Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

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Investment in Healthcare

Legal, Regulatory and Tax Overview

May 2020

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- **Chambers and Partners Asia Pacific:** Band 1 for Employment, Lifesciences, Tax and TMT *2020, 2019, 2018, 2017, 2016, 2015*
- **IFLR1000:** Tier 1 for Private Equity and Project Development: Telecommunications Networks. *2020, 2019, 2018, 2017, 2014*
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- **FT Innovative Lawyers Asia Pacific 2019 Awards:** NDA ranked 2nd in the Most Innovative Law Firm category (Asia-Pacific Headquartered)
- **RSG-Financial Times:** India's Most Innovative Law Firm *2019, 2017, 2016, 2015, 2014*
- **Benchmark Litigation Asia-Pacific:** Tier 1 for Government & Regulatory and Tax *2019, 2018*
- **Who's Who Legal 2019:**
  Nishith Desai, Corporate Tax and Private Funds – Thought Leader
  Vikram Shroff, HR and Employment Law- Global Thought Leader
  Vaibhav Parikh, Data Practices - Thought Leader (India)
  Dr. Milind Antani, Pharma & Healthcare – only Indian Lawyer to be recognized for 'Life sciences-Regulatory,' for 5 years consecutively
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- **IDEX Legal Awards 2015:** Nishith Desai Associates won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm"

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1. Introduction

India, one of the biggest emerging markets, is currently an important destination for foreign direct investment (**"FDI"**). Despite India's potential to become one of the most dominant economies in the world, its economic progress since gaining independence in 1947 has generally been masked by a perception of India being a closed, developing country. However, this perception has changed in the recent past and India is today accepted as one of the most stable and robust economies.

The healthcare sector as an industry is expanding rapidly in India. It comprises of hospital and diagnostic services, diagnostic products, medical devices, medical technology, e-health service, clinical trial services, and clinical research organizations. This sector is predominantly privatized with almost 75 to 80 percent of hospitals being run and managed by the private sector.

Indian healthcare sector was expected and continues to record a threefold rise, at a CAGR of 22 per cent during 2016-2022 to reach US$ 372 billion by 2022.[1] It is undergoing a metamorphosis by broadening the focus of its services using technology, deliverables, and newer applications. Hospitals that were con fined to a specified area with limited infrastructure and services are now expanding, mainly due to the foreign investment being received by the sector.

Further, the Government of India also aims to increase its healthcare spending to up to three percent of the Gross Domestic Product (GDP) by 2022.[2] This will lead to organic and inorganic expansion of existing hospitals in India. India has witnessed the emergence of various multi-specialty, single -specialty and super-specialty hospitals in Tier 1 and Tier 2 cities. These hospitals are predominantly managed by corporates.

Foreign investors are playing a significant role in the development of the hospital and diagnostic sector. Under the Union Budget 2020-2021, the allocation to the Ministry of Health and Family Welfare was INR 69,000 crore out of which INR 6,400 crore was allocated to India's flagship healthcare program the Prime Minister Jan Arogya Yojana, popularly known as Ayushman Bharat.[3] The budget also proposed a cess of 5% on the import of medical devices the funds from which would be used to set up more hospitals in public-private partnership models.[4]

1. https://www.ibef.org/download/healthcare-jan-2019.pdf

2. *Ibid.*

3. https://www.indiabudget.gov.in/doc/Budget_Speech.pdf

4. *Ibid.*

2. Opportunities

The Indian healthcare sector is ripe for expansion and significant growth.

I. Hospitals and Infrastructure

There is tremendous demand for tertiary care hospitals and specialty hospitals in India and there is a gap between the availability of beds and required beds. The Indian medical tourism industry is expected to reach USD 9 billion (around INR 68,000 crore) by 2020.[5] Due to increasing medical tourism, there is a need to upgrade service standards and provide state-of-the-art facilities to bring service levels on par with global standards. This demand has created excellent opportunities for investors.

Most healthcare players have been setting up additional facilities to cater to critical care or super-specialty health care and some leading hospital players are aggressively raising funds for their expansion. India is also witnessing growth in the medical infra- structure sector, including advanced diagnostic equipment. Separately, there is also a need for institutions that train professionals, both nursing and paramedic, to overcome the shortage of trained professionals in the healthcare sector in India.

The healthcare sector in India, especially hospital services, is dominated by the private sector which comprises of individual doctors or group of doctors running clinics or private nursing homes, and various corporate or trusts running single-specialty/ multi-specialty hospitals. Hospitals in India operate under various models. We have described them briefly below:

A. Trust and Management Services Company Model

This model is the prevalent model in India and this is how it works: A trust procures land from the government or local municipal body on a long lease and constructs a hospital on this land. The trust may then manage the hospital itself or if it does not have the management capability, it may engage professional service providers to run and manage the hospital. Regarding profit sharing, several commercial models have evolved. The challenges in this model are the restrictions imposed in the lease by the government body, such as restrictions on expansion and requirements of rendering services to poor patients. Additionally, the business models adopted by trust hospitals involve employees from the trust and from management services companies working together. Due to this, the hospital often faces issues relating to delegation of work and managing employees effectively.

B. Corporate Hospital Model

Of late this model is becoming popular. A company buys land, then constructs, sets up and manages a hospital. This model requires more funding on account of the land cost, and consequently, reputed and well-established corporate houses would tend to use this model. In another allied model, the corporate house sets up a trust and the trust manages the hospital. The corporate house may also hire a management services company to run and manage the hospital. This model gives more comfort to investors as compared to the trust models. Another recent trend is corporate hospitals partnering with successful doctors/specialists. The corporate house would acquire the doctor/specialist's practice, and consequently its patients. This also works very well from a branding perspective.

C. Group of Doctors Model

This model is fast emerging in Tier 2 and Tier 3 cities. Groups of successful doctors from different disciplines are joining hands to start large hospitals.

5. https://www.moneycontrol.com/news/business/indias-medical-tourism-market-expected-to-touch-9-billion-by-2020-report-4639931.html

A partnership, LLP or private limited company may be used by the doctors who come together. Though these doctors are comfortable with bank debt, they seem to be increasingly amenable to private equity investment as well. The challenge here is the relationship between company and doctors, especially key doctors who are shareholders of the company or partners. It is very important that these key doctors are bound by an agreement to continue serving the hospital.

Annexure A provides the schematic presentation of these models.

II. Technology Driven Services

A significantly low presence of doctors in rural and semi-urban areas has led to limited access to proper healthcare facilities for people living in these areas. Tele-medicine and e-Healthcare are considered to be solutions to this lack of access. The growth of the IT sector in India (which plays a crucial role in telemedicine) has led to the emergence of this sector in India. Tele-radiology has emerged very fast with an increasing number of foreign hospitals active in this space. The foreign hospitals consult Indian experts to provide opinions, i.e., on x-rays of patients in the hospital. Many hospitals have adopted the public-private partnership route to render services through tele-medicine. In 2018, the Ministry of Health and Family Welfare proposed to set up the National e-Health Authority (**"NEHA"**), which would be responsible for the development of an integrated health information system in India. This is a welcome step that would help develop telemedicine in India.

III. Medical Devices and Equipment

Generally speaking, a medical device includes any instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including the software intended by its manufacturer, to be used specially for human beings or animals for one or more specific purposes. It also includes a device which is a reagent, calibrator, control material, kit, equipment, or system, whether used alone or in combination, intended to be used for examination and providing information for medical or diagnostic purposes. Medical device has been defined under India's FDI Policy[6] as follows:

i. Any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specifically for human beings or animals for one or more of the specific purposes of –

ii. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

iii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

iv. Investigation, replacement or modification or support of the anatomy or of a physiological process;

v. Supporting or sustaining life;

vi. Disinfection of medical devices; and

vii. Control of conception.

Investment in the medical equipment manufacturing sector is one of the most attractive areas for investment. The medical equipment manufacturing industryis expected to grow in tandem with the hospital sector, which is expected to grow to USD 60 billion by 2016. The medical device sector has seen a significant flow of investments over the past few years and the government has allowed 100 percent FDI under the automatic route. We have discussed the Indian medical device sector in detail in a separate research paper available here.[7]

6. Review of Foreign Direct Investment policy on various sectors, available at: https://dipp.gov.in/sites/default/files/pn1_2018.pdf.

7. The Indian Medical Device Industry: Legal, Regulatory and Tax Overview, available at: http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/The_Indian_Medical_Device_Industry.pdf.

IV. Diagnostics

One also needs to pay attention to the segment of the diagnostic and pathology centers which have begun growing with rapid speed and are lucrative for FDI. These centers have expanded their service to include all kinds of diagnostic services including cardiology and neurology.

V. Health Insurance

The percentage of the Indian population that has been covered under health insurance is unfortunately very insignificant. The domestic health insurance business at INR 12,606 crore (USD 2.03 billion), accounts for about a quarter of the total non-life insurance business in the country.[8] An increase in people opting for health insurance has been witnessed over a period of time. New products that also cover certain ailments not covered earlier are seeing more buyers of such insurance policies.

In August 2018, the Government of India approved Ayushman Bharat-National Health Protection Mission as a centrally sponsored scheme contributed by both centre and the state government at a ratio of 60:40 for all states, 90:10 for the north eastern states and 60:40 for Union Territories with legislature. The centre will contribute 100 per cent for Union Territories without legislature. The National Health Protection Scheme is the largest government funded healthcare program in the world, which is expected to benefit 100 million poor families in the country by providing a cover of up to INR 5 lakh (US$ 7,723.2) per family per year for secondary and tertiary care hospitalization.[9]

8. Insurance Sector in India, available at: http://www.ibef.org/industry/insurance-sector-india.aspx.

9. Healthcare in India, available at: https://www.ibef.org/download/healthcare-jan-2019.pdf.

3. Emerging Trends

I. Consolidation of Hospitals – a Fast Emerging Trend

As per the Indian Brand Equity Foundation, the health- care industry size is expected to touch USD 160 billion by 2017 and USD 280 billion by 2020.[10] The increase in life style related diseases and an expanding middle class have led to a growing demand for quality healthcare services over the years. Unfortunately, India's healthcare infrastructure has been unable to keep pace with the demand. The large gap in demand and supply of quality health care services and a growing capital demand owing to operational costs and technology acquisitions have pushed health care service providers to expand inorganically by merging with competitors or by accepting large capital injections.

II. Emerging Tier 2 and Tier 3 Cities

Recent times have witnessed tremendous growth in secondary and tertiary care hospitals in Tier 2 and Tier 3 cities. The reasons for this trend are manifold. The per-capita income of residents of Tier 2 and Tier 3 cities has increased significantly in the last decade, resulting in a significant increase in their capacity to pay for healthcare. Another possible reason could be that the markets in Tier 1 cities have reached saturation because of an increase in competition, causing the serious players to explore opportunities outside the Tier 1 cities. The additional attraction of Tier 2 and Tier 3 cities is the availability of land, labour, electricity, etc. at low cost. Yet another major factor that is playing a role is the willingness of doctors who have been practicing for a long time and enjoying goodwill, to join hands to start big hospitals.

The Ayushman Bharat initiative is also likely to lead to an increase in the number of hospitals in Tier 2 and Tier 3 cities. Under the Union Budget 2020-2021, the Government has proposed to set up a viability gap funding window for setting up hospitals through public-private partnerships in Tier 2 and Tier 3 cities. These hospitals would be empaneled with the Ayushman Bharat scheme. One of the proposed means of funding the hospitals is also through the proceeds from taxes levied on medical devices.

III. Inclination of Doctors Towards Debt Funding

Debt finance is a major source of capital for the health- care service industry. The borrower must offer primary security and a collateral security before securing a loan. Primary security is usually provided in the form of a charge over the asset against which the loan is taken and collateral security is usually given in form of a personal guarantee. The requirement to offer collateral in the form of a personal guarantee is the biggest consideration for promoters of small and medium scale hospitals while accepting debt which, many a times, hinders expansion. Recently, Non-Banking Financial Companies (**"NBFCs"**) have emerged as preferred sources of debt- funding since they usually do not insist on collateral security.

Many new healthcare services are emerging quickly and are looking for funding. **Annexure B** sets out some of these healthcare services.

10. Healthcare Industry in India, available at: https://www.ibef.org/industry/healthcare-india.aspx#st-%20hash.XtwkL5ur.dpuf.

4. Investment in Healthcare Sector

I. Foreign Direct Investment

The economic reforms launched by the Government of India since 1991 have resulted in substantial economic growth and the integration of India into the global economy. The pace of reforms has gained momentum due to political stability and strong industrial growth.

Foreign investment into India is governed by the Foreign Exchange Management Act, 1999 (**"FEMA"**), the rules and regulations made by the Reserve Bank of India (**"RBI"**), and the Industrial Policy and Procedures issued by the Ministry of Commerce and Indus- try through the Secretariat for Industrial Assistance, DIPP.

The provisions pertaining to foreign investments (including foreign direct investments[11] and foreign portfolio investments[12])[13] are laid down in FEMA (Non-Debt Instruments) Rules, 2019 (**"NDI Rules"**). 100 percent foreign investment is permitted in most sectors under the automatic route, i.e., where prior approval of the Governmental Authority, as identified by the Department of Industrial Policy and Promotion, is not required. Currently, foreign investment is permitted up to 100 percent under the automatic route in the construction and development of hospitals and in the manufacture of medical devices.[14] In the pharmaceutical sector, foreign investments is permitted upto 100 % in greenfield projects (new projects coming up in India) and 74% in brownfield projects (existing projects in India) under the automatic route and foreign investment beyond 74% in brownfield projects is under the government.[15]

II. Foreign Venture Capital Investment

Another vital means of investment into the health- care, as well as medical and surgical appliances sec- tors is through venture capital investment by entities registered with the Securities Exchange Board of India (**"SEBI"**) as foreign venture capital investors. While it is not mandatory for a private equity investor to register as a Foreign Venture Capital Investor (**"FVCI"**) under the FVCI regulations,[16] there are some significant advantages to be gained by registering as an FVCI. A FVCI is exempt from compliance with the pricing guidelines under the NDI Rules for the acquisition of securities at the time of entry as well as for the transfer/sale of securities at the time of exit if such investment is made under Schedule VII of the NDI Rules. Secondly, in cases where the promoters of the company intend to buy-back the securities from an FVCI, they are exempted from making an open offer under the Takeover Code.[17] It should be noted that SEBI has been granting approvals to FVCIs only for investments in certain identified sectors, amongst them being research and development of new chemical entities in the pharmaceutical sector, and units of SEBI registered Venture Capital Funds (**"VCFs"**) and in SEBI registered Alternate Investment Funds (**"AIFs"**).[18]

11. Foreign Direct Investment' (FDI) means investment through equity instruments by a person resident outside India in an unlisted Indian company; or in 10 percent or more of the post issue paid-up equity capital on a fully diluted basis of a listed Indian company.
12. 'Foreign Portfolio Investment' means any investment made by a person resident outside India through equity instruments where such investment is less than 10 percent of the post issue paid-up share capital on a fully diluted basis of a listed Indian company or less than 10 percent of the paid-up value of each series of equity instruments of a listed Indian company.
13. Foreign investments mean any investment made by a person resident outside India on a repatriable basis in capital instruments of an Indian company or to the capital of an LLP.
14. Press Note 2 of 2015, available at: https://dipp.gov.in/sites/default/files/pn12_2015%20%281%29.pdf.
15. Press Note 5 of 2016, available at: https://dipp.gov.in/sites/default/files/pn5_2016.pdf
16. SEBI (Foreign Venture Capital Investor) Regulations, 2000.
17. Reg. 10, Securities Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulations, 2011.
18. SEBI introduced SEBI (Alternate Investment Funds) Regulations, 2012 to govern domestic pooling vehicles. RBI has issued Notification no. FEMA. 355/2015 that permits AIFs and other investment vehicles to accept foreign investments under the automatic route.

FVCI is also permitted to invest in the 'Infrastructure Sector' (as given in the Harmonised Master List of Infrastructure sub-sectors approved by Government of India vide Notification F. No. 13/06/2009-INF dated March 27, 2012 as amended/ updated) which includes hospitals, medical colleges, Para medical training institutes and diagnostics centres (as capital stock).

III. Transactional Issues for Investments in Healthcare

Investments in healthcare has seen immense interest from foreign investors. However, considering the healthcare sector, certain nuanced issues need to be considered whilst negotiating as an investor in such investments:

a. Representations and warranties, indemnities and covenants are the key clauses to focus on. Since the healthcare sector is highly regulated, there can be significant implications (both in terms of monetary and reputational) for non-compliance with the applicable regulatory provisions. Hospitals and healthcare sector are required to comply with various environmental laws such as Bio-Medical Waste Management and Handling Rules, 2016 obtaining the consent to operate under the Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act, 1974. Hospitals undertaking clinical trials may be further required to be ensure that a robust clinical trial policy is in place. Some of these non-compliances may actually lead to shutting down of hospitals and healthcare centres. Keeping this in view, the Investors need to evaluate the commercial and the legal risk involved in investing in such businesses which are not compliant with applicable laws and basis the magnitude of risk involved, appropriate representations/ warranties/ indemnities need to be negotiated and factored into the investment documents.

b. Land related diligence – it is important to determine if the hospital in which the potential investment is to be made, is constructed on a freehold land or leasehold land. In case of the latter, governmental leasehold land is subject to compliance with certain conditions (such as compulsory provision of benefits to the economically weaker classes etc.) which is crucial to be determined if the potential investee company is in compliance with.

c. Review of outsourcing agreements for non-core activities (such as diagnostic services, counselling etc.) and arrangements with key doctors and consultants is important. The terms of engagement with such doctors and consultants from a continuity perspective is crucial and also for purposes of determination of applicability of various labour laws such as Employee Provident Fund and Miscellaneous Provisions Act, 1952, Contract Labour (Regulation & Abolition) Act, 1970 etc.

5. Legal and Regulatory Aspects

The healthcare sector in India is highly regulated. It is governed by a host of laws that govern the establishment of hospitals, services offered, medical professionals, as well as additional services offered by the hospital such as cafeteria, pharmacy, ambulance, etc.

I. Authorities

The following authorities regulate healthcare sector in India:

A. Ministry of Health and Family Welfare:

- Department of Health;
- Department of Family & Welfare;
- Department of AYUSH;
- Central Drugs Standard Control Organization(**"CDSCO"**);
- Narcotic Controls Bureau; and
- Central Bureau of Narcotics.

B. State Level and Local Authorities;

- Pollution Control Boards;
- Biomedical Waste Disposal;
- State Food and Drugs Administrations;
- Municipal Corporation; and
- Municipality.

C. Other Institutions/Organizations

- Indian Council of Medical Research (**"ICMR"**);
- Atomic Energy Regulatory Board (**"AERB"**); and
- Department for Promotion of Industry and Internal Trade.

II. Hospitals

As a part of the due diligence of a hospital, the investor should typically ensure that the investee entity has complied with all applicable laws. There are multiple laws that govern the sub-sets of the healthcare sector, and there are a multitude of permissions and licenses that are required to be obtained. Such permissions and licenses include:

- Municipal permission for construction;
- Approvals under the Clinical Establishments (Registration and Regulation) Act, 2010 and rules framed thereunder;
- Licenses under Food Safety and Standards Act, 2006 for operating in-house catering and canteen services;
- Consent from State Pollution Control Board to establish and operate facility under the Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981;
- Fire safety Approvals;
- Municipal Trade license (State Specific);
- Registration under shops and establishment legislation specific to the State;
- Registration of facility with State Government / Authority as a private medical establishment (State Specific);
- Registration under the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and corresponding registration of ultrasound machine with appropriate authority under the Act;
- Compliance with Medical Termination of Pregnancy Act, 1971;
- Medical Council of India (**"MCI"**) (which will soon be replaced by the National Medical Commission);
- Indian Medical Association (**"IMA"**)

- Authorization for operation of a facility for generation, collection, reception, storage, transportation, treatment, and disposal of bio-medical wastes under Bio-Medical Waste Management Rules, 2016 of the Environmental Protection Act 1986 from the Pollution Control Board and corresponding compliances;
- License to store compressed gas in pressure vessels;
- Approval from State Food and Drug Administration to obtain and possess certain category of drugs for use on patients;
- License to operate X-Ray, CT Scan as well as Cathlab from AERB;
- License to operate a blood bank from State Food and Drug Administration for procession of whole human Blood for preparation for sale or distribution of its components; and
- Narcotic drug license;
- Permit for the purchase and possession of denatured spirit;
- Registration under various applicable Labour Laws; and
- Registration under various direct and indirect Tax statutes.

III. Medical Devices

Medical Devices in India are regulated under the Medical Device Rules, 2017 (**"MDR"**) – a set of rules framed under India's primary drug control legislation, the Drugs and Cosmetics Act, 1940. Under the MDR, only certain categories devices notified by the Government are regulated in addition to mechanical contraceptives (condoms, tubal rings and intra-uterine devices), surgical bandages, surgical dressings, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anti-coagulant. Therefore, devices that have not been notified by the Government are not regulated in India. Currently, the 29 categories of medical devices have been notified by the Ministry of Health and Family Welfare out of which 13 devices would come under the regulation at various points in 2020 and 2021. These devices are commonly referred toas the 'Notified Medical Devices'. The complete list of Notified Medical Devices is covered in **Annexure C.**

Given this, the vast majority of medical devices in India are unregulated. As a result, compliances prescribed under the MDR to ensure no quality standards for medical devices are not required to be followed by manufacturers, importers and sellers of medical devices. To remedy this, the Ministry of Health and Family Welfare released a notification on February 11, 2020 to bring all medical devices under the purview of the MDR with effect from April 01, 2020.[19] Under the notifications, a catch-all definition of medical devices has been notified (rather than notifying each individual medical device). Once the notification comes into effect, all medical devices would be regulated under the MDR and would therefore be required to obtain licenses from the relevant authorities to engage in the manufacture, import and sale of medical devices. Therefore, to ensure that medical device manufacturers and importers are able to carry on commercial activity in the interim period prior to obtaining the required licenses, the drug regulator has introduced a provisional registration mechanism under which the manufacturers and importers who have registered their device on a portal, specified portal are exempt from the MDR for a period of 30 months for Class A and Class B (low-risk and low-medium risk) devices, and 42 months for Class C and Class D (medium-high rise and high risk) devices. For more information on the notifications and their impact on the medical device industry, please see our hotline on this topic **here.**[20]

19. Notification no. S.O. 648(E) by Ministry of Health and Family Welfare dated February 11, 2020.

20. Dawn of a New Era: All Medical Devices in India to be Regulated from April 01, 2020, available at: http://www.nishithdesai.com/information/research-and-articles/nda-hotline/nda-hotline-single-view/article/dawn-of-a-new-era-all-medical-devices-in-india-to-be-regulated-from-april-2020.html?no_cache=1&cHash=8ff898d56d8cf2f41bf1c04836422b03

The medical device industry is rapidly evolving from a regulation perspective. Simultaneously, the drug regulator has been increasingly receptive to the concerns of the industry and has been taking steps to ensure that medical devices are regulated in an industry-friendly manner while ensuring the interests of patients are protected. Companies present in the market are well-placed to leverage the changing regulations to their advantage and remain ahead of the curve.

6. Taxation in India

I. Direct Taxes

A. General Overview

Taxation of income in India is governed by the provisions of the Income Tax Act, 1961 (**"ITA"**) as amended annually by the Finance Acts. Under the ITA, residents are subject to tax in India on their worldwide income, whereas non-residents are taxed only on Indian source income i.e. income that accrues or arises in India, is deemed to accrue or arise in India or which is received or is deemed to be received in India. A company is said to be resident in India if it is incorporated in India or its place of effective management (**"POEM"**) is located in India. 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 legitimatetax exemptions are not challenged by the tax department.

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

B. Taxes Applicable to Companies

Resident companies are taxed at the rate of 30%, while non-resident companies are taxed at the rate of 40%. A minimum alternative tax is payable by resident, and in certain circumstances, non-resident companies at the rate of around 18.5%. The corporate tax rate for domestic companies whose total turnover or gross receipts does not exceed INR 400 million is 25%. Resident companies are generally taxed at approximately 30%.

Further, on September 20, 2019, the Government promulgated the Taxation Laws (Amendment) Ordinance 2019, to primarily reduce corporate tax rates as a knee-jerk reaction to India's economic slowdown. (**'Ordinance'**) effective from April, 2019. As per the Ordinance,

domestic companies may choose to be taxed at the effective rate of 25.17% under the newly introduced section 115BAA of the ITA subject to certain conditions such as (i) total income is computed without claiming certain specified deductions and exemptions under the Income-tax Act, 1961 (**'Deductions'**); (ii) the company shall not be allowed to set off any carried forward losses from earlier assessment years if such loss is attributable to the Deductions; (iii) the company claims depreciation in the manner prescribed barring any depreciation in respect of plant and machinery; (iv) once exercised, the option to be taxed under this provision cannot be withdrawn and will continue to apply for subsequent assessment years etc.

The Ordinance also introduced section 115BAB to the ITA, as per which new manufacturing companies set up on or after October 1, 2019 may avail an effective tax rate of 17.16% subject to prescribed conditions, which are broadly similar to the conditions applicable for availing section 115BAA. Non-resident companies are taxed at the rate of about 42% (if net income is in the range of INR1 crore – 10 crores) and approximately 43% (if net income exceeds INR 10 crores). While residents are taxed on their worldwide income, non-residents are only taxed on income arising to them from sources in India. A company is said to be resident in India if it is incorporated in India or has its POEM in India. Minimum alternate tax (**"MAT"**) at the rate of 15% (excluding surcharge and education cess) is also payable on the book profits of a company, if the company's income due to exemptions is less than 15% of its book profits. The MAT rate was reduced from 18.5% to 15%, effective from April 1, 2019, by virtue of the Ordinance. Importantly, the Ordinance also provides that no MAT shall be applicable in case of companies opting to be taxed under section 115BAA / 115BAB. With respect to 'eligible start-ups' meeting certain specified criteria, a 100% tax holiday for any 3 consecutive assessment years out of a block of 7 years beginning from the year in which such start up is set up has been provided for.[21]

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

C. Dividends

Dividends distributed by Indian companies are subject to a dividend distribution tax (**"DDT"**) at the rate of around 15% (calculated on a gross-up basis), payable by the company. However, no further Indian taxes are payable by the shareholders on such dividend income once DDT is paid, except in certain specified situations. Finance Bill, 2020 has proposed to abolish DDT. Accordingly, from April 1, 2020, dividends declared by an Indian company would be subject tax in the hands of the recipient at slab rates and subject to necessary withholding tax in the hands of the Indian payer company. Unlike in case of DDT, the foreign recipients of the dividends should now be able to avail treaty benefits in respect of the taxes paid on dividends. Further, the mechanism to claim foreign tax credit on the taxes paid on the dividends would be much easier as it was in case of payment of DDT. This is because DDT was tax paid by the distribution company and the not the recipient and there needed to be necessary language in the laws of the relevant foreign jurisdiction / applicable treaty on availingthe underlying tax credits for availing foreign tax credit in respect of DDT paid in India.

D. 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%.[22] However this benefit has a sunset clause stating that the benefits would only be available for loan agreements entered into/ bonds issued on or after July 1, 2012 and before July 1, 2020. The said beneficial 5% rate of TDS is also available in relation to Rupee Denominated Bonds (**"RDB"**) issued until July 1, 2020. Similarly, interest payable to foreign institutional investors (**"FII"**) on investments made by them in RDBs and government securities is taxable at the rate of 5%. This benefit also has a sunset period and is applicable only in respect of interest payable until July 1, 2020.[23]

22. Section 194LC, Income Tax Act, 1961.

23. Section 194LD, Income Tax Act, 1961

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

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

E. Capital Gains

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

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

Long term capital gains earned by a non-resident on sale of unlisted securities may be taxed at the rate of 10%[24] (provided no benefit of indexation has been availed) or 20% (if benefit of indexation has been availed) depending on certain considerations. Long term gains on sale of listed securities on a stock exchange used to be exempted and only subject to a securities transaction tax (**"STT"**). However, the Finance Act, 2018 removed this exemption and introduced a levy of 10% tax on LTCG arising from the transfer of listed equity shares, units of an equity oriented mutual fund, or units of a business trust where such gains exceed INR 100,000 (approx. USD 1500). This tax is applicable on LTCG arising on or after April 1, 2018 and no indexation benefits can be availed of. However, the Finance Act 2018 also introduced limited grandfathering in respect of protecting the gains realized on a mark to market basis up to January 31, 2018 and only an increase in share value post this date would be brought within the tax net. Further, earlier, for the purposes of obtaining the LTCG exemption, the Finance Act, 2017 had introduced an additional requirement for STT to be paid at the time of acquisition of listed shares. However, the CBDT had exempted certain modes of acquisition from this requirement. Pursuant to withdrawal of the exemption in Finance Act, 2018, the CBDT issued a notification specifying that the requirement to pay STT at the time of acquisition will not apply to (1) share acquisitions undertaken prior to October 1, 2004, (2) share acquisitions undertaken on or after October 1, 2004 which are not chargeable to STT subject to certain exceptions for the purposes of obtaining the capital gains tax rate of 10% under section 112A.[25] 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%.

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.

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

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

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.

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 200 percent of such expenditure. Expenditure on scientific research includes expenditure incurred on medical device trial, obtaining approval from any regulatory authority under any Central, State or Provincial Act and filing an application for a patent under the Patents Act, 1970. However, the Finance Act2016 has restricted the rate of deduction to 150 percent with effect from 01.04.2017 to 31.03.2020. Further, the deduction shall be restricted to 100 percent from 01.04.2020 onwards.

It should be borne in mind here that no company would be entitled to the aforementioned deduction unless it enters into an agreement with the Department of Scientific and Industrial Research for co-operation in such research and development facility and for audit of the accounts maintained for that research and development facility.

This deduction is available for expenses incurred prior to March 31, 2017.

B. Contributions Made to Other Institutions for Scientific Research

The ITA provides for a deduction of 200 percent of sums paid to any scientific research association (having as its object the undertaking of scientific research), or to any university, college or other institution, for the purpose of scientific research approved by the concerned authority. Similar to the position in respect of an in-house research and development, the Finance Bill 2016 proposes to restrict the rate of deduction to 150 percent with effect from 01.04.2017 to 31.03.2020. Further, the deduction shall be restricted to 100 percent from 01.04.2020 onwards.

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,[26] as follows:

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

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

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)."*

C. Agency PE

Indian Tax Treaties typically contain a provision whereby an Indian entity may be treated as a PE of a foreign enterprise if the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise. Moreover, some Indian Tax Treaties, such as the India-US tax treaty, also contain an additional provision whereby an Indian entity may be regarded as a PE of the foreign enterprise, if the Indian entity maintains a stock of goods from which it regularly delivers such goods on behalf of the foreign enterprise and contributes to the sale of such goods.

An agent of independent nature is considered as an exception to the Agency PE rule.

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

26. 1983 144 ITR 146 AP.

This follows from the principle that, for the purpose of taxation, such a subsidiary company constitutes an independent legal entity.

IV. 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,[27] 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,[28] 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 suchan 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 essentialconditions for constituting an AOP may be said to be:

a. Two or more persons;

b. Voluntary Combinations;

c. A common purpose or common action with object to produce profit or gains;

d. Combination in Joint Enterprise; and

e. Some kind of scheme for common management.

V. Structuring Investments in India – Use of Intermediate Jurisdictions

Foreign entities that are looking at incorporating subsidiaries in India for outsourcing research and manufacturing functions can achieve tax efficiency by use of a tax neutral intermediate jurisdiction which has signed an Indian Tax Treaty (**"Treaty Jurisdiction"**) rather than directly investing into the Indian company. The foreign entity can achieve tax efficiency by incorporating a company (or any other entity which is eligible to benefits of the relevant Indian Tax Treaty) in the Treaty Jurisdiction which would, in turn, invest into the underlying Indian company.

The choice of an appropriate Treaty Jurisdiction, apart from tax neutrality and a good treaty network, would depend on factors such as political stability, ease of administration, availability of reliable administrators, favourable exchange controls and legal system, certainty in tax and legal framework and ease of winding up operations.

Indian Tax Treaties aim to prevent double taxation of income and capital gains for a person or entity resident in another jurisdiction.

27. [1960] 39 ITR 546 (SC)

28. [1977] 106 ITR 111 (AP)

VI. Indian Transfer Pricing Restrictions

Where entities are looking to outsource research and manufacturing functions to an associated enterprise, such as in cases of captive outsourcing, the fees payable to the service provider should take into account transfer pricing issues.

In India, transfer pricing regulations (**"TP Regulations"**) were introduced on April 1, 2001. The Indian Income Tax Act, 1961 lays down provisions that deal with the computation of income arising from "international transactions" between "associated enterprises". The basic rule enshrined in the TP Regulations is that any income arising from an "international transaction" shall be computed having regard to the arm's length price (discussed below). The TP Regulations define "associated enterprise" to include any enterprise that participates directly or indirectly or through one or more intermediaries in the management or control or capital of another enterprise. Enterprises may also be regarded as "associated" as a result of circumstances such as interdependence by virtue of borrowings, guarantees, licensing of trademarks, purchase, sales or where enterprises have "mutual interest" as may be prescribed by the revenue authorities. Here, "enterprise" is defined broadly and covers any entity (including a permanent establishment) which is or proposes to be engaged in any activity relating to the provision of goods / services of any kind, investment activity, dealing in securities and extending loans. The term "international transaction" has been defined as a transaction between two or more associated enterprises, either or both of which are non-residents. As mentioned earlier, the basic principle is that any income arising from such an "international transaction" shall be computed having regard to the "arm's length price".

Finance Act 2017 had 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:

a. has been made suo moto by the taxpayer in his income tax return,

b. has been made by the Assessing Officer and accepted by the taxpayer,

c. has been determined by and advanced pricing agreement,

d. is made as per safe harbor rules under the ITA,

e. is a result of mutual agreement procedure (**"MAP"**) under a tax treaty.

The provisions further prescribe that where, as a result of primary adjustment, there is an increase in the taxpayer's total income or a reduction in allowable loss, a secondary adjustment shall have to be made. The secondary adjustment is intended to reflect the actual allocation of profits between the taxpayer and the associated enterprise. The purpose of such secondary adjustment is also to eliminate the imbalance between the taxpayer's accounts and actual profits. The Section prescribes that the excess money (difference between the arm's length price determined in the primary adjustment and the actual consideration price) shall be deemed to be an advance made by the taxpayer to its associated enterprise, if it is not repatriated to India within a prescribed time. Once deemed to be an advance, interest shall also be payable on the excess income until the obligation to repatriate such amount is discharged. While the rate of interest is to be calculated in a manner prescribed by the government, it should also be determined at an arm's length price.

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

Although secondary adjustments are an internationally accepted principle and are in line with OECD's Transfer Pricing Guidelines, the implementation of Section 92CE may result

in various practical difficulties. For example, the foreign country in which the associated enterprise is located may have exchange control provisions that make it difficult to repatriate the excess money to India, or it may have adjusted the transaction as per its own transfer pricing provisions and already taxed a portion of the funds Indian tax authorities consider as excess income. The introduction of these provisions and also those relating to thin capitalization show the increasing tendencies of the government to look at international practices in molding tax legislation in India.

Under 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:

a. Comparable uncontrolled price method;

b. Resale price method;

c. Cost plus method;

d. Profit split method;

e. 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 Deductions Incurred in Unethical Promotion

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibit the medical practitioners and their professional associations from taking any Gift, Travel facility, Hospitality, Cash or monetary grant from the medical device industry. The Central Board of Direct Taxes has issued instructions45 to the revenue department that the claim of any expense incurred in providing above mentioned or similar 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.

VIII. 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, 2017with 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. 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. However Countervailing Duty (**"CVD"**) and Special Additional Duty (**"SAD"**) would be subsumed into the IGST, which would be levied on the imported goods.

IX. 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.

7. Issues and Concerns

Investments in hospitals carry a host of potential issues which an investor needs to be aware of and concerned with. As mentioned earlier, the hospital sector is a highly regulated sector in India and hence conducting proper due diligence for regulatory approvals and licenses is very crucial.

The major issues that can seriously impact functionality of the hospital arise from non-compliance with the Pre-conception and Pre-natal Diagnostic Techniques Act, 2003, Medical Termination of Pregnancy Act, 1971, Biomedical Waste Disposal, Drugs and Cosmetic Acts for pharmacy, and Atomic Energy Regulatory Board as well as other environmental consents.

Participation of the hospital in clinical trials poses another challenge since the enactment of the New Drugs and Clinical Trial Rules, 2019 (**"New Drugs and Clinical Trial Rules"**). The New Drugs and Clinical Trial Rules place various obligations on the hospital and the investigator e.g. reporting adverse events that take place in the clinical trial.

Another factor that poses issues and concerns is the operating model of the hospital. Models where hospitals are owned by trusts and managed by hospital management companies may lead to certain concerns from an investment perspective.

8. Conclusion

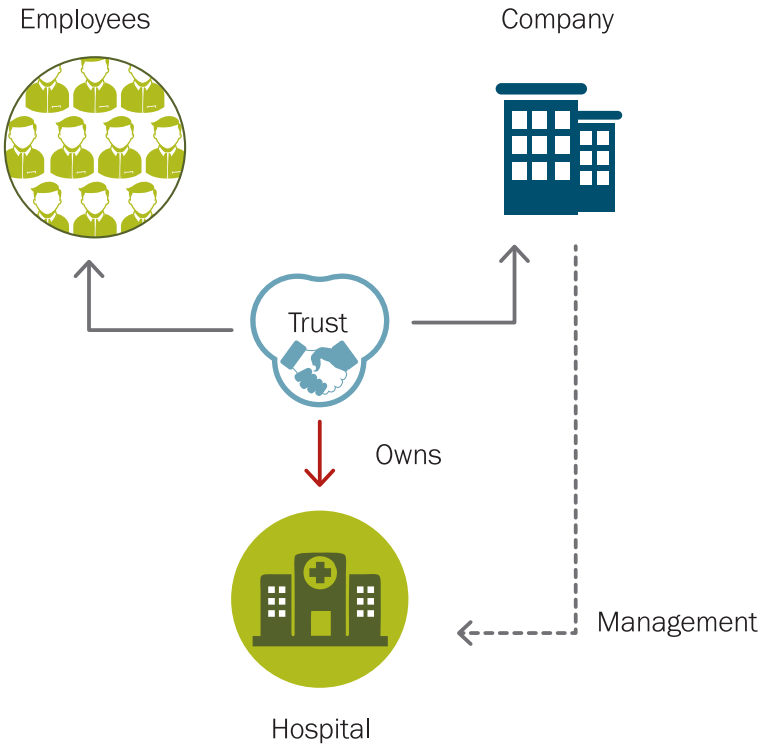
There are many positive implications of foreign investment in hospitals and other healthcare services especially medical device, diagnostics, and e-Health. One major impact foreign investment would have is the creation of the necessary infrastructure. Investments are also needed beyond the metropolitan areas to expand access to healthcare. In addition to helping increase physical capacity in the healthcare sector (such as increasing the number of hospital beds, diagnostic facilities, and increasing the supply of specialty and super-specialty centers), foreign investment can also help in raising the standards and quality of healthcare, in upgrading technology, and in creating employment opportunities, with potential benefits to the health sec- tor and the economy at large. However, the cost of medical care should be affordable most importantly in the Tier 2 and Tier 3 locations.

There is a significant potential for growth in Tier 2 and Tier 3 locations. Even though these Tier 2 and Tier 3 towns have a considerable number of primary health- care centers, they lack quality healthcare services. While Tier 2 and Tier 3 locations have lower populations when compared to a metropolitan area, they can serve as quality healthcare units to the nearby smaller villages and towns. Consequently, there is significant activity in these locations by both national players as well as regional hospitals who are either setting up hospitals or even tying up with existing hospitals in these locations. However, a careful analysis and evaluation is required in order to gain considerable returns from these Tier 2 and Tier 3 locations. We expect Ayushman Bharat to give a fillip to the development of hospitals in Tier 1 and Tier 2 cities as this has been specifically identified as a focus area by the Indian Government.

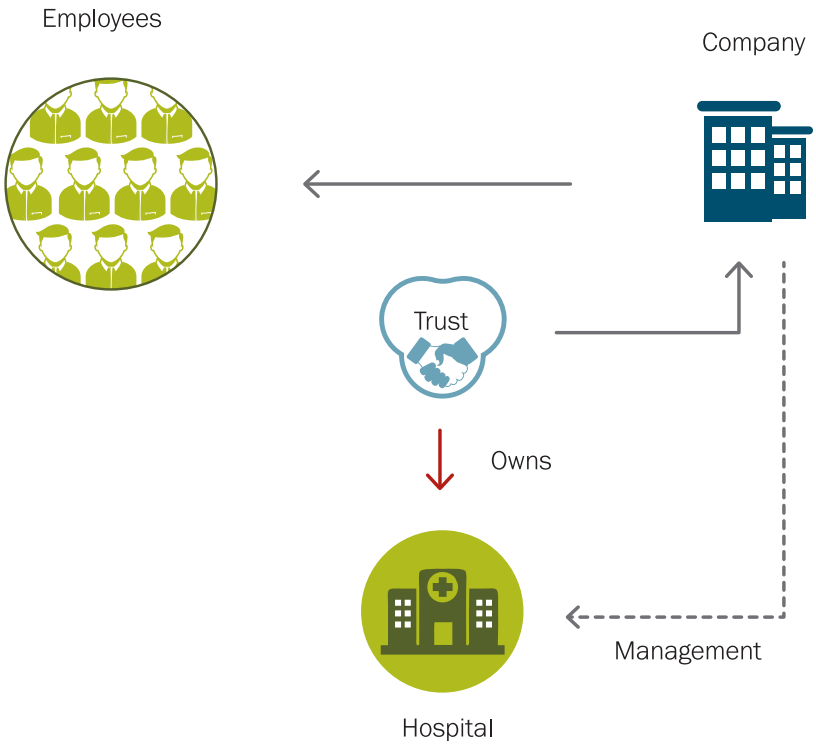
Annexure A

Schematic Representation of Various Business Models

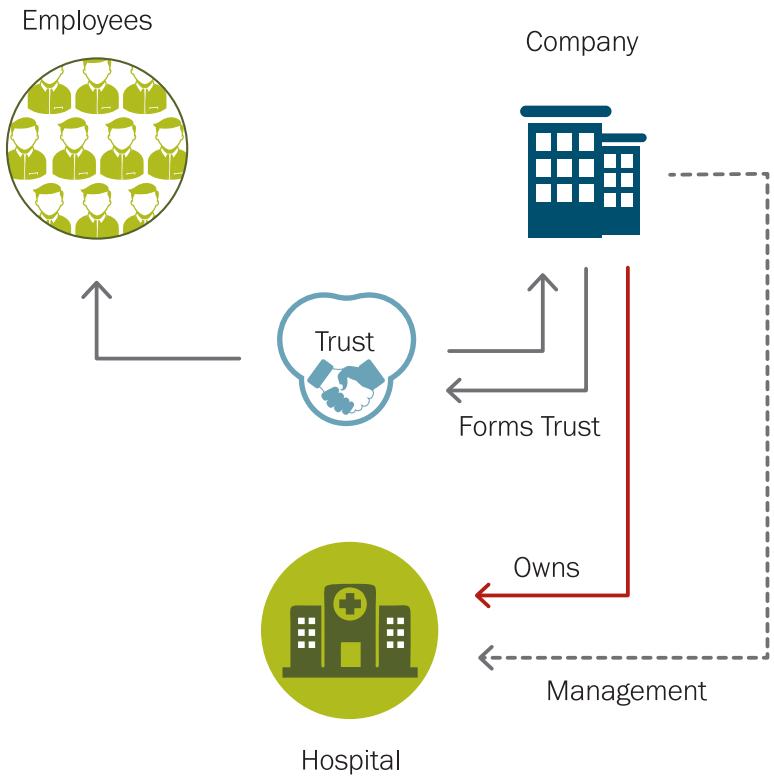
Model 1



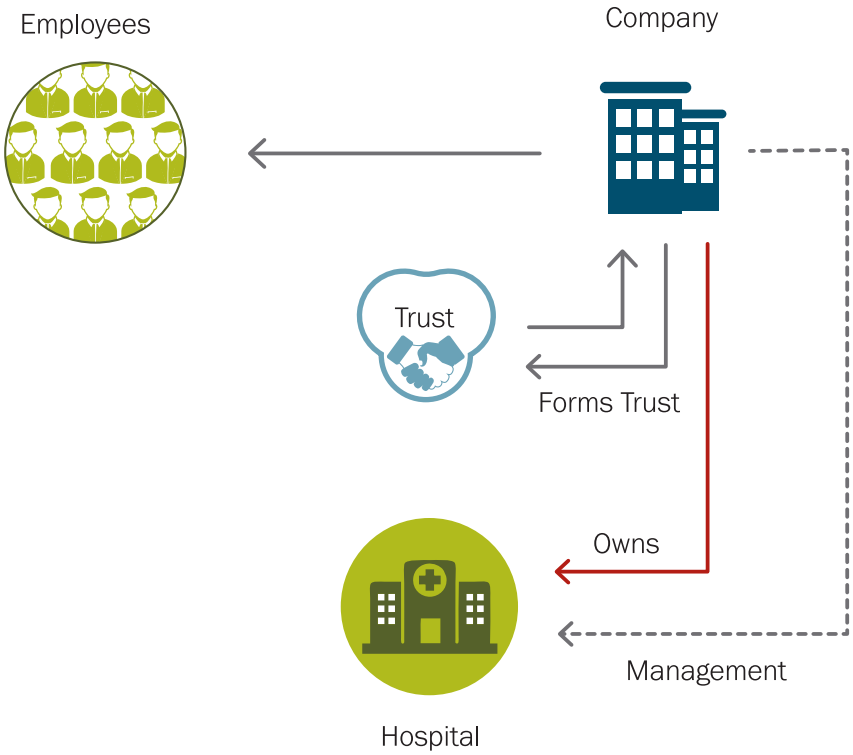
Model 1A



Model 2



Model 2A



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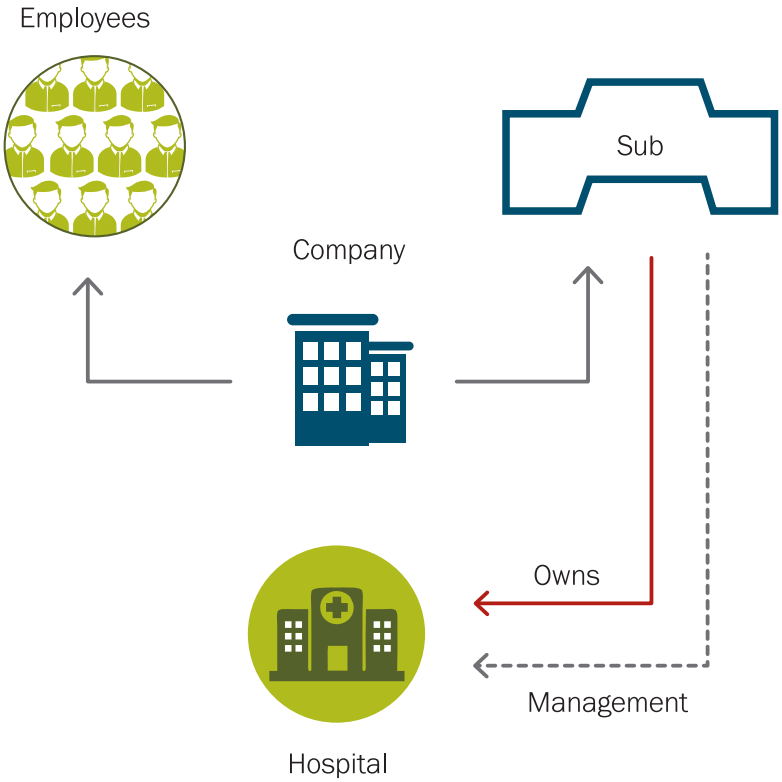
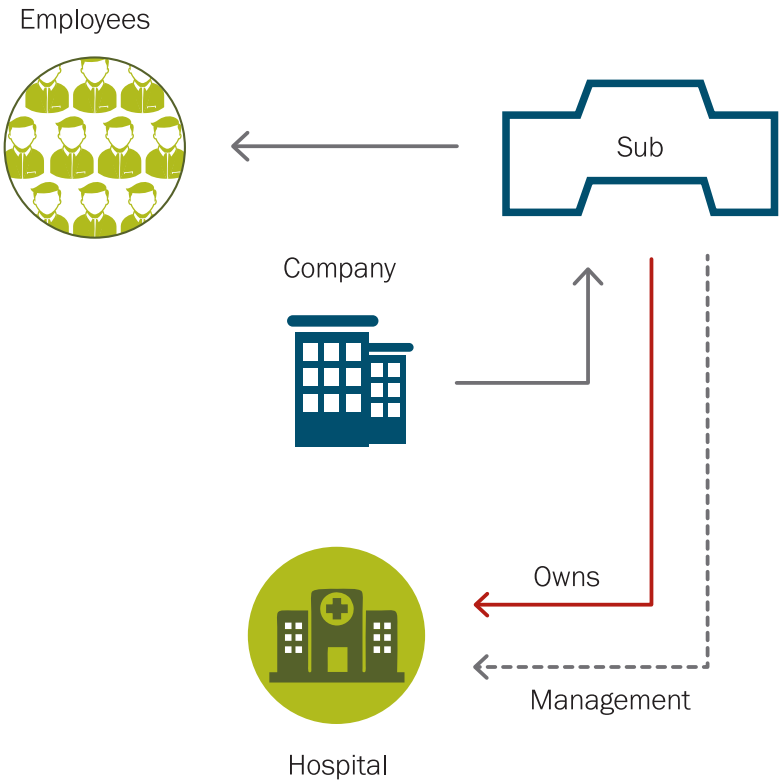
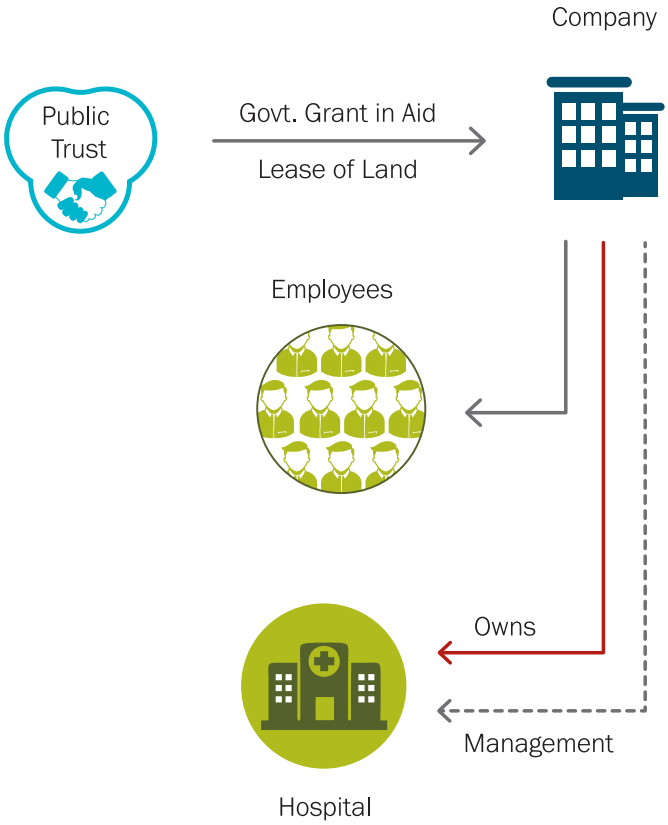


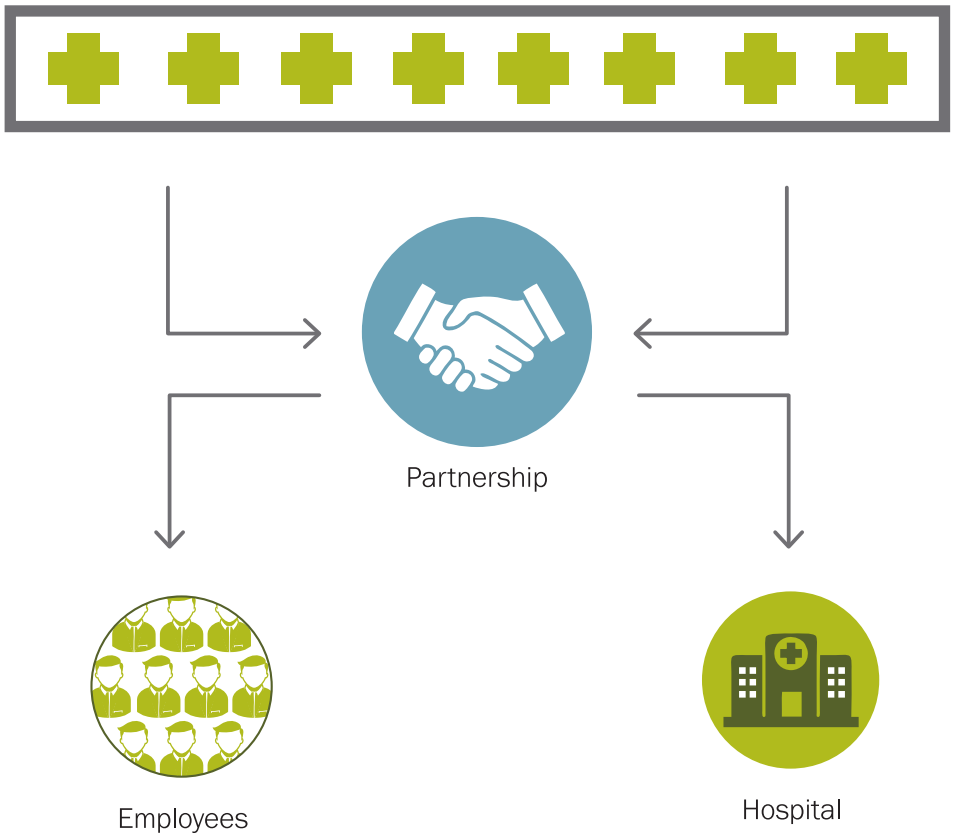
Model 3A



Model 4



Model 3A



Annexure B

Medical Device and Diagnostics

- Medical device companies
- Medical equipment companies
- Radio Imaging services
- Pathlabs
- National chains (less at the moment)

E-Health/Telemedicine

- Division of hospital rendering tele medicine services(tele radiology)
- Standalone tele radiology companies
- Service providers companies (IT)
- Tele monitoring / health monitoring

Preventive and Wellness Care

- Nutraceuticals and herbals
- Dietary supplement companies
- Organic foods and health supplements companies

Day Care/Short Stay Centers

- Chain of existing centers
- Hospitals having potential to start such centers
- Surgery / specific discipline

Critical Care Centers

- Emergency Operation Rooms and recovery centers
- Basic recovery centers
- Ambulance services

Geriatric Care Center

- General Care
- Hospice Centers

Physical Therapy Centers

- Post-trauma
- Post-therapy

General Diagnostics

- Neuro-physiology
- Advanced Radiology
- Hematology and Advanced Histopathology

Pain Clinics

- Advanced pain-relieving centers

Ancillary Care

- Nursing
- Para medics services
- Hospital Management Services
- Medical tourism companies
- Hospital housekeeping
- Ambulance services
- Low cost health services
- Equipment leasing / services

Annexure C

List of Notified Medical Devices

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

32.	PET Equipment	From April 01, 2021
33.	X-Ray Machine	From April 01, 2021
34.	Dialysis Machine	From April 01, 2021
35.	Bone Marrow Cell Separator	From April 01, 2021
36.	Ultrasound Equipment	From November 01, 2020
37.	Disinfectants and insecticide specified in Medical Devices Rules, 2017	In force

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

Private Equity and Private Debt Investments in India

May 2019

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August 2019

Digital Health in India

November 2019

Impact Investing Simplified

July 2019

IP Centric Deals: Key legal, tax and structuring considerations from Indian law perspective

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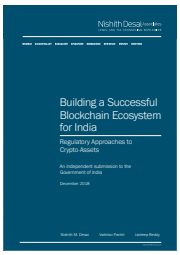
Fund Formation: Attracting Global Investors

February 2019



Building a Successful Blockchain Ecosystem for India

December 2018

NDA Insights

TITLE	TYPE	DATE
Delhi Tribunal: Hitachi Singapore's Liaison Office in India is a Permanent Establishment, Scope of Exclusion Under Singapore Treaty Restrictive	Tax	November 2019
CBDT issues clarification around availment of additional depreciation and MAT credit for companies availing lower rate of tax	Tax	October 2019
Bombay High Court quashes 197 order rejecting Mauritius tax treaty benefits	Tax	May 2019
Investment Arbitration & India – 2019 Year in review	Dispute	January2020
Changing landscape of confidentiality in international arbitration	Dispute	January2020
The Arbitration and Conciliation Amendment Act, 2019 – A new dawn or sinking into a morass?	Dispute	January2020
Why, how, and to what extent AI could enter the decision-making boardroom?	TMT	January2020
Privacy in India - Wheels in motion for an epic 2020	TMT	December 2019
Court orders Global Take Down of Content Uploaded from India	TMT	November 2019
Graveyard Shift in India: Employers in Bangalore / Karnataka Permitted to Engage Women Employees at Night in Factories	HR	December 2019
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Crèche Facility By Employers in India: Rules Notified for Bangalore	HR	August 2019
Pharma Year-End Wrap: Signs of exciting times ahead?	Pharma	December 2019
Medical Device Revamp: Regulatory Pathway or Regulatory Maze?	Pharma	November 2019
Prohibition of E-Cigarettes: End of ENDS?	Pharma	September 2019

Research @ NDA

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

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

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

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

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

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our Lab Reports dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical eco-system that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

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

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