Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI SILICON VALLEY BANGALORE SINGAPORE MUMBAI-BKC NEW DELHI MUNICH

Investment in Healthcare Sector in India

December 2013

About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Silicon Valley, Singapore, New Delhi, Munich. We specialize in strategic legal, regulatory and tax advice coupled with industry expertise in an integrated manner. We focus on niche areas in which we provide significant value and are invariably involved in select highly complex, innovative transactions. Our key clients include marquee repeat Fortune 500 clientele.

Core practice areas include International Tax, International Tax Litigation, Litigation & Dispute Resolution, Fund Formation, Fund Investments, Capital Markets, Employment and HR, Intellectual Property, Corporate & Securities Law, Competition Law, Mergers & Acquisitions, JVs & Restructuring, General Commercial Law and Succession and Estate Planning. Our specialized industry niches include financial services, IT and telecom, education, pharma and life sciences, media and entertainment, gaming, real estate and infrastructure.

IFLR1000 has ranked Nishith Desai Associates in Tier 1 for Private Equity (2014). Chambers & Partners has ranked us as # 1 for Tax, TMT and Private Equity (2013). Legal Era, a prestigious Legal Media Group has recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013). Legal 500 has ranked us in tier 1 for Investment Funds, Tax and TMT practices (2011/2012/2013). For the third consecutive year, International Financial Law Review (a Euromoney publication) has recognized us as the Indian "Firm of the Year" (2012) for our Technology - Media - Telecom (TMT) practice. We have been named an ASIAN-MENA COUNSEL 'IN-HOUSE COMMUNITY FIRM OF THE YEAR' in India for Life Sciences practice (2012) and also for International Arbitration (2011). We have received honorable mentions in Asian MENA Counsel Magazine for Alternative Investment Funds, Antitrust/Competition, Corporate and M&A, TMT and being Most Responsive Domestic Firm (2012). We have been ranked as the best performing Indian law firm of the year by the RSG India Consulting in its client satisfaction report (2011). Chambers & Partners has ranked us # 1 for Tax, TMT and Real Estate – FDI (2011). We've received honorable mentions in Asian MENA Counsel Magazine for Alternative Investment Funds, International Arbitration, Real Estate and Taxation for the year 2010. We have been adjudged the winner of the Indian Law Firm of the Year 2010 for TMT by IFLR. We have won the prestigious "Asian-Counsel's Socially Responsible Deals of the Year 2009" by Pacific Business Press, in addition to being Asian-Counsel Firm of the Year 2009 for the practice areas of Private Equity and Taxation in India. Indian Business Law Journal listed our Tax, PE & VC and Technology-Media-Telecom (TMT) practices in the India Law Firm Awards 2009. Legal 500 (Asia-Pacific) has also ranked us #1 in these practices for 2009-2010. We have been ranked the highest for 'Quality' in the Financial Times – RSG Consulting ranking of Indian law firms in 2009. The Tax Directors Handbook, 2009 lauded us for our constant and innovative out-of-the-box ideas. Other past recognitions include being named the Indian Law Firm of the Year 2000 and Asian Law Firm of the Year (Pro Bono) 2001 by the International Financial Law Review, a Euromoney publication. In an Asia survey by International Tax Review (September 2003), we were voted as a top-ranking law firm and recognized for our cross-border structuring work.

Our research oriented approach has also led to the team members being recognized and felicitated for thought leadership. Consecutively for the fifth year in 2010, NDAites have won the global competition for dissertations at the International Bar Association. Nishith Desai, Founder of Nishith Desai Associates, has been voted 'External Counsel of the Year 2009' by Asian Counsel and Pacific Business Press and the 'Most in Demand Practitioners' by Chambers Asia 2009. He has also been ranked No. 28 in a global Top 50 "Gold List" by Tax Business, a UK-based journal for the international tax community. He is listed in the Lex Witness 'Hall of fame: Top 50' individuals who have helped shape the legal landscape of modern India. He is also the recipient of Prof.

Yunus 'Social Business Pioneer of India' – 2010 award.

We believe strongly in constant knowledge expansion and have developed dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs, conducted both in-house and for select invitees. KM and CE programs cover key events, global and national trends as they unfold and examine case studies, debate and analyze emerging legal, regulatory and tax issues, serving as an effective forum for cross pollination of ideas.

Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has now been developed into a global case study and published by John Wiley & Sons, USA in a feature titled 'Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage' in the September 2009 issue of Global Business and Organizational Excellence (GBOE).

Disclaimer

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

Contact

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

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

Content

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, yet its economic progress since gaining its independence in 1947 has generally been masked by its perception of being a closed, developing country. However, this perception has changed in the recent past and India is accepted as one of the most stable and robust economies.

The healthcare sector as an industry is expanding rapidly and has not been as severely impacted by recent economic slowdown as some of the other industries. It comprises of hospital services, diagnostic services, diagnostic products, medical technology, clinical trial services and clinical research organizations. This sector is predominantly privatized and accounts for more than 80 percent of total healthcare spending in India[1] with almost 75 to 80 percent of hospitals being managed by private sector.

The Indian hospital industry was estimated to be worth about USD 65 billion as of 2012 and is predicted to be worth around USD 280 billion by 2020. Further, the Indian hospital service industry is projected to grow at a compounded annual growth rate of more than 9 percent.[2] It's undergoing metamorphosis by broadening focus of the services by using technology, deliverables and newer applications. The hospitals that were confined to a specified area with limited infrastructure and services are now expanding mainly due to the foreign investment being received by the sector. The Indian Healthcare sector is emerging as one of the fast-growing service sectors in India, contributing 6 – 7 percent to the country's Growth Domestic Product (GDP)[3]

According to 2001 population norms, there was still a shortage of 4,477 primary healthcare centers and 2,337 community healthcare centers and India would require 1.75 million beds by 2025. Over 6800 more hospitals are needed in India to provide basic health facilities to people in rural areas. In the recent past various hospitality brands such as Fortis, Apollo, Max, Global and Care have started aggressive expansion in the country.[4]

Foreign investors can play significant role in the development of the hospital sector. This is evident from the fact that private equity funds (including venture capital funds) have invested over USD 2 billion in healthcare and life science sector over the past five years.[5] Further, India has received USD 1, 32,837 million as aggregate FDI from April 2000 to April, 2011 and specifically hospital and diagnostic centers have received FDI of USD 1,593.88 million from April 2000 up to February 2013 constituting 0.83 percent of the total FDI into India.[6]

1. Northbridge Capital, Hospital Sector Research, November 2010, available at http://northbridgeasia.com/ResearchReports/HOSPITAL%20RESEARCH%20REPORT%20(1)%20(1).pdf, last visited on December 27, 2010.
2. Id; http://www.albrightstonebridge.com/healthcare_india/
3. http://www.cii.in/Sectors.aspx?enc=prvePUj2bdMtgTmvPwvisYH+5EnGjyGXO9hLECvTuNu2yMtqEr4D408mSsgiIyM /
4. iId
5. The Venture Intelligence survey of leading PE and VC players
6. FDI Statistics, Department of Industrial Policy & Promotion, Government of India available at http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_February2013.pdf last visited May 17, 2013.

2. Opportunities

The Indian healthcare sector is ripe for the expansion and significant growth due to the reasons mentioned above. One of the main factors is increase in the space of medical tourism in India. Medical tourism in India is growing at a compounded annual growth rate of over 27 per cent during 2009-2012. Medical tourism market is valued to be worth USD 310 million and is expected to generate USD 2.4 billion by 2013 and is growing at 30 percent a year.[7] Due to increasing medical tourism there is a need to upgrade the service standards and provide the state-of-the-art facilities to bring the service levels on par with global standards. This changed outlook has created an excellent opportunities for the investors to provide much needed managerial and financial support. The following sectors have significant opportunities for the investors.

I. Hospitals and Infrastructure

There is tremendous demand for tertiary care hospitals and specialty hospitals in India. There is a gap between the availability of the beds and required beds in the hospital in India. It is estimated that an investment of USD 25.7 billion will be required to meet the requirement of additional 450,000 beds by 2010. The government would not be playing significant role in bridging this gap giving private players immense opportunity.[8] Further, medical tourism industry in India with estimated market of USD 350 million in 2006 and likely to reach USD 2 billion by 2012[9] will also play significant role in the development of hospital sectors. It is estimated that this sector has a potential to attract one million medical tourists each year from all over the world.

We have also seen the concepts of "Medicity" emerging. Government is encouraging this sector by providing certain incentives like lower import duties, higher depreciation on medical equipments and expedited visa for patients from foreign countries. Some trends that have been observed are that most of the healthcare players have been setting up additional facilities to cater critical care or super specialty healthcare. Some leading hospital players are very aggressive on raising funds for their expansions. India is also witnessing growth of advanced diagnostic equipments and excellent infrastructure. Separately, there is also a need for institutions that train professionals, nursing and paramedics to overcome the shortage of trained professionals in the health care sector in India.

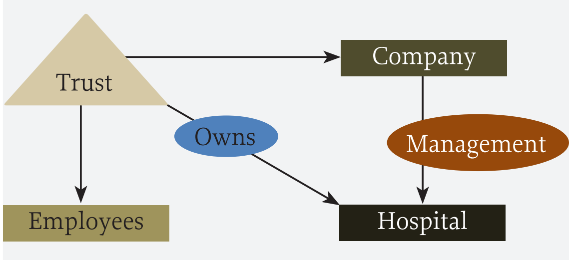
II. Various Models of Hospital Business

As mentioned earlier, healthcare sector especially hospital service is dominated predominantly by privates sector which comprises of individual doctors or group of doctors running clinics or private nursing homes as well as various corporates or trusts running single speciality to multi speciality hospitals.

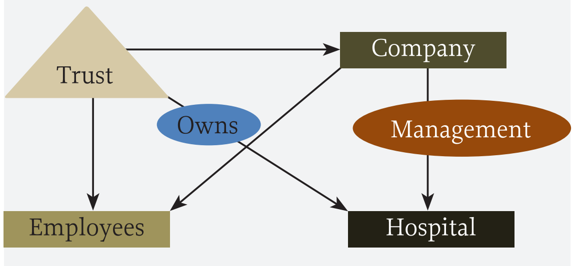
We have observed various models of functioning of the hospitals in India. We have schematically explained below various models of hospital business that are prevalent in India.

7. Northbridge Capital, Hospital Scetor Research, November 2010, available at http://northbridgeasia.com/ResearchReports/HOSPITAL%20RESEARCH%20REPORT%20(1)%20(1).pdf, last visited on May 17, 2013. http://m.oifc.in/Sectors/Healthcare
8. CRISIL. Healthcare in India. Emerging market report 2007 by PWC
9. CII-McKinsey report

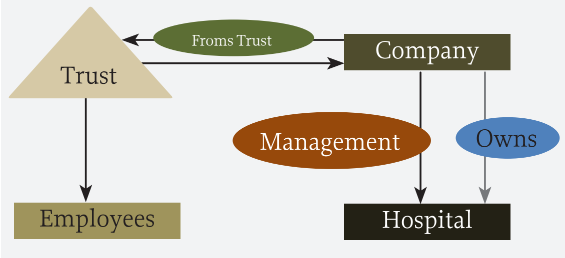
Model: 1



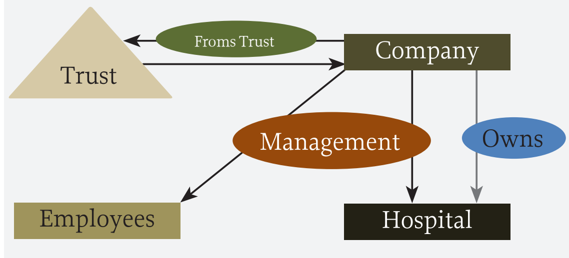
Model: 1a



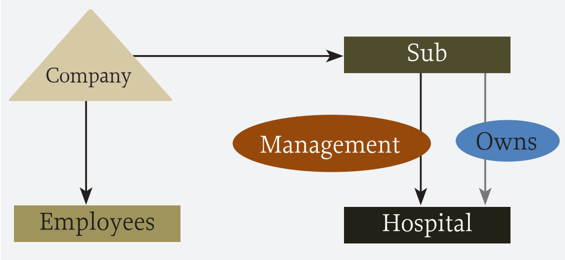
Model: 2



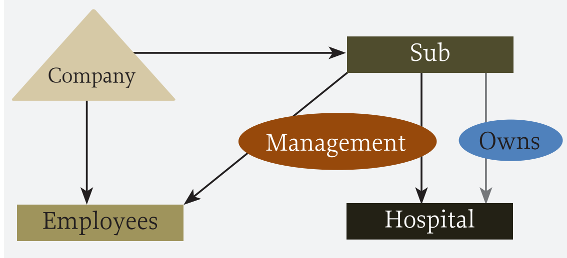
Model: 2a



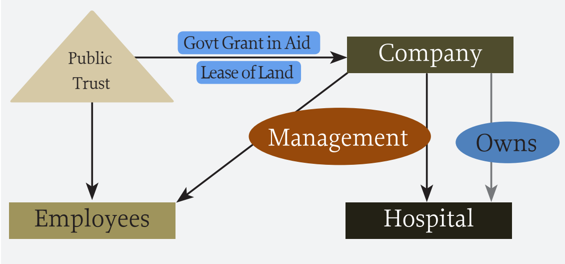
Model: 3



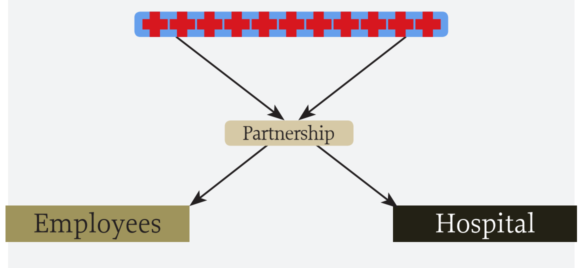
Model: 3a



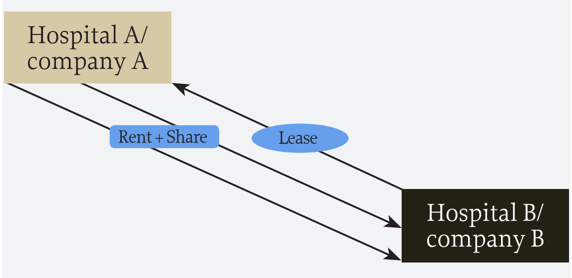
Model: 4



Model: 5



Model: 6



III. Health Insurance

The percentage of the Indian population that has been covered under health insurance is unfortunately very insignificant. Lack of awareness, casual approach is some of the reasons that have contributed to this. Though there is increase in number of health care insurance policies over past few years majority of the population remains without any coverage. Growing size of middle class population in India that spends on healthcare has led to the possibility of emergence of health insurance market. Health insurance is expected to touch USD 5.75 billion by 2010.[10]

IV. Technology Driven Services

Significantly low presence of physicians in rural and semi-urban areas has led to the limited access to proper healthcare facilities for the people living in these areas. Telemedicine is considered to be one of the solutions to this lacuna in accessibility to health care services in rural and semi-urban areas. Growth of IT sector in India which plays crucial role in telemedicine has led to emergence of this sector in India. Tele radiology has emerged very fast with increasing number of foreign hospitals active in this space. Many hospitals have adopted the approach of public – private partnerships ("**PPP**") to render services through telemedicine. Indian Space Research Organization has planned to set up telemedicine centers across the country by linking various district hospitals. India also has tremendous potential in the sector of medical equipments and devices ranging from basic equipments like EKG machines to high end equipments like CT scanners, MRIs etc.

V. Medical Device and Equipment

Even investment into the sector of manufacture of medical equipments is one of the most attractive areas for investment. The medical equipment manufacturing industry is expected to grow in tandem with hospital sector which is expected to grow to USD 60 billion by 2016. Further, the following graph shows the growth expected in the medical equipment market in India over the 2006-2012 period.[11] The market is expected to register an increase from USD 2 billion in 2010 to close to USD 8 billion in 2015.[12] India has received USD 600.53 million rupees as FDI from April 2000 to February 2013.[13] The medical and surgical appliances industry is clearly a high growth segment in the healthcare sector, where one could foresee increased FDI and collaborative arrangements to expand domestic manufacturing capacity.[14] The reasons which could be attributed to this rise in investments in the life sciences sector can be:

- Increasing per capita incomes and positive income elasticity of healthcare spends;
- Increasing urbanization and salience of lifestyle diseases;
- Increasing literacy and awareness;
- Increasing healthcare penetration and organized sector employment;
- Robust growth in demand for services;
- Significant supply shortfall in terms of quantum and quality;
- Ability to absorb significant amounts of capital due to high capital intensity; and
- Predictable demand and recession proof nature of the industry.

VI. Other Potential Services

Diagnostics

- Possible Targets
  - Medical device companies
  - Medical equipment companies
  - Radio Imaging services
  - Pathlabs

10. Study by PHD Chamber of commerce and industry, New Delhi.
11. Private Equity Pulse on Healthcare & Life Sciences, July 2009, available at www.ventureintelligence.in
12. http://indianresearchjournals.com/pdf/APJMMR/2012/October/5.pdf
13. FDI Statistics, Department of Industrial Policy & Promotion, Government of India available at http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_February2013.pdf last visited May 17, 2013.
14. supra note 12

- National chains (less at the moment)

Mobile Health – Tele Medicine

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

Preventive & Wellness Care

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

Day Care / Short Stay Centers

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

VII. Fast Emerging Services

Critical Care Centers

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

Geriatric Care Centers

- General care
- Hospice centers
- Hospice centers

Physical Therapy Centers

- Post trauma
- Post-surgery
- Along with other support services

General Diagnostics

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

Pain Clinics

- Advanced pain relieving centers

Support Services

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

3. Emerging Trends

I. Consolidation of Hospitals – Fast Emerging Trend

The Healthcare industry was estimated to be around USD 40 billion in 2012 by PriceWaterhouseCoopers (PWC). The rise in number of diseases and expanding middle class has led to growing demand of quality healthcare services over the years. Unfortunately, India's healthcare infrastructure has been unable to pace-up with the demand. The large gap in demand and supply of quality health care services, and growing capital demand owing to operational costs and technology acquisitions has pushed health care service providers to expand inorganically by merging with competitors or by accepting large capital injection

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, thus resulting in a significant increase in their capacity to pay towards healthcare. Another possible reason could be that the markets in Tier 1 cities have reached saturation because of increase in competition, causing the serious players to explore opportunities outside the Tier 1 cities. The additional attraction of the 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 desire and willingness of the doctors, who have been practicing for long time and enjoying good will, to join hands to start big hospitals.

III. Inclination of Doctors Towards Debt Funding

Debt financing is major source of capital for health care service industry. While borrowing money, the borrower of loan has to offer primary security and a collateral security before securing loan. The primary security is usually provided in form of a charge over the asset for which the loan is taken. The collateral security is usually given in form of a personal guarantee. The requirement to offer collateral in form of personal guarantee is the biggest consideration before promoters of small and medium scale hospitals while accepting debt and this many a times hinders expansion. Recently, Non- Banking Financial Companies (NBFCs) have emerged as preferred source of debt- funding since they do not insist of collateral security. Doctors feel comfortable with the funding by Bank. At the same time they are not very much aware of private equity funding.

4. Investment in Healthcare Sector

I. Foreign Direct Investment ("FDI")

The economic reforms launched by the Government from 1991 onwards have resulted in substantial economic growth and the integration of India into the global economy. The pace of reforms has gained a new momentum due to political stability and strong industrial growth. With the opening up of the Indian capital markets to Foreign Institutional Investors in 1993, the FDI regime too has been progressively liberalized.

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

The provisions pertaining to FDI are laid down in Schedule I of the FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000. These provisions are subject to compliance with the provisions of the Policy Guidelines and the Press Notes / Press Releases issued by the DIPP, from time to time.

The DIPP has issued a consolidated policy with respect to foreign investment into Indian companies. Currently, foreign investment is regulated by Consolidated FDI Policy issued by DIPP in the form of Circular 1 of 2013.[15] The exchange control regulations permit 100 percent FDI in most sectors under the automatic route, i.e., where no prior approval of the Foreign Investment Promotion Board ("**FIPB**") is required. Currently FDI is permitted up to 100 percent under the automatic route in hospital sector and manufacture of medical and surgical equipment. Further FDI in pharmaceutical sector is permitted upto 100 percent in all greenfield projects under automatic route and 100 percent in all brownfield projects under FIPB approval route. As most hospitals include some aspect of pharma, there is lack of clarity whether this would mean that any FDI in such brownfield hospitals require FIPB approval. In absence of clarity, the industry players have taken a conservative view as regards FDI in hospital sector and seek FIPB approval for FDI in brownfield hospitals. It is also proposed that in future, all brownfield investments will be scrutinized and approved by the Competition Commission of India ("**CCI**").

II. Foreign Venture Capital Investment

Another, vital means of investment into the healthcare as well as medical and surgical appliances is through venture capital investment by registered entities with Securities Exchange Board of India ("**SEBI**"). From the year 2000, SEBI has brought into effect new set of guidelines enabling foreign venture capitalists and private equity investors. It is not mandatory for a private equity investor to register as a Foreign Venture Capital Investor ("**FVCI**") under the FVCI regulations.[16] However, by registering the fund as a FVCI there are few advantages available. The FVCI's are exempted from compliance of the pricing guidelines for the acquisition of securities at the time of entry as well as exit. Secondly, in cases where the promoters of the company intend to buy-back the securities from FVCI, they are exempted from making an open offer under the Takeover code.[17] However, it may be noted that SEBI has been granting approvals to FVCI only for investments in

15. Consolidated FDI Policy, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion, SIA (FC Division), available at http://dipp.nic.in/English/Policies/FDI_Circular_01_2013.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.

certain identified sectors, one amongst them being research and development of new chemical entities in the pharmaceutical sector, and in units of SEBI registered Venture Capital Funds (“**VCF**”). Further to this SEBI has made recent amendments to permit FVCIs to invest in Category I Alternate Investment Funds.[18]

Further, under the ICDR Regulations,[19] the entire pre issue capital of a company going public is locked-in for a period of one-year from the date of allotment in the public issue. However, an exemption from this requirement is granted to FVCI’s registered with SEBI, provided the shares have been held by them for a period of at least one year as on the date of filing the draft prospectus with SEBI.

18. SEBI has recently introduced SEBI (Alternate Investment Funds) Regulations, 2012 to govern domestic pooling vehicles.
19. Securities Exchange Board of India (Issue of Capital and Disclosure Requirements) 2009.

5. Legal and Regulatory Aspects

Healthcare sector is highly regulated in India. It is governed by various acts that cover establishment of hospitals, various services offered, medical professionals rendering services in the hospital as well as additional service offered by the hospital like cafeteria, pharmacy, ambulance etc

I. Authorities

The following authorities regulate healthcare sector in India.

Ministry of Health and Family Welfare (MoHFW)

- Department of Health
- Department of Family & Welfare
- Department of AYUSH
- Central Drugs Standard Control Organization (CDSCO)
- Narcotic Controls Bureau

State Level and Local Authorities

- Pollution control boards
- Biomedical waste
- CDSCO (State)
- Municipal Corporation
- Municipality

Other Institutions / Organizations

- Indian Council of Medical Research (ICMR)
- Medical Council of India (MCI)
- Indian Medical Association (IMA)
- Atomic Energy Regulatory Board (AERB)
- Department of Industrial Policy and Promotion (DIPP)
- Foreign Investment Promotion Board (FIPB)

II. Hospitals

As a part of due diligence, the investor would typically ensure that the investee entity has complied with all applicable laws. There are multiple laws that govern the sub-sets of the health care sector. There are several permissions and licenses that are required to be obtained by the establishments.

- Municipal permission for construction;
- 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;
- Authorization for operation of a facility for generation, collection, reception, storage, transportation, treatment and disposal of bio-medical wastes under Bio-Medical Waste (Management and Handling) Rules, 1998 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;
- Narcotic drug license;
- Permit for the purchase and possession of denatured spirit;

- Registration under various applicable Labour Laws;
- Registration under various direct and indirect Tax statutes.

III. Medical Devices

The medical devices industry was not regulated in India which led to import and manufacturing of devices which could not meet the globally acceptable standards. The Central Government of India issued notifications, in the years 2005 and 2010 ("**Notifications**") respectively, for regulating the manufacture, sale and distribution of the certain sterile medical devices,[20] as "drugs" as per the Drugs and Cosmetic Act, 1940 ("**Drugs Act**").[21] In March 2006, the government issued guidelines for the Import and Manufacture of Medical Devices. These guidelines have been further supplemented by revised guidelines on manufacture of medical devices in India dated January 1, 2013 and a document containing frequently asked questions on registration and import of medical devices in India on February 21, 2013. All the aforesaid documents are available on the CDSCO official website www.cdsco.nic.in.

It may be noted that in respect of the medical devices other than those as laid down in the Notifications ("**Regulated Devices**"), at present there are no rules or regulatory mechanisms to regulate the manufacture, sale or import of such other devices. The CDSCO has further clarified by an office memorandum dated January 8, 2013 that import of medical devices which are not Regulated Devices will not require prior NOC from it, as is a norm with the Regulated Devices.

The issuance of the Notifications to identify Regulated Devices as drugs was the first step towards regulating medical devices in India. However, the larger issues still remained to be addressed regarding specific rules relating to product standards, safety, and clinical trials and manufacturing practices for each of the Regulated Devices.

The Ministry of Health and Family Welfare have now approved certain procedures to be adopted in respect of licensing of import as well as manufacture of these Regulated Devices in the country. The company should primarily obtain a license under the Drugs Act. For manufacturing and/or assembling medical and surgical appliances, the standards are prescribed under the Drugs Act. The institution should adhere to the standards prescribed under the Bureau of Indian Standards.[22] Further, the institution involved in manufacture of medical devices and surgical appliances has to adhere to the condition as mentioned under the Drugs Act.[23]

20. The list of these devices is available on the website www.cdsco.nic.in
21. The Drugs Act is the relevant legislation that regulates the manufacture, sale, distribution and import of pharmaceutical products in India.
22. Rule 109-A and 125 A, Drugs and Cosmetics Rules, 1945.
23. Schedule M and Schedule M-III, Drugs and Cosmetics Act, 1940.

6. Taxation in India

I. Corporate Tax

Income tax in India is levied under the Income Tax Act, 1961. Resident companies are taxed at the rate of 32.44% (rates mentioned herein are the maximum effective rates inclusive of applicable surcharge and education cess) and non-resident companies are taxed at the rate of 42.02%. While residents are taxed on their worldwide income, non-residents are only taxed on income arising from sources in India. A company is said to be resident in India if it is incorporated in India or is wholly controlled and managed in India. A minimum alternate tax is payable at the rate of around 20% (18.5% plus surcharge and education cess).

II. Dividends

Dividends distributed by Indian companies are subject to a dividend distribution tax at the rate of 16.22%, payable by the company. However, no further Indian taxes are payable by the shareholders on such dividend income once dividend distribution tax (“**DDT**”) is paid. An Indian company would also be taxed at the rate of 21.63% on gains arising to shareholders from distributions made in the course of buy-back or redemption of shares.

III. 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 (or 1 year for securities). Long term gains may arise if the asset is held for a period more than 3 years (or 1 year for securities). Long term capital gains earned by a non-resident on sale of unlisted securities may be taxed at the rate of 10.5% or 21% depending on certain considerations. Long term gains on sale of listed securities on a stock exchange is exempt, and only subject to a securities transaction tax (STT). Shorter term gains earned by a non-resident on sale of listed securities (subject to STT) is taxable at the rate of 15.76%, or at ordinary corporate tax rate with respect to other securities.

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.

IV. Interest, Royalties & Fees for Technical Services

Interest earned by a non-resident may be taxed at a rate between 5.26% to around 42.02% depending on the nature of the debt instrument.

Royalties and fees for technical services earned by a non-resident would be subject to tax at the rate of around 26.27% (which was recently increased from 11%). These rates are subject to available relief under an applicable tax treaty. The scope of royalties and fees for technical services under Indian domestic law is much wider than what is contemplated under most tax treaties signed by India.

V. Withholding Taxes

Tax would have to be withheld at the applicable rate on all payments made to a non-resident, which are taxable in India. The obligation to withhold tax applies to both residents and non-residents. Withholding tax obligations also arise with respect to specific payments made to residents. Failure to withhold tax could result in tax, interest and penal consequences.

VI. Double Tax Avoidance Treaties

India has entered into more than 80 treaties for avoidance of double taxation. A taxpayer may be taxed either under domestic law provisions or the tax treaty to the extent it is more beneficial. A non-resident claiming treaty relief would be required to file tax returns and furnish a tax residency certificate issued by the tax authority in its home country. The tax treaties also provide avenues for exchange of information between States and incorporate measures to curb fiscal evasion.

VII. Anti-Avoidance

A number of specific anti-avoidance rules apply to particular scenarios or arrangements. This includes elaborate transfer pricing regulations which tax related party transactions on an arm's length basis.

India has also introduced wide general anti avoidance rules (GAAR) which provide broad powers to the tax authorities to deny a tax benefit in the context of 'impermissible avoidance arrangements'. GAAR will come into effect from April 1, 2015 and would override tax treaties signed by India

VIII. Direct Taxes Code

A new Direct Taxes Code is currently pending consideration by the Indian Parliament. This new legislation, once enacted, will replace the existing law on income tax. Some of notable changes include change in residency criteria, structure of capital gains tax, introduction of controlled foreign corporation rules, etc.

IX. Structuring Investments

Investments into India are often structured through holding companies in various jurisdictions for number of strategic and tax reasons.

While choosing a holding company jurisdiction it is necessary to consider a range of factors including political and economic stability, investment protection, corporate and legal system, availability of high quality administrative and legal support, banking facilities, tax treaty network, reputation and costs.

Over the years, a major bulk of investments into India has been structured from countries such as Mauritius, Singapore and Netherlands, which are developed and established holding company jurisdictions that have favorable tax treaties with India. Subject to certain conditions, investments from Mauritius and Singapore benefit from an exemption from capital gains tax. Investments from Netherlands may benefit from a lower 10% withholding tax on interest payments and a limited capital gains tax exemption.

X. Indirect Taxes

A number of indirect or consumption taxes are levied at the central and state level. Value added tax (VAT) is levied on the sale of goods within a particular state and rates may vary from 0%, 1%, 4% to 12.5%, although there may be further variations depending on the state. Central sales tax (CST) is imposed on the sale of goods in the course of inter-state trade or commerce. Central VAT is a duty of excise which is levied on all goods that are produced or manufactured in India. Service tax is payable on all services others than those specifically exempted or set out in a negative list. The current rate of service tax is 12.36% payable by the service provider. India is planning to introduce a goods and service tax (GST) which will consolidate all indirect taxes.

XI. Specific Industry Incentives

Capital expenditure incurred in setting up a hospital with capacity of 100 beds or more is fully deductible.

A five year tax holiday was available in respect of profits derived operation and maintaining hospital located anywhere in India other than certain excluded areas (mainly larger / metropolitan cities) subject to the satisfaction of conditions including capacity of 100 beds and above. This tax holiday however only applies to hospitals constructed before March 31, 2013. Subject to certain conditions, tax exemptions are available for hospitals that are charitable and not-for-profit.

An exemption from service tax has been provided with respect to health care services by a clinical establishments (including hospitals, nursing homes, clinics, etc), authorized medical practitioners or paramedics.

7. Issues and Concerns

Investment in hospital has its bag of potential issues which an investor needs to aware and concerned of. 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.

Major issues that can seriously impact functioning of the hospital are non-compliance with Pre-conception and Pre-natal Diagnostic Techniques Act, 2003; Medical Termination of Pregnancy Act, 1971; Biomedical Waste Disposal, Drugs and Cosmetic Acts for pharmacy, Atomic Energy Regulatory Board. and other environmental consent.

Participation of the hospital in clinical trial poses another challenge in view of recent changes in the law specific to compensation to human subjects in clinical trials. It is very important to understand the liabilities of investigator and hospital.

Another fact that poses issues and concerns is the model in which the hospital is operating. Models where hospitals are owned by Trusts and managed by hospital management companies may lead to certain concerns from investment perspective.

8. New Developments

The Clinical Establishments (Registration and Regulation) Bill, 2007, prohibits any person from carrying on a clinical establishment unless it has been duly registered in accordance with the provisions of the Clinical Establishments (Registration and Regulation) Bill, 2007. The definition of clinical establishment encompasses all the facilities which offer services in recognized field of medicine. Not only clinical establishments which may be established after the promulgation of Clinical Establishments (Registration and Regulation) Bill, 2007, need to be registered, also clinical establishments in existence as on date of the enactment of the legislation need to obtain registration within one year from the enactment of the legislation. The main objectives of the legislation are to prescribe minimum standards for the facilities and services to be provided by the clinical establishment as well as the minimum qualifications for the personnel. Further, the enactment proposes to create a mechanism for reporting and maintenance of records with respect to clinical establishments. Though this is a welcome step for increasing the standard of healthcare in the country, on the downside, it may act as another additional hurdle from the perspective of an investor intending to set up clinical establishment.

9. Conclusion

There are many positive implications of foreign investment in hospitals. One of the major impacts foreign investment would have is the creation of the necessary infrastructure. Investments are also needed beyond the metros to expand access to healthcare. In addition to helping increase physical capacity in the health care 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 sector and the economy at large. However few things to be kept in mind for achieving success in hospital sector are that the cost of medical care should be affordable most importantly in the tier-II and tier-III locations; the hospitals in tier- II and tier-III locations should concentrate on the ailments which are geography specific.

The private sector, which already accounts for about 75 percent of the healthcare services delivered, is expected to account for over 90 percent of future investments in developing the country's hospital infrastructure. The role of the government will largely be focused towards disease prevention, improving access to primary care, increasing and improving the quality of the country's pool of medical manpower and incentivizing the private sector to invest in capacity building and improving access to healthcare services.[24]

The aspect which has to be looked at is that there is significant potential for growth in tier-II and tier-III locations. Even though these tier- II and tier- III towns have considerable number of primary healthcare centers, they lack quality healthcare services. These tier-II or tier-III locations have less population when compared to a metro; however these areas can serve as quality healthcare units to the nearby villages and towns. As a result of this, there is significant activity in these locations by both national players as well as regional hospitals either by setting up hospitals or even tying up with an existing hospital in these locations. However, a careful analysis and evaluation is required in order to gain considerable returns from these tier-II and tier-III locations. Therefore, the business or commercial strategy needs fine tuning for investing into hospitals located in these areas.

24. Siddharth Dondhiyal, Private Equity Pulse on Healthcare & Life Sciences, July 2009, available at www.ventureintelligence.in.

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

Doing Business in India

October 2013

Mergers & Acquisitions in India

July 2013

Joint Ventures in India

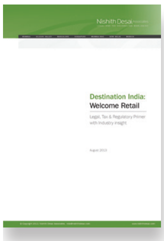
May 2013

Globalizing India Inc.

April 2013

Competition Law in India

April 2013



Destination India- Welcome Retail

August 2013

E-Commerce in India

January 2013

Cloud Computing Risks/Challenges- Legal & Tax Issues

March 2013

Private Equity in Real Estate

February 2013

NDA Insights

TITLE	TYPE	DATE
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	02 April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	01 January 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	26 November 2012
Copyright Amendment Bill 2012 receives Indian Parliament's assent	IP Lab	25 May 2012
Real Financing - Onshore and Offshore Debt Funding Realty in India	Realty Check	01 May 2012
Pharma Patent Case Study	IP Lab	21 March 2012
Patni plays to iGate's tunes	M&A Lab	04 January 2012
Vedanta Acquires Control Over Cairn India	M&A Lab	03 January 2012
Corporate Citizenry in the face of Corruption	Yes, Governance Matters!	15 September 2011
Funding Real Estate Projects - Exit Challenges	Realty Check	28 April 2011
Real Estate in India - A Practical Insight	Realty Check	22 March 2011
Hero to ride without its 'Pillion Rider'	M&A Lab	15 March 2011
Piramal - Abbott Deal: The Great Indian Pharma Story	M&A Lab	05 August 2010
Bharti connects with Zain after two missed calls with MTN	M&A Lab	17 May 2010
The Battle For Fame - Part I	M&A Lab	01 April 2010
Great Offshore Takeover Saga - Bharati Shipyard v/s ABG Shipyard	M&A Lab	16 December 2009
Second missed call: Bharti Airtel fails to reconnect with MTN	M&A Lab	09 October 2009

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.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our *"Hotlines".* 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 *NDA Insights* 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 papers and disseminate them through our website. Although we invest heavily in terms of associates' 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.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a 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. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports. Please feel free to contact us at **research@nishithdesai.com**

Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court,
Nariman Point,
Mumbai 400 021 INDIA
Tel: +91 - 22 - 6669 5000
Fax: +91 - 22 - 6669 5001

SILICON VALLEY

220 S California Ave., Suite 201,
Palo Alto, CA 94306,
USA
Tel: +1 - 650 - 325 7100
Fax: +1 - 650 - 325 7300

BANGALORE

Prestige Loka, G01,
7/1 Brunton Rd,
Bangalore 560 025 INDIA
Tel: +91 - 80 - 6693 5000
Fax: +91 - 80 - 6693 5001

SINGAPORE

Level 30,
Six Battery Road,
SINGAPORE 049909
Tel: +65 - 6550 9855
Fax: +65 - 6550 9856

MUMBAI - BKC

3, North Avenue
Maker Maxity
Bandra – Kurla Complex,
Mumbai 400 051 INDIA
Tel: +91 - 22 - 6159 5000
Fax: +91 - 22 - 6159 5001

NEW DELHI

C-5, Defence Colony
New Delhi - 110024
INDIA
Tel: +91 - 11 - 4906 5000
Fax: +91 - 11- 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich
GERMANY
Tel: +49 - 89 - 203006 - 268
Fax: +49 - 89 - 203006 - 450

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