

The Indian Medical Device Industry

Regulatory, Legal and Tax Overview

November 2018

The Indian Medical Device Industry

Regulatory, Legal and Tax Overview

November 2018

ndaconnect@nishithdesai.com

Contents

EXECUTIVE SUMMARY	01
1. INTRODUCTION	03
2. INDIA ENTRY STRATEGIES	05
3. INVESTMENT CLIMATE IN INDIA	06
4. INDIA'S POST-TRIPS INTELLECTUAL PROPERTY ENVIRONMENT	07
5. LEGAL AND REGULATORY REGIME	08
I. Authorities	08
II. Licenses Required for Import, Sale, Manufacture and Loan of Medical Devices Under the Mdr	11
III. Manufacturing a Notified Medical Device in India	12
IV. Importing a Notified Medical Device into India	13
V. Manufacture/Import of an Investigational Medical Device	13
VI. Clinical Investigation	14
VII. Product Standards	14
VIII. Labeling	15
IX. Quality Management System (Qms)	16
X. Penalties	16
XI. Export – Import Restrictions	16
XII. Advertising and Sales Promotion	16
XIII. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954	17
XIV. The Competition Act, 2002	17
XV. Patent Protection	18
XVI. Data Exclusivity	19
XVII. Trademarks	20
XVIII. Government Control Over Prices of Medical Devices	20
XIX. Medical Device Rules, 2017 - Salient Features	21
6. TAXATION REGIME	30
I. Direct Taxes	30
ii. Indirect Taxes	38
7. RECENT DEVELOPMENTS	40
8. CONCLUSION- TWO STEPS FORWARD, ONE STEP BACKWARD?	41

ANNEXURE A	42
List of Notified Medical Devices	42
ANNEXURE B	43
Labeling Requirements for Notified Medical Devices to be marketed in India under MDR	43
ANNEXURE C	45
Labeling requirements for Notified Medical Devices intended for export	45
ANNEXURE D	46
Parameters for classification of medical devices and in vitro diagnostic medical devices	46

Executive Summary

The medical device industry in India is presently valued at USD 5.2 Billion and is growing at 15.8% CAGR.¹ Currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea² and is poised to grow to USD 50 billion by 2025 as per some industry estimates.³

The medical device market is dominated by imported products, which comprise of around 80% of total sales.⁴ 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.

The Indian medical device market offers a great opportunity not only of its size, but also because of encouraging policies and regulations that the Government has introduced to give a fillip to the medical device industry. For instance, the government has overhauled the regulatory framework for medical device in 2017 and has brought it at par with international norms by introducing the concept of 'risk-based' regulation. The regulatory licenses issued for import, manufacture or sale of medical devices have been made perpetual in nature to cut down on unnecessary and time-consuming paper-work, in a bid to increase ease of doing business in India. Foreign direct investment in medical device manufacturing sector is permitted without any prior approval from the government, allowing business to quickly

scale-up existing operations by infusing capital or engage in time-sensitive strategic acquisitions. The already robust intellectual property rights regime in India has been strengthened further by tweaking of rules for grant of patent and trade mark in the last two years. The Indian Government has also introduced various fiscal measures to promote research, development, manufacturing and import of medical devices. For instance, the Government has incentivized scientific research and development by providing weighted deduction for the expense incurred on that front. There is minimal or no import duty on certain medical devices.

However, like any other country, there are certain challenges in doing business of medical devices in India that must be borne in mind. The first and foremost challenge is price control. The Government of India controls prices of certain medical devices by either fixing a price at which they may be sold under a formula or by restricting the ability of the marketer of the medical device to increase its price by more than a prescribed percentage at any given time. The second challenge is the presence of multiple regulators which may make simple tasks, such as rectification of erroneous declaration on the label, quite a tumultuous affair. The third challenge is presence of archaic laws that do not permit manufactures and importers of medical device to promote their product directly to the customer as cures for certain prescribed conditions and illnesses. All these challenges, and many more, are detailed in the body of this research paper.

1. <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices> (last accessed: February 27, 2018).
2. <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices> (last accessed: February 27, 2018).
3. <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices> (last accessed: February 27, 2018).
4. <https://timesofindia.indiatimes.com/business/india-business/80-medical-equipment-imported-doctors-say/articleshow/56081617.cms> (last accessed: February 27, 2018).

One must also not lose sight of the fact that 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.

Having said that, the Government remains extremely committed and sensitive to the demands of the industry, and, in fact, has earmarked medical device industry as a “sun-shine” sector. It is hoped that this research paper will act as a guide to everyone who is interested in doing business of medical device in India.

1. Introduction

The approximate USD 5.2 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 80% 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, 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 15.8% 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 9712 Crore (approx. USD 1.5 Billion) between 2000 and December 2017.⁵ In 2014 and 2015, the FDI inflow were 133.96 Million and 160.24 Million respectively.⁶ The FDI inflows jumped by almost 300% in 2016 to USD 439.01 Million.⁷

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,

5. Department of Industrial Policy and Promotion, Fact sheet on Foreign Direct Investment (FDI) from April, 2000 to December, 2017, available on: http://dipp.nic.in/sites/default/files/FDI_FactSheet_21February2018.pdf (last accessed: February 27, 2018).

6. Department of Industrial Policy and Promotion, Statement on sector-wise / year-wise FDI equity inflows from January, 2000 to September, 2017, available on: http://dipp.nic.in/sites/default/files/Table%20No%204_oct2017.pdf (last accessed: February 27, 2018).

7. Department of Industrial Policy and Promotion, Statement on sector-wise / year-wise FDI equity inflows from January, 2000 to September, 2017, available on: http://dipp.nic.in/sites/default/files/Table%20No%204_oct2017.pdf (last accessed: February 27, 2018).

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 (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 industry 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 has to come into effect from January 1, 2018, is expected to fill the legislative void that is currently present due to the absence of a medical device specific legislation in India. This aspect is discussed in detail in India under the chapter on Legal and Regulatory Regime.

All 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:

To be aware of the legal and regulatory framework is another must. Medical device industry is tightly regulated, and any non-compliance may result in penalty as well as

Strategy	Law	Tax
<ul style="list-style-type: none"> ■ Observing the economic and political environment in India from the perspective of the investment ■ 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 ■ To strategize the business model by identifying the correct modality to do business in India 	<ul style="list-style-type: none"> ■ <i>Exchange Control Laws:</i> Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same ■ <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>Sector Specific Laws:</i> Drugs & Cosmetics Act, 1940, the Drugs & Cosmetics Rules, 1945, the Medical Device Rules, 2017, the Patents Act, 1970 and other legislations, regulations and guidelines that affect the medical devices industry 	<ul style="list-style-type: none"> ■ <i>Domestic Taxation Laws:</i> The Income Tax Act, 1961; Goods and Service Tax, customs, and value added tax. ■ <i>International Tax Treaties:</i> Treaties with favorable jurisdictions such as Mauritius, Cyprus, Singapore and the Netherlands

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.

criminal prosecution of the management in extreme cases. 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. Multi-national companies should also keep an eye on the exchange control laws as they govern how profits made by the company can be realized out of India. Lastly, for such companies, if the investment is structured through favorable tax jurisdictions, it may lead to significant tax-savings.

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 government (“**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;

- a. 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 specifically for human beings or animals for one or more of the specific purposes of –
 - i. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
 - ii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

- iii. Investigation, replacement or modification or support of the anatomy or of a physiological process;
- iv. Supporting or sustaining life;
- v. Disinfection of medical devices;
- vi. Control of conception,

And which does not achieve 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;

- b. An accessory to such an instrument, apparatus, appliance, material or other article;
- c. In-vitro diagnostic device which is a 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 examination of specimens derived from the human bodies or animals.⁸

8. Department of Industrial Policy and Promotion; Press Note 1 (2018); January 23, 2018

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

The Medical Device Rules, 2017 (“MDR”), issued under the Drugs and Cosmetics Act, 1940 (“DCA”), regulate the following categories of substances –

- 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 DCA. Some categories of devices have already been notified by the government.
- b. Specific substances intended to affect the structure or any function of the human body which are notified by the government under the DCA. At present, the substances notified are mechanical contraceptives (eg. condoms, intra-uterine devices, tubal rings), insecticides 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.

The devices mentioned in (a) and (b) which have been notified by the Government and are covered in **Annexure A** and are popularly referred to as “**Notified Medical Devices**”. However, since the MDR apply to all substances covered under (a) - (d), for the purpose of this paper, any reference to Notified Medical Devices should be read to apply to all substances covered under (a) – (d).

Medical devices are categorized into one of four classes under the MDR – on the basis of increasing risk from Class A to Class D.

The DCA and MDR 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.

- It is important to note there that the government has been selective in regulation of medical devices. In other words, until a device has been notified by the government under the DCA and MDR, it will not be regulated by the MDR. This has been clarified by the Central Licensing Authority as well. However, it will do good to medical device companies who are in the business of unregulated devices to remain updated about the list of Notified Medical Devices. The government has the power to notify new devices and substances. Upon such notification, the said devices and substances will also be regulated by the DCA and the MDR.

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 division of responsibilities under the MDR between the central and state authorities are captured below:

A. DCGI (Central Licensing Authority)

Apart from co-ordination with state licensing authorities, the DCGI is responsible for handling matters of:

- a. import of all Classes of medical devices;
- b. manufacture of Classes C and D devices;
- c. clinical investigation and approval of investigational medical devices; and
- d. clinical performance evaluation and approval of new in vitro diagnostic devices.

B. State Drug Controller (State Licensing Authority)

The State Drug Controller (by whatever name called) is responsible for handling matters of:

- a. manufacture (for sale or distribution) of classes A and B devices;
- b. licensing for sale, stocking, exhibition or offer for sale or distribution of medical devices of all classes

The MDR has also introduced two new bodies – the National Accreditation Body and Notified Bodies.

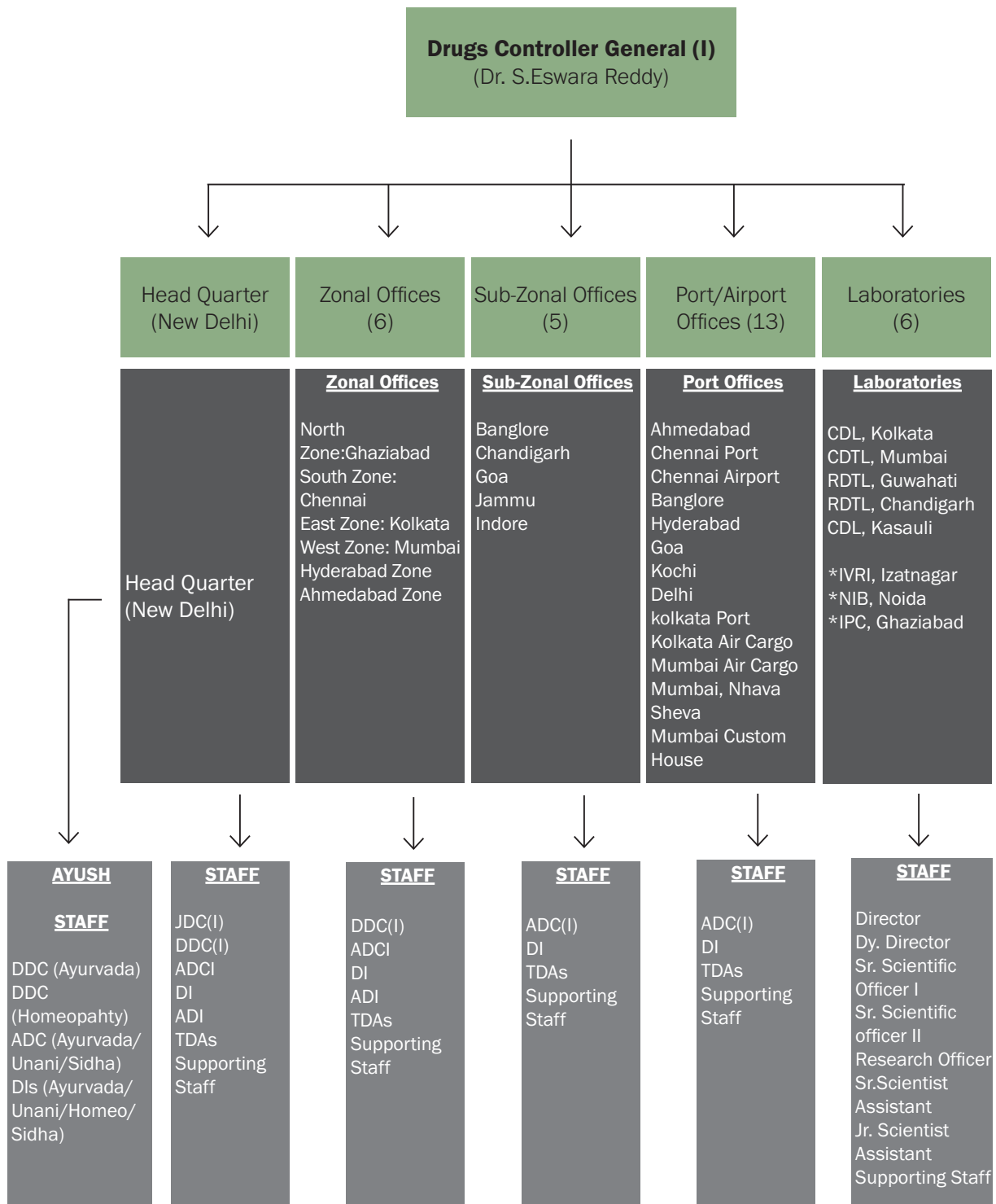
A notified body is responsible for carrying out audits of manufacturing sites of all classes of medical devices, to verify conformance with the Quality Management System (discussed later). An entity with the relevant experience and qualification as prescribed under the MDR can apply to the Central Licensing Authority for appointment as a notified body.

The National Accreditation Body is an entity notified by the Central Government, which fulfils certain criteria specified by the government from time to time. Until such time a National Accreditation Body is notified, the Quality Council of India shall act as the National Accreditation Body and carry out the functions as prescribed under the MDR.

The National Accreditation Body lays down standards and procedures for accreditation, and also assesses entities seeking accreditation as a notified body. The Body is also responsible for carrying out periodic audits of notified bodies, to assess conformance with the standards prescribed.

Orgazizational structure of the Central Drugs Standard Control Organisation (CDSCO)

Organisation Chart Central Drugs Standard Control Organisation



Abbreviations: CDSCO- Central Drugs Standard Control Organisation; CDL- Central Drug Laboratories; CDTL- Central Drugs Testing Laboratories; RDTL- Regional Drug Testing Laboratories; IVRI- Indian Veterinary Research Institute; NIB- National Institute of Biologicals; IPC- Indian Pharmacopoeia; JDC(I) Joint Drugs Controller India DDC(I) - Deputy Drugs Controller India ; ADC(I)- Asst. Drugs Controller India;

*Source: <http://www.cdsc0.nic.in/forms/list.aspx?lid=2121&ld=0>

II. Licenses Required for Import, Sale, Manufacture and Loan of Medical Devices Under the MDR

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 MDR 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)
Import of Notified Medical Devices	Form MD-15	Form MD-14	Rule 36(1)	Central Licensing Authority	9 months
Import of Notified Medical Devices for clinical investigation	Form MD-17	Form MD-16	Rule 41(1)	Central Licensing Authority	30 days
Permission to import new Notified Medical Device for clinical trial or marketing	Form MD-29	Form MD-28	Rule 64(2)	Central Licensing Authority	90 days
Permission to conduct clinical investigation	Form MD-25 Form MD-23	Form MD-24 Form MD-22	Rule 59(5) Rule 52(1)	Central Licensing Authority	90 days
Permission to import or manufacture medical device that does not have a predicate device	Form MD-27	Form MD-26	Rule 63(2)	Central Licensing Authority	120 days
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)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture Notified Medical Devices	Form MD-5 for Class A or Class B Form MD-9 for Class C or Class D	Form MD-3 for Class A or Class B Form MD-7 for Class C or Class D	Rule 20(4) and 20(6) for Class A or Class B Rule 25(1) for Class C or Class D	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority for Classes C and D devices	45 days from the date of application
License to manufacture a Notified Medical Device for Clinical investigation	Form MD-13	Form MD-12	Rule 31(3)	Central Licensing Authority	30 days
Loan License (manufacture in facility owned by third party)	Form MD-6 for Class A or Class B Form MD-10 for Class C or Class D	Form MD-4 for Class A or Class B Form MD-8 for Class C or Class D	Rule 20(4) and Rule 20 (6) for Class A or Class B Rule 25(1) for Class C or Class D	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority for Classes C and D devices	45 days

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.

The license for manufacturing a Class A or B device is issued by the State Licensing Authority, while the licensing to manufacture a Class C or D device is issued by the Central Licensing Authority.

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

IV. Importing a Notified Medical Device into India

Importing a medical device into India requires satisfaction of few additional legal requirements than those indicated above. The import of all products in India, including medical devices, is governed under the provisions of the Export and Import Policy. Before importing device into India, the importer is required to obtain Importer and Exporter Code (“IEC”) Number from the office of the Director General of Foreign Trade (“DGFT”). The IEC Number would be required to be mentioned in the documents filed with Customs for clearance of imported goods. For obtaining the IEC Number, an application in the prescribed form has to be submitted to the office of the jurisdictional Joint Director of Foreign Trade, wherein details of Bank Account Number and Permanent Account Number have to be furnished

Under the Act, the activity of import of Notified Medical Devices into India requires an import license from the office of the Drugs Controller General of India. 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 MDR or its authorized agent in India, either having a valid license under the MDR 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 an import license. The authorization by a manufacturer to its agent in India must be documented by a power of attorney.

Other documentation related requirements for import, which varies based on the class of medical device intended to be imported, including:

- Free Sale Certificate in country of origin issued by the National Regulatory Authority or equivalent competent authority
- Notarized copy of Quality Management System certificate/Full Quality Assurance certificate/Production Quality Assurance certificate issued by the competent authority, in respect of the manufacturing site
- Copy of latest inspection or audit report carried out by Notified Body/National Regulatory Authority or other competent authority within the last three years, if any.

V. Manufacture/Import of an Investigational Medical Device

Under the MDR, an investigational medical device is defined as a device which does not have its predicate device, or one which after being licensed for marketing, claims new intended use or new population or new material or major design change. A predicate device is defined as a device, first time and first of its kind, approved for manufacture for sale or import by the Central Licensing Authority and has similar intended use, material of construction, and design characteristics as the device which is proposed to be licensed in India.

The MDR mandates that, in addition to a license to manufacture or import the investigational medical device, the interested manufacturer/importer will have to obtain a permission to market the device in India from the Central Licensing Authority. The said permission will be given by the Central Licensing Authority only after review of clinical data establishing safety, performance or effectiveness of the device.

The catch here is that the clinical data has to be generated after undertaking clinical investigation in the manner prescribed by the MDR, which is discussed in the next paragraphs.

VI. Clinical Investigation

Clinical investigation refers to systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness.

The MDR make it mandatory to undertake clinical investigation of the Notified Medical Devices in the following situations:

1. When the device is an investigational medical device
2. When the device is imported from countries other than Australia, Canada, Japan, EU Countries or USA, thereby rendering it impossible for the importer to produce a free sale certificate from the national regulatory authority of one of the said countries. Though the above requirement applies to all classes of Notified Medical Devices (i.e. Class A, B, C and D), importers of Class A and Class B medical devices need not undertake clinical investigation in India. They have an option to submit published safety and performance data and a free sale certificate from the country of origin in lieu of undertaking clinical investigation in India.

The MDR envisages manufacturer and importers to undertake two types of clinical investigations - pilot clinical investigations and pivotal clinical investigations. Pilot clinical investigation is defined as those clinical investigations which are used to acquire specific essential information about a device before beginning the pivotal clinical investigation. A pivotal clinical investigation is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use.

The major distinction between the two types of investigations is that a pilot clinical investigation is an exploratory study, which may be conducted in a few numbers of patients with the disease or condition being studied, that gives insight into the performance and safety of a device but cannot provide definitive

support for specific mechanistic or therapeutic claims. On the other hand, a pivotal study is a confirmatory study which may be conducted in large number of patients with disease or condition being studied and scope to provide the effectiveness and adverse effects.

For investigational medical device developed in India, both types of clinical investigations are required to be carried out in India. For investigational medical devices developed and studied in country other than India, pilot clinical Investigation need not be undertaken in India provided it has already been undertaken and relevant clinical study data is submitted to the Central Licensing Authority. After submission of such data generated outside India to the Central Licensing Authority, permission may be granted to repeat pilot study or to conduct pivotal clinical investigation. Pivotal clinical investigation is required to be conducted in India before permission to market any investigational medical device in India except in case of a device that is classified under class A.

Of course, the number of study subjects and sites to be involved in the conduct of clinical investigation shall depend on the nature and objective of the clinical investigation.

VII. Product Standards

All medical devices are required to conform to the following standards, in the same order of relevance:

- 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.

Further, the Fifth Schedule of the MDR 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

The labeling of Notified Medical Devices is governed by three statutes:

The Medical Devices Rules, 2017

Before a Notified Medical Device is sold or distributed in India, it must be labeled according to specifications outlined in the MDR. It is permissible for importers to print the mandatory declarations on a label and stick the label to the package.

The MDR prescribes the contents of the label such as name of the medical device, the details necessary for the user to identify the device and its use, name of manufacturer and address of manufacturing premises where the device has been manufactured, statement as to the net contents (in terms of weight or measure), license number, date of manufacture, date of expiry (alternatively, its shelf life), applicable storing and handling conditions, warnings and precautions, the batch number, as well as the manufacturing license number under which it is manufactured (if manufactured in India). Imported products must display the import license number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture.

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 precise labelling requirements for medical devices under the MDR have been described in **ANNEXURE B** for devices intended to be marketed in India and **ANNEXURE C** for devices manufactured in India and intended to be exported out of India.

All labels may be printed in English.

The Legal Metrology (Packaged Commodity) Rules, 2011

The Legal Metrology (Packaged Commodity) Rules, 2011, notified under the Legal Metrology Act, 2009, regulates the packaging and labelling of pre-packed commodities in India. From January 1, 2018, Notified Medical Devices are required to bear additional declarations and particulars on the retail package as prescribed under the Legal Metrology (Packaged Commodity) Rules, 2011. Like the MDR, it is permissible for importers to print the mandatory declarations on a label and sticker the label to the package.

The additional declarations are:

1. Maximum retail price ("MRP");
2. Common or generic name of the commodity;
3. month and year in which the commodity is manufactured or packed or imported;
4. 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;
5. Actual corporate name and complete corporate registered address of domestic manufacturer or importer or packer;
6. Name of country of origin or manufacture or assembly

Drug (Prices Control) Order, 2013

The DPCO 2013 requires all manufacturers and importers of Notified Medical Devices to declare the MRP on the label.

IX. Quality Management System (QMS)

The Fifth Schedule to the MDR 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 (to the extent applicable) as a condition of its manufacturing license, else it may lead to cancellation or suspension of the manufacturing license. The QMS is comprehensive, laying down requirements such as the documentation required, management responsibilities, resource management and monitoring.

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, and distribution, stocking or exhibiting or offering for sale or distribution of spurious or counterfeit Notified Medical Devices to INR 1,000,000 (appx. USD 16,667) or 3 times the value of the notified medical device confiscated, whichever is higher and imprisonment of not less than 10 years which may extend up to life, for spurious or counterfeit notified medical device leading to death or grievous hurt. The entire amount of fine that is realized from the person convicted for the offence is now paid by way of compensation, to the person who is the victim of spurious or counterfeit Notified Medical Devices. If the victim has died due the effect of the spurious or counterfeit Notified Medical Devices, the

relative of the victim is entitled to receive the same amount by way of compensation.

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

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

XI. Export – Import Restrictions

Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992 along with the Customs Act, 1962 and the Export-Import Policy (“**EXIM Policy**”), issued by the Ministry of Commerce and Industry of the Government of India. The current EXIM policy also known as 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

The MDR does not specifically cover advertising and promotion of Notified Medical Devices and in vitro diagnostic devices. However, the MDR states that the Drugs and Cosmetics Rules, 1945 (“**D&C Rules**”) will continue to apply, so long as there is nothing inconsistent in the MDR. Therefore, the provisions of the D&C Rules with respect to advertising and sales promotion would apply to Notified Medical Devices and in vitro diagnostic devices.

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.

Apart from the D&C Rules and the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, the Department of Pharmaceuticals, Government of India also introduced a set of guidelines called the Uniform Code of Pharmaceutical Marketing Practices (“UCPMP”). The UCPMP does not have the force of law yet, as the guidelines have not been issued under a parent legislation. While the name of UCPMP suggests that the guidelines are applicable only to the interaction of pharmaceutical companies with HCPs, it has been clarified that these guidelines are applicable to medical device companies as well (the government is also reportedly planning on issuing a Uniform Code for Medical Device Marketing Practices⁹ (“UCMDMP”), which will specifically deal with marketing and promotion of medical devices). The UCPMP places restrictions on the interaction of pharmaceutical and medical device companies with medical practitioners. For instance, the UCPMP states that companies should not sponsor any cost related to the attendance of a healthcare practitioner in a conference, seminar, workshop, etc., where the practitioner is participating as a delegate. The UCPMP also lays down the information that should be presented to healthcare practitioners in promotional materials.

Recently, the central government reportedly came out with a draft Essential Commodities (Control of Unethical Practices in the Marketing of Drugs) Order, 2017 (“**Draft Order**”), intending to regulate promotion and marketing activities by companies before healthcare practitioners. The UCPMP and the Draft Order are discussed in detail here.¹⁰

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 rheumatism, diseases and disorders of the optical system, heart diseases, cancer, diabetes, 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.

9. Govt to issue uniform code for medical device marketing practices soon; available at: <http://pharmabiz.com/ArticleDetails.aspx?aid=105501&sid=1>; last accessed on: 27 February 2018.

10. http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Uniform-Code-for-Pharmaceutical-Marketing-Practices_Decoded.pdf

Cartels by industry associations have been widespread across jurisdictions to set standard prices for both stockiest 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 step¹¹ and capable of industrial application.”¹² 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 assignee¹³ or (iii) legal representatives¹⁴ 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.

11. 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.”

12. 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.”

13. 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”.

14. Section 2(1)(k) of the Patents Act: “Legal representative means a person who in law represents the estate of a deceased person.”

This provision, known as the 'Bolar provision', allows manufacturers to begin the research and development process in a timely manner in order to ensure that affordable equivalent generic medicines can be brought to market immediately upon the expiry of the product patent.

D. Parallel Imports

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

E. Enforcement

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

F. Rights prior to the Grant

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

G. Secrecy Provisions¹⁵

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,

15. 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

the Government may take some more time to announce its decision on 'Protection against unfair commercial use' as the Union ministry of health and the Department Of Pharmaceuticals wants further discussions with stakeholders.

XVII. Trademarks

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

Class 44 covers the services for Medical services, veterinary services and cosmetics; and Class 42 covers Scientific and technological services and research and design relating thereto.¹⁶

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, prices of all Notified Medical Devices are controlled by a regulation called Drugs Prices Control Order, 2013 ("**DPCO 2013**") made under Essential Commodities Act, 1955 ("**ECA**"). A schedule to DPCO 2013 contains a list of a few Notified Medical Devices which the government believes are "essential" for Indian population. As of now, it contains condoms, IUDs and coronary stents. These devices are misleadingly referred to as "Scheduled Formulations". Notified Medical Devices that are not covered in the schedule are referred to as "Non-Scheduled Formulations".

16. http://support.dialog.com/techdocs/international_class_codes_tmmarks.pdf

The prices of Notified Medical Devices are controlled in the following manner under DPCO 2013:

1. Of “Scheduled Formulations” – The National Pharmaceutical Pricing Authority (“NPPA”) fixes ceiling price for Scheduled Formulations by using a formula which essentially averages the price to retailer of Notified Medical Device manufacturers and importers, followed by addition of fixed margin of 16% to be given to retailers. Pursuant to fixation of ceiling price (and adjusting the same to applicable taxes), no manufacturer or importer is allowed to set MRP (i.e. maximum retail price) higher than the ceiling price.
2. Of “Non-Scheduled Formulations” - The NPPA does not allow any manufacturer and importer of Non-Schedule Formulations to increase the MRP by more than 10% of within a span of 12 months.
3. Of any Notified Medical Device in public interest - NPPA, in public interest and under extra-ordinary circumstances, can fix prices of any Notified Medical Device, irrespective of whether the device is a Scheduled Formulation or Non-Scheduled Formulation. Till date, NPPA has exercised this power twice for medical devices – in the case of Coronary Stents and Knee Implant Systems. The use of this power is very peculiar, because of the following reasons:
 - a. NPPA fixes price of the Notified Medical Device on the basis of average cost of manufacture or average landing cost (i.e. transfer price in case of import). The NPPA then adds 50-75% margin for manufacturer and importers on the average cost as profit margins for the manufacturers and importers.
 - b. NPPA fixes the distributor margin of its products. This means that a manufacturer or importer cannot pass a margin greater than what has been decided by the NPPA to

its distributor. The distributor margin varies from 8-16%.

- c. An importer, other than the marketing authorization holder in India, is treated as a distributor.
- d. The patient invoice must carry details of the price charged to the patient, even though the patient may have opted for the surgery in form of a “package” and paid lump-sum for it.

The NPPA has recently asked for details of manufacturing and landing cost of other Notified Medical Devices such as intra ocular lens and syringes along with the details of the margins offered to stockists and hospitals. It is entirely possible that the NPPA may fix ceiling prices of one or more of these devices in time to come.

The government agency under DPCO 2013, which is responsible for controlling the price of drugs, is called the NPPA. The DPCO 2013 also provides for controlling the prices of non-NLEM drugs in two other situations:

XIX. Medical Device Rules, 2017 - Salient Features

In the above paragraphs, it has been said that the Indian Government have introduced the MDR to regulate Notified Medical Device. However, the importance of this development has not been detailed. In order to appreciate this development, one must understand the position of regulation of medical devices prior to introduction of MDR.

Notified Medical Devices, historically, were treated as “drugs” and for a very long time, the standard that were applicable to drugs were extended to Notified Medical Devices as well. This created several issues. For instance, the good manufacturing practices for drugs require the manufacturers to maintain a quarantine room at the facility to control any untoward incident arising from the pharmaceuticals which pose risk to health. The manufacturers of Notified Medical Devices were also required

to maintain the same, even when the devices were made out of inert devices such as Titanium which cannot pose any risk to health. Similarly, the maximum shelf-life of drugs (i.e. 5 years) was extended unthoughtfully to medical devices. This resulted in a situation where medical devices that could easily survive for 10 years had to be taken off market every 5 years, only to be repackaged and re-introduced!

The MDR have been drafted with the intention to distinguish medical devices from pharmaceuticals in lien with internationally acceptable norms. The Salient features of MDR are described below.

A. Introduction of risk based classifications system

In tune with the global practice, the MDR 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 MDR (first schedule attached as **Annexure D**). 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 MDR do not provide this liberty and the manufacturers/importers will have to follow the classification decided by DCGI.¹⁷ 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:

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

17. Rule 4(3) of MDR.

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 party¹⁸ or official inspection; Class B medical devices require prior audit by third party¹⁹ but do not require official inspection, and; Class C or Class D medical devices require prior official inspection.²⁰

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.

B. 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.

C. Certainty and rationalization of timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market/

18. Rule 20(4)(i), of MDR

19. Rule 20(5) r/w Rule 20(6)(iii) of MDR

20. Rule 21(1) of MDR.

manufacture medical devices. Under the MDR, 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 inspection to happen because timelines have been assigned to each regulatory function. Further, unlike the D&C Rules, the MDR 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 application,²¹ the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application,²² the report of the inspection has to be forwarded to the applicant²³, and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.²⁴

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.²⁵

The MDR 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.²⁶

21. Rule 21(4) of MDR

22. Rule 23(1) of MDR

23. Rule 24 of MDR

24. Rule 25 of MDR

25. Rule 36(1) of MDR

26. Rule 26(iii); Rule 38(vi) of MDR

D. Perpetual licenses

The licenses granted under the MDR 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.²⁷

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

The MDR 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.²⁸

27. Rule 26(xii) of MDR

28. Rule 34(4)(ii) of MDR

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

The MDR 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).²⁹ Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.³⁰

What constitutes major change and minor change has also been specified.³¹ 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 MDR 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.³² 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:³³

- 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 MDR, 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 months³⁴ 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.³⁵ 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 MDR. Such a change now is required to be informed in writing to the licensing authority.³⁶ Due to this explicit requirement, it should not trigger requirement to make a fresh application.

29. Rule 26(iii); Rule 38(vi) of MDR

30. Rule 26(iv); Rule 38(vii) of MDR

31. Sixth Schedule of MDR

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

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

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

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

36. Rule 34(2) Proviso. of MDR

G. 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 MDR state that change in constitution of a licensee in relation to³⁷:

- 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 MDR:

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.

37. Rule 3(i) of MDR

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 MDR. 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.³⁸ An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.³⁹ 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 MDR.

H. License for sale of medical devices

The MDR do not have separate provisions for sale of medical devices. The provisions related to sale of drugs other than homeopathic medicines under the D&C Rules will apply to medical devices as if it was inserted within the MDR.⁴⁰ All licenses for sale of drugs other than homeopathic medicines issued prior to

38. Rule 27 of MDR

39. Rule 39 of MDR

40. Rule 87(1) of MDR

commencement of MDR shall be deemed to be valid for sale of medical devices as well.⁴¹

The MDR 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 device, 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 MDR have permitted supply of implantable medical devices against a delivery note (challan).⁴²

41. Rule 87(2) of MDR

42. Rule 88(1) of MDR

I. Mandatory recalls on knowledge of risk to safety

The MDR make it mandatory⁴³ 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.⁴⁴ 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.⁴⁵

J. 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.⁴⁶ This becomes an issue for importers of medical devices which have a short claimed shelf life.

The MDR have addressed the issue by relaxing the residual shelf life requirement for medical devices with short shelf life.⁴⁷ Any medical device, whose total shelf life claim is

43. Rule 89(1) of MDR

44. Rule 26(v); Rule 74(j); Rule 78(i) of Rules

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

46. Rule 31 Proviso of Rules.

47. Rule 47 of MDR

- 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.
- 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.

K. New regulatory framework for clinical investigation of medical device

The MDR 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;

L. Debarment on account of supply of misleading information

The MDR 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.⁴⁸ 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.

48. Rule 93(1) of MDR

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

The Medical Device Rules, 2017 have been notified under the Act. The Act requires that 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 MDR will soon be placed before the Indian Parliament. It will be interesting to see whether the Indian Parliament effects any modification to the MDR or rejects it completely. However, given the political and economic scenario, either event seems unlikely.

N. Next steps for existing importers, manufacturers and distributors

After the commencement of MDR, 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 MDR. Therefore, there is no need to rush to adopt to the MDR. However, it is important to start preparing for the new regulatory regime under MDR.

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

O. An opportunity lost

Though the MDR 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 MDR, 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 MDR and the very real possibility of it coming into effect in 2018 needs to be celebrated!

P. Classification of medical devices published

The government has published a classification for medical devices under MDR. The classification is available here: <https://tinyurl.com/y7unrwu2>

All Notified Medical Devices 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 classification and make application for import, manufacture or sale accordingly. Currently, those devices that have been classified are considered to be notified medical devices, for the purposes of the MDR.

Q. Frequently Asked Questions for Medical Devices and In Vitro Devices Published

Based on queries received from stakeholders over various meetings and representations, the CDSCO has released Frequently Asked Questions (“**FAQs**”) for medical devices and in vitro diagnostic devices.

The FAQ on medical devices can be found here,⁴⁹ and the FAQ on in vitro diagnostic devices can be found here.⁵⁰

49. <http://www.cdsc0.nic.in/writereaddata/IFianl%20draft%20FAQ%20MDR.pdf>

50. [http://www.cdsc0.nic.in/writereaddata/FAQ_IVD_MDR-2017\(r\).pdf](http://www.cdsc0.nic.in/writereaddata/FAQ_IVD_MDR-2017(r).pdf)

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.

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.

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 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 2017-2018 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 2017-2018 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.

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 corporate tax rate for domestic companies whose total turnover or gross receipts does not exceed INR 500 million (approx. USD 7.4 million) is 25%. The Finance Bill, 2018 (“**Finance Bill**”) provides that the income of companies whose turnover in FY 2016-17 does not exceed INR 2.5 billion (approx. USD 40 million) is to be taxed at the rate of 25% from FY 2017-18). 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 party,⁵⁶ 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 2017-18 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. LTGCGs 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.

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.

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, 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 Trust,⁶¹ as follows:

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

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

61. 1983 144 ITR 146 AP

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:

- “(l) the furnishing of services, other than included services as defined in article 12 (royalties and fees for included services), within a Contracting State by an enterprise through employees or other personnel, but only if:
- a. 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
 - b. 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 Balkrishna*,⁶² the Supreme Court has explained the concept of AOP as “an association of persons must be one in which two or more persons join in a common purpose or a common action, and as the words occur in a section which imposes a tax on income, the association must be one the object of which is to produce income, profits or gains.”

Further, in the case of *Deccan Wine and General Stores*,⁶³ the Andhra Pradesh High Court further examined this concept and observed that “it is,

62. [1960] 39 ITR 546 (SC)

63. ([1977] 106 ITR 111 (AP)

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 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.

The Budget had proposed two important changes with respect to transfer pricing under the ITA which will come into effect on April 1, 2018, and will accordingly apply to assessment year 2018-19.

a. International Transaction

The first amendment introduces Section 92CE which requires a resident taxpayer who has entered into an international transaction to make a secondary adjustment in the event that a primary adjustment as per transfer pricing provisions:

1. has been made suo moto by the taxpayer in his income tax return,
2. has been made by the Assessing Officer and accepted by the taxpayer,
3. has been determined by and advanced pricing agreement,
4. is made as per safe harbor rules under the ITA,
5. is a result of mutual agreement procedure (“MAP”) under a tax treaty

The provisions further prescribe that where, as a result of primary adjustment, there is an increase in the taxpayer’s total income or a reduction in allowable loss, a secondary adjustment shall have to be made. The secondary adjustment is intended to reflect the actual allocation of profits between the taxpayer and the associated enterprise. The purpose of such secondary adjustment is also to eliminate the imbalance between the taxpayer’s accounts and actual profits. The Section prescribes that the excess money (difference between the

arm’s length price determined in the primary adjustment and the actual consideration price) shall be deemed to be an advance made by the taxpayer to its associated enterprise, if it is not repatriated to India within a prescribed time. Once deemed to be an advance, interest shall also be payable on the excess income until the obligation to repatriate such amount is discharged. While the rate of interest is to be calculated in a manner prescribed by the government, it should also be determined at an arm’s length price.

However, Section 92CE will not be applicable where the amount of primary adjustment made in any previous year does not exceed INR 10 million (approx. USD 150,000), and is made in respect of an assessment year commencing on or before the April 1, 2016.

Although secondary adjustments are an internationally accepted principle and are in line with OECD’s Transfer Pricing Guidelines, the implementation of Section 92CE may result in various practical difficulties. For example, the foreign country in which the associated enterprise is located may have exchange control provisions that make it difficult to repatriate the excess money to India, or it may have adjusted the transaction as per its own transfer pricing provisions and already taxed a portion of the funds Indian tax authorities consider as excess income. The introduction of these provisions and also those relating to thin capitalization show the increasing tendencies of the government to look at international practices in molding tax legislation in India.

b. Specified Domestic Transaction

The second amendment involves restricting the scope of *specified domestic transactions* which are subject to transfer pricing by introducing an amendment to Section 92BA of the ITA. Currently, transfer pricing provisions under the ITA are applicable to *specified domestic transactions* where the aggregate of such transactions in the previous year exceeds INR 200 million (approx. USD 3 million). The condition that transfer pricing will be applied in respect of determining the arm’s

length nature of expenditure incurred has now been removed. This is intended to reduce the compliance burden on the following taxpayers who are currently related parties under Section 40A(2)(b).

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 instructions⁴⁵ 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, 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.⁶⁴

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.⁶⁵ However Countervailing Duty (“CVD”) and Special Additional Duty (“SAD”) would be subsumed into the IGST, which would be levied on the imported goods. However, the Research and Development Cess on the import of technology (levied at 5%) was also abolished earlier in the year. On the manufacturing front the existing duty regime will be different for each class and type of medical device.⁶⁶ The duty on import of goods is discussed in some detail in the section below.

A. 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.

64. Notification No.1/2017-Integrated Tax (Rate) <http://www.cbec.gov.in/resources/htdocs-cbec/gst/Notification%20for%20IGST%20rate%20Schedule-I.pdf> (last accessed on August 1, 2017). The rates mentioned here apply to IGST.

65. 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)

66. Finance Act, 2017, No 7 of 2017, <http://egazette.nic.in/WriteReadData/2017/175141.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. Recent Developments

Drug Regulator Proposes to Include Additional Medical Devices within the Regulatory Framework

The Drugs Controller General (India) on June 22, 2018 issued a public notice regarding the proposal for inclusion of eight categories of medical devices (“**Additional Devices**”) for comments and suggestions. The Additional Devices are:

1. All implantable medical devices
2. CT scan equipment
3. MRI equipment
4. Defibrillators
5. Dialysis Machine
6. PET equipment
7. X-Ray Machine
8. Bone marrow cell separator

The notice has also stated that a gazette notification would soon follow and come into force after one year from the date of notification. The Drug Technical Advisory Board (“**DTAB**”) – the apex body that advises the state and central governments on technical matters of India’s drug regulatory framework – has agreed to the proposal of including the Additional Devices and has in fact, also agreed the inclusion of four more devices to the list (blood pressure monitoring devices, digital thermometers, nebulizers and glucometers). A notification in this regard is likely to be issued soon as well.

The inclusion of the Additional Devices to the list of notified medical devices would significantly widen the scope of regulation of medical devices in the country. Currently, only 15 categories of medical devices are regulated as ‘drugs’ under the Drugs and Cosmetics Act, 1940 (“**D&C Act**”). The blanket entry for all implantable medical devices as a category in the list of Additional Devices would allow the government to regulate a wide array of medical devices within the entry, such as pacemakers and Left Ventricular Assist Devices.

It remains to be seen whether the Additional Devices that are already in the market would be exempt from the requirements under the regulatory framework, but it is likely that the one-year window between notification in the official gazette and coming into force would be for all existing players within the eight categories to get their devices registered with the drug regulator.

It would also be interesting to see what risk-based classification would be provided to the new products falling within the scope of the Additional Devices, and the industry is hoping that the list is published as soon as possible to gear up for the upcoming changes.

Another collateral outcome of the inclusion of the Additional Devices would be that these devices would be subject to some form of price control under the Drugs (Prices Control) Order, 2013, either being restricted from increasing the price of the product by more than 10% over the preceding twelve months, or having its ceiling price notified by the National Pharmaceutical Pricing Authority.

8. Conclusion- Two Steps Forward, One Step Backward?

The Indian medical device industry continues its upward march of growth and is strongly supported by India's robust legal framework. As discussed in the paper, there are certain challenges to do business of medical device in India, but they can be easily overcome.

The biggest concern for the industry in 2018 appears to be lack of certainty in government policies, especially in relation to price control. The government will do well to publish the

National Medical Device Policy, which help allay the concerns of the industry with respect to government policies and instill confidence in the industry to look far ahead and plan its business in the long term.

Having said that, there is no denying that despite the odds, the medical devices industry in India continues to offer unprecedented opportunities to present and potential investors and 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 Notified Medical Devices to be marketed in India under MDR

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely,-

- a. name of the medical device;
- b. the details necessary for the user to identify the device and its use;
- c. the name of manufacturer and address of manufacturing premises where the device has been manufactured;
- d. the correct statement about 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 expressed in metric system;
- e. the month and year of manufacture and expiry (alternately the label shall bear the shelf life of the product):

Provided that in case of sterile devices, the date of sterilization may be given as date of manufacture of the device:

Provided further that where the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile or in case of medical equipment or instruments or apparatus, the date of expiry may not be necessary.

Explanation.- For the purposes of this clause, the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life";

- f. to provide, wherever required, an indication that the device contains medicinal or biological substance;
- g. to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";
- h. to indicate, wherever required, any special storage or handling conditions applicable to the device;
- i. to indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method;
- j. to give, if considered relevant, warnings or precautions to draw the attention of the user of medical device;
- k. to label the device appropriately, if the device is intended for single use;
- l. 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;
- m. to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M. L.";
- n. to provide on the label, in case of imported devices, by way of stickering, where such details are not already printed, the import licence number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture:

Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardisation (ISO) in lieu of the text and the device safety is not compromised by a lack of understanding on the part of the user, in case the meaning of the symbol is not obvious to the device user;

- o. in case of small sized medical devices on which information cannot be printed legibly, shall include the information necessary for product identification and safety such as information covered by clauses (a), (b), (c), (d), (e), (g), (k), and (m) shall be included.

Annexure C

Labeling requirements for Notified Medical Devices intended for export

The labels on packages or container of devices for export shall be adopted to meet the specific requirements of law of the country to which the device is to be exported, but the following particulars shall appear in a conspicuous manner on the label of the inner most pack or shelf pack of the medical device in which the device is packed and every other outer covering in which the container is packed:-

- a. name of the device;
- b. the distinctive batch number or lot number or serial number preceded by the word “Lot No.” or “Lot” or “Batch No.” or “B. No.” or “Serial No.”;
- c. date of expiry, if any;
- d. the name and address of manufacturer and address of actual premises where the device has been manufactured;
- e. licence number preceded by letters “Licence No. or Lic. No.”;
- f. internationally recognised symbols in lieu of text, wherever required:
Provided that where a device is required by the consignee not to be labeled with the name and address of manufacturer, the label on the package or container shall bear a code number as approved by the Central Licensing Authority and the code number shall bear the name of the State or Union territory, in abbreviation, followed by the word “Device” and “manufacturing licence number”;
- i. Provided further that where a device is required by the consignee not to be labeled with the code number also, the label on the packages or container shall bear a special code number, as requested by the consignee, and approved by the Central Licensing Authority.

Annexure D

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,-
 - i. 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
 - ii. 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

At Nishith Desai Associates, we have earned the reputation of being Asia's most Innovative Law Firm – and the go-to specialists for companies around the world, looking to conduct businesses in India and for Indian companies considering business expansion abroad. In fact, we have conceptualized and created a state-of-the-art Blue Sky Thinking and Research Campus, Imaginarium *Aligunjan*, an international institution dedicated to designing a premeditated future with an embedded strategic foresight capability.

We are a research and strategy driven international firm with offices in Mumbai, Palo Alto (Silicon Valley), Bangalore, Singapore, New Delhi, Munich, and New York. Our team comprises of specialists who provide strategic advice on legal, regulatory, and tax related matters in an integrated manner basis key insights carefully culled from the allied industries.

As an active participant in shaping India's regulatory environment, we at NDA, have the expertise and more importantly – the VISION – to navigate its complexities. Our ongoing endeavors in conducting and facilitating original research in emerging areas of law has helped us develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

As a firm of doyens, we pride ourselves in working with select clients within select verticals on complex matters. Our forte lies in providing innovative and strategic advice in futuristic areas of law such as those relating to Blockchain and virtual currencies, Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Ed-Tech, Med-Tech & Medical Devices and Nanotechnology with our key clientele comprising of marquee Fortune 500 corporations.

The firm has been consistently ranked as one of the Most Innovative Law Firms, across the globe. In fact, NDA has been the proud recipient of the Financial Times – RSG award 4 times in a row, (2014-2017) as the **Most Innovative Indian Law Firm**.

We are a trust based, non-hierarchical, democratic organization that leverages research and knowledge to deliver extraordinary value to our clients. Datum, our unique employer proposition has been developed into a global case study, aptly titled 'Management by Trust in a Democratic Enterprise,' published by John Wiley & Sons, USA.

A brief chronicle our firm's global acclaim for its achievements and prowess through the years -

- **AsiaLaw 2019:** Ranked 'Outstanding' for Technology, Labour & Employment, Private Equity, Regulatory and Tax
- **RSG-Financial Times:** India's Most Innovative Law Firm (2014-2017)
- **Merger Market 2018:** Fastest growing M&A Law Firm
- **IFLR 1000 (International Financial Review - a Euromoney Publication):** Tier 1 for TMT, Private Equity
- **IFLR:** Indian Firm of the Year (2010-2013)
- **Legal 500 2018:** Tier 1 for Disputes, International Taxation, Investment Funds, Labour & Employment, TMT
- **Legal 500 (2011, 2012, 2013, 2014):** No. 1 for International Tax, Investment Funds and TMT

- **Chambers and Partners Asia Pacific (2017 – 2018):** Tier 1 for Labour & Employment, Tax, TMT
- **IDEX Legal Awards 2015:** Nishith Desai Associates 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”

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










Disclaimer

This report is a copy right of Nishith Desai Associates. No reader should act on the basis of any statement contained herein without seeking professional advice. The authors and the firm expressly disclaim all and any liability to any person who has read this report, or otherwise, in respect of anything, and of consequences of anything done, or omitted to be done by any such person in reliance upon the contents of this report.

Contact

For any help or assistance please email us on ndaconnect@nishithdesai.com or visit us at www.nishithdesai.com

The following research papers and much more are available on our Knowledge Site: www.nishithdesai.com

	Fund Formation: Attracting Global Investors		Social Impact Investing in India		The Curious Case of the Indian Gambling Laws
	March 2018		July 2018		February 2018
	Corporate Social Responsibility & Social Business Models in India		Incorporation of Company LLP in India		Outbound Acquisitions by India-Inc
	March 2018		April 2017		September 2014
	Internet of Things		Doing Business in India		Private Equity and Private Debt Investments in India
	January 2017		September 2018		March 2018

NDA Insights

TITLE	TYPE	DATE
Blackstone's Boldest Bet in India	M&A Lab	January 2017
Foreign Investment Into Indian Special Situation Assets	M&A Lab	November 2016
Recent Learnings from Deal Making in India	M&A Lab	June 2016
ING Vysya - Kotak Bank : Rising M&As in Banking Sector	M&A Lab	January 2016
Cairn – Vedanta : 'Fair' or Socializing Vedanta's Debt?	M&A Lab	January 2016
Reliance – Pipavav : Anil Ambani scoops Pipavav Defence	M&A Lab	January 2016
Sun Pharma – Ranbaxy: A Panacea for Ranbaxy's ills?	M&A Lab	January 2015
Reliance – Network18: Reliance tunes into Network18!	M&A Lab	January 2015
Thomas Cook – Sterling Holiday: Let's Holiday Together!	M&A Lab	January 2015
Jet Etihad Jet Gets a Co-Pilot	M&A Lab	May 2014
Apollo's Bumpy Ride in Pursuit of Cooper	M&A Lab	May 2014
Diageo-USL- 'King of Good Times; Hands over Crown Jewel to Diageo	M&A Lab	May 2014
Copyright Amendment Bill 2012 receives Indian Parliament's assent	IP Lab	September 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	August 2013
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	January 2013
Real Financing - Onshore and Offshore Debt Funding Realty in India	Realty Check	May 2012

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.

Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparalleled mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to *Intellectual Property*.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. 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 Lab Reports 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 articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of 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.

As we continue to grow through our research-based approach, we now have established an exclusive 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. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical ecosystem that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at

research@nishithdesai.com



Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India

tel +91 22 6669 5000
fax +91 22 6669 5001

SILICON VALLEY

220 California Avenue, Suite 201
Palo Alto, CA 94306-1636, USA

tel +1 650 325 7100
fax +1 650 325 7300

BANGALORE

Prestige Loka, G01, 7/1 Brunton Rd
Bangalore 560 025, India

tel +91 80 6693 5000
fax +91 80 6693 5001

SINGAPORE

Level 30, Six Battery Road
Singapore 049 909

tel + 65 65509855

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra-Kurla Complex
Mumbai 400 051, India

tel +91 22 6159 5000
fax +91 22 6159 5001

NEW DELHI

C-5, Defence Colony
New Delhi 110 024, India

tel +91 11 4906 5000
fax +91 11 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich, Germany

tel +49 89 203 006 268
fax +49 89 203 006 450

NEW YORK

375 Park Ave Suite 2607
New York, NY 10152

tel +1 212 763 0080