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Research

Medical Device Industry in India

Regulatory, Legal and Tax Issues

February 2025

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Executive Summary

India is counted among the top 20 global medical devices market and is expected to grow at a CAGR of 16.4% reach USD 50 billion by 2030.[1] The Indian medical device market is dominated by imported products, which comprise of around 80% of total sales.[2] The domestic companies are largely involved in manufacturing low-end products for local as well as international consumption. Lately, many multinational companies have established local presence by acquiring established domestic companies or starting a new business.

Medical devices play a role not only in screening, diagnosing and treating patients but also in restoring patients to normal lives and in regularly monitoring health indicators to prevent diseases. With technological advancements, the role of medical devices is now expanding to improve quality of care across each stage of the healthcare sector. 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, in March 2020, the government approved 'Production-Linked Incentives (PLI) Scheme for Medical Devices. Earlier in 2019, the government undertook to set up four medical devices parks in Andhra Pradesh, Telangana, Tamil Nadu and Kerala. The medical device parks are expected to reduce manufacturing costs, as these will be equipped with the necessary infrastructure.

The importance of the medical device industry was catapulted into the public eye during the early stages of the COVID-19 pandemic. In March 2020, when COVID-19 cases first started increasing in India, there was a corresponding steep increase in the demand of COVID-19 diagnostic test kits and ventilators. The Indian medical device industry comprising of both domestic and foreign players rallied together to bridge the gap. The Indian government also stepped in to expedite approvals for test kits and encourage manufacturing of ventilators. Over the few past years, the medical device industry has been crucial in ensuring a steady supply of diagnostic kits and ventilators. The rise of domestic manufacturing in these areas has led to the start of a new chapter for India's medical device companies.

Medical devices in India are regulated under the Medical Device Rules, 2017. The rules are at par with international norms and utilize the concept of 'risk-based' regulation. The regulatory licenses issued for import, manufacture or sale of medical devices are perpetual in nature which helps cut down on unnecessary and time-consuming paperwork. In February 2020, the Indian Government also significantly expanded the scope of India's medical device regulation by way of a notification. When the above-mentioned notification came into effect on April 01, 2020, all medical devices were brought under the purview of India's medical device regulatory framework, prior to the notification, only 29 categories of medical devices were regulated in India.

As part of ensuring ease of doing business in India, foreign direct investment in medical device manufacturing sector is permitted without any prior approval from the government, allowing business to quickly scale-up existing operations by infusing capital or engage in time-sensitive strategic acquisitions. The already robust intellectual property rights regime in India has been strengthened further by allowing for grant of patent and trademarks for medical devices. 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.

1 Available at: https://www.ibef.org/industry/medical-devices.aspx, last accessed on January 25, 2023.

2 https://www.ibef.org/industry/medical-devices.aspx, last accessed January 25, 2023.

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 an erroneous declaration on the label, quite a drawn-out process. The third challenge is presence of laws that restrict manufactures and importers of medical device from promoting their products directly to the customers in certain circumstances. All these challenges, and many more, are detailed in the body of this research paper.

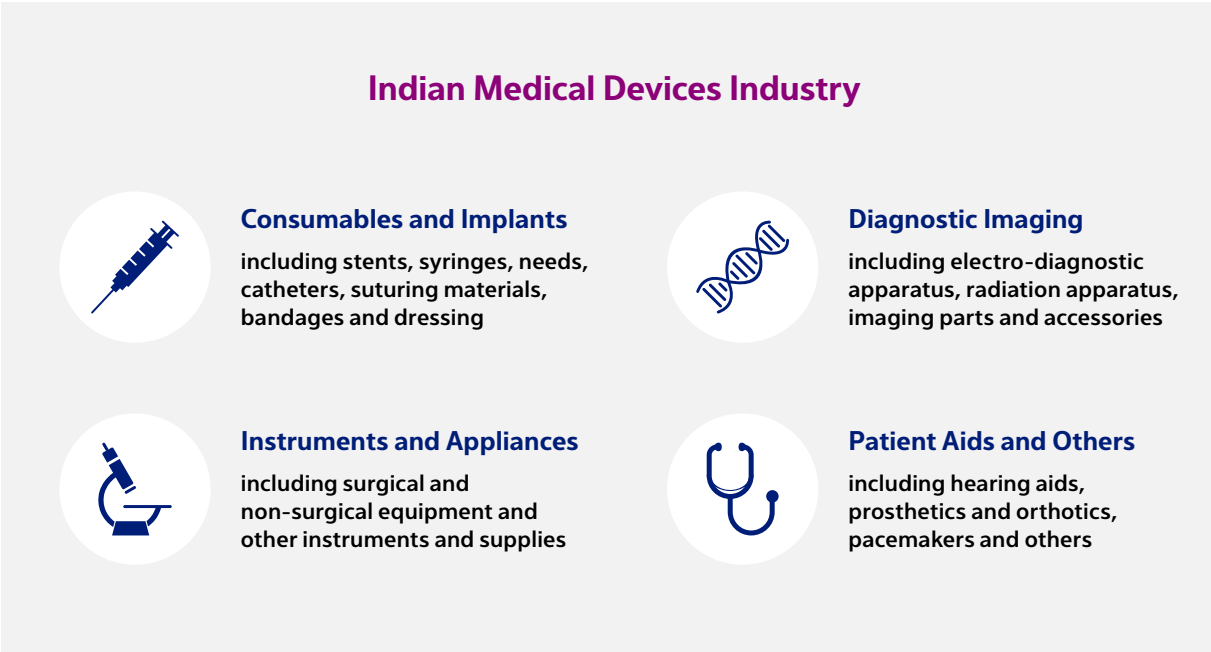
One must also not lose sight of the fact that the Indian consumer mindset and local business practices are unique and must be carefully studied while developing a business model. Certain laws, such as the foreign exchange regulations and the tax statute must also be assessed in-depth because they affect 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 ear-marked 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.

Introduction

The approximate USD 11 Billion worth Indian medical device sector 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. 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 segments of the medical device industry are illustrated below:



Source: Deloitte Medical Devices Report [1]

1 Medical Devices Making in India — A Leap for Indian Healthcare, Delloite, available at: https://www2.deloitte.com/in/en/pages/life-sciences-and-healthcare/articles/medical-devices-making-in-india.html, last accessed on January 25, 2023.

The sector is at present growing at around 35.4% Compound Annual Growth Rate ("**CAGR**") for a plethora of reasons.[2] 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 14,526 Crore (approx. USD 2.3 Billion) between April 2000 to September 2021.[3] By 2025, the Indian market for medical equipment is predicted to increase to USD 50 billion.[4]

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), Eastern Medikit, Harsoria health care, Nidhi Meditech System, Philips Medical, Wipro Technologies, HCL Technologies and Texas Instruments.

Some of the major industry associations include 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.

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

2 https://www.ibef.org/industry/medical-devices.aspx, last accessed January 25, 2023.

3 https://dpiit.gov.in/sites/default/files/FDI_Factsheet_Spetember-21.pdf, last accessed January 31, 2023.

4 https://www.ibef.org/industry/medical-devices.aspx, last accessed January 25, 2023.

India Entry Strategies

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

Strategy	Law	Tax
▪ Observing the economic and political environment in India from the perspective of the investment ▪ Understanding the ability of the multinational company or an investor to carry out operations in India, the location of its customers, the quality and location of its workforce ▪ To strategize the business model by identifying the correct modality to do business in India	▪ Exchange Control Laws: Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same ▪ Corporate Laws: Primarily the Companies Act, 1956, the Companies Act, 2013 and the regulations laid down by the Securities and Exchanges Board of India ("SEBI") ▪ Sector Specific Laws: Drugs & Cosmetics Act, 1940, the Drugs Rules, 1945, the Medical Device Rules, 2017, the Patents Act, 1970 and other legislations, regulations and guidelines that affect the medical devices industry	▪ Domestic Taxation Laws: The Income Tax Act, 1961; Goods and Service Tax, customs law. ▪ International Tax Treaties: Treaties with favorable jurisdictions such as Mauritius, Cyprus, Singapore and the Netherlands

The healthcare sector in India has long been conservative about foreign investment stating concerns of foreign influence over public-focused sector such as healthcare. However, in recent times, there is growing governmental and popular support for foreign investment in all sectors, including health.

It is also important to be familiar of the legal and regulatory framework governing medical devices. The medical device industry is tightly regulated, and any non-compliance may result in penalty, closure of business, 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 ensure that the subsidiary is compliant with India's medical device regulatory framework and other product liability legislation 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 and consider structuring investments through favorable tax jurisdictions, as it may lead to significant tax-savings.

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,

   vii. 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.[1]

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

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 medical device companies seeking to enter India. Post-TRIPS, India has a well established statutory, administrative, and judicial framework to safeguard IPRs. A patented invention (which includes medical devices) 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.

Legal and Regulatory Regime

The Medical Device Rules, 2017 ("**MDR**"), issued under the Drugs and Cosmetics Act, 1940 ("**DCA**"), constitutes India's primary medical device regulatory framework. The MDR regulates 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 time to time under the DCA;

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 (e.g. 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.

At the time the MDR came into effect on January 1, 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. All 14 devices (except ultrasound equipment) are presently regulated under the MDR. The complete list of 37 products specified here is captured in **Annexure A.**

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,[1] out of which only 28 were specifically notified under the MDR. To remedy this, the Ministry of Health and Family Welfare ("**Health Ministry**") issued a notification 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:

1 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 January 30, 2023.

> *"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."*

Medical devices are categorized into one of four classes under the MDR- on the basis of increasing risk from Class A to Class D. As a result, regulatory compliance requirements for Class D devices are more stringent than those of Class A devices.

The DCA and MDR collectively seek to:

- Regulate the import, manufacture, distribution and sale of medical devices.
- Prescribe quality control requirements in respect of medical devices.

A. Authorities

The Central Government and the State Governments are responsible for the enforcement of the DCA. 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:

I. 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.

II. 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. issuance of license or registration certificate, as applicable, 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.

B. Licenses required for Import, Sale, Manufacture and Loan of Medical Devices under the MDR

The regulation of medical devices is overseen by both the central government and the state governments. Under the MDR, medical devices many 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 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	Form (template) of the license	Application form	Relevant rule	Licensing authority	Timelines (from the date of application)
Import of Medical Devices	Form MD-15	Form MD-14	Rule 36(1)	Central Licensing Authority	9 months
Import of Medical Devices for clinical investigation	Form MD-17	Form MD-16	Rule 41(1)	Central Licensing Authority	30 days

License	Form (template) of the license	Application form	Relevant rule	Licensing authority	Timelines (from the date of application)
Permission to import new 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
Registration certificate to sell, stock, exhibit or offer for sale or distribution[2]	Form MD-42	Form MD-41	Rule 87A	The State Licensing Authority	10 days from the date of application
Retail sale of Medical Devices[3]	Form 21 of Drugs Rules	Form 19 of Drugs Rules	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
Whole sale of Medical Devices[4]	Form 21-B of Drugs Rules	Form 19 of Drugs Rules	Rule61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture 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 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 Devices	45 days

2 A registration certificate under the MDR need not be obtained by a person who holds a wholesale or retail license (as applicable) under the Drugs Rules, 1945.

3 Sale of medical devices under the license issued under the Drugs Rules is permitted. However, there is no requirement for a person not intending to sell drugs to obtain such a license.

4 Sale of medical devices under the license issued under the Drugs Rules is permitted. However, there is no requirement for a person not intending to sell drugs to obtain such a license.

C. Manufacturing Medical Devices in India

A separate license is required for each manufacturing location and for each 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, labelling, 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.

D. Importing Medical Devices 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 MDR, the activity of import of medical devices into India requires an import license from the office of the Drugs Controller General of India. An application for grant of an import license may be made by the authorized agent of the foreign manufacturer in India. The authorized agent may be an Indian subsidiary of the foreign manufacturer or a third party. In either case, the authorized agent is required to either be licensed to manufacture or sell medical devices by wholesale in India. 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.

E. Registration of Medical Devices

The MDR provides an exemption from the compliances relating to the manufacture or import (as applicable), clinical investigations and sale of medical devices for Class A non-sterile and non-measuring medical devices. Such devices must obtain a registration on the Online System for Medical Devices. The manufacturer is required to self-certify that the product conforms to the essential principles checklist of safety and performance of such devices as well as the standards specified under the MDR.

Additionally, importers are required to submit a self-attested copy of the overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority or Free Sale Certificate issued by the National Regulatory Authority.

F. Manufacturing/Import of an Investigational Medical Device and New Invitro 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.

G. 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 requires the manufacturer/importer to undertake local clinical investigation/clinical performance evaluation of investigational medical devices/new In-Vitro diagnostic devices as a pre-condition for such devices to be approved in India. The DCGI, however, has the power to waive or relax local clinical trial requirements in the following instances.

Sr. No	Investigational Medical Device	In-Vitro Diagnostic Device
1	The CDSCO may abbreviate defer or omit the requirement for a local clinical trial for investigational medical devices indicated in life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic and medical devices indicated for conditions, diseases for which there is no therapy.	The CDSCO may abbreviate, defer or omit the requirement to submit clinical performance evaluation data in the event the new IVD may be used for "diagnosis of life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic" as well as "diagnostic medical devices used for diagnosis of conditions, diseases for which there is no diagnostic medical device available in the country".
2	There is no requirement to submit clinical investigation data for Class A (low-risk) devices, unless the CDSCO deems it necessary.	There is no requirement to submit clinical performance evaluation data for Class A (low-risk) devices, unless the CDSCO deems it necessary.
3	Local clinical investigation may not be required if the investigational medical device has been marketed in the United Kingdom, United States, Australia, Canada or Japan for at least two years and the following conditions are fulfilled: The CDSCO is satisfied with the data of safety, performance and pharmacovigilance of the device generated in clinical studies that have already take place; There is no evidence or theoretical possibility, on the basis of existing knowledge, of any difference in the behaviour and performance in Indian population; The applicant has given an undertaking in writing to conduct post marketing clinical investigation with the objective of safety and performance of such investigational medical device as per protocol approved by the CDSCO.	The CDSCO has released a notice dated March 19, 2020 ("Notice") stating that any diagnostic test kit for COVID-19 under development or approved in a foreign jurisdiction may directly approach the office of the DCGI for expedited review or accelerated approval for marketing the device in India. The DCGI may abbreviate, defer or waive the local clinical performance evaluation requirement on a case-to- case basis depending on the type and nature of the diagnostic kit, existing data on the product and previous clinical performance data available. In the event clinical performance evaluation is required to be conducted locally, the Notice states that the CDSCO will consider all applications necessary for conducting such evaluation on an expedited basis.

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 CDSCO.

After submission of such data generated outside India to the CDSCO, 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.

The number of study subjects and sites to be involved in the conduct of clinical investigation depends on the nature and objective of the clinical investigation.

H. 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 devices 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 pharmacopoeia 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.

The Health Ministry released a draft amendment to the MDR proposing to recognize American Standard Test Methods (ASTM) as acceptable an acceptable standard for medical devices marketed in India.

It should be noted that the Central Government has the power to prohibit the import, manufacture or sale of any 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.

I. Labelling

The labelling of medical devices is governed by three statutes:

I. The Medical Devices Rules, 2017

Before a medical device is sold or distributed in India, it must be labelled 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 labelling 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.

In the future,[5] all medical devices approved for sale or distribution or import in India will be required to bear a unique device identification ("**UDI**"). The UDI will consist of two parts: a device identifier (which will be the global trade item number) and a product identifier which consists of a serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.

II. 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. 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:

a. Maximum retail price ("**MRP**");

b. Common or generic name of the commodity;

c. month and year in which the commodity is manufactured or packed or imported;

d. 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;

e. Actual corporate name and complete corporate registered address of domestic manufacturer or importer or packer;

f. Name of country of origin or manufacture or assembly

III. Drug (Prices Control) Order, 2013

The DPCO 2013 requires all manufacturers and importers of medical devices to declare the MRP on the label.

A. Quality Management System (QMS)

The Fifth Schedule to the MDR prescribes the QMS for manufacture of medical devices and In-Vitro diagnostics in India. Every company manufacturing 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

5 Originally, this provision was to take effect on January 1, 2022, but the date has been postponed indefinitely.

the manufacturing license. The QMS is comprehensive, laying down requirements such as the documentation required, management responsibilities, resource management and monitoring.

B. 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 favourable balance of payments positions.

C. Advertising and Sales Promotion

The MDR does not specifically cover advertising and promotion of medical devices and in vitro diagnostic devices. However, the MDR states that the Drugs Rules, 1945 ("**Drugs Rules**") 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 medical devices and in vitro diagnostic devices.

Advertising medical devices is strictly regulated. The DCR prohibits labelling of 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 labelling applies only to medical devices, Indian law specifies restrictions on advertisements of medical devices in general under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 ("**DMRA**").

IV. 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 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.

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.

V. The Uniform Code of Pharmaceutical Marketing Practices ("UCPMP")

The Department of Pharmaceuticals has issued the Uniform Code of Pharmaceutical Marketing Practices ("**UCPMP**") on March 12, 2024, in supersession of the UCPMP issued by the Government in 2014 ("**UCPMP 2014**").[6] While the UCPMP did not contain a reference to medical devices, the DoP - in a clarification issued in 2015 - had extended the applicability of UCPMP 2014 to the medical devices industry. Furthermore, the 2024 version of the UCPMP expressly states that it will be applicable mutatis mutandis to medical devices. The UCPMP provides guidance on the requirements for promotional materials issued or authorized by medical devices companies as well as the interactions with healthcare practitioners. Our detailed note on the UCPMP may be accessed **here**.

VI. Draft Uniform Code for Medical Device Marketing Practices ("Draft UCMDMP")

In March 2022, the Department of Pharmaceuticals released a draft set of guidelines that would specifically govern the marketing practices of medical devices companies. The Draft UCMDMP is substantially similar to the UCPMP in terms of the promotional materials, restrictions on interactions with health care professionals. The Draft UCMDMP introduced the concept of demonstration products which are either single use products, mock-ups, temporary software or equipment that are used for HCP and patient awareness and education. These are separate from evaluation samples which are provided for the purpose of acquiring experience in using the product. It also directs medical device companies to provide consulting service, training and education, product training, product service and technical support for the safe and effective use of the device.

A. Anti-Competitive Practices

i. 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.[7]

6 It was made effective (on a voluntary basis) on January 1, 2015

7 Section 3(5) of the Competition Act.

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.

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.

B. 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.

i. Patentability of Medical Devices

The Patents Act grants a patent to 'inventions' which is "a new product or process involving an inventive step[8] and capable of industrial application[9]." 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.

8 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."

9 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.

The patent application can be made by either

i. the inventor or

ii. the assignee[10] or

iii. legal representatives[11] of the inventor.

ii. 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.

iii. Infringement

If a patented invention is made, constructed, used sold or imported 'solely' for uses reasonably related to the development and submission of information required under any law (Indian or foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the 'Bolar 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.

iv. 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.

v. 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.

10 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.

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

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.

vi. 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.

vii. Secrecy Provision[12]

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.

C. 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.[13]

12 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.

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

- 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 fulfil 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.

D. Pricing of Medical Devices

In India, prices of all 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 medical devices which the government believes are "essential" for Indian population.

As of now, it contains condoms, and IUDs,.. These devices are referred to as "Scheduled Formulations". Medical devices that are not covered in the schedule as referred to as "Non-Scheduled Formulations".

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 medical devices are controlled in the following manner under DPCO 2013:

i. "Scheduled Formulations" — The NPPA fixes ceiling price for Scheduled Formulations by using a formula which essentially averages the price to retailer of medical devices 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.

ii. "Non-Scheduled Formulations"— The NPPA does not allows any manufacturers and importer of Non- Schedule Formulations to increases the MRP by more than 10% of within a span of 12 months.

iii. Medical Devices in public interest — NPPA, in public interest and under extra-ordinary circumstances, can fix prices of any medical devices, irrespective of whether the device is a Scheduled Formulation or Non-Scheduled Formulation.

Till date, NPPA has exercised this power to fix the price of Knee Implant Systems[14]. The use of this power is very peculiar, because of the following reasons:

iv. NPPA fixes price of the 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.

v. 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%.

vi. An importer, other than the marketing authorization holder in India, is treated as a distributor.

vii. 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.

In response to requirements of the COVID-19 pandemic, the NPPA had invoked its powers under Paragraph 19 to cap the trade margin at the point of first sale (price to distributor) of oxygen concentrators, pulse oximeters, blood pressure monitoring machines, nebulisers, digital thermometers, and glucometers.

Following the inclusion of all medical devices under the MDR from April 01, 2020, these 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 have come under the purview of the DPCO as and when they were brought under the purview of the MDR. 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.

E. 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 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 medical devices to INR 1,000,000 (appx. USD 16,667) or 3 times the value of the medical device confiscated, whichever is higher and imprisonment of not less than 10 years which may extend up to life, for spurious or counterfeit

14 Available at: nppaindia.nic.in/wp-content/uploads/2022/09/Color0126.pdf last accessed on January 31, 2023. Available at: https://www.nppaindia.nic.in/wp-content/uploads/2022/07/Notification-regarding-extension-of-TMR-notification-on-Oxygen-Concentrators-till-31.12.2022.pdf and https://www.nppaindia.nic.in/wp-content/uploads/2022/08/Gazett-Notification.pdf, last accessed on January 31, 2023.

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 medical devices. If the victim has died due the effect of the spurious or counterfeit medical devices, the relative of the victim is entitled to receive the same amount by way of compensation.

In case the spurious or counterfeit 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 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 medical devices.

Medical Device Rules 2017 — An Analysis

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

Medical Devices were historically treated as "drugs" and for a very long time, the standards that were applicable to drugs were extended to 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 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 un-thoughtfully 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 lieu with internationally acceptable norms. The Salient features of MDR are described below.

A. Risk-based Classifications System

In tune with the global practice, the MDR will introduce a risked based classification system for regulation of medical devices. The classification is 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.[1] 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.

1 Rule 4(3) of MDR.

Similarly, audit/inspection requirements of manufacturing facilities as a pre-condition to the 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[2] or official inspection;

b. Class B medical devices require prior audit by third party[3] but do not require official inspection; and

c. Class C or Class D medical devices require prior official inspection[4].

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

B. Single Window Clearance

All applications for import, manufacture, sale or distribution and clinical investigation, whether to be assessed by the DCGI or State licensing authority, will have to be made through a single online portal of the central government i.e. the Online System for medical devices.

C. Certainty and Rationalization of Timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market/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 submitted within forty five (45) days of the date of the application,[5] the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application,[6] the report of the inspection has to be forwarded to the applicant,[7] and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.[8]

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.[9]

2 Rule 20(4) (I) of MDR.
3 Rule 20(5) r/w Rule 20(6) (III) of MDR.
4 Rule 21(1) of MDR.
5 Rule 21(4) of MDR.
6 Rule 23(1) of MDR.
7 Rule 24 of MDR.
8 Rule 25 of MDR.
9 Rule 36(1) of MDR.

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.[10]

D. Perpetual Licenses

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

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

Please note that while the license may be perpetual, if a licensed manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, it is obligated to inform the appropriate licensing authority.[11]

E. Consolidation of Registration Certificate and Import License into a Single License

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

Further, it will not be possible for two different importers to import different products manufactured at the same manufacturing site. Where an importer has been licensed to import certain products from a manufacturing site, all other products manufactured at the same site are mandatorily required to be licensed to the same importer.[12]

10 Rule 26(III); Rule 38(vi) of MDR.

11 Rule 26(xii) of MDR.

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

F. 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).[13] Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.[14]

What constitutes major change and minor change has also been specified.[15] 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.

G. 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 is constitution has been defined as that change in constitution of a licensee in relation to[16]:

i. a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;

ii. a company means-

   a. its conversion from a private to a public company, or from a public to a private company; or

   b. any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate;

Therefore, it is 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.

13 Rule 26(ii); Rule 38(vi) of MDR.

14 Rule 26 (v): Rule 38(vii) of MDR.

15 Sixth schedule of MDR.

16 Rule 3(j) of MDR.

Upon a change in constitution as defined before, a manufacturer licensee has forty five (45) days to inform the licensing authority and one hundred eighty (180) days to make a fresh application.[17] An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.[18] 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.

H. License for Sale of Medical Devices

Prior to September 2022, the MDR did not contain separate provisions for sale of medical devices. The provisions related to 'sale of drugs other than homeopathic medicines' in Part VI of the DCR alone applied to medical devices as if it was inserted within the MDR,[19] and licenses issued for the sale of drugs are valid for the sale of medical devices as well.

However, sellers who dealt exclusively in medical devices (and did not sell drugs) contended that some of the pre-requisites for a license for sale of drugs were redundant and burdensome for medical devices.[20] Therefore, in September 2022, the MDR was amended to introduce a process and form for the application and grant of a registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device.[21]

The MDR addresses 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).[22]

17 Rule 27 of MDR.

18 Rule 39 of MDR.

19 Rule 87(1) of MDR.

20 Rule 87(2) of MDR.

21 Rule 87A of MDR.

22 Rule 88(1) of MDR.

I. Mandatory Recalls on Knowledge of Risk to Safety

The MDR make it mandatory[23] 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.

In contrast, the DCR do not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to user or patients.[24] 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.[25]

J. 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. 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 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.

K. 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;

23 Rule 88(1) of MDR.

24 Rule 89(1) of MDR.

25 Schedule Y, para 3(4) of Rules.

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.

L. 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 fit.[26] 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.

M. Moving towards Independent Regulation

Though the MDR and the Notifications have introduced a number of business-friendly provisions, 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 the DCA.

The medical device industry has long sought to be regulated under a separate parent legislation. This is because the industry believes that drugs and medical devices should not be regulated in the same manner as they are very distinct products. To this end, the Niti Aayog had reportedly prepared a new draft law Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019.[27] While the CDSCO was initially opposed to the bill as it proposed the creation of a new regulator for medical devices, the CDSCO and Niti Aayog have reportedly reached a consensus on the bill such that a separate division under the CDSCO headed by a technical expert will regulate medical devices. However, this bill appears to have been shelved.

In July 2022, the Ministry of Health and Family Welfare released a draft of the New Drugs, Medical Devices and Cosmetics Bill 2022 (“**Bill**”). In the Bill, medical devices been wholly demarcated from the definition of drugs, and are regarded them as a separate category of products for the purpose of the law. The Bill was released for public consultation and received widespread commentary from the industry, and is still in the process of being finalised.

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26 Rule 93(1) of MDR.

27 https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/niti-aayog-health-ministry-reach-consensus-on-medical-devices-bill/articleshow/74432464.cms?from=mdr ,Last accessed on January 28, 2023.

Taxation Regime

A. Direct Taxes

I. 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.[1] In this regard, the Central Board of Direct Taxes ("**CBDT**") recently released the final guidelines for determination of POEM.

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

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

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

In recent times, the Indian income tax authorities have been adopting an aggressive approach to transactions where any form of exemption from taxation is sought by the taxpayer. Their approach is even more hostile when the transaction in question has an offshore element to it.

Hence, it is has become critical to ensure that offshore transactions are structured in a manner such that legitimate tax exemptions are not challenged by the tax department.

1 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.

Before delving into specific tax issues concerning contract research and manufacturing, set out below is a snapshot 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.

A. Taxes Applicable to Companies

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. Resident companies are taxed at the rate of 30%,[2] 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 15%. 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 December 12, 2019, the Government enacted the Taxation Laws (Amendment) Act 2019, to primarily reduce corporate tax rates as a knee-jerk reaction to India's economic slowdown (**'Amendment Act'**) effective from April 1, 2019. As per the Amendment Act, 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 Amendment Act 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.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 Amendment Act. Importantly, the Amendment Act 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 10 years beginning from the year in which such start up is set up has been provided for.[3]

2 All tax rates are applicable to Financial Year 2020-21 and are exclusive of surcharge and education cess.

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

B. Dividends

Earlier, dividends distributed by Indian companies were subject to a dividend distribution tax ("**DDT**") at the rate of around 15% (calculated on a gross-up basis), payable by the company and no further Indian taxes were payable by the shareholders on such dividend income once DDT is paid, except in certain specified situations. Finance Act, 2020 abolished DDT. Accordingly, since April 1, 2020, dividends declared by an Indian company is 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 should 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.

C. 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%.[4] 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, 2023. The said beneficial 5% rate of TDS is also available in relation to Rupee Denominated Bonds ("**RDB**") issued until July 1, 2023. 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, 2023.[5]

Also as regards interest payments made by an Indian company to its associated enterprises/related party,[6] 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.

D. 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.

4 Section 194LC, Income Tax Act, 1961.

5 Section 194LD, Income Tax Act, 1961.

6 Section 92A, Income Tax Act, 1961 defines 'associated enterprises.

Long term capital gains earned by a non-resident on sale of unlisted securities may be taxed at the rate of 10%[7] (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. 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

i. share acquisitions undertaken prior to October 1, 2004,

ii. 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.[8] 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%.

E. 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.

II. 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.

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

8 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-26-4-2018.pdf.

A. 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 100 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.

B. Contributions made to other Institutions for Scientific Research

The ITA provides for a deduction of 100 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.

C. Capital Expenditure

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

III. 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,[9] 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.*"

9 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.

A. 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.

B. Service PE

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

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

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

ii. the services are performed within that State for a related enterprise (within the meaning of paragraph 1 of article 9 (associated enterprises)."

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 or plays a principal role in conclusion of the contracts[10]. 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.

10 This is as per the new standard introduced by the BEPS MLI – discussed below.

IV. 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,[11] 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,[12] 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.

V. Structuring Investment into India — Use of Intermediate Jurisdictions

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

11 [1960] 39 ITR 546 (SC).

12 1977] 106 ITR 111 (AP).

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.

In the aftermath of the 2008 financial crisis, the Organization for Economic Co-operation and Development ('OECD') along with the G20 had launched the Base Erosion and Profit Shifting ('BEPS') project. The primary aim of the BEPS project was to align taxation of income with economic activities that generate them.

As part of the BEPS project, in 2013 the OECD Committee on Fiscal Affairs ('OECD CFA') released the BEPS Action Plans to counter base erosion and profit shifting, i.e.:

"tax planning strategies that exploit gaps and mismatches in tax rules to artificially shift profits to low or no tax jurisdictions where there is little or no economic activity, resulting in little or no overall corporate tax being paid." [13]

BEPS Action Plan 15 envisaged the development of a multilateral instrument to provide for an effective, swift and innovative approach to implement the BEPS Action Plans. In line with the same, the OECD CFA constituted an ad hoc group which drew up the coveted Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting ('MLI'). Upon coming into effect, the MLI will not replace the existing treaty provisions; instead it will supplement, complement or modify the existing treaty provisions to bring them in line with recommendations in the BEPS Action Plans.

VI. 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.

13 OECD (2013), Action Plan on Base Erosion and Profit Shifting, OECD Publishing. http://dx.doi.org/10.1787/9789264202719-en, last accessed on January 28, 2023.

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 moulding 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.

VII. 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 freebees in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible as expense because it is an expense prohibited by the law. In 2022, the Supreme Court, in the case of Apex Labs[14] confirmed that all expenses incurred towards freebies, hospitality etc. are likely to be disqualified from deductions.

14 Apex Laboratories Pvt. Ltd. v. Deputy Commissioner of Income Tax, Large Taxpayer Unit II, Civil Appeal No. 1554/2022 (Arising out of Special Leave Petition (Civil) No. 23207 of 2019).

B. 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.[15] 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[16]. However Countervailing Duty ("**CVD**") and Special Additional Duty ("**SAD**") would be subsumed into the IGST, which would be levied on the imported goods.

I. 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.

15 Notification NO.1/2017-INTEGRATED Tax (Rate): https://www.cbic.gov.in/resources//htdocs-cbec/gst/Notification%20for%20IGST%20rate%20Schedule-1.pdf, last accessed on January 31, 2023. The rates mentioned here apply to IGST.

16 Guidance note for importers and exporters http://www.cbec.gov.in/resources//htdocs-cbec/guidnce-note-imprtrs-exprtrs.pdf, (as last accessed on January 31, 2023.

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.

II. Challenges and Opportunities

The medical device industry in India faces challenges at various stages starting from the demand supply stage where the dependency of the manufacturing units in our country continues to be based on imports of various devices to aid the manufacture and assembly of medical devices extending to the slow regulatory regimes surrounding manufacture of such devices in India. Few other challenges facing the medical device industry are as follows:

a. An unfavourable duty structure in many segments/sub-segments of the industry makes imports cheaper than manufacturing in India. This further limits the scope for local value addition, especially in segments conducive for manufacturing at present.

b. Small markets for most segments/sub-segments of the medical devices industry limit investments, as any investment would require scale for viability.

c. Insufficient human capital due to restrictive labor laws and limited trained workforce in India to install operate, repair and service equipment.

As the market has been majorly dependent upon imports, the scope for 'local innovation' has been limited. Barring a few players, most have looked at India as one of many export markets, with a primary focus on extensive sales and distribution.

The ever-expanding medical device market also offers various opportunities for its growth in terms of increase in the per capita consumption of medical devices, enabling new market access for medical device manufacturers in India due to incentives for make in India leading to domestic innovation and manufacture. This has been evident in the collaboration and manufacturing of Covid-19 vaccines in our country, where companies and institutions received investments to encourage innovation and find a cure for the pandemic looming over the world which was followed by the manufacture and supply of syringes and needles from the allied markets.

III. Conclusion

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. Several MNCs have been increasing their manufacturing footprint and locating research centers in India to serve both the Indian and global markets. Increased funding and investments have also reflected in other supply side changes in healthcare delivery in India such as the growth in the healthcare infrastructure post pandemic, increasing recognition to healthcare providers and focus on availability and distribution of medical devices, etc.

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. With increasing investments flowing into the industry the medical device sector shows immense potential for growth in our country and the proactive steps taken by the government in this regard by way of introduction of the Make in India schemes and online registration of medical devices is aiding this growth. Make in India initiative is essential to leverage the initiative to kickstart indigenous manufacturing and realize the twin objectives of accessibility and affordability.

Annexure A

Labelling Requirements for 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 B

Labelling Requirements for 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":

vii. 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 C

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.

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.

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

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.

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.

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.

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

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.

A long term use medical device shall be assigned to Class B, if it is intended to be placed into any tooth.

A long term use medical device shall be assigned to Class D, if it is intended,–

- to be used in direct contact with the heart, the central circulatory system or the central nervous system;
- to be life supporting or life sustaining;
- to be an active medical device;
- to be wholly or mainly absorbed by the human body;
- for the administration of any medicinal product; or
- to be a breast implant.

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.

b. Active therapeutic medical devices for administering or exchanging energy

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.

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 ofionizing radiation), taking into account the nature, density and site of application of the energy and the type of technology involved.

a. 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.

xi. Active Diagnostic Medical Devices.

a. Subject to clauses (b) and (c), an active diagnostic medical device shall be assigned to Class B, if it is intended,—

1. to be used to supply energy which will be absorbed by the human body;
2. to be used to capture any image of the in vivo distribution of radiopharmaceuticals; or
3. for the direct diagnosis or monitoring of vital physiological processes.

b. An active diagnostic medical device referred to in sub-clause (1) of clause (a) shall be assigned to Class A, if it is intended to be used solely to illuminate a patient's body with light in the visible or near infrared spectrum.

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

1. the monitoring of vital physiological parameters, where the nature of any variation is such that it could result in immediate danger to the patient (such as any variation in cardiac performance, respiration or activity of the central nervous system); or
2. diagnosing in a clinical situation where the patient is in immediate danger.

d. An active diagnostic medical device shall be assigned to Class C, if it is intended for the emission of ionising radiation and to be used in diagnostic or interventional radiology. 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).

e. 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.

f. 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.

xii. 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.

xiii. 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.

xiv. 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.

xv. 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.

xvi. 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

A. 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.

B. 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,—

1. is in any blood, blood component, blood derivative, cell, tissue or organ, in order to assess the suitability of the blood, blood component, blood derivative, cell, tissue or organ, as the case may be, for transfusion or transplantation; or

2. causes a life-threatening disease with a high risk of propagation.

b. An in Vitro Diagnostic Medical Device shall be Assigned to Class C, if it is Intended for Use in,—

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

ii. In Vitro Diagnostic Medical Devices for Self-Testing:

a. Subject to clause (b), an in vitro diagnostic medical device shall be assigned to Class C,

b. if it is intended to be used for self-testing.

c. An in vitro diagnostic medical device referred to in clause (a) shall be assigned to Class B, if it is intended to be used to obtain,—

1. test results that are not for the determination of a medically-critical status; or
2. preliminary test results which require confirmation by appropriate laboratory tests.

iii. In Vitro Diagnostic Medical Devices for Near-Patient Testing:

An in vitro diagnostic medical device shall be assigned to Class C, if it is to be used for near-patient testing in a blood gas analysis or a blood glucose determination. Illustration: Anticoagulant monitoring, diabetes management, and testing for C-reactive protein and Helicobacter pylori.

iv. In Vitro Diagnostic Medical Devices used in in Vitro Diagnostic Procedures:

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

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

v. Other in Vitro Diagnostic Medical Devices:

a. An in vitro diagnostic medical device shall be assigned to Class B, if sub-paragraphs (i) to (v) of paragraph 2 do not apply to it; or

b. It is a substance or device used for the assessment of the performance of an analytical procedure or a part thereof, without a quantitative or qualitative assigned value.

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

vi. In Vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing:

a. Subject to clause (b), an in vitro diagnostic medical device shall be assigned to Class C, if it is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of any blood, blood component, blood derivative, cell, tissue or organ that is intended for transfusion or transplantation, as the case may be.

b. An in vitro diagnostic medical device referred to in clause (a) shall be assigned to Class D, if it is intended to be used for blood grouping or tissue typing according to the ABO system, the, the Duff-ysystem, 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**[1].

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng==.

Annexure D

Sr. No	Document	Manufacturer	Importer
1	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,
2	Details of Medical Device	Generic Name Model Number Intended Use Class of Medical Device Material of Construction Dimension (if any) Shelf Life Sterile or Non-Sterile Brand Name (Registered under the Trademarks Act, 1999)	Generic Name Model Number Intended Use Class of Medical Device Material of Construction Dimension (if any) Shelf Life Sterile or Non-Sterile Brand Name (Registered under the Trademarks Act, 1999)
3	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
4	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.

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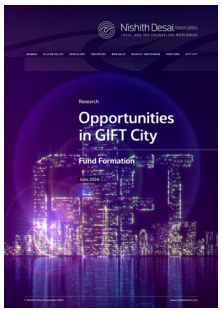

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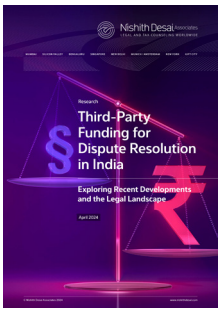

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