing which, criminal prosecution may be initiated.

A. Background

The Legal Metrology Act, 2009 (“LM Act”), as its name suggests, lays down the standards of measurements in India (metrology means the science of measurement). It prescribes the units of weights and measures (eg. Liter, meter, kilogram, second etc.) that are to be followed for any measurement. The LM Act also mandates

that all pre-packaged commodities (“pre-packaged goods”) should carry declarations and particulars that may be prescribed by the government from time to time. These declarations and particulars are prescribed in the Legal Metrology (Packaged Commodities) Rules, 2011 (“LM Rules”). Any person who sells or distributes a pre-packaged good that does not carry the required declarations and particulars is punished with a fine of INR 25,000 (approx. USD 390) and INR 50,000 (approx. USD 780) respectively for the first two offences and fine of INR 1,00,000 (approx. USD 1550) or simple imprisonment of a term up to one year or both for subsequent offences.

Notified Medical Devices at present are exempted from compliance with the LM Rules. This is because ‘drugs’ that are covered by Drug Price Control Order, 2013 (“DPCO”) are exempted from the application of LM Rules. All Notified Medical Devices are, in fact, notified and regulated as ‘drugs’ under Indian law.

The LM Rules were amended by the Government of India on June 23, 2017. We have described and analyzed the major changes introduced by the amendment in the paragraphs below:

B. Changes introduced by the amendment with respect to medical devices and its analysis

1. *Notified Medical Devices to comply with LM Rules:* LM Rules will apply to Notified Medical Devices from January 1, 2018. At present only 15 categories of medical devices are regulated. As discussed in earlier section, the Medical Device Rules, 2017 will take effect from January 1, 2018. The Medical Device Rules, 2017 intend to bring all medical devices within its fold. In other words, the government intends to regulate all medical devices as “drugs” from January 1, 2018 or soon thereafter.

If the LM Rules had not been amended, the impact could have been that no medical device would have been regulated by LM

Rules from January 1, 2018 owing to the exemption for drugs. By notifying the amendment, the government has made it clear that it wants to ensure that all medical devices (both regulated and unregulated) remain within the scope of the LM Rules after January 1, 2018.

2. *But what does that mean? It means that :*

a. The label of the Notified Medical Devices will have to carry the following additional declarations and particulars:

- i. Maximum retail price (“MRP”);
- ii. Common or generic name of the commodity;
- iii. month and year in which the commodity is manufactured or packed or imported;
- iv. name, address, telephone number, e-mail address of the person who can be or the office which can be contacted, in case of consumer complaints;
- v. Actual corporate name and complete address of domestic manufacturer or importer or packer;
- vi. Other particulars and declarations that are discussed in paragraphs below.

b. The label of wholesale package⁵⁰ of Notified Medical Devices will have to carry the following declarations:

- i. The name and address of the manufacturer or importer or where the manufacturer or importer is not the packer, of the packer

- ii. the identity of the commodity contained in the package
- iii. the total number of retail package contained in such wholesale package or the net quantity in terms of standard units of weights, measures or number of the commodity contained in wholesale package

- c. The domestic manufacturer, packer or importer of Notified Medical Devices will have to register themselves under appropriate authority identified by the LM Rules
- d. Any alteration of any declaration or particular on the label may require permission from the appropriate authority identified by the LM Rules
- e. Any revision in price due to change in a central tax ought to be intimated to the public, distributors and the appropriate authority identified by the LM Rules.

3. *New declaration of country of origin to be made:* All medical device importers will have to declare the name of country of origin or manufacture or assembly on the package.

Please note that most of these declarations are not required under the D&C Rules issued under the Drugs & Cosmetics Act, 1940 (“Rules”) or the DPCO. The only overlap is the name and address of the manufacturer or importer, net quantity and expiry date.

4. *Declaration to be made on the outer package only:* Where a pre-packaged good has two or more levels of packaging, it has been clarified that no such declarations on the inner package is required, if the outer package contains all declarations required under the LM Rules. This may be relevant to manufacturers and importers of medical devices, who sometimes put an additional quality packaging on the medical device. In such cases, it should be sufficient compliance of the LM Rules if the mandatory dec-

50. “wholesale package” means a package containing-

- (i) a number of retail packages, where such first mentioned package is intended for sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer; or
- (ii) a commodity sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity to the consumer in smaller quantities;
- (iii) ten or more than ten retail packages provided that the retail packages are labeled as required under the LM rules.

larations and particulars appear on the quality packaging only. Similarly, retail packs of medical devices may be packed in packs of three or packs of five etc. In such cases as well, putting mandatory declarations and particulars on the outer packaging should be sufficient compliance of the LM Rules. Please note the aforesaid clarification applies to retail packages only and not to wholesale packages. In case of wholesale packages, each retail package is required to be labeled separately.

C. Issues

Multiple regulators for same subject: At present, the labelling requirements of Notified Medical Devices are prescribed by the D&C Rules and DPCO. After the amendment, LM Rules will be added to this list. One major inconvenience of being subjected to multiple laws is that alteration of any particular or declaration on the label may require approval (or no objection) of multiple authorities which may result in loss of precious time. In order to avoid approaching different regulators for approval, it is suggested that separate labels are affixed on the medical device to meet the requirements of different laws.

Another inconvenience of being subject to multiple law is that any non-compliance of labelling requirements that are common to these laws (i.e. name and address of the manufacturer or importer, net quantity and expiry date) may lead to parallel prosecution under these laws.

Multiplicity of proceedings for non-compliance of LM Rules: The enforcement of LM Rules is done at a state-level. This means that every state in India has its own enforcement wing to examine violations that take place with respect to pre-packaged goods sold in that state. This could be a matter of concern for medical device companies that have a pan-India presence because in case of any enforcement action due to alleged non-compliance in one state, there is a risk that same enforcement action may be initiated in the remaining 28 or so states of India.

Draconian law: The LM Act is a draconian piece of legislation because it does not prescribe a process for showing cause behind any alleged non-compliance. In other words, the law itself does not prescribe any process that supports issuance of show-cause notice prior to proceeding for prosecution. In fact, it is common for companies in India to have directly received a notice that orders the company to admit the alleged offence or resolve the matter before court after a criminal case has been lodged against the company and its officers responsible for the operation of the company (usually its directors). There is little or no scope for submitting an explanation to the officer who issues the notice.

D. Grey areas

The amendment to LM Rules are not without grey areas. In our view, the biggest grey area is the use of expression “not for commercial or trade purpose” in the definition of “institutional consumer”. In case the sale of pre-packaged goods is to institutional consumer, then LM Rules are not required to be complied with. In case of such sales, the LM Rules require manufacturer, importer or packer to label the pre-packaged goods with the declaration - “not for retail sale”. The exemption is significant because it reduces the administrative cost of labelling as well as the probability of occurrence of non-compliance, given that there is little to be declared on the label.

For the benefit of the reader, the amended definition of institutional consumer is as follows:

■ *“Institutional consumer” means the institution which buys packaged commodities bearing a declaration ‘not for retail sale’, directly from the manufacturer or from an importer or from wholesale dealer for use by that institution and not for commercial or trade purposes*

■

In the old definition of institutional consumer, the expression “and not for commercial or

trade purpose” was absent. The scope of the aforementioned expression is not clear because the expression has not been defined in the amendment. Specifically, it is not clear whether exhausting a pre-packaged commodity while providing a service would amount to using the pre-packaged commodity for “commercial or trade purpose”. For instance, if medical devices such as catheters are used while rendering service to a patient as part of a treatment package and such catheter is not invoiced separately to the patient, can the hospital that offers such a treatment be said to be an ‘institutional consumer’? It is unclear, how the suppliers of medical devices to the hospitals are supposed to understand whether or not the medical device will be used by the hospital for commercial or trade purposes.

Some of the other grey areas that have come to our notice are:

1. How should a specialized and unique medical device, which does not have a comparator, declare its “common or generic name” on its label? and
2. Would declaration of date in day-month-year format, which is the international standard, suffice for the purpose of declaration of date of import or manufacture given that the LM Rules require such declaration in month and year format?

E. Going forward

The requirements to put new declarations and particulars on the label as per the LM Rules and be regulated by LM Rules may understandably lead to some anxiety amongst manufacturers and importers of medical devices. However, given that manufactures and importers of almost all pre-packaged commodities (including unregulated medical devices) sold in India are complying with these labelling requirements at present and are also regulated by LM Rules, the amendment should not be difficult to adopt to. In fact, there is sufficient time left to adopt to the compliance requirements of the LM Rules since the amendment comes into effect on January 1, 2018.

Also, in the available time, it will be helpful if the medical device industry could seek clarity on various grey areas that exist within the amendment, especially the scope of expression “commercial or trade purpose” in the context of hospitals and their use of medical devices in treatment of patients. A clarification that allows hospital to be treated as institutional consumer in aforementioned context may make a significant difference in the impact of the amendment on manufacturers and importers of medical devices.

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. A company is said to be resident in India if it is incorporated in India or its place of effective management (“**POEM**”) is located in India.⁵¹ In this regard, the Central Board of Direct Taxes (“**CBDT**”) recently released the final guidelines for determination of POEM. (Please click here to read our hotline on the same).

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. The tax rates mentioned in this section are exclusive of applicable surcharge and education cess, unless otherwise specified. As per the Finance Act, 2016, the surcharge applicable to income generated by resident companies for the financial year 2016-2017 is 7% where the income exceeds INR 10 Million but does not exceed INR 100 Million and 12% where the income exceeds INR 100 Million. Additionally, as per Finance Act, 2016 surcharge applicable to income generated by companies other than domestic companies, for the financial year 2016-2017 is 2% where the income exceeds INR 10 Million but does not exceed INR 100 Million and 5% where the income exceeds INR 100 Million.

51. India introduced the ‘place of effective management (“**POEM**”)’ test for determining the residential status of a company in 2016. Under the POEM test, a company is said to be resident in India if it is incorporated in India or; if its place of effective management is in India. POEM has been defined to mean the place where key management decisions that are necessary for the conduct of the business of an entity as a whole are, in substance made. Until the introduction of POEM, foreign companies were characterized as being tax resident of India only on the satisfaction of the ‘control and management’ test, which required that the foreign company’s control and management be wholly situated in India.

i. Taxes Applicable to companies

Resident companies are taxed at the rate of 30%⁵², while non-resident companies are taxed at the rate of 40%. A minimum alternative tax is payable by resident, and in certain circumstances, non-resident companies at the rate of around 18.5%. The Indian Finance Minister in his budget speech in 2017 (“**Budget 2017**”) has proposed to reduce the corporate tax rate to 25% (as opposed to the current rate of 30%) for domestic companies whose total turnover or gross receipts does not exceed INR 500 million (approx. USD 7.4 million). For the remainder of the companies, the corporate tax rates continue to be 30%.

ii. Dividends

Dividends distributed by Indian companies are subject to a dividend distribution tax (“**DDT**”) at the rate of around 15% (calculated on a gross-up basis), payable by the company. However, except as stated immediately below, no further Indian taxes are payable by the shareholders on such dividend income once DDT is paid. Accordingly, there should be no withholding tax applicable on the payment of dividends to a non-resident.

Further tax at the rate of 10% is levied on dividends received from a domestic company, by a resident individual, HUF or firm, where the amount of dividend received exceeds INR 1 million.⁵³ Budget 2017 proposes to amend this provision by providing that this additional tax rate of 10% should be applicable to dividends received by all resident taxpayers except domestic companies, certain kinds of funds, institutions, trusts, educational institutions, hospital and medical institution as specified in the ITA. Dividends received from a domestic company by a non-resident company should

continue to be Indian tax exempt in the hands of the foreign company, provided that DDT has been paid by the distributing domestic company.

iii. Interest, Royalties and Fees for Technical Services

Interest payable to non-residents on loans taken/ debt securities issued in foreign currency are taxable at a beneficial rate of 5%.⁵⁴ However this benefit has a sunset clause stating that the benefits would only be available for loan agreements entered into/ bonds issued on or after July 1, 2012 and before July 1, 2017. The Budget 2017 has proposed to extend this benefit to Rupee Denominated Bonds (“**RDB**”) and extend the sunset clause to July 1, 2020. Similarly, interest payable to foreign portfolio investors (“**FPI**”) on investments made by them in RDBs and government securities is taxable at the rate of 5%.⁵⁵ Further, the Budget 2017 has proposed to amend the sunset clause for this benefit as well to state this it shall be applicable to bonds issued till July 1, 2020 as opposed July 1, 2017. Interest payable on majority of other circumstances not covered under the abovementioned benefits are taxable at a rate ranging from 20% to 40%.

Also as regards interest payments made by an Indian company to its associated enterprises/ related party⁵⁶, the Budget 2017 has proposed to introduce Thin Capitalization Rules as per which, interest payments exceeding 30% of the Earnings Before Interest, Taxes, Depreciation and Amortization (“**EBITDA**”) of the payer of interest shall not be deductible as an expense.

The withholding tax on royalties and fees for technical services earned by a non-resident is 10%. These rates are subject to available relief under an applicable tax treaty. In this context, it is important to note that the definition of royalties and fees for technical services under

52. All tax rates are applicable to Financial Year 2016-17 and are exclusive of surcharge and education cess.

53. Section 115BBDA, Income Tax Act, 1961

54. Section 194LC, Income Tax Act, 1961

55. Section 194LD, Income Tax Act, 1961

56. Section 92A, Income Tax Act, 1961 defines ‘associated enterprises.’

Indian domestic law is much wider than the definition under most tax treaties signed by India.

iv. Capital Gains

Gains earned by a resident company from the transfer of capital assets situated anywhere in the world are taxable in India. In the case of non-residents, only those gains arising out of the transfer of a capital asset in India should be taxable.⁵⁷ The tax treatment of capital gains depends mainly on whether the gains are short term or long term. Short term capital gains (“STCG”) arise upon the transfer of assets held by a taxpayer for a period of 36 months or less before the date of transfer (12 months or less in the case of securities listed on a recognized stock exchange in India, and 24 months in the case of unlisted shares of an Indian company). Long term capital gains (“LTCG”) arise upon the transfer of a capital asset held for a period of more than 36 months (12 months in the case of listed securities and 24 months in the case of unlisted shares of an Indian company).

Listed: STCGs arising from the transfer of a listed equity share are taxable at the beneficial rate of 15%,⁵⁸ while long term capital gains arising from the transfer of listed equity share are tax exempt under the ITA generally.⁵⁹ This is applicable to both residents and non-residents.

Unlisted: STCGs arising from transfer of unlisted securities are taxable at slab rates both in the hands of residents and non-residents. LTCGs arising out of unlisted securities are taxable at the rate of (i) 10% in the hands of a non-resident, (ii) 20% in the hands of a resident.⁶⁰

An Indian company would also be taxed at the rate of around 20% on gains arising to

shareholders from distributions made in the course of a buy-back or redemption of shares.

v. Withholding Taxes

Tax would have to be withheld at the applicable rate on all payments made to a non-resident, which are taxable in India. The obligation to withhold tax applies to both residents and non-residents. Withholding tax obligations may also arise with respect to specific payments made to residents and the failure to withhold tax could result in tax, interest and penal consequences.

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 medical device sector. The term “scientific research” 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 medical device industry, fiscal incentives are awarded to research and development units towards the development of new technology that adds medical benefits and for life-saving medical equipment.

i. In-House Research and Development

Companies that 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 medical device 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,

57. Having said that, India has recently introduced a rule to tax non-residents on the transfer of foreign securities the value of which are substantially (directly or indirectly) derived from assets situated in India.

58. Section 111A, Income Tax Act 1961.

59. Section 10(38), Income Tax Act, 1961.

60. Section 112, Income Tax Act, 1961.

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.

C. Potential Permanent Establishment Issues

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 Trust⁶¹, 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

61. 1983 144 ITR 146 AP

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.

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:

“(I) 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).”

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 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.

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 Balkrishna⁶², 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

62. [1960] 39 ITR 546 (SC)

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 Stores⁶³, 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 essential conditions 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.

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.

F. Indian Transfer Pricing Issues

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 establishment) which

63. (1977) 106 ITR 111 (AP)

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”.

The Budget 2017 has introduced the concept of secondary adjustment under the transfer pricing regulations.

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;

A challenge faced by Indian medical device 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.

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.

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 medical device industry. The Central Board of Direct Taxes has issued instructions⁶⁴ to the revenue department that the claim of any expense incurred in providing above mentioned or similar freebies in violation of the provisions of Indian Medical Council (Professional Conduct,

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

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 indirect tax structure and has recently introduced Goods and Services Tax (“GST”). Prior to the introduction of GST, it used to be the case that the Central Government levied taxes such as central excise, customs duties and service tax and the State Government levied taxes like Value Added Tax (Sales tax in states where VAT was not implemented), stamp duty and tax on professions. The GST has brought about a unification of the goods and services tax regime in the country and has replaced the aforementioned taxes barring certain duties on import of goods.

GST is meant to be a comprehensive tax on the manufacture, import, sale and consumption of goods as well as services, and replaces most major indirect taxes on goods and services. The tax system has taken the form of “Dual GST”, which is concurrently levied by the Central and State Government. This comprises of:

- Central GST (“CGST”) –levied by the Centre on intra-state supply of goods and services.
- State GST (“SGST”) –levied by each state on intra-state supply of goods and services in that state. A state also includes a Union Territory.
- Integrated GST (“IGST”) –to be levied by the Central Government on inter-State supply of goods and services.

Unlike the previous indirect tax regime, GST is applicable on a single taxable event at each stage, i.e., supply. Further, it is a destination based tax, i.e., it accrues to the State where the goods / services are consumed. The GST has been rolled out from July 1, 2017 with a tiered rate structure for tax on goods and services. Depending on the nature of medical devices, they will fall under the 5%, 12%, 18% and 28% tier as applicable.⁶⁵

65. Notification No.1/2017-Integrated Tax (Rate) <http://www.cbec.gov.in/resources/htdocs-cbec/gst/Notifica>

Interestingly, the GST has not brought about significant difference to the duty on import. The basic customs duty will remain in place along with Education cess, Anti-dumping Duty, Safeguard Duty, etc.⁶⁶ However Countervailing Duty (“CVD”) and Special Additional Duty (“SAD”) would be subsumed into the IGST, which would be levied on the imported goods. The duty on import of goods is discussed in some detail in the section below.

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.

tion%20for%20IGST%20rate%20Schedule-1.pdf (last accessed on August 1, 2017). The rates mentioned here apply to IGST.

66. Guidance note for importers and exporters <http://www.cbec.gov.in/resources/htdocs-cbec/guidnce-note-imprtrs-exprtrs.pdf> (as last accessed on August 1, 2017)

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.

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.

7. Conclusion

The Indian medical device industry continues its upward march of growth and is strongly supported by India's robust legal framework.

The Indian Government has identified the medical device industry as a focus industry for its flagship "Make in India" programme. Due to this, the government is especially committed to easing the processes and compliances for doing business of medical devices in India. This commitment was reflected in the government's decision to relax foreign direct investment restriction for companies engaged in manufacturing of medical devices in 2015. In 2016 and 2017, the Indian Government hosted a three day medical device conference that saw participation of top government functionaries, regulators and industry participants. There were several invite only events aptly titled CEO's roundtable where the leaders of the industry enjoyed direct access to the relevant government functionaries and regulators and could share their concerns within closed doors. There is also a proposal to launch new medical device parks in which government will provide fiscal and monetary incentives. This should give lot of confidence to potential stakeholders to consider the Indian medical device industry seriously.

Having said that, it is understandable that certain decisions of the government such as the recent notification to fix prices of coronary stents cannot be said to be exactly "industry friendly". However, as discussed earlier in the paper, the price control was triggered in case of coronary stents only because it was found to be an "essential" device by an expert committee.

All medical devices, other than those mentioned in Annexure D below, are completely outside the scope of price control. With respect to the singular event of price fixation of Coronary Stents, The government had several interactions with the importers and manufacturers of Coronary Stent and took their feedback into account before fixing the price. Thus, it appears that the government sought to be restrained and transparent in its approach. Also, it is still possible for importers and manufacturers of Coronary Stents to increase their current margins by structuring their business model or by using the available relaxations as discussed in the body of this paper.

Lastly, with the introduction of the Medical Device Rules, 2017, the medical device industry in India is certain to receive a fillip.

Therefore, the medical devices industry in India continues to offer unparalleled opportunities to present and potential stake holders, now more than ever before.

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
15. Ablation Devices

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

Annexure B

Labeling Requirements for medical devices

- i. Proper name of the medical device;
- ii. The details necessary for the user to identify the device and its use;
- iii. The name of the manufacturer and address of the manufacturing premises where the device has been manufactured;
- iv. 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;
- v. Date of manufacture and date of expiry;
- vi. Indication that the device contains medicinal or biological substances, where necessary;
- vii. Batch number or lot number;
- viii. Special storage and handling conditions, where required;
- ix. Indication if the product is a sterile product, its sterile state and sterilization method;
- x. Warnings or precautions where required;
- xi. To label the device, if the device is intended for single use;
- xii. To overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;
- xiii. 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;
- xiv. To provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L.";
- xv. 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.¹

Annexure C

Labeling requirements for medical devices intended for export

- i. name of the Device;
- ii. distinctive batch number or lot number preceded by the word “Lot No.” or “Lot” or “Batch No.” or “B. No.”;
- iii. date of expiry, if any;
- iv. name and address of the manufacturer and address of actual premises where the device has been manufactured
- v. manufacturing Licence No. preceded by the letters “M.L. No.” or “Manufacturing Licence No.”;
- vi. internationally recognised symbols in lieu of text, wherever required

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
15. Ablation Devices

Annexure E

First Schedule

[See rule 4]

Parameters for classification of medical devices and *in vitro* diagnostic medical devices

Part I

Parameters for classification of medical devices other than *in vitro* diagnostic medical devices

Basic Principles for classification.

- i. Application of the classification provisions shall be governed by the intended purpose of the device.
 - ii. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
 - iii. Software, which drives a device or influences the use of a device, falls automatically in the same class.
 - iv. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.
 - v. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.
- i. Parameters for classification of medical devices.
- i. Non-invasive medical devices which come into contact with injured skin.**
 - a. A non-invasive medical device which comes into contact with injured skin shall be assigned to Class A, if it is intended to be used as a mechanical barrier, for compression or

for absorption of exudates only, for wounds which have not breached the dermis and can heal by primary intention;

- b. Subject to clause (c), a non-invasive medical device which comes into contact with injured skin shall be assigned to Class B, if it is intended to be used principally with wounds which have breached the dermis, or is principally intended for the management of the microenvironment of a wound;
- c. a non-invasive medical device which comes into contact with injured skin shall be assigned to Class C, if it is intended to be used principally with wounds which have breached the dermis and cannot heal by primary intention.

ii. Non-invasive medical devices for channeling or storing substances.

- a. Subject to clauses (b) and (c), a non-invasive medical device shall be assigned to Class A, if it is intended for channeling or storing body liquids or tissues or liquids or gases for the purpose of eventual infusion, administration or introduction into a human body;
- b. A non-invasive medical device referred to in clause (a) shall be assigned to Class B, if it is intended to be connected to an active medical device which is in Class B, C or D or for channeling blood or storing or channeling other body liquids or storing organs, parts of organs or body tissues:

Provided, that the circumstances when a non-invasive medical device is connected to an active medical device include circumstances where the safety and performance of the active medical device is influenced by the non-invasive medical device, or vice versa; or

- c. A non-invasive medical device referred to in clause (a) shall be assigned to Class C,

if it is a blood bag that does not incorporate a medicinal product.

iii. Non-invasive medical devices for modifying compositions of substances.

- a. Subject to clause (b), a non-invasive medical device shall be assigned to Class C, if it is intended for modifying the biological or the chemical composition of blood or other body liquids or other liquids intended for infusion into the body.
- b. A non-invasive medical device as referred to in clause (a) shall be assigned to Class B, if the intended modification is carried out by filtration, centrifuging or any exchange of gas or of heat.

iv. Other non-invasive medical devices.

A non-invasive medical device to which sub-paragraphs (i), (ii) and (iii) do not apply shall be assigned to

Class A, if it does not come into contact with a person or comes into contact with intact skin only.

v. Invasive (body orifice) medical devices for transient use.

- a. Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class A, if,-
 - 1. it is intended for transient use; and
 - 2. it is not intended to be connected to an active medical device; or
 - 3. it is intended to be connected to a Class A medical device only.
- b. An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class B, if,-
 - 1. it is intended for use on the external surface of an eyeball; or
 - 2. it is liable to be absorbed by the mucous membrane.

vi. Invasive (body orifice) medical devices for short term use.

- a. Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class B, if,-
 - 1. it is intended for short term use; and
 - 2. it is not intended to be connected to an active medical device; or
 - 3. it is intended to be connected to a Class A medical device only.
- b. An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class A, if,-
 - 1. it is intended for use in an oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and
 - 2. it is not liable to be absorbed by the mucous membrane.

vii. Invasive (body orifice) medical devices for long term use.

- a. Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class C, if it is intended for long term use and, not intended to be connected to an active medical device or it is to be connected to a Class A medical device only.
- b. An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class B, if,-
 - 1. it is intended for use in an oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and
 - 2. it is not liable to be absorbed by the mucous membrane.

viii. Invasive (body orifice) medical devices for connection to active medical devices.

An invasive (body orifice) medical device shall be assigned to Class B, regardless of the duration of its use, if it is intended to be connected to an active medical device which is in Class B, C or D.

ix. Surgically invasive medical devices for transient use.

- a. Subject to clauses (b) to (g), a surgically invasive medical device intended for transient use shall be assigned to Class B.
- b. Subject to clauses (c) to (g), a transient use surgically invasive medical device shall be assigned to Class A, if it is a reusable surgical instrument.
- c. A transient use surgically invasive medical device shall be assigned to the same class as the active medical device to which it is intended to be connected.
- d. A transient use surgically invasive medical device shall be assigned to Class C, if it is intended for the supply of energy in the form of ionising radiation.
- e. A transient use surgically invasive medical device shall be assigned to Class C, if it is intended to have a biological effect or to be wholly or mainly absorbed by the human body.
- f. A transient use surgically invasive medical device shall be assigned to Class C, if it is intended for the administration of any medicinal product by means of a delivery system and such administration is done in a manner that is potentially hazardous.
- g. A transient use surgically invasive medical device shall be assigned to Class D, if it is intended to be used specifically in direct contact with the central nervous system or for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

x. Surgically invasive medical devices for short term use.

- a. Subject to clause (b), (d) and (e), a surgically invasive medical device intended for short term use shall be assigned to Class B.
- b. Subject to clause (c), a short term use surgically invasive medical device shall

be assigned to Class C, if it is intended to undergo a chemical change in the body.

- c. A short term use surgically invasive medical device referred to in clause (b) shall be assigned to Class B, if it is intended to be placed into any tooth.
- d. A short term use surgically invasive medical device shall be assigned to Class C, if it is intended for the administration of any medicinal product or the supply of energy in the form of ionising radiation.
- e. A short term use surgically invasive medical device shall be assigned to Class D, if it is intended to have a biological effect or to be wholly or mainly absorbed by the human body or to be used specifically in direct contact with the central nervous system or for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

xi. Implantable medical devices and surgically invasive medical devices for long term use.

- a. Subject to clauses (b), (c) and (d), an implantable medical device or a surgically invasive medical device intended for long term use shall be assigned to Class C.
- b. A long term use medical device shall be assigned to Class B, if it is intended to be placed into any tooth.
- c. A long term use medical device shall be assigned to Class D, if it is intended,-
 1. to be used in direct contact with the heart, the central circulatory system or the central nervous system;
 2. to be life supporting or life sustaining;
 3. to be an active medical device;
 4. to be wholly or mainly absorbed by the human body;
 5. for the administration of any medicinal product; or
 6. to be a breast implant.

d. Subject to clause (b), a long term use medical device shall be assigned to Class D, if it is intended to undergo chemical change in the body.

xii. Active therapeutic medical devices for administering or exchanging energy.

- a. Subject to clause (b), an active therapeutic medical device shall be assigned to Class B, if it is intended for the administration or exchange of energy to or with a human body.
- b. An active therapeutic medical device referred to in (a) shall be assigned to Class C, if the administration or exchange of energy may be done in a potentially hazardous way (such as through the emission of ionizing radiation), taking into account the nature, density and site of application of the energy and the type of technology involved.
- c. An active therapeutic medical device shall be assigned to Class C, if it is intended for the control or monitoring, or to be used to directly influence the performance, of a Class C active therapeutic device.

xiii. Active diagnostic medical devices.

- a. Subject to clauses (b) and (c), an active diagnostic medical device shall be assigned to Class B, if it is intended,
 - 1. to be used to supply energy which will be absorbed by the human body;
 - 2. to be used to capture any image of the in vivo distribution of radiopharmaceuticals; or
 - 3. for the direct diagnosis or monitoring of vital physiological processes.
- b. An active diagnostic medical device referred to in sub-clause (1) of clause (a) shall be assigned to Class A, if it is intended to be used solely to illuminate a patient's body with light in the visible or near infrared spectrum.

c. An active diagnostic medical device referred to in clause (a) shall be assigned to Class C, if it is intended specifically for,-

- 1. the monitoring of vital physiological parameters, where the nature of any variation is such that it could result in immediate danger to the patient (such as any variation in cardiac performance, respiration or activity of the central nervous system); or
 - 2. diagnosing in a clinical situation where the patient is in immediate danger.
- d. An active diagnostic medical device shall be assigned to Class C, if it is intended for the emission of ionising radiation and to be used in diagnostic or interventional radiology.
 - e. An active diagnostic medical device shall be assigned to Class C, if it is intended for the control or monitoring, or to be used to directly influence the performance, of any active diagnostic medical device referred to in clause (d).
 - f. Subject to clause (g), an active medical device shall be assigned to Class B, if it is intended for the administration, or removal of, any medicinal product, body liquid or other substance to or from a human body.
 - g. An active medical device referred to in clause (f) shall be assigned to Class C, if the administration or removal of the medicinal product, body liquid or other substance is done in a manner that is potentially hazardous, taking into account,
 - 1. the nature of the medicinal product, body liquid or substance;
 - 2. the part of the body concerned; and
 - 3. the mode and route of the administration or removal.

xiv. Other active medical devices.

An active medical device to which provisions of sub-paragraphs (xii) and (xiii) do not apply shall be assigned to Class A.

xv. Medical devices incorporating medicinal products.

- a. Subject to clause (b), a medical device shall be assigned to Class D, if it incorporates as an integral part a substance which,
 1. if used separately, may be considered to be a medicinal product; and
 2. is liable to act on a human body with an action ancillary to that of the medical device.
- b. A medical device referred to in clause (a) shall be assigned to Class B, if the incorporated substance is a medicinal product exempted from the licensing requirements of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder.

xvi. Medical devices incorporating animal or human cells, tissues or derivatives.

- a. Subject to clause (b), a medical device shall be assigned to Class D, if it is manufactured from or incorporates,
 1. cells, tissues or derivatives of cells or tissues, or any combination thereof, of animal or human origin, which are or have been rendered non-viable; or
 2. cells, tissues or derivatives of cells or tissues, or any combination thereof, of microbial or recombinant origin.
- b. A medical device referred to in clause (a) shall be assigned to Class A, if it is manufactured from or incorporates non-viable animal tissues, or their derivatives, that come in contact with intact skin only.

xvii Medical devices for sterilization or disinfection.

- a. Subject to clause (b), a medical device shall be assigned to Class C, if it is intended to be used specifically for,
 1. the sterilization of any other medical device;

2. the end-point disinfection of any other medical device; or

3. the disinfection, cleaning, rinsing or hydration of contact lenses.

- b. A medical device shall be assigned to Class B, if it is intended for the disinfection of any other medical device before the latter is sterilized or undergoes end-point disinfection:

Provided, that “end-point disinfection” means the disinfection of a medical device immediately before its use by or on a patient.

xviii. Medical devices for contraceptive use.

- a. Subject to clause (b), a medical device intended to be used for contraception or the prevention of the transmission of any sexually transmitted disease shall be assigned to Class C.
- b. A medical device referred to in clause (a) shall be assigned to Class D, if it is an implantable medical device or an invasive medical device intended for long term use.

Part II**Parameters for classification for *in vitro* diagnostic medical devices**

1. Basic principles for classification of *in vitro* diagnostic medical devices:
 - a. Application of the classification provisions shall be governed by the intended purpose of the devices.
 - b. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
 - c. Software, which drives a device or influences the use of a device, falls automatically in the same class.
 - d. Standalone software, which are not incorporated into the medical device

itself and provide an analysis based on the results from the analyser, shall be classified in to the same category that of the *in vitro* diagnostic medical device where it controls or influences the intended output of a separate *in vitro* diagnostic medical device.

- e. Subject to the clause (c) and (d), software that is not incorporated in an *in vitro* diagnostic medical device, shall be classified using the classification provisions as specified in paragraph 2.
 - f. Calibrators intended to be used with a reagent should be treated in the same class as the *in vitro* diagnostic medical device reagent.
 - g. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the stringent rules resulting in the higher classification shall apply.
2. The parameters for classification of *in vitro* diagnostic medical devices as follows:-
- i. In vitro diagnostic medical devices for detecting transmissible agents, etc.:**
 - a. An *in vitro* diagnostic medical device shall be assigned to Class D, if it is intended to be used for detecting the presence of, or exposure to, a transmissible agent that-
 - i. is in any blood, blood component, blood derivative, cell, tissue or organ, in order to assess the suitability of the blood, blood component, blood derivative, cell, tissue or organ, as the case may be, for transfusion or transplantation; or
 2. causes a life-threatening disease with a high risk of propagation.
 - b. An *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended for use in-
 1. detecting the presence of, or exposure to, a sexually transmitted agent;
 2. detecting the presence in cerebrospinal

fluid or blood of an infectious agent with a risk of limited propagation (for example, *Cryptococcus neoformans* or *Neisseria meningitidis*);

3. detecting the presence of an infectious agent, where there is a significant risk that an erroneous result will cause death or severe disability to the individual or foetus being tested (for example, a diagnostic assay for *Chlamydia pneumoniae*, *Cytomegalovirus* or Methicillin-resistant *Staphylococcus aureus*);
4. pre-natal screening of women in order to determine their immune status towards transmissible agents such as immune status tests for *Rubella* or *Toxoplasmosis*;
5. determining infective disease status or immune status, where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient being tested (for example, *Cytomegalovirus*, *Enterovirus* or *Herpes simplex virus* in transplant patients);
6. screening for disease stages, for the selection of patients for selective therapy and management, or in the diagnosis of cancer;

ii. In vitro diagnostic medical devices for self-testing:

- a. Subject to clause (b), an *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended to be used for self-testing.
- b. An *in vitro* diagnostic medical device referred to in clause (a) shall be assigned to Class B, if it is intended to be used to obtain,
 1. test results that are not for the determination of a medically-critical status; or
 2. preliminary test results which require confirmation by appropriate laboratory tests.

iii. In vitro diagnostic medical devices for near-patient testing:

An *in vitro* diagnostic medical device shall be assigned to Class C, if it is to be used for near-patient testing in a blood gas analysis or a blood glucose determination.

Illustration: Anticoagulant monitoring, diabetes management, and testing for C-reactive protein and *Helicobacter pylori*.

iv. In vitro diagnostic medical devices used in in vitro diagnostic procedures:

An *in vitro* diagnostic medical device shall be assigned to Class A:

1. if it is a reagent or an article which possesses any specific characteristic that is intended by its product owner to make it suitable for an *in vitro* diagnostic procedure related to a specific examination;
2. an instrument intended specifically to be used for an *in vitro* diagnostic procedure; or
3. a specimen receptacle.

v. Other in vitro diagnostic medical devices:

- a. An *in vitro* diagnostic medical device shall be assigned to Class B, if sub-paragraphs (i) to (v) of paragraph 2 do not apply to it; or
- b. It is a substance or device used for the assessment of the performance of an analytical procedure or a part thereof, without a quantitative or qualitative assigned value.
 1. human genetic testing, such as the testing for cystic fibrosis or Huntington's disease;

2. monitoring levels of medicinal products, substances or biological components, where there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient being tested (*for example*, cardiac markers, cyclosporin or prothrombin time testing);
3. management of patients suffering from a life-threatening infectious disease such as viral load of *Human immunodeficiency virus* or *Hepatitis C virus*, or genotyping and sub-typing *Hepatitis C virus* or *Human immunodeficiency virus*; or
4. screening for congenital disorders in the foetus such as Down's syndrome or spina bifida.

vi. In vitro diagnostic medical devices for blood grouping or tissue typing:

- a. Subject to clause (b), an *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of any blood, blood component, blood derivative, cell, tissue or organ that is intended for transfusion or transplantation, as the case may be.
- b. An *in vitro* diagnostic medical device referred to in clause (a) shall be assigned to Class D, if it is intended to be used for blood grouping or tissue typing according to the ABO system, the, the Duffy system, the Kell system, the Kidd system, the rhesus system (for example, HLA, Anti-Duffy, Anti-Kidd).

About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. We provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner.

As a firm of specialists, we work with select clients in select verticals on very complex and innovative transactions and disputes.

Our forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and Medical Devices and Nanotechnology.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automobile, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprise marquee Fortune 500 corporations.

Our ability to innovate is endorsed through the numerous accolades gained over the years and we are also commended by industry peers for our inventive excellence that inspires others.

NDA was ranked the 'Most Innovative Asia Pacific Law Firm in 2016' by the *Financial Times - RSG Consulting Group* in its prestigious FT Innovative Lawyers Asia-Pacific 2016 Awards. While this recognition marks NDA's ingress as an innovator among the globe's best law firms, NDA has previously won the award for the 'Most Innovative Indian Law Firm' for two consecutive years in 2014 and 2015.

As a research-centric firm, we strongly believe in constant knowledge expansion enabled through our dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs. Our constant output through Webinars, Nishith.TV and 'Hotlines' also serves as effective platforms for cross pollination of ideas and latest trends.

Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has been developed into a global case study and published by John Wiley & Sons, USA in a feature titled 'Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage' in the September 2009 issue of *Global Business and Organizational Excellence (GBOE)*.

A brief below chronicles our firm's global acclaim for its achievements and prowess through the years.

- IDEX Legal Awards: In 2015, NDA won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm" <<http://idexlegalawards.in/ArticlePage.aspx?aid=6>>. Nishith Desai was also recognized as the 'Managing Partner of the Year' in 2014.
- Merger Market: has recognized NDA as the fastest growing M&A law firm in India for the year 2015.
- Legal 500 has ranked us in tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014, 2017)

- International Financial Law Review (a Euromoney publication) in its IFLR1000 has placed Nishith Desai Associates in Tier 1 for Private Equity (2014, 2017). For three consecutive years, IFLR recognized us as the Indian “Firm of the Year” (2010-2013) for our Technology - Media - Telecom (TMT) practice.
- Chambers and Partners has ranked us # 1 for Tax and Technology-Media-Telecom (2014, 2015, 2017); #1 in Employment Law (2015 & 2017); # 1 in Tax, TMT and Private Equity (2013, 2017); and # 1 for Tax, TMT and Real Estate – FDI (2011).
- India Business Law Journal (IBLJ) has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015
- Legal Era recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013).

Please see the last page of this paper for the most recent research papers by our experts.

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Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *NDA Insights* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction.

We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports.

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