INDIAN DENTAL MARKET OUTLOOK 2020
FOSTERING BIG GROWTH

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Ministero dello Sviluppo Economico

ITA

ITALIAN TRADE AGENCY

ICE - Italian Trade Commission

Trade Promotion Office of the Italian Consulate

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INTRODUCTION

Indication & objective of Study:

The study primarily focuses on the key Legal and Regulatory stipulations influencing the Indian Dental Market in the current times. This report incorporates a holistic study of the market by observing and analyzing various factors, such as demographic conditions, regulatory conditions, and business cycles, to market-specific microeconomic influences. These are especially crucial to help forecast the market size in the future. The report also provides a comprehensive review of market drivers, restraints, opportunities, and key challenges. The research seeks to uncover paradigm shifts in the Indian market space, in terms of regional competitive advantage and dynamics. A brief analysis of key vendors, new products, and developments has been included as well.

In this report, primary sources have been analyzed and scrutinized by our specialists, supported through our own data intelligence repository and established in-house research expertise. The market has been studied holistically from both demand and supply-side perspectives. This was carried out to analyze both end-user and producer behavior patterns, which have a direct effect on demand and consumption trends. The study demands analyzing the long-term nature of the market, the identification of factors influencing the market is based on the fundamentality of the study market. Through secondary and primary research, endogenous & exogenous factors have been identified and are transformed to quantitative data through data extraction, and further applied for inference and thought progression.

Present Landscape of the Indian Dental Sector:

The global dental market has grown at the CGAR of 5% over the last five years with the Asian markets showing the highest growth of 10% followed by the US at almost half the rate of 5.5%.[1]

Market trends predict that **India is all set to become the single largest country for dental products and materials**. With over 5000 dental laboratories and over 297 dental institutes, the Indian Dental Market is vast indeed. As of 2017, the overall market size of the Indian Dental market was approximated to be around $ 2 billion USD and is expected to grow at CGAR of 6.97% for the duration of 2016-21.[2]

As of March 2019, independent studies show that the dental market in India is expected to grow at an unprecedented rate of 20-30% Y-O-Y (year on year,) with investment groups building multispecialty hospitals offering general dentistry and specialist treatments. Merely gauging the size of the potential market is enough to give us the scale of potential. The current dentist to population ration in urban area is 1:9000 and in rural areas, it is 1:200000. The value of dental equipment and laboratories market itself is about US$ 90 million annually.[3] An

[1] Morulaa - https://morulaa.com/medical-device/dental-market-india/ Maiervidorno - https://www.maiervidorno.com/dental-industry-india-insight/
[2] https://ehealth.eletsonline.com/2017/11/india-rapidly-catching-up-in-dental-equipment-manufacturing-clove-dental/
[3] https://ehealth.eletsonline.com/2017/11/india-rapidly-catching-up-in-dental-equipment-manufacturing-clove-dental/

indicative list of dental importers (along with import data for various dental products) and dental associations in India are covered in **Annexure A** and **Annexure B** respectively.

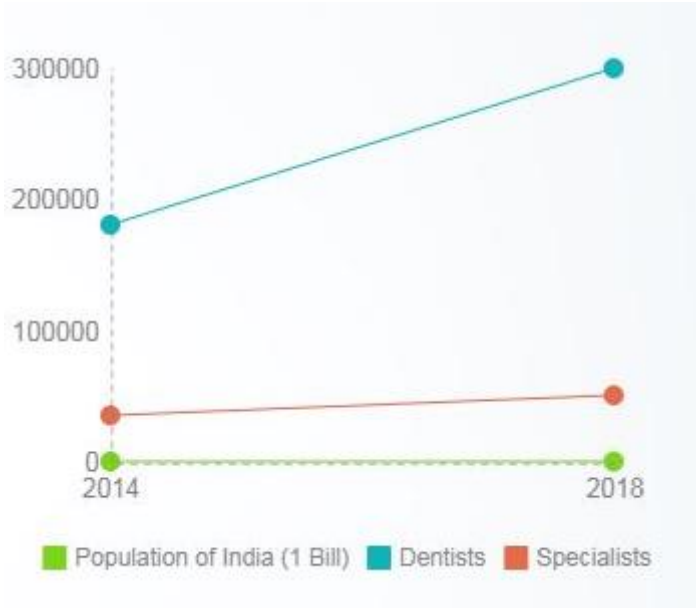
Growth Opportunities

There are a number of reasons for the dental market boom in India. As India progresses towards becoming a fully developed nation, the oral care infrastructure is improving rapidly. To set the context, 99% of the dental market in India is private. Most practices in India run by sole proprietors with multi-operations. Several large multi-national players such as the Apollo Group, Wockhardt, and Fortis are setting up a chain of dental clinics to tap into this swiftly growing dental market. Approximately 90% of the dentists currently work in and around major cities of India. As job opportunities in both the public and private sector are relatively less, most dentists set up their own private clinic. Every year approximately 12,000 to 15,000 new practices start in the country.[4]

Statistics indicate that there is a greater demand than supply of dental technicians in India. Currently there are about 5000 dental laboratories yet only 32 colleges that offer diploma courses for the post of a dental technician. More colleges are now offering the course to match the growing demand.[5]

Yet another reason for the market growth is the expanding multinational presence in the in the fast-growing dental market. KAVO G C, Ivoclar – Vivadent, Dentsply, 3M, Nobel Biocare, Mecktron, Sirona, Aceton, Ultradent, COLTENE, Voco, S S White, Shofu and others have set up offices in India.

Another growth contributor is 'Dental Tourism,' which forms 10% of the total medical tourism industry and is projected to grow at 30% per annum by 2015 to INR 95,000 million (USD 1,4 million) The introduction of quality assurance certificates such as ISO, NABH by the Quality



[4] https://ehealth.eletsonline.com/2017/11/india-rapidly-catching-up-in-dental-equipment-manufacturing-clove-dental/
[5] International Journal of Contemporary Dental and medical Review (2015) Article ID 010715

Control of India and formation of many dental corporates are helping in increasing the avenues for dentistry.

Market Trajectory[6]

Growing Investor Hub:

Foreign entities are investing in the Indian dental device or equipment market by establishing their manufacturing hubs in India itself and now India is rapidly becoming the manufacturing hub or supplying dental equipment and material to Pakistan, Africa, Sri Lanka and some parts of Middle East. Significant portions of dental products are imported into the country. About 85% of India's annual requirement is supplied by Germany, USA, Italy, Japan, and China. Most of the imports are in the implants segment[7].

Under the current government, a greater level of liberalizing of government policies has been observed. Now, up to 100% Foreign Direct Investment is permitted in Medical devices through the automatic route. During the period between April 2000 and March 2017, USD 1.57 billion worth FDI came into the country[8]. Taking advantage of this lucrative opportunity, an increasing number of MNCs are setting up their manufacturing bases in India. Some instances include the Becton Dickinson's manufacturing plant in Haryana[9] and Philips Medical Systems' acquisition of Medtronics[10].

Other contributing factors include, but are not limited to –

1) Growing Healthcare Awareness
2) Better Economic Growth
3) Increased healthcare Expenditure
4) Investor friendly Government policies; and
5) Reduction on Customs Duty

The road ahead certainly seems promising for the sector. There is a huge opportunity in India for any country to maximize the investment potential that exists in India within the healthcare environment.

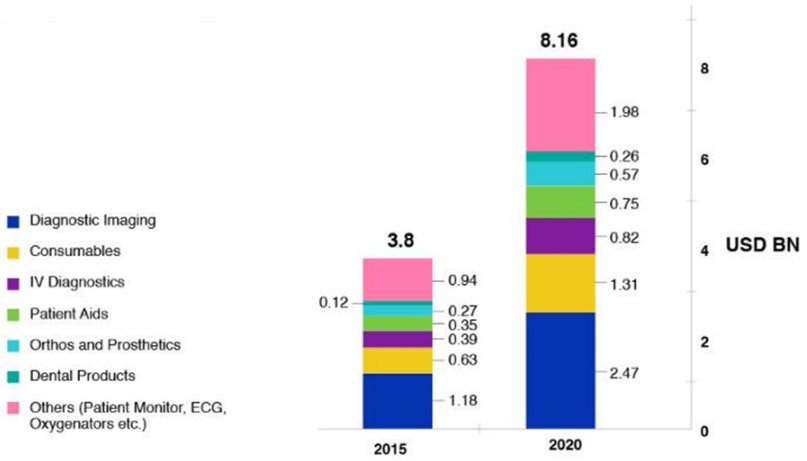
However, as is with any market, some gaps within could negatively affect the projected growth rate to a certain extent. A significant factor be that as automation (especially CAD or Computer Aided Design and CAM or computer-aided manufacturing) becomes more prominent, the cost of the treatment delivery for patients may also increase significantly. Automation is often expensive; especially when the science is behind it is new and innovative. Without a defined system of 'Dental Insurance' in place, patient affordability will remain a major challenge. New

[6] www.morulaa.com
[7] Morulaa - https://morulaa.com/medical-device/dental-market-india/ Maiervidorno - https://www.maiervidorno.com/dental-industry-india-insight/
[8] http://dipp.nic.in/English/Publications/FDI_Statistics/2017/FDI_FactSheet_January_March2017.pdf
[9] http://www.bd.com/india/aboutus.asp
[10] http://www.medtronic.com/covidien/products/oem-monitoring-solutions/oem-partners/Philips healthcare

technologies will invariably require patients to shell out more for better care with shortened healing time.

Additionally, in India, we yet do not have a body to keep a strict check on the quality of dental professionals and their work ethics. The guidelines maybe be up for revisions at regular intervals but there are no audit teams to run effective crosschecks on the actual success rate of the newer technologies being introduced.

In 2015, the Indian dental device market size by summing up the value of the market segments was evaluated to be upwards of $0.63 billion and growing at a CGAR of 10-15%. Data generated based on the product type and treatment-based devices. The Medical Devices industry in India is presently valued at USD 5.2 billion and contributes 4-5% to the USD 96.7 billion Indian health care industry. Out of this, by projected growth rates, the Indian Dental Products is estimated to be 1.31 billion USD by 2020.



Segment wise Market share of Medical devices
11

To set context, Currently, India has about 750–800 medical device manufacturers in the country, with an average investment of Rs 170–200 million and an average turnover of Rs 450–500 million[12].

According to a report published by the government of India, with technological advancements such as the Medical Parks being planned in Gujarat, Andhra Pradesh and Maharashtra and continued Research and Development (R & D), the medical devices industry in India is poised to cross a market size of USD 50 billion by 2025.

Currently, India is among the top 20 global medical devices market and is the fourth largest medical devices market in Asia after Japan, China and South Korea. Equipment and

[11] www.makeinindia.com
[12] http://pharmaceuticals.gov.in/sites/default/files/medicaldevicemanufacturinginindia-asunrise-170221053503%20%281%29.pdf

Instruments (surgical and non-surgical) form the largest segment (53% of the Indian medical device industry), constituting about USD 2.7 Billion (2017), while the estimated market size of the consumer and durable segment is USD 1404 million[13].

Further, each of these segments is sub-divided to cover all relevant categories. Under the product type segmentation, the market is further segmented into general and diagnostic equipment, radiology equipment, dental chairs & equipment, dental consumables, and other dental devices. The treatment-based device segment is further segmented into orthodontics, endodontics, periodontics, and prosthodontics.

The demand for dental devices and products is expected to grow in the long run driven by the growing awareness about oral healthcare. As more people opt for cosmetic changes and focus on the prevention of dental ailments, the market is beginning to witness introduction of procedures and products that aim at reducing patient discomfort. Patients and dentists are increasingly adopting dental membrane materials, tissue regeneration and dental bone graft materials as highly advanced versions of these products continue to be developed.

Current Economic and Political Situation in the country:

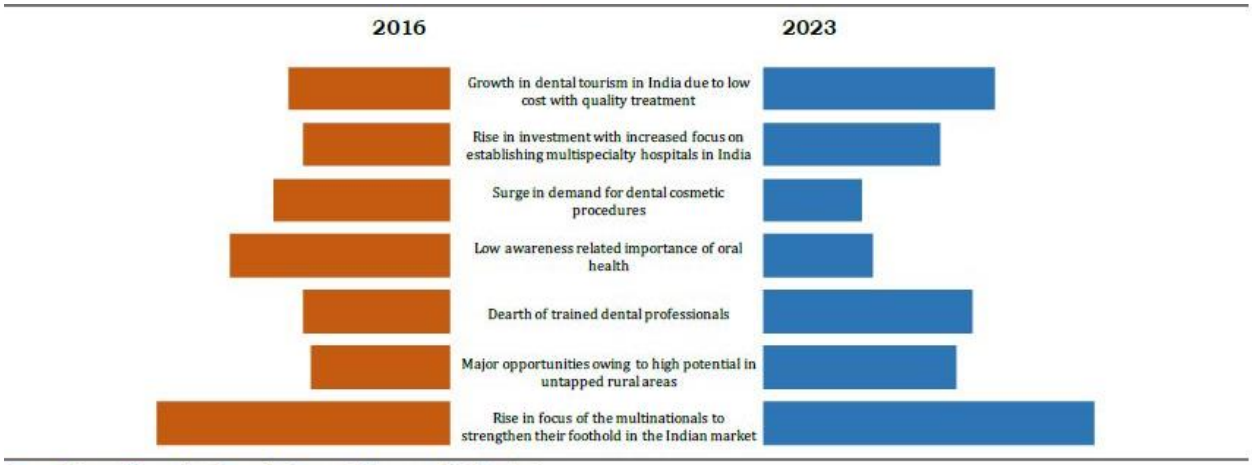
In India, the Medical Device industry had been constantly evolving and re-inventing itself. Over the last two decades, the Medical Devices Industry has undergone a massive transformation. Before 1991, it used to be a domestic-industry- dominated sector but quickly switched gears to become an import-dependent industry under the New Economic Policy of 1991, and then changed yet again to being a non-regulated sector prior to 2006 and, finally to regulation of 15 notified devices to the new Medical Device Rules announced in 2017.

The second being the government approved National Health Policy, 2017, which is the first step towards realization of quality health care through both promotive and preventive practices. Through this Policy, the health care system will be made stronger and registries will be established for diseases of public importance[14].

Of the many policies implemented within the sector, two are particularly notable as 'growth drivers' for the industry. The first of the two being, the Draft National Medical Device Policy – 2015 that was proposed to strengthen the Medical Devices sector by reducing dependence on imports, thereby giving impetus to the 'Make in India' initiative. Under this Policy, a single-window mechanism will be provided to the industry to not just focus on self-reliance, but also work towards making India the global hub of production in medical devices. Additionally, the Policy envisages interest subsidy for MSMEs, concession on power tariffs, seed capital and minimum or zero duty on raw materials, among others. Currently, the policy is awaiting inputs from stakeholders and their validation[15].

[13] http://www.medicalbuyer.co.in/index.php/medical-technology/patient-monitoring-equipment/198-medical-buyer/medical-technology/3980-making-in-india-a-leap-for-indian-healthcare
[14] http://pib.nic.in/newsite/PrintRelease.aspx?relid=157955
[15] http://economictimes.indiatimes.com/news/economy/policy/after-pmo-push-medical-devices-policy-likely-soon/articleshow/58048905.cms

Top Impacting factors 2016 to 2023 –Indian Dental Industry



Source: Primary & Secondary Research, Company Releases, and AMR Analysis

Recommended model to capitalize on the growing market:

In India, one needs to have specific strategies in place that will help them navigate to a successful position within the marketspace, given the unique dynamics at play.

An ideal model could look like –

DOING BUSINESS IN INDIA

A. Starting a Dental Product Business in India

i. Choosing the right operation entity

Depending upon the proposed operations in India, a foreign dental company may consider setting up following entities, which may either be unincorporated or incorporated.

Unincorporated Entities

A foreign dental company can use unincorporated entities to do business in India via 'offices' of certain types. These options are as follows:

Liaison Office

Setting up a liaison office in a sector in which 100% Foreign Direct Investment is allowed under the automatic route requires the prior consent of the Authorized Dealer ("**AD**").[16] For the remaining sectors, RBI grants its approval after consultation with the Ministry of Finance. A liaison office acts as a representative of the parent foreign company in India. However, a liaison office cannot undertake any commercial activities and must maintain itself from the remittances received from its parent foreign company. The approval for setting up a liaison office is generally valid for 3 years and can be extended by making an application to AD before the date of expiry of validity. It is an option usually preferred by companies that wish to explore business opportunities in India.

Branch Office

Similar to a liaison office, the branch office of a foreign company in India must be set up with the prior consent of the AD[17] for sectors under which 100% FDI is permissible under automatic route, with approval under other sectors accorded after consultation with Ministry of Finance. It can represent the foreign parent company in India and act as its buying or selling agent in India. However, a branch office cannot carry out any retail, manufacturing or processing activities. The branch office is permitted to remit surplus revenues to its foreign parent company subject to applicable taxes. Operations of a branch office are restricted due to limitation on the activities that it can undertake. The tax on branch offices is 40% plus applicable surcharges and the education cess. It is an option that is useful for companies that intend to undertake research and development activities in India.

Project Office

A foreign company, subject to obtaining approval from the AD, may set up a project office in India under the automatic route subject to certain conditions being fulfilled including existence of a contract with an Indian company to execute a project in India. A project office is permitted to operate a bank account in India and may remit surplus revenue from the project to the foreign parent company. The tax on project offices is 40% plus applicable surcharges and the

[16] Application made from certain countries as well as for certain sectors still requires approval of the RBI. For details please refer to https://rbidocs.rbi.org.in/rdocs/notification/ PDFs/22RNT04042016CCF68741715D47F887DE23B7B550A83A.PDF

[17] Application made from certain countries as well as for certain sectors still requires approval of the RBI. For details please refer to https://rbidocs.rbi.org.in/rdocs/notification/PDFs/22RNT04042016CCF68741715D47F887DE23B7B550A83A.PDF

education cess. Project offices are generally preferred by companies engaged in one-time turnkey or installation projects.

Other unincorporated entities (such as partnership or trust) are not usually recommended structures for investment, as there are certain restrictions on the foreign direct investment in such structures.

Incorporated Entities

Incorporated entities in India are governed by the provisions of the Companies Act, 2013 / Limited Liability Partnership Act, 2008.

a. Limited Liability Partnership (LLP)

A LLP is a form of business entity which permits individual partners to be shielded from the liabilities created by another partner's business decision or misconduct. In India, LLPs are governed by the Limited Liability Partnership Act, 2008. A LLP is a body corporate and exists as a legal person separate from its partners.

Limited liability Company

Companies may either be 'private limited companies' or 'public limited companies'.

Private Limited Company

A private limited company has certain distinguishing characteristics. It must, in its articles of association, restrict the right to transfer shares; the number of members in a private limited company is minimum of 2 and a maximum of 200 members (excluding the present and past employees of the company); its Articles of Association must prohibit any invitation to the public to subscribe to the securities of the company

Under the Companies Act, 2013, a natural person who is an Indian citizen and resident in India can incorporate a one-person company. However, it shall be required to convert itself into public or private company, in case its paid up share capital is increased beyond INR 5 million or its average annual turnover exceeds INR 20 million

Public Limited Company

A public limited company is defined as a company which is not a private company (but includes a private company that is the subsidiary of a public company). A public limited company shall have a minimum of 7 members but may have more than 200 shareholders and may invite public to subscribe to its securities. A public limited company may also list its shares on a recognized stock exchange by way of an IPO. Every listed company shall maintain public shareholding of at least 25% (with a maximum period of 12 months to restore the same from the date of a fall).

Bringing foreign capital into India: Legal Framework and Considerations

Setting up India operations or investing in India by non-residents requires conformity with India's foreign exchange regulations, specifically, the regulations governing FDI. Most aspects

of foreign currency transactions with India are governed by the Foreign Exchange Management Act, 1999 ("**FEMA**") and the delegated legislations thereunder. Investments in, and acquisitions (complete and partial) of, Indian companies by foreign entities, are governed by the terms of the Foreign Exchange Management (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2017 (**"TISPRO Regulations"**) and the provisions of the annual Consolidated Foreign Direct Investment Policy Circular ("**FDI Policy**") issued by the Department of Industrial Policy and Promotion (**"DIPP"**) in the Ministry of Commerce and Industry, Government of 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 (including dental products) is permitted to the extent of 100% under the automatic route. The Department for Promotion of Industry and Internal Trade (formerly the Department of Industrial Policy & Promotion) ("**DPIT**") - a body under the Ministry of Commerce and Industry entrusted with the role of formulating the Foreign Direct Investment ("**FDI**") Policy - issued a press note on January 23 2018 amending the definition of medical devices under the policy.[18] Under the current FDI policy, the definition of medical devices was subject to amendments to the Drugs and Cosmetics Act, 1940 ("**D&C Act**") – the legislation regulating the manufacture and sale of drugs, cosmetics and medical devices in India. The amendment to the FDI Policy now provides for an independent definition of medical devices, and is no longer subject to amendments to the D&C Act.

The decision to amend the FDI Policy has been taken on a very timely basis in light of the relatively narrow definition under the Drugs and Cosmetics Act, 1940 ("**DCA**"), which defines "Medical Devices" to cover only those notified categories of medical devices (15 currently) that are regulated as drugs under D&C Act. The policy amendment avoids conflicting interpretation of definition of "Medical Devices". The decision restores the status quo whereby a wider range of items may be categorized as medical devices, and a company engaged in its manufacture could attract FDI up to 100% under the automatic route (without prior approval of the government).

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 –*

[18] Press Note by Department of Industrial Policy and Promotion on 'Review of Foreign Direct Investment policy on various sectors, available at: https://dipp.gov.in/sites/default/files/pn1_2018.pdf.

(i) Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) Investigation, replacement or modification or support of the anatomy or of a physiological process;

(iv) Supporting or sustaining life;

(v) Disinfection of medical devices;

(vi) Control of conception,

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

(b) An accessory to such an instrument, apparatus, appliance, material or other article;

(c) *In-vitro diagnostic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of examination of specimens derived from the human bodies or animals."* [19]

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

LEGAL, REGULATORY AND TAX FRAMEWORK

A. Overview

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

Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the DCA. Some categories of devices have already been notified by the government.

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

Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;

Substances used for in vitro diagnosis.

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

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

The DCA and MDR seek to:

Regulate the import, manufacture, distribution and sale of Notified Medical Devices.

Ensure the availability of standard quality Notified Medical Devices to the consumer.

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

Currently, dental products such as dental implants, dental needles, orthodontic guide wires, endosseous dental implants and endosseous dental implant abutments are covered within the

MDR and DCA's regulatory framework. Those devices that are not covered within its scope are not regulated under the DCA (although other general approvals may be required). To this extent, the Central Drugs Standard Control Organization ("**CDSCO**") released a clarification in 2013, stating that the import of devices not specifically covered under the ambit of the DCA, do not require an import license from the CDSCO.

Authorities

The Central Government and the State Governments are responsible for the enforcement of the Act. The CDSCO, headed by the Drugs Controller General of India ("**DCGI**") is primarily responsible for coordinating the activities of the State Drugs Licensing Authorities, formulating policies, and ensuring uniform implementation of the Act throughout India. The division of responsibilities under the MDR between the central and state authorities are captured below:

a. DCGI (Central Licensing Authority)

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

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

State Drug Controller (State Licensing Authority)

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

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

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

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

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

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

Regulation of import, distribution and sale of Notified Dental Products

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

The MDR have prescribed the standard format of the application forms for relevant licenses for the benefit of the applicants. It has also prescribed the standard form (template) of the licenses that may be issued for the benefit of the regulatory authorities and the applicants. The types of licenses required, relevant form numbers as well as the indicative timeline for approvals under the MDR are covered in **Annexure C**.

Procedure for Importing a Notified Dental Product into India

Importing a notified dental product into India requires satisfaction of few additional legal requirements than those indicated above. The import of all products in India, including dental products, is governed under the provisions of the Export and Import Policy. Before importing a dental product 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 is 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 DCA, the activity of import of notified dental products 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 foreign manufacturer itself if it has a valid wholesale license for sale or distribution of notified dental products under the MDR or its authorized agent in India, either having a valid license under the MDR to manufacture for sale of a notified dental product or having a valid wholesale license for sale or distribution of notified dental products in India. Many a times, foreign manufacturers do not have an Indian subsidiary which has a wholesale license for sale or distribution of notified dental products. Hence, the manufacturers choose to appoint a third party as an authorized agent to make the application for grant of an import license. The authorization by a manufacturer to its agent in India must be documented by a power of attorney.

An application for the import of a notified dental product is to be made to the CDSCO. All applications to the CDSCO are now done online, through a portal set up by the CDSCO

referred to as SUGAM[20]. The CDSCO may decide to inspect the foreign manufacturing site before deciding on an application for import of the notified dental product. Based on the findings of the inspection (if any) and examination of the documents provided to the CDSCO as part of the application of import, the CDSCO may grant the Indian applicant to import the specified notified dental product from the foreign manufacturer.

Other documentation related requirements for import, which varies based on the class of dental product 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.

Regulation on Promotion and Advertising

The promotion and advertising of medical products are regulated in India, under various legislations and voluntary codes. They are:

a. *Uniform Code of Pharmaceutical Marketing Practices ("**UCPMP**")*

The UCPMP is a set of guidelines published by Department of Pharmaceuticals, Government of India ("**DoP**"). The UCPMP currently does not have the force of law, as the guidelines have not been issued under a parent legislation. While the UCPMP was initially applicable to the interaction of pharmaceutical companies with HCPs, the DoP later clarified[21] that it is applicable to medical device companies as well.

Broadly, the restrictions placed by UCPMP on the interaction of pharmaceutical and medical device companies with HCPs include[22]:

- providing travel facility to HCPs for attending conferences, seminars, workshops, CME programmes etc. as a delegate irrespective of the whether the event is organized by the company or a third party;
- sponsoring any cost related to attendance of the HCP, where the HCP is participating as a delegate;
- extending any hospitality like hotel accommodation to a HCP and his/her family members under any pretext;
- offering gifts, pecuniary advantages or benefits in kind to HCPs or their family members.

[20] SUGAM portal can be accessed at: https://cdscoonline.gov.in/CDSCO/homepage
[21] Available at http://pharmaceuticals.gov.in/sites/default/files/clarificationUCPMP.pdf

[22] Sections 6 and 7 of the UCPMP.

The UCPMP is not administered by the Government. It is administered, instead, by industry associations. There is no penalty prescribed for violation of UCPMP Codes other than to[23]:

- suspend or expel the company from the association;
- reprimand the company and publish details of the reprimand;
- require the company to issue corrective statement in the media (covering all media) which was used to issue promotional material textual and audiovisual;
- ask the company to recover items (such as gifts or other facilities like travel and hospitality).

Additionally, a proven violation of UCPMP amounts to unethical conduct on the part of the pharmaceutical/medical device company and is published on the website of the relevant industry association to which the company belongs (or where the company does not belong to any industry association, it may be published by that industry association that receives the complaint regarding breach of UCPMP). There was a proposal to have another code - the Uniform Code for Medical Device Marketing Practices ("**UCMDMP**") - to separately regulate medical device promotional activities. However, the UCMDMP is still at proposal stage and until then, the UCPMP is be applicable to medical device companies.

The central government had reportedly come out with a draft Essential Commodities (Control of Unethical Practices in the Marketing of Drugs) Order, 2017 ("**Draft Order**"), intending to regulate promotion and marketing activities by companies before healthcare practitioners. However, the Draft Order is yet to be formally published or notified.

*Revised Dentists (Code of Ethics) Regulations, 2014 ("**DCI Code**")*

The DCI Code has been issued under the Dentists Act, 1948. The DCI Code is a comprehensive code which governs the professional conduct of dental practitioners, including their interaction with dental product companies and patients.

The restrictions placed on HCPs in the DCI Code are largely similar to the restrictions under the UCPMP with respect to not accepting travel facilities, accommodation, sponsorship, gifts or other monetary benefits. A violation of the DCI Code amounts to professional misconduct on part of the dental practitioners and may lead to suspension and/or cancellation of the dental practitioner's registration with the dental council.

- Dentists are prohibited under the DCI Code from:

  - advertising in electronic media, such that it displays the name, address or telephone number of the dentist *etc.*

  - publishing their opinion on any procedure, equipment, in the general or lay papers or lay journals except when validated or supported by evidence based studies;

[23] Section 12 of the UCPMP.

- indulging in surrogate advertisement in the garb of educating the public through TV programs, magazines and periodicals;
- disseminating information to the public in good faith and intention by the dental practitioner carrying their addresses, telephone numbers, email addresses etc. to attract patients;
- using themselves or their name as subject of any form of advertisement or publicity;
- providing an approval, recommendation, endorsement, certificate, report or statement with respect to any drug or medical device, for use in connection with their name, signature or photograph in any advertisement;
- giving, soliciting, receiving or offering to give, solicit or receive any gift, gratuity, commission or bonus in consideration of or return for referring, recommending or procuring any patient for any dental, medical, surgical or other treatment.
- Accepting travel facilities from the industry for personal purpose (eg. vacation) or for participating as a delegate in an educational event (conferences, seminars, workshops, CME programmes, etc), whether the event is organized by the company or a third party;
- Accepting gifts, cash or monetary grants in any form from the industry.

However, the DCI Code applies only to dental practitioners and not to dental product companies. A pharmaceutical/medical device company cannot be proceeded against for a violation of the DCI Code along with a defaulting dental practitioner, but may be proceeded against for corresponding violation under the UCPMP and may face non-statutory penalty as described earlier.

The DCI Code permits dental practitioners to be engaged with dental product companies for rendering professional services or advisory services, provided the dental practitioner maintains professional autonomy. Payments/reimbursements given to dental practitioners in the course of performance of such services should not be in violation of the DCI Code or the UCPMP.

Interactions with Government Dental Practitioners

A dental practitioner that is employed or affiliated with a government run or funded healthcare institution ("**Government Dental Practitioner**") may be considered a public servant for the purposes of the Prevention of Corruption Act, 1988 ("**PCA**") as well as various central and state-level legislations prescribing service rules for public servants (the Central Civil Services (Conduct) Rules, 1964, for example) ("**Service Rules**").

In addition to the general restrictions on dental practitioners, in order for a Government Dental Practitioner to render any services in his/her private *and* professional capacity, he/she must be compliant with the requirements of the PCA and the applicable Service Rules. The PCA

prohibits a) the offer[24] and/or acceptance[25] of gratification other than legal remuneration by public servants in respect of an official act or under PCA; and b) offer[26] and/or acceptance[27] of any valuable thing without consideration in connection with the official function of the public servant. However, the Supreme Court in the case of *Kanwarjit Singh Kakkar v. State of Punjab*[28] had clarified that the receipt of a fee by a Government Dental Practitioner for professional services rendered in his/her private capacity should not be considered a violation of the PCA, provided the Government HCP is not otherwise prohibited from doing so by way of a Service Rule.

Therefore, it should be possible to engage and provide remuneration to a Government Dental Practitioner in his/her private and professional capacity, provided the Government Dental Practitioner is not otherwise prohibited from doing so under any applicable Service Rules. Generally, Service Rules have provisions that permit public servants to engage in certain private professional activities, with the prior approval of the authority. As a good practice, it is advisable to retain a copy of such permission/no-objection for the specific activity that the Government Dental Practitioner will provide, prior to engaging the Government Dental Practitioner.

*The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 ("**DMRA**") and Rules, 1955 ("**DMRR**")*

The DMRA and DMRR regulate advertisement of drugs. Though the legislation does not expressly state that it will be applicable to medical devices (including dental products), the Supreme Court of India has held that the DMRA would be applicable to medical devices.[29] One of the important features of the DMRA is that it imposes a bar on participation by any person in the publication of any advertisement referring to any drug (which includes dental products), the terms of which are suggested or calculated to lead to the use of that drug for "diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule"[30]. Violation of any provision of DMRA may lead to imprisonment which may extend to six months, or with fine, or with both[31].

Medical Device Rules, 2017

The MDR does not specifically cover advertising and promotion of notified dental products. However, the MDR states that the D&C Rules will continue to apply, so long as there is nothing inconsistent in the MDR. Therefore, the provisions of the D&C Rules with respect to advertising and sales promotion should apply to notified dental products.

[24] Section 12, the Prevention of Corruption Act, 1988.

[25] Section 7, the Prevention of Corruption Act, 1988.

[26] Section 12, the Prevention of Corruption Act, 1988.

[27] Section 11, the Prevention of Corruption Act, 1988

[28] ([2011] 6 SCR 895)

[29] *Zaffar Mohd.* v. *State of W.B.* (1976) 1 SCC 428.

[30] Section 3 of the DMRA.

[31] Section 7 of the DMRA.

The D&C Rules prohibits labelling of notified dental products in a manner that may convey to the intending user that the enclosed device may be used for prevention or cure of certain ailments and diseases specified in Schedule J of the D&C Rules. Some examples of such diseases and ailments are: Blindness, Bronchial Asthma, Cataract, Growth of New Hair, Deafness, Genetic Disorders, Improvement in vision, Myocardial Infarction *etc.*

Regulation of Price

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

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

a. "Scheduled Formulations"

The National Pharmaceutical Pricing Authority ("**NPPA**") fixes ceiling price for Scheduled Formulations by using a formula which essentially averages the price to retailer of Notified Medical Device manufacturers and importers, followed by addition of fixed margin of 16% to be given to retailers. Pursuant to fixation of ceiling price (and adjusting the same to applicable taxes), no manufacturer or importer is allowed to set MRP (i.e. maximum retail price) higher than the ceiling price.

"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.

Notified Medical Device in public interest

NPPA, in public interest and under extra-ordinary circumstances, can fix prices of any Notified Medical Device, irrespective of whether the device is a Scheduled Formulation or Non-Scheduled Formulation. Till date, NPPA has exercised this power twice for medical devices – in the case of Coronary Stents and Knee Implant Systems. The use of this power is very peculiar, because of the following reasons:

- NPPA fixes price of the Notified Medical Device on the basis of average cost of manufacture or average landing cost (i.e. transfer price in case of import). The NPPA then adds 50-75% margin for manufacturer and importers on the average cost as profit margins for the manufacturers and importers.
- 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%.
- An importer, other than the marketing authorization holder in India, is treated as a distributor.

- The patient invoice must carry details of the price charged to the patient, even though the patient may have opted for the surgery in form of a "package" and paid lump-sum for it.

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

Direct Tax Laws

a. General overview

Taxation of income in India is governed by the provisions of the Income Tax Act, 1961 ("**ITA**") as amended annually by the Finance Acts. Under the ITA, residents are subject to tax in India on their worldwide income, whereas non-residents are taxed only on Indian source income i.e. income that accrues or arises in India, is deemed to accrue or arise in India or which is received or is deemed to be received in India. A company is said to be resident in India if it is incorporated in India or its place of effective management ("**POEM**") is located in India.32 In this regard, the Central Board of Direct Taxes ("**CBDT**") 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.

[32] 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.

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

Before delving into specific tax issues concerning contract research and manufacturing, set out below is a snap shot of the taxation regime in India. The tax rates mentioned in this section are exclusive of applicable surcharge and education cess, unless otherwise specified. As per the Finance Act, 2016, the surcharge applicable to income generated by resident companies for the financial year 2017-2018 is 7% where the income exceeds INR 10 Million but does not exceed INR 100 Million and 12% where the income exceeds INR 100 Million. Additionally, as per Finance Act, 2016 surcharge applicable to income generated by companies other than domestic companies, for the financial year 2017-2018 is 2% where the income exceeds INR 10 Million but does not exceed INR 100 Million and 5% where the income exceeds INR 100 Million.

Taxes Applicable to companies

Resident companies are taxed at the rate of 30%[33], while non-resident companies are taxed at the rate of 40%. A minimum alternative tax is payable by resident, and in certain circumstances, non-resident companies at the rate of around 18.5%. The corporate tax rate for domestic companies whose total turnover or gross receipts does not exceed INR 500 million (approx. USD 7.4 million is 25%. The Finance Act, 2018 ("**Finance Act**") provided that the income of companies whose turnover in FY 2016-17 does not exceed INR 2.5 billion (approx. USD 40 million) is to be taxed at the rate of 25% from FY 2017-18). For the remainder of the companies, the corporate tax rates continue to be 30%.

Dividends

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

Further tax at the rate of 10% is levied on dividends received from a domestic company, by a resident individual, HUF or firm, where the amount of dividend received exceeds INR 1 million.[34] Budget 2017 proposes to amend this provision by providing that this additional tax rate of 10% should be applicable to dividends received by all resident taxpayers except domestic companies, certain kinds of funds, institutions, trusts, educational institutions, hospital and medical institution as specified in the ITA. Dividends received from a domestic company by a non-resident company should continue to be Indian tax exempt in the hands of the foreign company, provided that DDT has been paid by the distributing domestic company.

Interest, Royalties and Fees for Technical Services

Interest payable to non-residents on loans taken/debt securities issued in foreign currency are taxable at a beneficial rate of 5%.35 However this benefit has a sunset clause stating that the

[33] All tax rates are applicable to Financial Year 2017-18 and are exclusive of surcharge and education cess.
[34] Section 115BBDA, Income Tax Act, 1961
[35] Section 194LC, Income Tax Act, 1961

benefits would only be available for loan agreements entered into/ bonds issued on or after July 1, 2012 and before July 1, 2017. The Budget 2017 has proposed to extend this benefit to Rupee Denominated Bonds ("**RDB**") and extend the sunset clause to July 1, 2020. Similarly, interest payable to foreign portfolio investors ("**FPI**") on investments made by them in RDBs and government securities is taxable at the rate of 5%.36 Further, the Budget 2017 has proposed to amend the sunset clause for this benefit as well to state this it shall be applicable to bonds issued till July 1, 2020 as opposed July 1, 2017. Interest payable on majority of other circumstances not covered under the abovementioned benefits are taxable at a rate ranging from 20% to 40%.

Also, as regards interest payments made by an Indian company to its associated enterprises/related party37, the Budget 2017 has proposed to introduce Thin Capitalization Rules as per which, interest payments exceeding 30% of the Earnings Before Interest, Taxes, Depreciation and Amortization ("**EBITDA**") of the payer of interest shall not be deductible as an expense.

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

Capital Gains

Gains earned by a resident company from the transfer of capital assets situated anywhere in the world are taxable in India. In the case of non-residents, only those gains arising out of the transfer of a capital asset in India should be taxable.[38] The tax treatment of capital gains depends mainly on whether the gains are short term or long term. Short term capital gains ("**STCG**") arise upon the transfer of assets held by a taxpayer for a period of 36 months or less before the date of transfer (12 months or less in the case of securities listed on a recognized stock exchange in India, and 24 months in the case of unlisted shares of an Indian company). Long term capital gains ("**LTCG**") arise upon the transfer of a capital asset held for a period of more than 36 months (12 months in the case of listed securities and 24 months in the case of unlisted shares of an Indian company).

Listed: STCGs arising from the transfer of a listed equity share are taxable at the beneficial rate of 15%,[39] while long term capital gains arising from the transfer of listed equity share are tax exempt under the ITA generally.[40] This is applicable to both residents and non-residents.

[36] Section 194LD, Income Tax Act, 1961
[37] Section 92A, Income Tax Act, 1961 defines 'associated enterprises.'
[38] Having said that, India has recently introduced a rule to tax non- residents on the transfer of foreign securities the value of which are substantially (directly or indirectly) derived from assets situated in India.
[39] Section 111A, Income Tax Act 1961.
[40] Section 10(38), Income Tax Act, 1961.

Unlisted: STCGs arising from transfer of unlisted securities are taxable at slab rates both in the hands of residents and non-residents. LTCGs arising out of unlisted securities are taxable at the rate of (i) 10% in the hands of a non-resident, (ii) 20% in the hands of a resident.[41]

An Indian company would also be taxed at the rate of around 20% on gains arising to shareholders from distributions made in the course of a buy-back or redemption of shares.

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.

Indirect Tax Laws

a. GST

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, 2017with a tiered rate structure for tax on goods and services. Depending on the nature of dental product, they would fall under the 5%, 12%, 18% and 28% tier as applicable.[42]

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,

[41] Section 112, Income Tax Act, 1961.
[42] Notification No.1/2017-Integrated Tax (Rate) http://www.cbec.gov.in/resources//htdocs-cbec/gst/Notification%20for%20IGST%20rate%20Schedule-1.pdf (last accessed on August 1, 2017). The rates mentioned here apply to IGST.

Safeguard Duty, etc[43]. However Countervailing Duty ("**CVD**") and Special Additional Duty ("**SAD**") would be subsumed into the IGST, which would be levied on the imported goods. However, the Research and Development Cess on the import of technology (levied at 5%) was also abolished. On the manufacturing front the existing duty regime will be different for each class and type of medical device.[44] The duty on import of goods is discussed in some detail in the section below.

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.

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.

Import Clearance

Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992 along with the Customs Act, 1962 and the Export-Import Policy ("**EXIM Policy**"), issued by the Ministry of Commerce and Industry of the Government of India. The current EXIM policy also known as the Foreign Trade Policy covers the period 2015 – 2020. The purpose of the EXIM policy is to develop export potential, improve export performance, encourage foreign trade and create a favourable balance of payments positions.

Packaging and Labelling Laws

The labelling of Notified Medical Devices (including notified dental products) is governed by three statutes:

[43] Guidance note for importers and exporters http://www.cbec.gov.in/resources//htdocs-cbec/guidnce-note-imprtrs-exprtrs.pdf (as last accessed on August 1, 2017)
[44] Finance Act, 2017, No 7 of 2017, http://egazette.nic.in/WriteReadData/2017/175141.pdf (as last accessed on August 1, 2017)

a. The Medical Devices Rules, 2017

Before a Notified 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. All labels may be printed in English.

The Legal Metrology (Packaged Commodity) Rules, 2011

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

The additional declarations are:

1. Maximum retail price ("**MRP**");
2. Common or generic name of the commodity;
3. month and year in which the commodity is manufactured or packed or imported;
4. name, address, telephone number, e-mail address of the person who can be or the office which can be contacted, in case of consumer complaints;
5. Actual corporate name and complete corporate registered address of domestic manufacturer or importer or packer;
6. Name of country of origin or manufacture or assembly

Drug (Prices Control) Order, 2013

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

Conclusion

In India, the multibillion-dollar dental product market is only expanding. Given the slew of reforms that the government is undertaking for doing business in India, even in the medical device and healthcare sector, companies that had kept India in the wait-and-watch list, may want to consider starting business activities here.

Overall, the sector is moving in the right direction, as the industry continues its upward march of growth, strongly supported by India's robust legal framework. As discussed in the report, there are certain challenges to do business of medical device in India, but they can be easily overcome. The government is also actively looking into

With more devices being included in the list of medical devices and new clarifications and guidelines being issued by the regulator on a frequent basis, the industry has a lot to look forward to in 2019. One of the biggest concerns for the device industry is the uncertainty around price control. This uncertainty may be resolved over the year, given that the government is also looking into revising the pricing framework. Despite some challenges, the medical device industry is poised to offer unprecedented opportunities to both existing and future investors.

Having said that, there is no denying that despite the odds, the medical devices industry in India continues to offer unprecedented opportunities to present and potential investors and stake holders, now more than ever before.

ANNEXURE A

INDICATIVE LIST OF SELECT DENTAL IMPORTERS IN INDIA[45]

HS Code	Company Name	Class of Products
940290	MSR Dentistry	Dental Implants
330690	• Colgate Palmolive (India) Ltd • Umang Pharmatech Pvt.Ltd. • Nirjay Impex Pvt Ltd • The Bombay Burmah Trading Corporation Limited • Verna Trading • Leon Traders	Oral & Dental Hygiene Preparations,
300640	• D Tech Dental Technologies • Prevest Denpro Ltd. • Septodont Healthcare India Private Limited • Ids Denmed Private Limited • Sai Dental • Union Dental • Inova Dental India • Powerteck Products India Private Limited • Horizon International	Dental Cements and Other Dental Fil
340700	• Dental Cements and Other Dental Fil Importer • Laxmi Dental Export Pvt. Ltd. • Illusion Dental Laboratory Pvt Ltd • Laxmi Dental Exports Pvt. Ltd.	Model Paste, Dental Paste and Wax

[45] Source: connect2india.com/dental-importers

	• Sofine Exim Private Limited • Glaze Dental Depo Pvt.Ltd. • Platinum Painting Essentials & Trading Pvt. Ltd. • Kalabhai Karson Pvt Ltd • Kores (India) Ltd. • Sqi India • Arjun Enterprise • Pearl Pride Trade Pvt Ltd • Mitsu Dental Products • Medicept Dental India Private Limited • Premier Dent Intl. • F S Global Sourcing	
30064000	• Depuy Medical Pvt. Ltd. • Doshi Marketing Corporation • Meril Healthcare Pvt. Ltd.	• Dental Cements and Other Dental Filling
9018	• South India Surgical Co Ltd • Cancer Institute Wia) • Indian Institute Of Technology Ropar • Satelec (India) Pvt. Ltd. • Asian Surgical Corportaion • Terra India • Shaili Endoscopy • Sri Sathya Sai Central Trust • The Kuppuswamy Naidu Charity Trust For Education And Medical Relief • Anand R Healthcare Pvt. Ltd. • The Calcutta Medical Research Institute	• Instruments for Medical, Surgical

	• National Institute Of Science Education & Research Institute Of Physics Campur • S. B. Dr. Sohan Singh Eye Hospital Pvt. Ltd. • Indian Institute Of Technology • Shalby Limited • S K Hospital • Sri Kanchi Sankara Health And Educational Foundation • Brightway Agencies • Anshu Hospitals Limited • Life Care Medical & Surgical Appliances • Shekhar Hospital (P) Ltd. • Atlas Surgical. • Ujjain Charitable Trust Hospital & Research Centre	
9402	• Suz-Dent India Pvt. Ltd • Gokula Education Foundation (Medical) • Shree Enterprises	• Medical, Dental, Surgical products
90184100	• Army Surgical Works	• Dental Drill Engines,
33069000	• Group Pharmaceuticals Ltd.	• Preparations for Oral or Dental Hygiene
90221900	• Ads Diagnostic Ltd. • Tata Elxsi Limited	• Apparatus Based on The Use of X-Ray Importer
90212900	• Dentcare Dental Lab Private Limited	• Dental Fittings Importer

Import Data of Various Dental Products[46]

Imports (Million US$)

Plasters (HS Code 252020)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	Thailand	3.35	2.32	44.4	2.67
2	Iran	3.31	3.39	-2.3	1.79
3	UAE	1.26	0.59	113.6	1.97
4	Oman	0.75	0.58	29.3	0.84
5	China	0.42	0.46	-8.7	0.31
12	Italy	0.11	0.13	-15.4	0.11
	Total Imports	10.68	9.18	16.3	9.54

Dentifrices (HS Code 330610)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	Nepal	7.51	7.48	0.4	6.03
2	USA	0.44	1.45	-69.6	1.25
3	Italy	0.19	0.17	11.7	0.18
4	Malaysia	0.19	0.15	0.1	0.05
5	Australia	0.14	0.14	0	0.07
6	China	0.12	0.12	0	0.10
	Total Imports	8.79	10.24	-14.2	7.85

Medical, Surgical/Laboratory Sterilisers (HS Code 841920)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	Italy	8.73	11.81	-26.1	5.12
2	Germany	6.34	5.23	21.2	3.46
3	USA	4.58	4.62	-0.9	4.00
4	China	4.04	3.23	25.1	4.18
5	Sweden	1.65	2.04	-19.1	0.56
6	Singapore	1.56	1.14	36.8	3.76
	Total Imports	26.9	28.07	-4.2	21.08

[46] Department of Commerce; Export Import Data Bank; https://commerce-app.gov.in/eidb/icomcntq.asp

STM/SND Blastng Machines and Jet Projecting Machines (HS Code 842430)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	China	5.20	1.11	368.5	4.62
2	Germany	3.28	1.98	65.7	3.08
3	Japan	2.12	0.68	211.8	2.08
4	Italy	1.22	0.84	45.2	1.46
5	Czech Republic	1.20	0.06	1900.0	0.00
6	Korea	0.66	0.79	-16.5	1.64
	Total Imports	13.08	5.89	122.07	13.39

Instruments and Appliances, Used in Dentistry (HS Code 901849)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	China	10.61	7.95	33.5	11.42
2	Switzerland	7.42	8.03	-7.6	9.12
3	Korea RP	7.40	5.01	47.7	7.34
4	Germany	5.69	5.12	11.1	3.89
5	USA	4.51	5.51	-18.1	3.49
10	Italy	1.94	1.30	49.2	0.92
	Total Imports	37.57	32.92	14.12515	36.18

Instruments and Appliances Used in Medical, Surgical, Dental or Veterinary Sciences (HS Code 901890)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	USA	161.45	179.93	-10.3	128.73
2	Germany	140.91	137.93	2.2	120.34
3	China	83.93	62.95	33.3	80.48
4	Japan	45.91	39.30	16.8	38.97
5	Singapore	24.42	14.83	64.7	36.19
14	Italy	8.36	7.08	18.1	8.42
	Total Imports	464.98	442.02	5.194335	413.13

Artificial Teeth (HS Code 902121)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	USA	0.34	0.34	0.0	0.32
2	Germany	0.28	0.13	115.4	0.26

3	Japan	0.25	0.02	1150.0	0.37
4	Switzerland	0.12	0.1	20.0	0.13
5	Italy	0.08	0.11	-27.3	0.00
6	Turkey	0.04	0.01	300.0	0.05
	Total Imports	1.07	0.84	27.4	1.08

Other (Dental Fittings) (HS Code 902129)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	USA	7.36	13.48	-45.4	3.86
2	Korea	6.66	4.55	46.4	8.55
3	Sweden	5.85	1.33	339.8	----
4	Netherland	4.61	4.69	-1.7	8.99
5	Israel	3.88	1.41	175.2	0.99
11	Italy	0.20	0.24	-16.7	0.30
	Total Imports	23.01	26.78	-14.1	22.59

Other, For Dental Uses (HS Code 902213)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	Korea RP	7.12	2.81	153.4	3.77
2	Finland	2.23	1.11	100.9	2.41
3	Italy	1.45	1.08	34.3	1.16
4	Germany	1.13	1.11	1.8	1.19
5	USA	0.85	0.13	553.8	0.55
6	Japan	0.12	0.12	0.0	-----
	Total Imports	12.9	6.36	102.8	9.08

Apparatus Based on The Use of Alpha, Beta or Gamma Radiations for Medical, Surgical, Dental or Veterinary Uses (HS Code 902221)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	UK	7.54	11.92	-36.7	12.19
2	USA	3.63	5.98	-39.3	9.75
3	Germany	2.51	1.62	54.9	1.90
4	France	2.40	1.82	31.9	2.07
5	Sweden	2.15	1.21	77.7	0.00
7	Italy	0.97	0.97	0.0	0.03
	Total Imports	19.20	23.52	-18.4	25.94

Swivel Seats with Variable Height Adjustment (HS Code 940130)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	Malaysia	11.59	12.65	-8.4	10.08
2	China	6.44	4.05	59.0	9.91
3	USA	2.33	1.09	113.8	2.09
4	Singapore	1.87	0.16	1068.7	1.86
5	Hong Kong	0.89	0.97	-8.2	3.07
7	Italy	0.33	0.11	200	0.28
	Total Imports	22.45	19.41	15.7	26.35

Dentists Chairs and Parts Thereof (HS Code 940210)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	China	6.11	3.19	91.5	3.86
2	Italy	1.81	0.40	352.5	1.56
3	Germany	1.56	2.33	-33.0	0.47
4	USA	0.80	0.85	-5.9	0.31
5	UK	0.60	0.32	87.5	0.13
6	Brazil	0.58	0.09	544.4	0.02
	Total Imports	11.25	7.58	48.4	6.60

Medical, Surgical, Veterinary Furniture and Parts (HS Code 940290)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	China	12.17	8.69	40.0	11.89
2	Germany	6.32	6.09	3.8	7.65
3	Taiwan	3.87	2.25	72.0	2.14
4	USA	3.15	2.48	27.0	2.97
6	Turkey	1.89	1.57	20.4	0.25
9	Italy	1.30	0.66	96.7	2.09
	Total Imports	27.72	24.56	12.9	28.10

Other Electric Lamps and Lighting Fittings (HS Code 940540)					
No	**Countries**	**FY 2017-18**	**FY 2016-17**	**Growth %**	**FY 2018-19 (Apr-Jan)**
1	China	347.6	163.64	112.4	246.71
2	Germany	10.07	5.84	72.4	7.34
3	Italy	5.38	4.05	32.8	4.21
4	Korea RP	5.20	6.04	-13.9	7.35
5	Hong Kong	2.76	1.63	69.3	14.98
6	USA	2.30	2.33	-1.3	5.19
	Total Imports	372.77	183.85	102.8	275.74

ANNEXURE B

DENTAL ASSOCIATIONS IN INDIA

- Indian Dental Association (Foremost and key organization)

- Association of Dental Research and Scientific Development
- Association of Dental Industry & Trade of India
- South Asian Association of Paediatric Dentistry
- Indian Association of Conservative Dentistry and Endodontics
- Indian Society for Dental Research
- IDA Dental Congress
- Asian Institute of Advanced Dentistry (AIAD)
- Telangana Dentist's Association

ANNEXURE C

List of Notified Medical Devices

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

*Dental implants and related accessories fall in this category at present

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

1. Blood Grouping Sera
2. Skin Ligatures, Sutures and Staplers
3. Intra-uterine devices (Cu-T)
4. Condoms
5. Tubal Rings
6. Surgical Dressings
7. Umbilical Tapes
8. Blood/ Blood Component Bags

Additional Medical Devices

Four additional medical devices were notified and included within the regulatory framework in 2018. These devices are nebulizer, blood pressure monitoring device, digital thermometer and glucometer (**"New Medical Devices"**).[47] The inclusion of the New Medical Devices will take effect from January 2020.

[47] Notification S.O 5980(E) by the Ministry of Health and Family Welfare available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzE0Mw==.

The CDSCO had also proposed to include the following devices in the list of notified medical devices[48]:

1. All implantable medical devices;
2. CT scan equipment
3. MRI equipment
4. Defibrillators
5. Dialysis machine
6. PET equipment
7. X-Ray machine
8. Bone marrow cell separator
9. Surgical gowns and drapes

Save for surgical gowns and drapes, readers may note that the other proposed medical devices were notified in February of this year, and will take effect from April 2020.

Indicative list of Classifications for Dental Products issued by CDSCO

Sl. No.	Notified Category	Device Name	General Intended Use	Risk Class
1.	Disposable Hypodermic Needles	Dental needles	Dental needles are used to deliver local anaesthetic to the operative site in order to make a patient as comfortable as possible.	B
2.	Catheters	Orthodontic Guide Wire	A wire conforming to the alveolar or dental arch that can be used with dental braces as a source of force in correcting irregularities in the position of the teeth	B
3.	Internal Prosthetic Replacements	Endosseous dental implant	Intended to be surgically placed in the bone of jaw arches to provide support for prosthetic devices, such as artificial teeth	C
4.	Internal Prosthetic Replacements	Dental Implant	A dental implant is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as crown,	C

[48] Public Notice by Central Drugs Standard Control Organization available at: http://www.cdsco.nic.in/writereaddata/2018_06_22_Public%20notice%20for%20commen.pdf (last checked January 28, 2018); Public Notice by Central Drugs Standard Control Organization available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjE2OA==.

			bridge, denture, facial prosthesis or to act as an orthodontic anchor	
5.	Internal Prosthetic Replacements	Endosseous dental implant abutment	Intended for use as an aid in prosthetic rehabilitation	C

ANNEXURE D

LICENSES UNDER THE MEDICAL DEVICE RULES

License for or Registration Certificate	Form (template) of the License	Application form	Relevant Rule	Licensing Authority	Timelines (from the date of application)
Import of Notified Medical Devices	Form MD-15	Form MD-14	Rule 36(1)	Central Licensing Authority	9 months
Import of Notified Medical Devices for clinical investigation	Form MD-17	Form MD-16	Rule 41(1)	Central Licensing Authority	30 days
Permission to import new Notified Medical Device for clinical trial or marketing	Form MD-29	Form MD-28	Rule 64(2)	Central Licensing Authority	90 days
Permission to conduct clinical investigation	Form MD-25 Form MD-23	Form MD-24 Form MD-22	Rule 59(5) Rule 52(1)	Central Licensing Authority	90 days
Permission to import or manufacture medical device that does not have a predicate device	Form MD-27	Form MD-26	Rule 63(2)	Central Licensing Authority	120 days
Retail sale of Notified Medical Devices	Form 21	Form 19	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)

Whole sale of Notified Medical Devices	Form 21-B	Form 19	Rule 61(2)	State Drug Licensing Authority	No time period prescribed (usually between three to six months)
License to manufacture Notified Medical Devices	Form MD-5 for Class A or Class B Form MD-9 for Class C or Class D	Form MD-3 for Class A or Class B Form MD-7 for Class C or Class D	Rule 20(4) and 20(6) for Class A or Class B Rule 25(1) for Class C or Class D	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority for Classes C and D devices	45 days from the date of application
License to manufacture a Notified Medical Device for Clinical investigation	Form MD-13	Form MD-12	Rule 31(3)	Central Licensing Authority	30 days
Loan License (manufacture in facility owned by third party)	Form MD-6 for Class A or Class B Form MD-10 for Class C or Class D	Form MD-4 for Class A or Class B Form MD-8 for Class C or Class D	Rule 20(4) and Rule 20 (6) for Class A or Class B Rule 25(1) for Class C or Class D	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority for Classes C and D devices	45 days

Process to procure Import License under the MDR

1. Identify Indian agent (if the foreign company does not have presence in India);
2. Obtain a wholesale license under the appropriate application listed above;
3. Make an application for import license for the specific dental products, along with supporting documents;
4. Prepare for inspection of the manufacturing site, if such requirement is communicated by the regulator;
5. If all documents and inspection (if any) are in order, import license is issued within 9 months of the application.