

# The Indian Medical Device Industry

---

## Regulatory, Legal and Tax Overview

March 2020

---

# The Indian Medical Device Industry

## **Regulatory, Legal and Tax Overview**

---

March 2020

[ndaconnect@nishithdesai.com](mailto:ndaconnect@nishithdesai.com)

DMS Code: 537688,1:

## About NDA

We are an India Centric Global law firm ([www.nishithdesai.com](http://www.nishithdesai.com)) with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue remain respected industry experts.

We are a research based law firm and have just set up a first-of-its kind IOT-driven Blue Sky Thinking & Research Campus named Imaginarium AliGunjan (near Mumbai, India), dedicated to exploring the future of law & society. We are consistently ranked at the top as Asia's most innovative law practice by Financial Times. NDA is renowned for its advanced predictive legal practice and constantly conducts original research into emerging areas of the law such as Blockchain, Artificial Intelligence, Designer Babies, Flying Cars, Autonomous vehicles, IOT, AI & Robotics, Medical Devices, Genetic Engineering amongst others and enjoy high credibility in respect of our independent research and assist number of ministries in their policy and regulatory work.

The safety and security of our client's information and confidentiality is of paramount importance to us. To this end, we are hugely invested in the latest security systems and technology of military grade. We are a socially conscious law firm and do extensive pro-bono and public policy work. We have significant diversity with female employees in the range of about 49% and many in leadership positions.

## Accolades

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

- **Legal500:** Tier 1 for Tax, Investment Funds, Labour & Employment, TMT and Corporate M&A 2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013, 2012
- **Chambers and Partners Asia Pacific:** Band 1 for Employment, Lifesciences, Tax and TMT 2020, 2019, 2018, 2017, 2016, 2015
- **IFLR1000:** Tier 1 for Private Equity and Project Development: Telecommunications Networks. 2020, 2019, 2018, 2017, 2014
- **AsiaLaw Asia-Pacific Guide 2020:** Tier 1 (Outstanding) for TMT, Labour & Employment, Private Equity, Regulatory and Tax
- **FT Innovative Lawyers Asia Pacific 2019 Awards:** NDA ranked 2nd in the Most Innovative Law Firm category (Asia-Pacific Headquartered)
- **RSG-Financial Times:** India's Most Innovative Law Firm 2019, 2017, 2016, 2015, 2014
- **Benchmark Litigation Asia-Pacific:** Tier 1 for Government & Regulatory and Tax 2019, 2018
- **Who's Who Legal 2019:**  
**Nishith Desai**, Corporate Tax and Private Funds – Thought Leader  
**Vikram Shroff**, HR and Employment Law- Global Thought Leader  
**Vaibhav Parikh**, Data Practices - Thought Leader (India)  
**Dr. Milind Antani**, Pharma & Healthcare – only Indian Lawyer to be recognized for 'Life sciences-Regulatory,' for 5 years consecutively
- **Merger Market 2018:** Fastest growing M&A Law Firm in India
- **Asia Mena Counsel's In-House Community Firms Survey 2018:** The only Indian Firm recognized for Life Sciences
- **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](mailto:ndaconnect@nishithdesai.com) or visit us at [www.nishithdesai.com](http://www.nishithdesai.com)

## Acknowledgements

**Dr. Milind Antani**

[milind.antani@nishithdesai.com](mailto:milind.antani@nishithdesai.com)

**Darren Punnen**

[darren.punnen@nishithdesai.com](mailto:darren.punnen@nishithdesai.com)

**Shreya Shenolikar**

[shreya.shenolikar@nishithdesai.com](mailto:shreya.shenolikar@nishithdesai.com)

# Contents

<b>1. EXECUTIVE SUMMARY</b>	<b>01</b>
<b>2. INTRODUCTION</b>	<b>03</b>
<b>3. INDIA ENTRY STRATEGIES</b>	<b>05</b>
<b>4. INVESTMENT CLIMATE IN INDIA</b>	<b>06</b>
<b>5. INDIA'S POST-TRIPS INTELLECTUAL PROPERTY ENVIRONMENT</b>	<b>07</b>
<b>6. LEGAL AND REGULATORY REGIME</b>	<b>08</b>
I. Authorities	09
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	12
V. Manufacture/Import of an Investigational Medical Device and New in vitro Diagnostic Medical Device	13
VI. Clinical Investigation/Clinical Performance Evaluation	14
VII. Product Standards	15
VIII. Labeling	15
IX. Quality Management System (QMS)	16
X. Export – Import Restrictions	16
XI. Advertising and Sales Promotion	16
XII. Anti-Competitive Practices	17
XIII. Patent Protection	18
XIV. Data Exclusivity	19
XV. Trademarks	20
XVI. Pricing of Medical Devices	20
XVII. Penalties	21
<b>7. MEDICAL DEVICE RULES 2017 – AN ANALYSIS</b>	<b>23</b>
I. Risk-based classifications system	23
II. Single window clearance	24
III. Certainty and rationalization of timelines	24
IV. Perpetual licenses	24
V. Consolidation of registration certificate and import license into a single license	25
VI. Certainty on consequence of change in particulars contained in the license	25

VII. Meaning of “change in constitution” explained and change in constitution rationalized	25
VIII. License for sale of medical devices	26
IX. Mandatory recalls on knowledge of risk to safety	26
X. New thresholds for residual shelf life of imported products	27
XI. New regulatory framework for clinical investigation/clinical performance evaluation of medical device	27
XII. Debarment on account of supply of misleading information	27
XIII. Notifications issued to regulate all medical devices in India	28
XIV. An opportunity lost	31
<b>8. TAXATION REGIME</b>	<b>32</b>
I. Direct Taxes	32
ii. Indirect Taxes	40
<b>9. CONCLUSION - FOUR STEPS FORWARD, TWO STEPS BACKWARD?</b>	<b>42</b>
<b>ANNEXURE - A</b>	<b>43</b>
<b>ANNEXURE - B</b>	<b>45</b>
Labeling Requirements for Notified Medical Devices to be marketed in India under MDR	45
<b>ANNEXURE - C</b>	<b>47</b>
Labeling requirements for Notified Medical Devices intended for export	47
<b>ANNEXURE - D</b>	<b>48</b>
Parameters for classification of medical devices and in vitro diagnostic medical devices	48
<b>ANNEXURE - E</b>	<b>56</b>

# 1. Executive Summary

The medical device industry in India is presently valued at USD 5.2 Billion and is growing at 15.8% CAGR.<sup>1</sup> Currently, India is counted among the top 20 global medical devices market and is the 4<sup>th</sup> largest medical devices market in Asia after Japan, China and South Korea<sup>2</sup> and is poised to grow to USD 50 billion by 2025 as per some industry estimates.<sup>3</sup>

The medical device market is dominated by imported products, which comprise of around 80% of total sales.<sup>4</sup> 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. Recently, the Indian Government has also released notifications significantly increasing the number of medical devices governed by the medical device regulation. Currently, only 16 medical devices are regulated in India, with 13 other medical devices to come under regulation

at various points in 2020 and 2021. After the above-mentioned notification comes into effect, all devices will be brought under the purview of India's medical device framework. These notifications are set to come into effect on April 01, 2020. 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.

One must also not lose sight of the fact that the Indian consumer mindset and local business

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).



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.

## 2. 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.<sup>5</sup> In 2014 and 2015, the FDI inflow were 133.96 Million and 160.24 Million respectively.<sup>6</sup> The FDI inflows jumped by almost 300% in 2016 to USD 439.01 Million.<sup>7</sup>

The major players in Indian market are (in no particular order): Hindustan Syringes & Medical Devices, Opto Circuits (India), Wipro GE Healthcare, 3 M, Medtronic, Johnson & Johnson, Becton Dickinson, Abbott Vascular, Bausch & Lomb, Baxter, Zimmer India, Edwards Life Sciences, St. Jude Medical (now a part of Abbott), Smith & Nephew, Cochlear, Stryker, Baxter, Boston Scientific, BPL Healthcare India, Sushrut Surgicals, Trivitron Diagnostics, Accurex Biomedical, Biopore Surgicals, Endomed Technologies, HD Medical Services (India),

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](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](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](http://dipp.nic.in/sites/default/files/Table%20No%204_oct2017.pdf) (last accessed: February 27, 2018).

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), Medical Technology Association of India (MTai), Asia Pacific Medical Technology Association (APACMed), 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 until now it was largely unregulated. The Indian government has regulated only a few types of medical devices

through various notifications. All other types of medical devices are unregulated, meaning there is no specific government oversight on its manufacture, import, distribution and sale. The Medical Device Rules, 2017 (“MDR”), which came into effect from January 1, 2018, was expected to fill the legislative void that was present due to the absence of a medical device specific legislation in India. The Indian Government has also recently issued a notification to amend the Medical Device Rules, 2017 to effectively govern all types of medical devices 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.

### 3. India Entry Strategies

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

Strategy	Law	Tax
<ul style="list-style-type: none"> <li>Observing the economic and political environment in India from the perspective of the investment</li> <li>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</li> <li>To strategize the business model by identifying the correct modality to do business in India</li> </ul>	<ul style="list-style-type: none"> <li><b>Exchange Control Laws:</b> Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same</li> <li><b>Corporate Laws:</b> Primarily the Companies Act, 1956, the Companies Act, 2013 and the regulations laid down by the Securities and Exchanges Board of India (“<b>SEBI</b>”)</li> <li><b>Sector Specific Laws:</b> Drugs &amp; Cosmetics Act, 1940, the Drugs &amp; Cosmetics Rules, 1945, the Medical Device Rules, 2017, the Patents Act, 1970 and other legislations, regulations and guidelines that affect the medical devices industry</li> </ul>	<ul style="list-style-type: none"> <li><b>Domestic Taxation Laws:</b> The Income Tax Act, 1961; Goods and Service Tax, customs.</li> <li><b>International Tax Treaties:</b> Treaties with favorable jurisdictions such as Mauritius, Cyprus, Singapore and the Netherlands</li> </ul>

The healthcare sector in India has long been conservative about foreign investment stating concerns of foreign influence over health priorities of domestic manufacturers. However, in recent times, there is growing governmental and popular support for foreign investment in all sectors, including health. It is, therefore, significant to observe the political and economic environment of India.

It is equally important to understand the business culture and consumer mindset prevalent in India. Companies that are quick to adapt to it turn out to be more profitable.

To be aware of the legal and regulatory framework is another must. Medical device

industry is tightly regulated, and any non-compliance may result in penalty as well as criminal prosecution of the management in extreme cases. If a multi-national company is operating a wholly owned subsidiary in India, it must be ensure 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.

## 4. 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.<sup>8</sup>

The definition of medical device in the FDI Policy is different from the definition of medical device under the MDR. This is because the definition of medical devices under the MDR is limited to devices that have been notified as medical devices by the Central Government while the definition under the FDI Policy is expansive enough to include all medical devices.

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

## 5. India's Post-Trips Intellectual Property Environment

In March 2005, India's patent law was amended to incorporate India's obligations under 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 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.

## 6. Legal and Regulatory Regime

The MDR, issued under the Drugs and Cosmetics Act, 1940 (“DCA”), regulate the following categories of substances as medical devices –

- 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). Devices that have not been specifically notified by the Government are not governed under the MDR and therefore are not required to undertake the compliances under the rules.

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.
- Prescribe quality control requirements in respect of Notified Medical Devices.

At the time the MDR came into effect on January 01, 2018, 15 medical devices were regulated under the MDR, while 8 others were regulated as drugs. Since then, the Government has notified 14 additional medical devices, most of which will come under the ambit of the MDR at various points in 2020 and 2021.

The slow pace of bringing medical devices under the purview of the MDR has been a concern for the industry. There are over 1700 types of medical devices in the global market,<sup>9</sup> out of which only 29 would be governed under MDR by April 2021 at the current pace of regulation. To remedy this, the Ministry of Health and Family Welfare (“**Health Ministry**”) issued two notifications on February 11, 2020, effectively bringing all medical devices in India under regulation of the MDR. It is noteworthy that the manner in which all medical devices have been brought under regulation is not by notifying each individual category of medical device, but rather notifying a catch-all definition of medical device as follows:

*“All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means 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;*

9. Article on Technological Innovation: Comparing Development of Drugs, Devices, and Procedures in Medicine, available at: <https://www.ncbi.nlm.nih.gov/books/NBK222708/> (last accessed February 24, 2020).



- 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; and*
- vi. *control of conception.”*

The notifications, which are set to come into effect on April 01, 2020, have been discussed in greater detail in the section titled ‘Medical Device Rules 2017 – an Analysis’ below.

## 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 DCA and MDR 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 introduces two new bodies – the National Accreditation Body and Notified Bodies.

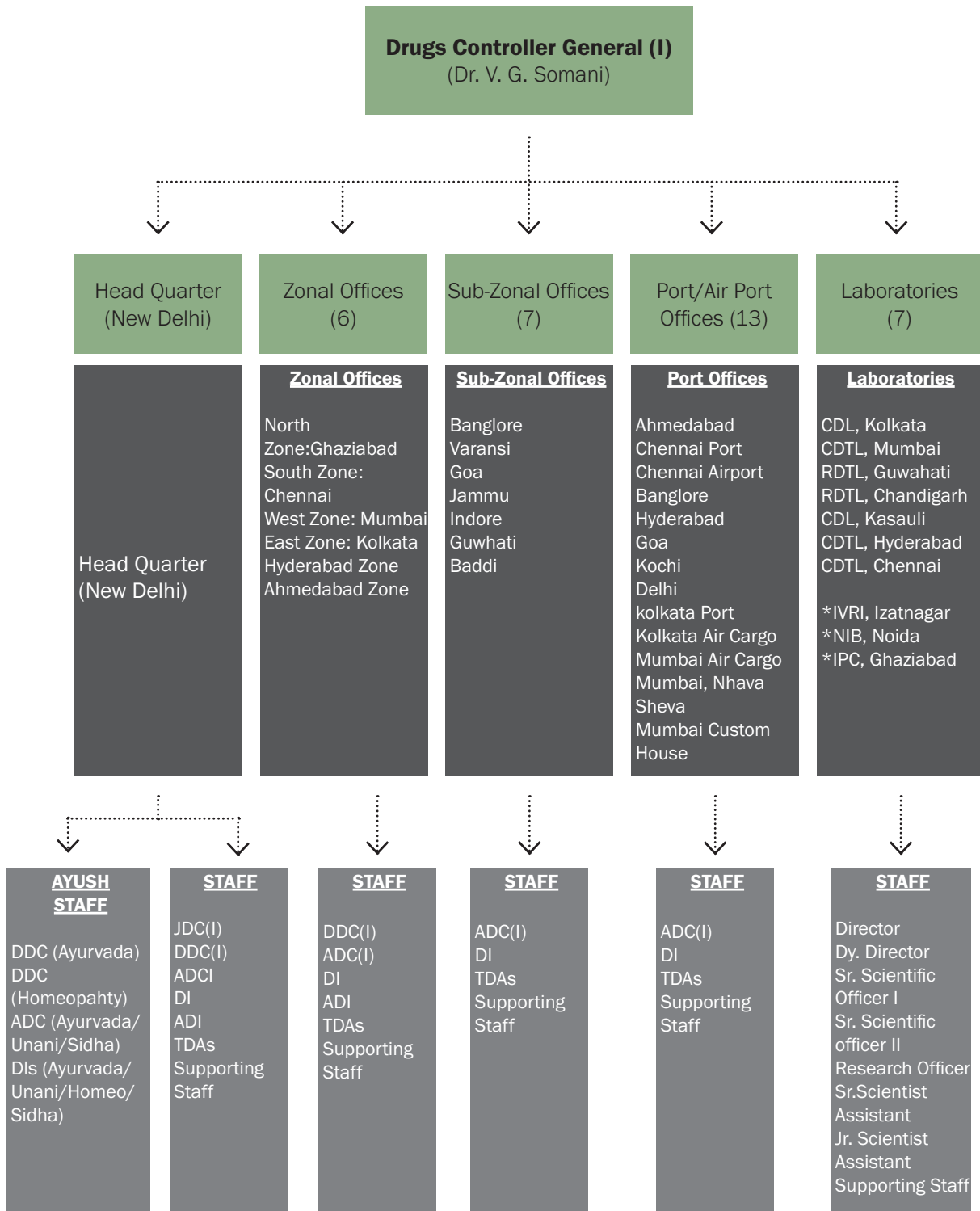
A notified body is responsible for carrying out audits of manufacturing sites of all classes of medical devices, to verify conformance with the Quality Management System (discussed later). An entity with the relevant experience and qualification as prescribed under the MDR can apply to the Central Licensing 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. Currently, the Quality Council of India acts as the National Accreditation Body and carries out the functions 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.



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



Source: <https://cdsco.gov.in/opencms/opencms/en/About-us/Introduction/>

## 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 MDR, Notified Medical Devices may only be imported, manufactured or sold on the basis of a license granted by the CDSCO. 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-Import Policy (“**EXIM 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 a Notified Medical Device for sale 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 and New *in vitro* Diagnostic 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.

A ‘new *in vitro* diagnostic medical device’ is a medical device used for *in vitro* diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for the relevant analyte or other parameter related thereto including details of technology and procedure required.

The MDR mandates that, in addition to a license to manufacture or import the investigational medical device/new *in vitro* diagnostic medical device for sale, 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. This clinical data has to be generated by undertaking clinical investigation/clinical performance evaluation in the manner prescribed by the MDR, as discussed in the next paragraphs.

## VI. Clinical Investigation/ Clinical Performance Evaluation

Clinical investigation refers to systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness. Under the MDR, clinical investigation is required to be carried out for 'investigational medical devices' as pre-condition to manufacturing/importing the investigational medical device for sale in India.

Clinical performance evaluation refers to any systematic investigation by which data is assessed and analyzed to establish or verify performance of the *in vitro* diagnostic medical device for its intended use. Under the MDR, clinical performance evaluation is required to be carried out for 'new *in vitro* diagnostic device' as pre-condition to manufacturing/importing the diagnostic device for sale in India.

The MDR makes it mandatory to undertake clinical investigation/clinical performance evaluation of investigational medical devices/new *in-vitro* diagnostic devices in the following situations:

1. When the device is an investigational medical device; and
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 the clinical investigation carried out for the first time in human participants including 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. A standard notified by the Health Ministry; or
- c. Where (a) or (b) 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
- d. Where both (a), (b) and (c) 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 sticker 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 prescribes the 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. 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 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.

## **XI. 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 (“DCR”) will continue to apply, so long as there is nothing inconsistent in the MDR. Therefore, the provisions of the DCR 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 DCR 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 DCR. 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 in addition to the restriction on labeling applies only to Notified Medical Devices, Indian law specifies restrictions on advertisements of medical devices in general under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 (“DMRA”).

### **Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954**

The DMRA earlier applied only to drugs, but has since been extended to medical devices by the Indian Courts. The DMRA prohibits advertisements about drugs that in terms which suggest or are calculated to lead to the use of that drug for –

- a. The procurement of miscarriage in women or prevention of conception in women; or
- b. The maintenance or improvement of the capacity of human beings for sexual pleasure; or
- c. The correction of menstrual disorder in women; or

- d. The diagnosis, cure mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule to the DMRA.

The schedule to the DMRA specified in (d) above contains 54 disorders such as rheumatism, diseases and disorders of the optical system, heart disease, cancer and diabetes. It should be noted, however, that the DMRA does not prohibit advertisements made to healthcare practitioners in a confidential manner as prescribed under the rules framed under the DMRA.

Recently, the Health Ministry has proposed an amendment to the DMRA. This amendment would modify the definition of 'advertisement' under the DMRA to specifically include advertisements over an electronic medium, websites, social media etc. The amendment also expands the list of diseases in the schedule to the DMRA, by broadly combining the conditions listed in Schedule J to the DCR with the disorders listed in the schedule to the DMRA.

### **The Uniform Code of Pharmaceutical Marketing Practices (“UCPMP”)**

Apart from the DCR and the DMRA, the Department of Pharmaceuticals, Government of India also introduced a set of guidelines in the form of 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 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.

Additionally, 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 **in our paper titled ‘Uniform Code for Pharmaceutical Marketing Practices Decoded’**.<sup>10</sup>

## **XII. Anti-Competitive Practices**

### **The Competition Act, 2002 (“Competition Act”)**

The growth of medical devices industry 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**”) which states agreements entered into to restrain the infringement of the intellectual property rights of medical device companies would not be considered to be anti-competitive agreements.<sup>11</sup>

Under the Competition Act, anti-competitive agreements may either be 'horizontal agreements' or 'vertical agreements'. Horizontal agreements in the medical devices sector would involve agreements entered at same level between medical device manufacturers to restrict supply/fix prices whereas vertical agreements are entered between players at different levels in the supply chain being manufacturers and hospitals in the form of tie-in arrangements.

Cartels by industry associations have been widespread across jurisdictions to set standard prices for both stockists and retailers but this may be considered as price fixing or resale price maintenance under the Competition Act. Although the provisions of the Competition Act recognize protection granted under IP legislations, associations formed to exchange data and information for purposes other than protection of the intellectual property could be considered to be possible competition law violations.

10. [http://www.nishithdesai.com/fileadmin/user\\_upload/pdfs/Research\\_Papers/Uniform-Code-for-Pharmaceutical-Marketing-Practices\\_Decoded.pdf](http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Uniform-Code-for-Pharmaceutical-Marketing-Practices_Decoded.pdf)

11. Section 3(5) of the Competition Act.



Mergers and Takeovers in the medical devices sector have also grown considerably in the past few years. Under the Competition Act, mergers or amalgamations (combinations) exceeding a specified threshold of assets/turnover require prior approval of the Competition Commission of India (“CCI”) (the regulator responsible for administering and enforcing the Competition Act). The CCI is empowered to grant, modify or refuse the combination based on whether the CCI believes the combination would have an appreciable adverse effect on competition in India.

### XIII. Patent Protection

The grant, revocation and regulation of patents takes place under the Patents Act of 1970 (“**Patents Act**”) and is supported by the Patents Rule, 2003, (“**Patents Rules**”). Under the Patents Act, both products and processes are eligible for patents for a span of 20 years.

#### Patentability of medical devices

The Patents Act grants a patent to ‘inventions’ which is “a new product or process involving an inventive step<sup>12</sup> and capable of industrial application<sup>13</sup>.” However, some innovations though falling within the definition of invention above, would not be considered to be ‘inventions’ under the Patents Act and therefore would not be eligible for a patent. One such exception is for a process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease. However, medical devices should not be covered under this exemption as a medical device is not a process for treatment of human beings but instead a device used during such treatment. Therefore, while the process/method of performing a surgery is not patentable, the tools used to

perform such surgery may be patented. Thus, invention of a medical device (or process) is granted patent in India.

The patent rights with respect to any invention are created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Patent Rules. India follows a declarative system with respect to patent rights. Patents are granted on a “first to file” basis. The patent application can be made by either (i) the inventor or (ii) the assignee<sup>14</sup> or (iii) legal representatives<sup>15</sup> of the inventor.

#### A. Convention Application

India, a member of the Paris Convention for the Protection of Industrial Property, has published a list of convention countries from which convention applications are accepted, 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.

#### B. 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

12. 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.”

13. 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.”

14. 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”.

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

or foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the ‘Bolar Exemption’, 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.

### C. 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.

### D. 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 Patents 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.

### E. 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.

### F. Secrecy Provisions<sup>16</sup>

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.

## XIV. Data Exclusivity

When the Indian Government began the process of introducing the 2<sup>nd</sup> 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

16. 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

may offer ‘protection against disclosure’ to the pharma/medical device companies. However, the Government may take some more time to announce its decision on ‘Protection against unfair commercial use’ as the Union ministry of health and the Department of Pharmaceuticals wants further discussions with stakeholders.

## XV. 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.<sup>17</sup>

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.

## XVI. Pricing 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, knee implants and coronary stents. These devices are misleadingly referred to as “Scheduled Formulations”. Notified Medical Devices that are not covered in the schedule as referred to as “Non-Scheduled Formulations”.

17. [http://support.dialog.com/techdocs/international\\_class\\_codes\\_tmarks.pdf](http://support.dialog.com/techdocs/international_class_codes_tmarks.pdf)

The DPCO is administered and enforced by the National Pharmaceutical Pricing Authority (“NPPA”). Generally, the NPPA is empowered to fix prices of drugs in the ‘National List of Essential Medicines’ (“NLEM”) a list of medicines considered to be essential and revised from time to time by the Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers). However, the NPPA may in public interest fix prices of drugs and medical devices that are not in the NLEM.

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

- a. “Scheduled Formulations” – The 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.
- b. “Non-Scheduled Formulations” - The NPPA does not allow any manufacturers and importer of Non-Schedule Formulations to increase the MRP by more than 10% of within a span of 12 months.
- c. Notified Medical Device in public interest - NPPA, in public interest and under extraordinary 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:
  - i. 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.
  - ii. 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%.
  - iii. An importer, other than the marketing authorization holder in India, is treated as a distributor.
  - iv. 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.

Once the Notifications to regulate all medical devices come into effect on April 01, 2020, all medical devices (except the devices in Annexure A) would be treated as ‘non-scheduled formulations’ under the DPCO. As a result, the prices of such medical devices cannot be increased by more than 10% within a given 12-month period. The medical devices under Annexure A would come under the purview of the DPCO as and when they are notified. Further, once notified, the Government would be empowered to add medical devices to the NLEM following which the NPPA would fix a ceiling price for such devices. Separately, the NPPA may also choose to fix the prices of these medical devices in public interest even though the device is not under the NLEM.

## XVII. Penalties

The Ministry of Health and Family Welfare, Government of India (“Ministry”) in the year 2009 notified an amendment to the DCA 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 DCA that specifically relate to the offences of manufacture and trade of spurious Notified Medical Devices.

The penalties under the DCA 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.



## 7. Medical Device Rules 2017 – An Analysis

The introduction of the MDR is a watershed moment in the regulation of medical devices.

Notified Medical Devices were historically treated as “drugs” and for a very long time, the standards 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 has been drafted with the intention to distinguish medical devices from pharmaceuticals in line with internationally acceptable norms. The Salient features of MDR are described below.

### I. 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 does not provide this liberty and the manufacturers/importers will have to follow the classification decided by DCGI.<sup>18</sup> 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 countries other than United Kingdom, United States of America or Australia or Canada or Japan (“**Unregulated Jurisdictions**”) can be granted on the strength of a free sale certificate and either 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.

Similarly, audit/inspection requirements of manufacturing facilities as a pre-condition to grant of manufacturing license are as per the risk classification of the device in question:

- a. Class A medical devices: do not require prior audit by third party<sup>19</sup> or official inspection;
- b. Class B medical devices require prior audit by third party<sup>20</sup> but do not require official inspection; and
- c. Class C or Class D medical devices require prior official inspection.<sup>21</sup>

Further, the application for manufacture of Class A or Class B medical device will be assessed by the State licensing authority whereas the

18. Rule 4(3) of MDR.

19. Rule 20(4)(i). of MDR

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

21. Rule 21(1) of MDR.

application for manufacture of Class C or Class D medical device will be assessed by DCGI.

## II. 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 i.e. the Online System for medical devices.

## III. Certainty and rationalization of timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market/manufacture medical devices. Under the 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 DCR, the MDR do not give any scope to the regulators to extend the timeline 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,<sup>22</sup> the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application,<sup>23</sup> the report of the inspection has to be forwarded to the applicant,<sup>24</sup> and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.<sup>25</sup>

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.<sup>26</sup>

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.<sup>27</sup>

## IV. 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.<sup>28</sup>

22. Rule 21(4) of MDR

23. Rule 23(r) of MDR

24. Rule 24 of MDR

25. Rule 25 of MDR

26. Rule 36(r) of MDR

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

28. Rule 26(xii) of MDR

## V. 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.<sup>29</sup>

## VI. Certainty on consequence of change in particulars contained in the license

The MDR is 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).<sup>30</sup> Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.<sup>31</sup>

What constitutes major change and minor change has also been specified.<sup>32</sup> 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.

Further, in case the particulars of the applicant e.g. manufacturing site, or the name of the applicant changes during the pendency of the license, the applicant has the option to notify the licensing authority regarding the change is not required to make a fresh application.

## VII. Meaning of “change in constitution” explained and change in constitution rationalized

“Change in constitution” was not defined under the DCR and was a source of much confusion. Under the MDR, change in constitution has been defined as that change in constitution of a licensee in relation to<sup>33</sup>:

- 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;*

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

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

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

32. Sixth Schedule of MDR

33. Rule 3(j) of MDR



Therefore, it is clear that:

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.

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.<sup>34</sup> An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.<sup>35</sup> After making such an application, the existing license is deemed to be valid until the fresh application is decided by the licensing authority. Thus, business continuity is ensured during this time.

## VIII. License for sale of medical devices

The MDR does not have separate provisions for sale of medical devices. The provisions related to 'sale of drugs other than homeopathic medicines' in Part VI of the DCR will apply to medical devices as if it was inserted within the MDR.<sup>36</sup> All such licenses issued prior to commencement of MDR shall be deemed to be valid for sale of medical devices as well.<sup>37</sup>

The MDR does, 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 these medical devices are expensive

and its demand is difficult to predict, hospitals are hesitant to purchase such 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 DCR 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).<sup>38</sup>

## IX. Mandatory recalls on knowledge of risk to safety

The MDR make it mandatory<sup>39</sup> for manufacturers and importers to immediately initiate recall in case the manufacturer/importer has reasons to believe that a medical device is likely to pose risk to the health of a user or patient during its use. 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.

34. Rule 27 of MDR

35. Rule 39 of MDR

36. Rule 87(1) of MDR

37. Rule 87(2) of MDR

38. Rule 88(1) of MDR

39. Rule 89(1) of MDR

In contrast, the DCR do not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to user or patients.<sup>40</sup> 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.<sup>41</sup>

## X. New thresholds for residual shelf life of imported products

The MDR prescribes residual shelf life requirement for import of medical devices with short shelf life.<sup>42</sup> Any medical device, whose total shelf life claim is

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

## XI. New regulatory framework for clinical investigation/ clinical performance evaluation of medical device

The MDR introduces a new regulatory framework for clinical investigation of medical devices and clinical performance evaluation of in-vitro diagnostic devices. Some of the interesting provisions of this framework are:

- a. A fixed timeline of ninety (90) days has been prescribed for the licensing authority to arrive at a decision on application for permission to conduct clinical trial;
- b. After obtaining permission to conduct clinical trial, the first subject is required to be enrolled within one year;
- c. New concepts of Pilot Study (i.e. exploratory study) and Pivotal Study (i.e. confirmatory study) have been introduced with respect to approval of investigation medical device;
- d. New concept of “substantial equivalence” to predicate devices has been introduced with respect to approval of medical devices other than investigational medical devices;
- e. The clinical performance evaluation of In Vitro Diagnostic Devices is now part of the regulatory framework;
- f. Any institute, organization, hospital run or funded by the Central Government or the State Government is exempted from payment of fees for conduct of clinical investigation; and
- g. Academic clinical trials do not require prior approval of the licensing authority for its initiation if the data generated during the study will not be used for obtaining manufacturing or import license.

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

## XII. Debarment on account of supply of misleading information

The MDR frowns 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

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

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

42. Rule 47 of MDR

fit.<sup>43</sup> 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.

### XIII. Notifications issued to regulate all medical devices in India

The Health Ministry on February 11, 2020 published two notifications, the first effectively notifying all medical devices by way of an expansive and catch-all definition of medical devices (“**New Definition Notification**”), and the second requiring the registration of such newly notified medical devices on a portal (“**Portal**”) developed by the CDSCO (“**Registration Notification**”) (collectively referred to as the “**Notifications**”). The Notifications will come into effect on April 01, 2020.

The Health Ministry had released a draft version of the Notifications for public comments on October 18, 2019 (“**Draft Notifications**”). However, there are no changes between the Draft Notifications and the Notifications.

The Notifications were both released on the same day and would also come into effect on the same day i.e. April 01, 2020. The Notifications are largely based on the roadmap for medical devices discussed by the Drugs Technical Advisory Board – India’s apex body on technical matters related to drugs – in April 2018, and the Draft Notifications published thereafter.

Once the New Definition Notification comes into force, the MDR will apply to all medical

devices except for the devices in Annexure A (“**New Devices**”).

Interestingly, the New Definition Notification does not change the existing definition of medical devices under section 3(b)(iv) of the DCA. Instead, the New Definition Notification notifies a catch-all definition of medical devices, effectively bringing all medical devices under the regulation of the MDR as follows:

*“All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means 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; and*
- vi. control of conception.”*

Therefore, once the New Definition Notification comes into effect, manufacturers and importers of New Devices would be required to obtain manufacturing and import licenses under the MDR to engage in the manufacture and import of medical devices.

However, once the New Device has been registered on the Portal as per the procedure described in the Registration Notification, such device will be exempt from the MDR (and consequently from obtaining the above-mentioned manufacturing and import licenses) for a period of 30 months from April 01, 2020 if the New Device is a Class A or Class B device, and for a period of 42 months if the New Device

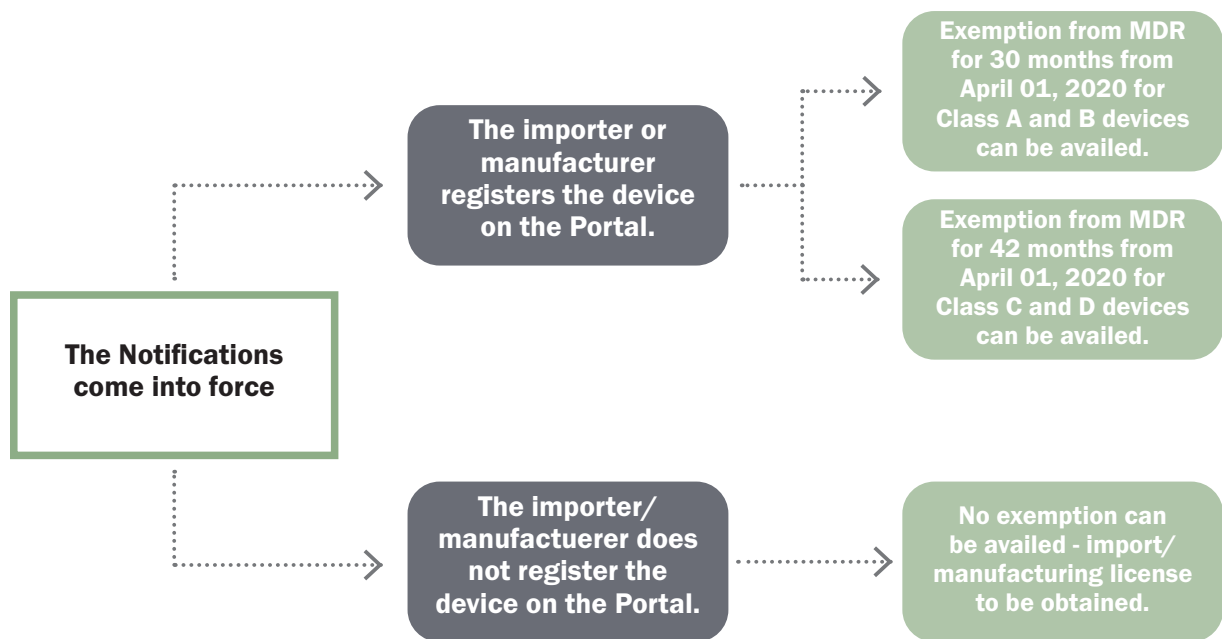
43. Rule 93(1) of MDR

is a class C or Class D device (“**Exemption Provision**”).

Notably, the registration of New Devices on the Portal is on an optional basis for 18 months and mandatory thereafter. However, as the Exemption Provision is applicable only for New Devices that have been registered on the Portal, manufacturers and importers have a strong incentive to register their New Devices as soon as the Portal becomes operative so that they can avail of the Exemption Provision.

the New Device until they obtain the requisite licenses. In the event the Portal is not operational on time or experiences technical difficulties, medical device companies may be forced to halt operations entirely after April 01, 2020 until they are able to register their medical device.

Alongside the registration process, manufacturers and importers will be required to apply for manufacturing and import licenses with the CDSCO, in order to comply with the larger ambit of the MDR once the Exemption Provision expires – a process that typically takes



**Chart 1: Overview of Registration Process**

The Notifications constitute the most significant development in medical device regulation, second only to the enactment of the MDR itself.

However, there are some concerns with respect to both clarity and expected impact with respect to the Notifications, as outlined below.

### A. Tight Timelines For Ensuring Compliance

Registering the New Devices is a pre-condition to availing the Exemption Provision. Therefore, manufacturers and importers will be compelled to register the New Devices to avail the Exemption Provision or not import/manufacture

nine months to complete. However, given the large volume of applications the CDSCO is bound to receive, processing the applications may take even longer. This issue may be further compounded as the CDSCO is currently inadequately staffed to deal with such a large volume of applications.

As a result, manufacturers and importers who have not been granted the required licenses at the expiry of the Exemption Provision despite having registered their New Devices and applied for licenses well in time will be forced to halt operations.

While halting business operations is certainly a concern from a business perspective, the more

significant ramification is from a patient safety perspective. Gaps in supply of medical devices could leave patients without the care they need and can even be life threatening in cases where patients need devices such as pacemakers.

Ideally, the Exemption Provision should have been de-linked from the requirement to register the device. This way, New Device manufacturers/importers would have had the full 30 or 42 months to register their New Device. Additionally, manufacturers and importers who have registered their New Device on the Portal and applied for a manufacturing/import license should have been permitted to carry on business activities on a provisional basis at the expiry of the Exemption Provision, until either a license is granted or the application is rejected. This may have helped stagger the workload on the CDSCO without requiring medical device companies to halt their business activities.

## B. Ambiguities On Registration Process

The details required to be uploaded by the manufacturer and importer (specified in **Annexure E**) contemplate the manufacture or import of a medical device as a whole. However, a medical device could also be partly manufactured in India and partly imported. Additionally, spare parts of medical devices may also be imported separately for repairing the medical device. Clarification is still required from the CDSCO on how registration numbers will be generated for medical devices which cannot be registered as a whole. Further, the manufacturer/importer is also required to upload the ISO 13485 certification<sup>44</sup> obtained in respect of the medical devices. Medical device manufactures/importers who are yet to obtain this certification may be forced to halt operations until they obtain the certificate.

The manufacturer or importer is also required to specify the class of the medical device sought to be manufactured or imported when entering

the details of the medical device on the Portal. The CDSCO will therefore be required to classify a large number of medical devices before the registration requirement comes into effect which, given the impending timeline, appears to be a herculean task. The CDSCO should ideally clarify whether importers/manufacturers can self-classify based on similar classifications in other jurisdictions, in order to ease the transition.

Additionally, before the Exemption Provision expires, the CDSCO would also be required to ascertain which of the medical devices registered on the Portal may be considered to be investigational medical devices/new in-vitro diagnostic devices. Broadly, this would require the CDSCO to look into whether each device registered on the Portal has a history of safe use in India, or whether the medical device needs to undergo clinical testing before it can be considered to be safe and efficacious for use in India. It is currently unclear whether existing devices in the market, although sold for a long time in India, would be considered to be investigational devices, given that safety and efficacy data was not required to be generated when the device was first launched. Due to this, it is possible that the first applicant of each category of medical device would be required to undergo clinical evaluations before the device can be re-introduced into the market. Effectively, this means that there could be an availability gap of numerous devices, until approvals are granted for the re-introduction of the device post the expiry of the Exemption Provision. Ideally, the CDSCO should clarify the parameters to determine when a New Device would be considered to be an investigational medical device.

To add to the ambiguity, as of this writing, the Portal i.e. the Online System for Medical Devices does not appear to provide for registration of medical devices. It is therefore unclear whether the registration process would start only once the Notifications come into effect, in which case, importers and manufacturers would be required to wait until the registration is issued post April 2020 (unless the entire process as envisaged under the Notifications runs smoothly and registration numbers are auto-generated immediately upon submission of

44. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes



the application), before commercial activities can continue. Hopefully, the Portal would be operational soon so that medical device manufacturers and importers can register their devices by the time the Notifications come into effect. Alternatively, the CDSCO should allow for a grace period after April 2020, wherein medical device manufacturers/importers who have made the application for registration can continue to manufacture/import, until such time a registration is granted.

### C. Status of Medical Devices Exempted Under The Registration Notification

The medical devices that have already come under the purview of the MDR or will be coming under the purview of the MDR over the next year (as specified in Annexure A) have been specifically excluded under the Registration Notification. As a result, these devices are not required to be registered on the Portal. Further, these devices would also be exempt from compliances under the MDR until the date the medical device is slated to come under regulation. For instance, MRI equipment which has been notified under the MDR with effect from April 01, 2021 would not be governed under the MDR by virtue the Notifications (and therefore no registration of MRI equipment would be required).

However, MRI Equipment would be governed by the MDR with effect from April 01, 2021. Therefore, manufactures and importers of MRI Equipment would be required to obtain the requisite licenses prior to April 01, 2021 to carry on commercial activity relating to MRI Equipment thereafter. Typically, the regulators take anywhere between 9 to 12 months to grant

an import/manufacturing license. Therefore, the CDSCO and state licensing authorities should start accepting applications for the granting manufacture/import licenses in respect of the devices in Annexure A which are yet to come under regulation. A delay in obtaining/grant of license would force the manufactures/importers of these devices to cease business operations in respect of the device and would lead to a loss in business and revenue for the medical device manufacturers.

For more information on the impact of the notifications, please refer to our hotline on this subject [here](#).<sup>45</sup>

## XIV. An opportunity lost

Though the MDR and the Notifications 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 under 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.

45. [http://www.nishithdesai.com/information/research-and-articles/nda-hotline/nda-hotline-single-view/newsid/5906/html/1.html?no\\_cache=1](http://www.nishithdesai.com/information/research-and-articles/nda-hotline/nda-hotline-single-view/newsid/5906/html/1.html?no_cache=1)

## 8. 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.<sup>46</sup> In this regard, the Central Board of Direct Taxes (“**CBDT**”) recently released the final guidelines for determination of POEM. ([Please click here](#) to read our hotline on the same).

Section 9 of the ITA deems certain income of non-residents to be Indian source income. Under section 9(1), “capital gains” are considered to have their source in India and are taxable in India if they arise directly or indirectly, through the transfer of a capital asset situated in India. Similarly, the “business income” of a non-resident is taxable in India only if it accrues or arises, directly or indirectly, through or from any business connection in India.

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

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

In recent times, the Indian income tax authorities have been adopting an aggressive approach to transactions where any form of exemption from taxation is sought by the taxpayer. Their approach is even more hostile when the transaction in question has an offshore element to it. Hence, it 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. The surcharge applicable to income generated by resident companies for the financial year 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, surcharge applicable to income generated by companies other than domestic companies, for the financial year 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.

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

## i. Taxes Applicable to companies

Resident companies are taxed at the rate of 30%<sup>47</sup>, 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 400 million (approx. USD 5.5 million) is 25%.

Further, on September 20, 2019, the Government promulgated the Taxation Laws (Amendment) Ordinance 2019, to primarily reduce corporate tax rates as a knee-jerk reaction to India's economic slowdown. ('**Ordinance**') effective from April, 2019. As per the Ordinance, domestic companies may choose to be taxed at the effective rate of 25.17% under the newly introduced section 115BAA of the ITA subject to certain conditions such as (i) total income is computed without claiming certain specified deductions and exemptions under the Income-tax Act, 1961 ('Deductions'); (ii) the company shall not be allowed to set off any carried forward losses from earlier assessment years if such loss is attributable to the Deductions; (iii) the company claims depreciation in the manner prescribed barring any depreciation in respect of plant and machinery; (iv) once exercised, the option to be taxed under this provision cannot be withdrawn and will continue to apply for subsequent assessment years etc.

The Ordinance also introduced section 115BAB to the ITA, as per which new manufacturing companies set up on or after October 1, 2019 may avail an effective tax rate of 17.16% subject to prescribed conditions, which are broadly similar to the conditions applicable for availing section 115BAA. Non-resident companies are taxed at the rate of about 42% (if net income is in the range of INR1 crore – 10 crores) and approximately 43% (if net income exceeds INR 10 crores). While residents are taxed on their worldwide income, non-residents are only taxed on income arising to them from sources in India.

A company is said to be resident in India if it is incorporated in India or has its POEM in India. Minimum alternate tax ("**MAT**") at the rate of 15% (excluding surcharge and education cess) is also payable on the book profits of a company, if the company's income due to exemptions is less than 15% of its book profits. The MAT rate was reduced from 18.5% to 15%, effective from April 1, 2019, by virtue of the Ordinance. Importantly, the Ordinance also provides that no MAT shall be applicable in case of companies opting to be taxed under section 115BAA / 115BAB. With respect to 'eligible start-ups' meeting certain specified criteria, a 100% tax holiday for any 3 consecutive assessment years out of a block of 7 years beginning from the year in which such start up is set up has been provided for.<sup>48</sup>..

## 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, no further Indian taxes are payable by the shareholders on such dividend income once DDT is paid, except in certain specified situations. Finance Bill, 2020 has proposed to abolish Dividend Distribution Tax (DDT). Accordingly, from April 1, 2020, dividends declared by an Indian company would be subject tax in the hands of the recipient at slab rates and subject to necessary withholding tax in the hands of the Indian payer company. Unlike in case of DDT, the foreign recipients of the dividends should now be able to avail treaty benefits in respect of the taxes paid on dividends. Further, the mechanism to claim foreign tax credit on the taxes paid on the dividends would be much easier as it was in case of payment of DDT. This is because DDT was tax paid by the distribution company and the not the recipient and there needed to be necessary language in the laws of the relevant foreign jurisdiction / applicable treaty on availment of underlying tax credits for availing foreign tax credit in respect of DDT paid in India.

47. All tax rates are applicable to Financial Year 2017-18 and are exclusive of surcharge and education cess.

48. Section 80-IAC, Income Tax Act, 1961



### 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 TDS at 5%.<sup>49</sup> 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, 2020. The said beneficial 5% rate of TDS is also available in relation to Rupee Denominated Bonds (“RDB”) issued until July 1, 2020. Similarly, interest payable to foreign institutional investors (“FII”) on investments made by them in RDBs and government securities is taxable at the rate of 5%. This benefit also has a sunset period and is applicable only in respect of interest payable until July 1, 2020.<sup>50</sup>

In all cases above, the Finance Bill, 2020 has proposed to extend the end of the sunset period, wherever applicable, from July 1, 2020 to July 1, 2023.

Also as regards interest payments made by an Indian company to its associated enterprises/ related party,<sup>51</sup> the Thin Capitalization Rules would apply, 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 Indian domestic law is much wider than the definition under most tax treaties signed by India.

49. Section 194LC, Income Tax Act, 1961

50. Section 194LD, Income Tax Act, 1961

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

### iv. Capital Gains

Tax on capital gains depends on the period of holding of a capital asset. Short term gains may arise if the asset is held for a period lesser than 3 years. Long term gains may arise if the asset is held for a period more than 3 years. Gains from listed shares which are held for a period of more than 12 months are categorized as long term.

Unlisted shares and immovable property (being land or buildings or both) are treated as long term only when held for more than 24 months.

Long term capital gains earned by a non-resident on sale of unlisted securities may be taxed at the rate of 10%<sup>52</sup> (provided no benefit of indexation has been availed) or 20% (if benefit of indexation has been availed) depending on certain considerations. Long term gains on sale of listed securities on a stock exchange used to be exempted and only subject to a securities transaction tax (“STT”). However, the Finance Act, 2018 removed this exemption and introduced a levy of 10% tax on LTCG arising from the transfer of listed equity shares, units of an equity oriented mutual fund, or units of a business trust where such gains exceed INR 100,000 (approx. USD 1500). This tax is applicable on LTCG arising on or after April 1, 2018 and no indexation benefits can be availed of. However, the Finance Act 2018 also introduced limited grandfathering in respect of protecting the gains realized on a mark to market basis up to January 31, 2018 and only an increase in share value post this date would be brought within the tax net. Further, earlier, for the purposes of obtaining the LTCG exemption, the Finance Act, 2017 had introduced an additional requirement for STT to be paid at the time of acquisition of listed shares. However, the CBDT had exempted certain modes of acquisition from this requirement. Pursuant to withdrawal of the exemption in Finance Act, 2018, the CBDT issued a notification specifying that the requirement to pay STT at the time of acquisition will not apply to (1) share acquisitions undertaken prior to October 1, 2004,

52. All the tax rates mentioned in this section are exclusive of applicable surcharge and cess

(2) share acquisitions undertaken on or after October 1, 2004 which are not chargeable to STT subject to certain exceptions for the purposes of obtaining the capital gains tax rate of 10% under section 112A.<sup>53</sup> Short term capital gains arising out of sale of listed shares on the stock exchange are taxed at the rate of 15%, while such gains arising to a non-resident from sale of unlisted shares is 40%.

## 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, under the Finance Act 2016 the rate of deduction has been restricted 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.

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,

53. Draft of Notification issued under section 112A(4) of the Income tax Act, 1961, available at <https://incometaxindia.gov.in/Lists/Latest%20News/Attachments/240/Draft-Notification-24042018.pdf>

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,<sup>54</sup> 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."

54. 1983 144 ITR 146 AP

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

#### i. Fixed Place of Business PE

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

#### 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:

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

- i. activities of that nature continue within that State for a period or periods aggregating to more than 90 days within any twelve-month period; or
- ii. the services are performed within that State for a related enterprise (within the meaning of paragraph 1 of article 9 (associated enterprises))."

#### iii. Agency PE

Indian Tax Treaties typically contain a provision whereby an Indian entity may be treated as a PE of a foreign enterprise if the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise. Moreover, some Indian Tax Treaties, such as the India-US tax treaty, also contain an additional provision whereby an Indian entity may be

regarded as a PE of the foreign enterprise, if the Indian entity maintains a stock of goods from which it regularly delivers such goods on behalf of the foreign enterprise and contributes to the sale of such goods. An agent of independent nature is considered as an exception to the Agency PE rule.

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

#### D. Issue of taxation as an Association of Persons

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

Although there is no definition of AOP under the ITA, there have been a number of cases in which this issue has been discussed. In the case of Commissioner of Income Tax v. Indira Balkrishna,<sup>55</sup> 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,<sup>56</sup> the Andhra Pradesh High Court further examined this concept and observed that “it is, therefore, clear that an association of persons does not mean any and every combination of persons. It is only when they associate themselves in an income-producing activity that they become an association of persons. They must combine to engage in such an activity; the engagement must be pursuant to the combined will of the persons constituting the association; there must be a meeting of the minds,

so to speak. In a nutshell, there must be a common design to produce income. If there is no common design, there is no association. Common interest is not enough. Production of income is not enough.”

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

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

#### E. Structuring Investment into India – Use of Intermediate Jurisdictions

Foreign entities that are looking at incorporating subsidiaries in India for outsourcing research and manufacturing functions can achieve tax efficiency by use of a tax neutral intermediate jurisdiction which has signed an Indian Tax Treaty (“**Treaty Jurisdiction**”) rather than

55. [1960] 39 ITR 546 (SC)

56. [1977] 106 ITR 111 (AP)

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 Finance Act, 2017 introduced the concept of secondary adjustment under the transfer pricing regulations through introduction of 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 does not apply 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.

Under the transfer pricing regime, 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 instructions 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.<sup>57</sup>

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.<sup>58</sup> However Countervailing Duty (“CVD”) and Special Additional Duty (“SAD”) would be subsumed into the IGST, which would be levied on the imported goods.

### 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.

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

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

Further, the Central Government, if satisfied that circumstances exist which render it necessary to take immediate action to provide for the protection of the interests of any industry, from a sudden upsurge in the import of goods of a particular class or classes, may provide for a Safeguard Duty. Safeguard Duty is levied on such goods as a temporary measure and the intention for the same is protection of a particular industry from the sudden rise in import.

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

## 9. Conclusion- Four Steps Forward, Two Steps Backward?

We are seeing significant positive changes in the regulatory regime for medical device in India. From “Two Steps Forward and Four Steps Backwards” it is now Four Steps Forward and Two Steps Backwards”.

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 2020 appears to be the implementation of the

Notifications and the way the large number of medical devices in the market would be brought under regulation. While the industry’s concern with respect to the Notifications is justified, the CDSCO over the past year has demonstrated willingness to consider the industry’s concerns and cooperate with the industry to arrive at solutions for the same.

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<sup>59</sup>

Sr. No	Medical Device	Status
1	Disposable Hypodermic Syringes	In force
2	Disposable Hypodermic Needles	In force
3	Disposable Perfusion Sets	In force
4	Substances used for in vitro diagnosis including Blood Grouping Sera	In force
5	Cardiac Stents	In force
6	Drug Eluting Stents	In force
7	Catheters	In force
8	Intra Ocular Lenses	In force
9	I.V. Cannulae	In force
10	Bone Cements	In force
11	Heart Valves	In force
12	Scalp Vein Set	In force
13	Orthopedic Implants	In force
14	Internal Prosthetic Replacements	In force
15	Ablation Devices	In force
16	Ligatures, Sutures and Staplers	In force
17	Intra Uterine Devices (Cu-T)	In force
18	Condoms	In force
19	Tubal Rings	In force
20	Surgical Dressing	In force
21	Umbilical Tapes	In force
22	Blood/Blood Component Bags	In force
23	Organ Preservation Solution	In force
24	Nebulizer	From January 01, 2021
25	Blood Pressure Monitoring Device	From January 01, 2021
26	Glucometer	From January 01, 2021
27	Digital Thermometer	From January 01, 2021
28	All Implantable Medical Devices	From April 01, 2021

59. Annexure A contains the list of medical devices that are exempt from the registration requirements under the Notifications as per the Eighth Schedule of the MDR.

<b>29</b>	CT Scan Equipment	From April 01, 2021
<b>30</b>	MRI Equipment	From April 01, 2021
<b>31</b>	Defibrillators	From April 01, 2021
<b>32</b>	PET Equipment	From April 01, 2021
<b>33</b>	X-Ray Machine	From April 01, 2021
<b>34</b>	Dialysis Machine	From April 01, 2021
<b>35</b>	Bone Marrow Cell Separator	From April 01, 2021
<b>36</b>	Ultrasound Equipment	From November 01, 2020
<b>37</b>	Disinfectants and insecticide specified in Medical Devices Rules, 2017	In force

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,-

1. to be used in direct contact with the heart, the central circulatory system or the central nervous system;
  2. to be life supporting or life sustaining;
  3. to be an active medical device;
  4. to be wholly or mainly absorbed by the human body;
  5. for the administration of any medicinal product; or
  6. to be a breast implant.
- d. Subject to clause (b), a long term use medical device shall be assigned to Class D, if it is intended to undergo chemical change in the body.

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

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

#### **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;
- 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

- i. Basic principles for classification of *in vitro* diagnostic medical devices:
  - a. Application of the classification provisions shall be governed by the intended purpose of the devices.
  - b. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
  - c. Software, which drives a device or influences the use of a device, falls automatically in the same class.
  - d. Standalone software, which are not incorporated into the medical device itself and provide an analysis based on the results from the analyser, shall be classified in to the same category that of the *in vitro* diagnostic medical device where it controls or influences the intended output of a separate *in vitro* diagnostic medical device.
  - e. Subject to the clause (c) and (d), software that is not incorporated in an *in vitro* diagnostic medical device, shall be classified using the classification provisions as specified in paragraph 2.
  - f. Calibrators intended to be used with a reagent should be treated in the same class as the *in vitro* diagnostic medical device reagent.
  - g. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the stringent rules resulting in the higher classification shall apply.
2. The parameters for classification of *in vitro* diagnostic medical devices as follows:-
  - i. ***In vitro* diagnostic medical devices for detecting transmissible agents, etc.:**
    - a. An *in vitro* diagnostic medical device shall be assigned to Class D, if it is intended to be used for detecting the presence of, or exposure to, a transmissible agent that,-
      - i. is in any blood, blood component, blood derivative, cell, tissue or organ, in order to assess the suitability of the blood, blood component, blood derivative, cell, tissue or organ, as the case may be, for transfusion or transplantation; or
      2. causes a life-threatening disease with a high risk of propagation.
    - b. An *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended for use in,-
      - i. 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;

**iii. *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.

**iv. *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.

**v. *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.

**vi. Other *in vitro* diagnostic medical devices:**

- a. An *in vitro* diagnostic medical device shall be assigned to Class B, if subparagraphs (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.

**vii. *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).

The Complete List of devices classified so far may be accessed **here**.<sup>60</sup>

---

60. [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NDM5Ng==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng==)

## Annexure - E

Sr. No	Document	Manufacturer	Importer
<b>1.</b>	Details of Applicant	Name and address of entity manufacturing the medical device and the name and address of the manufacturing site.	Name of the entity importing the medical device and specification and standards of that medical device,
<b>2.</b>	Details of Medical Device	<ul style="list-style-type: none"> <li>■ Generic Name</li> <li>■ Model Number</li> <li>■ Intended Use</li> <li>■ Class of Medical Device</li> <li>■ Material of Construction</li> <li>■ Dimension (if any)</li> <li>■ Shelf Life</li> <li>■ Sterile or Non-Sterile</li> <li>■ Brand Name (Registered under the Trademarks Act, 1999)</li> </ul>	<ul style="list-style-type: none"> <li>■ Generic Name</li> <li>■ Model Number</li> <li>■ Intended Use</li> <li>■ Class of Medical Device</li> <li>■ Material of Construction</li> <li>■ Dimension (if any)</li> <li>■ Shelf Life</li> <li>■ Sterile or Non-Sterile</li> <li>■ Brand Name (Registered under the Trademarks Act, 1999)</li> </ul>
<b>3.</b>	Certificate of Compliance	Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device	Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device
<b>4.</b>	Undertaking	Undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.	Undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

The following research papers and much more are available on our Knowledge Site: [www.nishithdesai.com](http://www.nishithdesai.com)

	<p><b>Private Equity and Private Debt Investments in India</b></p>		<p><b>International Commercial Arbitration: Law and Recent Developments in India</b></p>		<p><b>Are we ready for Designer Babies?</b></p>
	May 2019		May 2019		June 2019
	<p><b>India Opens Skies for Drones</b></p>		<p><b>Digital Health in India</b></p>		<p><b>Impact Investing Simplified</b></p>
	August 2019		November 2019		July 2019
	<p><b>IP Centric Deals: Key legal, tax and structuring considerations from Indian law perspective</b></p>		<p><b>Fund Formation: Attracting Global Investors</b></p>		<p><b>Building a Successful Blockchain Ecosystem for India</b></p>
	February 2019		February 2019		December 2018

## NDA Insights

TITLE	TYPE	DATE
Delhi Tribunal: Hitachi Singapore’s Liaison Office in India is a Permanent Establishment, Scope of Exclusion Under Singapore Treaty Restrictive	Tax	November 2019
CBDT issues clarification around availment of additional depreciation and MAT credit for companies availing lower rate of tax	Tax	October 2019
Bombay High Court quashes 197 order rejecting Mauritius tax treaty benefits	Tax	May 2019
Investment Arbitration & India – 2019 Year in review	Dispute	January 2020
Changing landscape of confidentiality in international arbitration	Dispute	January 2020
The Arbitration and Conciliation Amendment Act, 2019 – A new dawn or sinking into a morass?	Dispute	January 2020
Why, how, and to what extent AI could enter the decision-making boardroom?	TMT	January 2020
Privacy in India - Wheels in motion for an epic 2020	TMT	December 2019
Court orders Global Take Down of Content Uploaded from India	TMT	November 2019
Graveyard Shift in India: Employers in Bangalore / Karnataka Permitted to Engage Women Employees at Night in Factories	HR	December 2019
India’s Provident Fund law: proposed amendments and new circular helps employers see light at the tunnel’s end	HR	August 2019
Crèche Facility By Employers in India: Rules Notified for Bangalore	HR	August 2019
Pharma Year-End Wrap: Signs of exciting times ahead?	Pharma	December 2019
Medical Device Revamp: Regulatory Pathway or Regulatory Maze?	Pharma	November 2019
Prohibition of E-Cigarettes: End of ENDS?	Pharma	September 2019



## 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](mailto: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

1185 Avenue of the Americas,  
Suite 326 New York, NY 10036, USA

tel +1 212 464 7050