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LEGAL AND TAX COUNSELING WORLDWIDE

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e-Health in India

Legal, Regulatory and Tax Overview

February 2017

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1. Introduction

"*I think the biggest innovations of the twenty-first century will be the intersection of biology and technology*" – Steve Jobs, as told to Walter Isaacson.

In 2001, Dr. Jacques Marescaux surgically removed the gall bladder of a 68 year old woman. While thousands of these procedures are done on a daily basis, the reason this particular surgery stands out is because the surgeon was in New York, while the patient was in France. Separated by a distance of thousands of miles, this robot-assisted 'tele-surgery' was made possible using dedicated Asynchronous Transfer Mode ("**ATM**") telecommunication technology, which provided minimum response time between the surgeon and the robot.

At a time when such activities were not even anticipated, the United States Food and Drug Administration ("**USFDA**") took a very conservative approach while granting approvals for the procedure. To minimize liabilities and ambiguities, the USFDA allowed the surgery to be performed by French surgeons on a French patient while the French government was to take all the responsibilities. The whole procedure cost a whopping $11 million, but served the purpose of demonstrating to the world the potential of the amalgamation of healthcare and technology.

The world has come a long way since then, with the development of information technology culminating to a phase where such innovative procedures are steadily gaining acceptance. Healthcare technology is pushing boundaries, broadening its scope every day and with it, the opportunities. From heart rate monitors built into watches to glucose monitors integrated into contact lenses, the healthcare industry is heading into some interesting and revolutionary times.

What is e-Health?

There is a popular tendency to group every technological advancement in healthcare under the umbrella of "e-Health". But what exactly is e-Health?

As per the World Health Organization ("**WHO**"), e-Health means "the use of information and communication technologies ("**ICT**") for health". The definition, though very concise, is not very helpful. The European Commission has put forth a more elaborate definition of e-Health. e-Health refers to "tools and services using information and communication technologies that can improve prevention, diagnosis, treatment, monitoring and management". Therefore, the expression e-Health may be safely said to include both tools and services that use ICTs for purposes connected to health.

What was the need to write this paper and what does it propose to do?

"*The hare of science and technology lurches ahead. The tortoise of the law ambles slowly behind*"[1]

A patient survey predicts that 75% of all patients expect to use digital services in the future. With the healthcare sector expected to touch $158.2 billion by 2017, one should not harbor a doubt that e-Health services would bite into a large portion of the pie.

However, the current legal and regulatory landscape that governs e-Health is scattered and ambiguous. To make matters worse, there is none or very little legal scholarship in the area of e-Health in India. The scope of e-Health is vast and covers various business models, which inherently makes it difficult to regulate as a whole.

1. Michael Kirby, Medical Technology and New Frontiers of Family Law, 1 AUSTL. J. FAM. L. 196, 212 (1987).

This paper seeks knit together existing laws and regulations into what may be called an "ad-hoc" legal framework for e-Health in India. It is being written for those who are already invested in e-Health as workforce or capital contributors as well as those who are still testing the grounds.

Since this is a research paper, it also seeks raises questions and takes positions which are yet to be tested with the hope that it would set the tone for legal discussions in larger platforms.

2. Some prominent examples of e-Health

I. Telemedicine

75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.[2] Telemedicine, which is the use of telecommunications technology to provide healthcare, could effectively bridge the gap between the patient and the doctor.

While telemedicine is not a separate specialty in itself, its standout is the use of various technologies in providing traditional healthcare services. It is a broad concept that covers within its ambit various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery. Each brings its own advantages and challenges and have to be examined individually in order to be able to run the service efficiently and in compliance with the law.

II. Robot-Assisted Surgery

Using the assistance of robots, doctors are able to perform surgical procedures more efficiently. Minimally invasive surgeries have been around for a while, but with the assistance of robotics, surgeons are able to maneuver more precisely and with smaller incisions.[3] This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient.

With advancements in deep learning, robots would be able to observe and replicate procedures that are simple and repetitive, while the surgeon concentrates on more complex tasks.[4]

III. Self-Monitoring Healthcare Devices

Monitors and sensors are now being integrated into wearables, which allow it to detect various physiological changes in the body. These smart devices are capable of tracking weight, sleep patterns, posture, diet and exercise.[5] The raw data that is collected can be used to self-monitor by detecting various health symptoms and alert the user in case of potential issues.

IV. Electronic Health Records ("EHR")

An EHR is a digital version of a patient's health records. EHRs help eliminate the problems ssociated with physical records such as loss and lack of accessibility. EHRs can be stored centrally and accessed at any time, irrespective of where or when the information was collected.[6] With EHRs, doctors are able to view their patient's complete medical history even if they are treating the patient for the first time. This would help reduce duplication of tests and facilitate the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

V. Health Service Aggregation

Information asymmetry is one of the biggest challenges in healthcare. Patients are not privy to information which is essential in aiding with their choice of doctors, and at times doctors are not able to reach out to a large number of patients due to a lack of visibility. A number

2. Ashok Vikhe Patil, K. V. Somasundaram and R. C. Goyal; Current Health Scenario In Rural India; available at http://www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf
3. Johns Hopkins Medicine; Types of Minimally Invasive Surgery; available at http://www.hopkinsmedicine.org/minimally_invasive_robotic_surgery/types.html
4. IEEE Spectrum; Robot Surgeones are Taking over the Operating Room; available at http://spectrum.ieee.org/video/robotics/medical-robots/robot-surgeons-are-taking-over-the-operating-room
5. Geoff Appelboom, Elvis Camacho, Mickey E Abraham; Smart wearable body sensors for patient self-assessment and monitoring; available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166023/
6. Lise Poissant, Jennifer Pereira, Robyn Tamblyn; The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review; available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1205599/

of online platforms are springing up which attempt to solve this problem. These platforms list the names of doctors with their specialties, and allow for patients to search for and make an appointment with the right doctor to suit their specific needs. Patients are also able to rate and review the quality of the service provided by the doctor or institution, which serves as guidance for future patients to make an informed decision.

VI. m-Health

Mobile health, or m-Health, is the provision of e-Health services on a mobile platform. India is home to the 3rd largest smartphone market in the world, which makes m-Health a very lucrative option. Providing access to such applications on smartphones would also not be a big hurdle, with the country expecting to reach 314 million mobile internet users by 2017. The convenience of e-Health coupled with the mobility of m-Health opens the arena for a lot more players to actively take part in the revolution.

VII. Big Data in healthcare

Raw data is collected from the use of various e-Health services. EHRs in itself generates a massive amount of information that can be put to use in different ways. 25 billion devices are expected to be connected through the Internet of Things (**"IOT"**),[7] and the data that these connected devices are expected to churn out have to be processed. The sheer volume of information generated requires solutions such as big data processing, which then can be put to use by various companies.

VIII. Targeted advertising

Wearables and information provided by users generate information related to the user's medical history and health conditions. This information can be used by companies to provide targeted advertising of products to users who are more likely to purchase or use such products.[8] For instance, glucose monitoring products could be advertised to diabetic patients based on the medical history provided by them. Targeted advertising however, throws up various legal and ethical questions where in some instances, it is a blurred line.

IX. e-Pharmacies

An interesting concept that is cropping up worldwide is online pharmacies or e-Pharmacies. There are various models that have been adopted such as online-only pharmacies and physical pharmacies with an online presence. Online pharmacies allow pharmacists to cater to a larger group of patients as the inherent geographical restrictions on physical pharmacies are removed in the online model.

X. e-Learning in the health-care sector

Continuous Medical Education (**"CME"**) being a mandatory requirement and necessary for doctors to keep in touch with the current trends and developments in the field of medicine, e-Learning is a more convenient platform for doctors to attend such programmes. E-Learning also saves on time and costs by being accessible from anywhere.

7. Guy Daniels; Internet of Things to Reach 25 Billion Devices within Five Years; available at http://www.telecomtv.com/articles/iot/internet-of-things-to-reach-25-billion-devices-within-five-years-11931/

8. Vinny La Barbera; Wearable Technology and Its Impact on Internet Marketing; available at https://www.imforza.com/blog/wearable-technology-impact-on-internet-marketing/

3. Investment in e-Health

The healthcare sector as an industry is expanding rapidly in India and has not been as severely impacted by the economic slowdown as some of the other industries.

India, one of the biggest emerging markets, is currently an important destination for Foreign Direct Investment ("**FDI**").

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. Telemedicine and e-Health are considered to be some 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 as a fast growing area with an increasing number of foreign hospitals active in this space. These 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 telemedicine.

Some investment options are discussed below:

I. Foreign Direct Investment

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 Industry through the Secretariat for Industrial Assistance, Department of Industrial Policy and Promotion ("**DIPP**").

The provisions pertaining to FDI are laid down in Schedule I of FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000.

While the DIPP issues policy guidelines and press notes/releases from time to time regarding foreign investment into India, it also issues a consolidated policy on an annual basis ("**Consolidated FDI Policy**"). Currently, foreign investment is regulated by the Consolidated FDI Policy of 2016.[9]

100% FDI is permitted in most sectors under the automatic route, i.e., where prior approval of the government, specifically the Foreign Investment Promotion Board ("**FIPB**"), is not required. Generally, there are no restrictions prescribed for e-Health services, and therefore FDI up to 100% should be permitted without government approval. It may also be noted that FDI is permitted up to 100% under the automatic route in the hospital sector and in the manufacture of medical devices. In the pharmaceutical sector, FDI is permitted upto 100% in Greenfield projects and 74% in Brownfield projects under the automatic route and FDI beyond 74% in Brownfield projects requires FIPB approval.[10] Green field projects are new projects that are coming up in India while Brownfield projects are existing projects in India.

II. Foreign Venture Capital Investment

Another vital means of investment 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,[11] there are some significant advantages to be gained by registering as an FVCI. An FVCI is exempt from compliance with the pricing guidelines under the Consolidated FDI Policy for the acquisition of securities at the time of entry as well as for the transfer/sale of securities

9. 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_2016.pdf
10. Press Note 5 of 2016, available at: http://dipp.nic.in/English/acts_rules/Press_Notes/pn5_2016.pdf
11. SEBI (Foreign Venture Capital Investor) Regulations, 2000.

at the time of exit. 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.[12] 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**"). Further, the Reserve Bank of India ("**RBI**") has made recent amendments to the foreign exchange control regulations to permit FVCIs to invest in SEBI registered Alternate Investment Funds ("**AIFs**").[13]

12. Regulation 10 of the Securities Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulations, 2011.

13. 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

4. Legal and Regulatory Framework

The laws that broadly cover e-Health services are discussed below:

I. The Information Technology Act, 2000 ("IT Act"), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 ("Data Protection Rules") and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("Intermediary Guidelines")

e-Health involves a constant exchange of information between the patient and the service provider. The patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information[14] (**"SPDI"**) under the Data Protection Rules. When a body corporate[15] collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

Consent is one of the major requirements under the Data Protection Rules. Before a doctor or an institution does anything with a patient's data, they are required by law to obtain the recipient's consent in writing.[16] The patient must be informed about the fact that the data is being collected, what it will be used for and whether it would be transferred to any third parties, along with the contact details of the agency collecting the information.[17] There is also a requirement for body corporates to have a privacy policy in place and published on its website.[18] This consent is usually obtained by having the patient accept the terms of the body corporate's privacy policy, which is also required to have such information, in addition to the security practices the body corporate has adopted to keep the information safe.

If the SPDI is planned to be disclosed to a third party, prior permission of the owner of the SPDI is to be obtained. In cases where the SPDI is being transferred, the body corporate transferring the SPDI must ensure that the receiver of the SPDI has adequate security practices in place.[19]

The Data Protection Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure. This requirement is fulfilled if the body corporate conforms to the international standard IS/ ISO/IEC 27001 on "Information Technology – Security Techniques – Information Security Management System – Requirements" or similar standards that are approved and notified by the Central Government. As on date, no such standards have been notified.

There is also a requirement to appoint a 'Grievance Officer',[20] whose contact details are to be published on the website. Apart from these, there are also other requirements such as allowing users to opt-out[21] or modify[22] their SPDI if required.

14. Rule 3 of the Data Protection Rules defines Sensitive personal data or information of a person to mean such personal information which consists of information relating to (i) password; (ii) financial information such as Bank account or credit card or debit card or other payment instrument details; (iii) physical, physiological and mental health condition; (iv) sexual orientation; (v) medical records and history; (vi) Biometric information
15. Section 43A of the IT Act defines "body corporate" means any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities
16. Rule 5(1) of the Data Protection Rules
17. Rule 5(3) of the Data Protection Rules
18. Rule 4(1) of the Data Protection Rules
19. Rule 7 of the Data Protection Rules
20. Rule 5(9) of the Data Protection Rules
21. Rule 5(7) of the Data Protection Rules
22. Rule 5(7) of the Data Protection Rules

In 2013, the Ministry of Communications and Information Technology came out with a clarification[23] which stated that body corporates that were collecting, storing, processing or transferring information out of a contractual obligation were not required to observe some of the requirements of the Data Protection Rules such as obtaining consent from the owner of the SPDI for collecting or disclosing the SPDI. The other requirements, however, must still be observed.

Some e-Health services have set ups that merely facilitate the interaction between the patient and the service provider and are not directly involved in the provision of the services. In such cases, the service provider would be considered an intermediary[24] under the Intermediary Guidelines and the IT Act. There are certain relaxations that are given to intermediaries in terms of liability of third party data or communication, provided they observe certain due diligence requirements[25] under the Intermediary Guidelines. These requirements are extensive, and include having a terms of use in place, removal of offending/unlawful[26] material within 36 hours of a request and appointing a grievance officer. The relaxation would apply only if the intermediary does not initiate the transmission of the data/communication, select the receiver of the transmission or select or modify the information in the transmission.[27]

The constitutionality of the Intermediary Guidelines and section 79[28] of the IT Act were challenged before the Supreme Court in the case of *Shreya Singhal v. Union of India*,[29] stating that these provisions were vague, broad and in violation of Article 19 of the Constitution of India, which provides for the fundamental right to the freedom of speech and expression.

It was argued that section 79 and the Intermediary Guidelines allow the intermediary the discretion to decide upon whether an unlawful/offending material is being published and that the restrictions under the Intermediary Rules go beyond the permitted restrictions under Article 19(2).

The Supreme Court read down the provisions of section 79 and the Intermediary Guidelines to mean that the intermediary must receive a court order or notification from a government agency requiring it to remove specific information. The court also stated that any such court order or notification must necessarily fall within the ambit of reasonable restrictions under Article 19(2), meaning that such removal must be in the interest of the sovereignty and integrity of India, the security of the State, friendly relations with foreign States, public order, decency or morality or in relation to contempt of court, defamation or incitement to an offence. The judgment was, however, silent on which administrative authority could pass such an order or notification.

II. Other Service Providers Regulations under the New Telecom Policy 1999 ("OSP Regulations")

Service providers who render "Application Services" - which includes telemedicine services – using telecom resources provided by telecom service providers, are required to be registered as an 'Other Service Provider' ("**OSP**") with the Department of Telecommunications.

23. Clarification on The Information Technology (Intermediary Guidelines) Rules, 2011 under section 79 of the Information Technology Act, 2000 issued on 18th March, 2013; available at: http://deity.gov.in/sites/upload_files/dit/files/Clarification%2079rules_1.pdf

24. Intermediary under the IT Act is defined as any person who on behalf of another person receives, stores or transmits that record or provides any service with respect to that record and includes telecom service providers, network service providers, internet service providers, web hosting service providers, search engines, online payment sites, online-auction sites, online market places and cyber cafes.

25. Rule 3 of the Intermediaries Guidelines

26. Rule 3(2) of the Intermediaries Guidelines

27. Section 79 of the IT Act

28. Section 79 of the IT Act provides intermediaries with exemption from liability if it meets the requirements laid down under the section

29. Writ Petition (Criminal) No.167 Of 2012

III. The Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs and Cosmetics Rules, 1945 ("D&C Rules")

The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India. In many foreign jurisdictions, there is a clear distinction between a drug that must be sold under the supervision of a registered pharmacist on the production of a valid prescription (signed by a registered medical practitioner) and those that can be sold by general retailers over-the-counter ("**OTC**"). OTC drugs have a different meaning in the context of Indian laws. The D&C Act requires that all drugs must be sold under a license. The D&C Rules clearly lay down which drugs can be sold only on the production of a prescription issued by a registered doctor, which implies that there is a distinction between prescription and non-prescription drugs. Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules.

The D&C Act states that no person can sell any drug without a license issued by the licensing authority. However, it provides for certain drugs, namely those falling under schedule K of the D&C Rules, to be sold by persons who do not have such a license. Hence, OTC drugs in the Indian context would mean only those drugs that are specified under schedule K. These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulfate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others.

The D&C Rules also state that prescription drugs can only be dispensed on the production of a prescription which is in accordance with the provisions of the rules. For a prescription to be considered valid under the D&C Rules, it must be in writing, signed and dated by the doctor issuing the prescription.[30] The prescription must also state the name and address of the person for whose treatment it is given and also the quantity to be supplied.[31]

IV. The Indian Medical Council Act, 1956 ("MCI Act") and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 ("MCI Code")

The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with one of state medical councils have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients. The MCI Code also specifies that efforts are to be made to computerize medical records so that they can be retrieved quickly.[32] Doctors are bound by the MCI Code and are required to submit a declaration to that effect.[33] The apex body currently regulating the practice of medicine is the Medical Council of India. However, the proposed National Medical Commission Bill, 2016,[34] which has been drafted by the National Institution for Transforming India ("**NITI Aayog**"), intends to replace the current Medical Council of India with a 'National Medical Commission'. The passing of the National Medical Commission Bill would see a change in the current regulatory framework regulating medical practitioners.

30. Rule 65(10)(a) of the D&C Rules

31. Rule 65(10)(b),(c) of the D&C Rules

32. Regulation 1.3.4 of the MCI Code

33. Regulation 1.A of the MCI Code

34. Proposed National Medical Commission Bill, 2016; available at: http://niti.gov.in/writereaddata/files/document_publication/MCI%20Bill%20Final.pdf

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

The DMRA makes it punishable, with imprisonment or fine or both, to participate in any advertisements in reference to a medicine which:

i. directly or indirectly gives a false impression regarding the true character of the medicine covered in the advertisement; or

ii. make a false claim regarding a drug; or

iii. is otherwise false or misleading in any material particular regarding a drug.

Advertisements are, however, permitted to be sent confidentially to registered medical practitioners and chemists, so long as such communication bears the words 'For the use only of registered medical practitioners or a hospital or a laboratory' at the top of the document in indelible ink and in a conspicuous manner.

VI. Unsolicited Commercial Communications Regulations, 2007 ("UCC Regulations") and Telecom Commercial Communication Customer Preference Regulations, 2010 ("TCCP Regulations")

Sending unsolicited commercial communications over voice or SMS are prohibited under the TCCP Regulations and UCC Regulations. However, there is no legal bar over sending transaction messages. For example, any information sent by any company pertaining to delivery of services to be delivered to such customers would be identified as a transactional message.

VII. The Clinical Establishments (Registration and Regulation) Act, 2010 ("Clinical Establishments Act")

Establishments falling under the definition of a 'clinical establishment' under the Clinical Establishments Act would be required to register with the relevant authority and conform to the minimum standards as prescribed under the act. The Clinical Establishments Act is applicable in Arunachal Pradesh, Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Himachal Pradesh, Mizoram, Sikkim and all Union Territories except the NCT of Delhi. Certain states such as Maharashtra and Karnataka have their own state clinical establishment legislations.

5. Intellectual Property

The e-Health space has seen a lot of innovative products being developed. Protection of these ideas and inventions becomes essential in this highly competitive market. India's Intellectual Property Rights ("**IPR**") regime allows for such protection in various forms, notably patents, copyright, trademarks and designs.

In the context of e-Health, development is concentrated in the areas of software applications (including mobile applications) and wearable devices. This section covers the various forms of IP protection available with such developments in mind.

I. Patent

The Patents Act, 1970 ("**Patent Act**") provides for patent protection in India. The Patent Act is largely compliant with the Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**") and India, being a signatory, has been committed to fully adopting and implementing the provisions of the agreement.

In order for an innovative product to be considered an 'invention' under the Patent Act, it must fulfill three criteria – novelty, non-obviousness and utility. Apart from meeting these requirements, the inventions must also not be specifically excluded from being considered an 'invention' under sections 3 and 4 of the Patent Act. These exclusions include ' a process for the medicinal or other treatment of human beings and animals' and a 'computer program per se'.

Behind every e-Health application is the software that runs it, which is essentially a computer program. A computer program 'per se' is excluded from patentability under Section 3(k) of the Patent Act, 1970. The Indian Patent Office, however, in its 'Guidelines for Examination of Computer Related Inventions ("**CRI**")' in 2016, states that while the CRI in itself is not patentable, it is possible for a CRI claimed in conjunction with a novel hardware to be patented, provided it meets the other requirements such as the three prong test laid down under the guidelines. Patents for software programs have been issued in the past where it involves a hardware component as well. If the technology/software fulfills these requirements, it could file for a patent and receive protection if the same is granted.

A patent may not be granted if the device or program is determined to be 'a process for the medicinal or other treatment of human beings and animals' under section 3(i) of the Patent Act (section 3 deals with what are not considered inventions). However, the Patent examiner's observations in *Lalit Mahajan's* patent application[35] distinguished between a device and process, where 'a device for detection of antibodies to HIV and p24 antigen of HIV in human serum or plasma' was found to be outside of the scope of section 3(i).

II. Copyright

The Copyright Act, 1957 ("**Copyright Act**") provides for copyright protection in India. Copyright can subsist in the form of original literary, dramatic, musical or artistic work, cinematograph films, and sound recordings. While registering a copyright is not essential since copyright in a work exists regardless of its registration, the registration serves as evidence as to the existence of the right.

Software would fall under the definition of "computer programme" under the Copyright Act and according to section 2(o), a literary work includes computer programmes. Hence the literal part, i.e., the source code, is protected under copyright law. The copyright, however, extends to the form and substance of the work, and not the idea itself. This would mean that the idea would have to be expressed in some form of medium before it can be protected.

35. Patent Application No. 693/KOL/2007 decided on 11.01.2010

Clinical guidelines and data could be protected under the Copyright Act, provided that it is expressed in some form of medium. A mere compilation of data without any further effort may not be protected by copyright law. This is derived from the 'sweat of the brow' doctrine, where even though there may not be any originality in content such as tables or databases, copyright would subsist only when a person undertakes an independent collection of the information. The person is then entitled to have his effort and expense protected.

III. Design

Industrial designs are protected under the Designs Act, 2000 ("**Designs Act**"). A 'design' has been defined to mean only features of shapes, configurations, patterns, ornaments or composition of lines or colors that are applied to an 'article'.[36]

In terms of e-Health, the two major components that would require design protection would be the Graphical User Interface ("**GUI**") of applications and the design of the devices.

GUI may be protected under the Designs Act, more specifically under Article 14-04 of the Design Rules, 2001, which covers 'Screen Displays and Icons'. However, there have been applications by companies for registration of its GUI which were rejected. The reasoning of the authorities have been that a GUI cannot be registered as a design, as screen displays do not constitute an article, which is one of the requirements for design protection. However, some icons and user interfaces have been registered as a design under Article 14-99 (miscellaneous). A company could, therefore, apply for design protection of its GUI.

The design of various devices could also be protected under the Designs Act. However, 'design' under this act excludes any mode or principle of construction, or anything which is in substance a mere mechanical device. The design of the device can thus be protected provided it does not fall within the exceptions under the Designs Act.

Registration of a design under the Designs Act confers copyright protection upon the proprietor of the design. This would give the proprietor the exclusive right to apply the design to any article in any class in which the design is registered.

IV. Trademark

The Trade Marks Act, 1999 ("**TM Act**") governs and protects trade marks in India. Apart from statutory protection, unregistered marks are also protected under common law. A 'mark' under the TM Act has been defined to include "a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or, combination of colors, or any combination thereof".[37] Any mark that is capable of being 'graphically represented' and indicative of a trade connection with the proprietor can be registered as a trademark. The rules formulated under the TM Act provide for the classification of trade marks. India follows the NICE Classification of Goods and Services,[38] which has been incorporated in the schedule to the rules. One of the classes under which a trademark can be registered is class 9, which includes "all computer programs and software regardless of recording media or means of dissemination, that is, software recorded on magnetic media or downloaded from a remote computer network".

The 'mark' of an e-Health application or device could be registered as a trade mark under the TM Act, subject to certain exclusion criteria that form grounds for refusal of the trade mark, such as

36. Section 2(a) of the Designs Act defines an 'article' to mean any article of manufacture and any substance, artificial, or partly artificial and partly natural and includes any part of an article capable of being made and sold separately

37. Section 2(m) of the TM Act

38. The Nice Classification, established by the Nice Agreement (1957), is an international classification of goods and services applied for the registration of marks

being devoid of distinctive character or marks or indications which have become customary in the current language or established practice of trade.[39]

V. Trade Secrets

In a nascent industry such as e-Health, ideas are everything. Business strategy and cutting-edge technology must be protected before they are disclosed, in order to prevent misuse. There are no exclusive legislations that deal with confidential information and trade secrets in India. However, judicial decisions have helped secure protection of such information, albeit with the necessity of agreements to the effect.

The first frontier of protection for any company would start right at the workplace. Confidential information that is shared with employees can be protected by means of contractual obligations tailored to protect the company's formulae, products, databases and strategic business plans.

One of the most effective forms of contractual protection would be to enter into Non-Disclosure Agreements with employees which provide remedies in case of disclosure of sensitive business information. Companies can limit their exposure by disclosing sensitive information to employees on a need-to-know basis, providing only what is necessary for effective completion of tasks.

Non-compete clauses are another way in which companies can limit the unwanted disclosure of information. However, care must be taken while drafting such clauses as Indian courts have, in the past, treated unreasonable non-compete clauses as being unenforceable. A combination of confidentiality and non-compete clauses would add an essential layer of protection for companies, especially in the absence of legislation in this regard. Developing detailed protocols for handling confidential information would also go a long way in ensuring that such information stays within the company.

39. Section 9 of the TM Act

6. Taxation Regime

The power to levy direct and indirect taxes in India are distributed between the central and state governments. The Income Tax Act, 1961 ("**ITA**"), imposed by the central government, is the main source of direct tax, while indirect taxes are split between multiple legislations at the central and state levels. Examples include service tax that is levied at the central level, with state governments having their own sales tax legislations (excluding inter-state transactions which are taxed at the central level under the Central Sales Tax Act, 1956). India is currently moving towards consolidating most indirect taxes into a Goods and Service Tax ("**GST**").

Some direct and indirect taxes that may be applicable to e-Health services are discussed below.

I. Indirect Taxes

A number of indirect or consumption taxes are levied at the central and state level. 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 14%[40] payable by the service provider. However, health care services by a clinical establishment, an authorized medical practitioners or para-medics are exempt from service tax.[41]

Further, Value Added Tax (VAT) is levied on the sale of goods within a particular state and rates vary widely anywhere from 0%-1% to 4%-12.5%. Central Sales Tax 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.

The government is in the process of introducing the GST, which will consolidate most indirect taxes. The constitutional amendment required for the introduction of GST has been ratified by the required majority of the state legislatures and has also received the assent of the President of India, thereby making it a law. The government is currently deliberating on the implementation aspects of the GST, and is hoping to roll it out by April 2017.

II. Corporate Tax

Income tax in India is levied under the ITA. While residents are taxed on their worldwide income, non-residents are only taxed on income arising from sources in India. Resident companies are taxed at the rate of 30%,[42] while non-resident companies are taxed at the rate of 40%. A minimum alternate tax is also payable, by resident and, in certain circumstances, non-resident companies, at the rate of around 18.5%.[43] The Finance Act, 2016 has initiated a gradual reduction in the corporate tax rate. The headline domestic corporate tax rate has been lowered to 29% for those domestic companies whose turnover in the financial year 2014-15 did not exceed INR 5 crores (approx. USD 800k).

III. Structuring investments

Foreign enterprises could make investments into the Indian companies through an intermediate holding company set up in a tax friendly jurisdiction. India has a wide treaty network and the judicious use of an appropriate offshore jurisdiction could result in benefits for the foreign company, such as a reduced or nil-rate of tax on capital gains income, reduction

40. Additional cess of 1% is also applicable, making the effective service tax rate 15%

41. Central Board of Excise and Customs; Notification No. 25/2012-Service Tax; available at: http://www.cbec.gov.in/htdocs-servicetax/st-notifications/st-notifications-2012/st25-2012

42. Unless otherwise specified, all tax rates are applicable to Assessment Year 2017-2018 and are exclusive of surcharge and education cess.

43. The exact figure is based on the amount of book profits the company makes in the relevant financial year, and includes both surcharge and education cess

in withholding tax rates, etc. The choice of an offshore .entity would depend on the benefits available under the treaty between India and the offshore jurisdiction and the domestic tax laws of that jurisdiction. Additional concerns include economic stability, investment protection, corporate and legal system, availability of high quality administrative and legal support, banking facilities, reputation and costs, etc.

7. Liability and Dispute Resolution

The liabilities that could arise for contraventions of the various legal requirements can be civil or criminal in nature, and different for doctors running the services and for service providers such as online platforms, institutions, etc.

I. Suits before a Civil Court

Civil suits could arise out of a breach of contractual obligations between the e-Health service provider and the patient/user. It could also be instituted due to the commission of a tort such as negligence on the part of the service provider or its employees.

A breach in contractual obligations could lead to payment of damages that are either decided at the time of execution of the contract (liquidated damages) or based on the decision of the court (unliquidated damages).

In the case of negligence, the Supreme Court has explained it to mean a "breach of a duty caused by the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs would do, or doing something which a prudent and reasonable man would not do."[44] To establish negligence in a civil suit, it must be proved that there was: (1) A legal duty to exercise due care; (2) a breach of that duty; and (3) consequential damage due to the breach.

In the context of a doctor-patient relationship, as would be the case in many e-Health services, the Supreme Court has held that a "person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of those, duties gives a right of action for negligence to, the patient."[45] There is no limit to the amount that can be claimed as damages in such cases, provided the damages claimed are consequential in nature.

II. Vicarious Liability

In the provision of e-Health services where there is an employer-employee relationship, the employer could also be proceeded against due to the principle of vicarious liability, where the employer is deemed to be vicariously liable for acts and omissions of the employee arising in course of his/her employment. This would not usually be the case in an employer-independent contractor relationship, where the service provider does not have much control or supervision over the acts of the independent contractor.

III. Liability under the Consumer Protection Act, 1986 ("CPA")

The CPA was enacted with a view to allow for consumers to address their grievances rather than having to go to a civil court, which turns out to be a very expensive and time consuming affair. The CPA allows consumers to claim compensation from service providers in case there is a deficiency in the service that is provided. Apart from deficiency of services, consumers can also institute claims for defective products and unfair trade practices. Consumer forums have been set up at the district, state and national level in order to hear such matters.

Earlier, there was some ambiguity with regard to whether medical services provided by doctors, hospitals or other institutions were covered under the ambit of the CPA. The Supreme Court in the case of *Indian Medical Association v. V. P.*

44. Jacob Mathew v. State of Punjab & Anr. (2005) 6 SCC 1

45. Laxman Balkrishna Joshi v. Trimbak Bapu Godbole and Anr. 1969 SCR (1) 206

Shantha and Ors.[46] clarified the position and held that medical services would fall within the ambit of the CPA, provided the patient is being charged for the service.

One of the essential elements to a claim is the payment for the services, as the CPA excludes services that are performed free of charge. However, a notable exception that was discussed in the V. P Shantha case was in situations where the service rendered is usually chargeable, but waived in certain cases such as for persons who cannot afford it. In such cases, the person who received the services without charge would still be able to institute a claim under the CPA.

For claims raised with consumer forums, there is no limit to the amount of compensation that can be sought. While the quantum of compensation granted varies, the average compensation is between INR 2 Lakh to INR 6 Lakh. There have also been instances where compensations of up to INR 11 crore[47] have been granted in medical negligence cases.

IV. Disciplinary Action by the MCI

A consumer is entitled to raise a complaint with the relevant state medical council against a doctor for professional misconduct. If a complaint against a doctor has not been decided by the state medical council within six months from the date of receipt of the complaint, the MCI may, on its own or on the request of the consumer, impress on the relevant state medical council to decide on the complaint or refer the same to the Ethical Committee of the MCI for expeditious disposal.[48] Consumers who are aggrieved by the decision of the state medical council also has the right to appeal to the MCI within a period of 60 days from the date of the order passed by the state medical council.[49]

Instances of professional misconduct are specified in the MCI Code, such as non-maintenance of medical records,[50] refusing treatment on religious grounds, performing operations without written consent,[51] etc. These are not exhaustive and complaints can be made for acts or omissions that are not covered under the MCI Code as well. If a complaint is found to be valid, the doctor faces the risk of suspension or cancelation of his/her medical license.

V. Criminal Liability

Criminal prosecution takes place before criminal courts for grounds such as the commission of offences under any criminal statute, most notably the Indian Penal Code, 1860 (**"IPC"**).

In the case of e-Health services, if a person is rash or negligent in rendering a service and the service results in bodily injury or death of the patient/user, the person may face criminal prosecution. The common charges faced by doctors and other providers of such services are causing death by negligence,[52] act endangering life or personal safety of others,[53] causing hurt by an act endangering life or personal safety of others[54] and causing grievous hurt by an act endangering the life or personal safety of others.[55] In case a person is convicted under a criminal charge as described above, he/she may face imprisonment as well as fine.

Unlike criminal prosecution in ordinary cases, criminal prosecution in cases of medical negligence only takes place when the negligence is "gross" in nature. In fact,

46. AIR 1996 SC 550
47. INR 5.9 Crore plus interest; *Balram Prasad v. Kunal Saha;* (2014) 1 SCC 384
48. Regulation 8.7 of the MCI Code
49. Regulation 8.8 of the MCI Code
50. Regulation 7.2 of the MCI Code
51. Regulation 7.16 of the MCI Code
52. Section 304-A of the IPC
53. Section 336 of the IPC
54. Section 337 of the IPC
55. Secction 338 of the IPC

the Supreme Court has taken a sympathetic view towards criminal prosecution of doctors. In the words of the Supreme Court, "if the hands be trembling with the dangling fear of facing a criminal prosecution in the event of failure for whatever reason whether attributable to himself or not, neither a surgeon can successfully wield his life-saving scalper to perform an essential surgery, nor can a physician successfully administer the life-saving dose of medicine."[56] A special exception has been carved out by the Supreme Court for initiation of prosecution in medical negligence cases. A criminal prosecution cannot be initiated unless there exists credible opinion of another doctor to support the charge of rashness or negligence on the part of the accused doctor.

Another special exception that has been carved out by the Supreme Court is in matters of the arrest of doctors. The Court has laid down that "a doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been levelled against him) unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested.".[57]

The principle of vicarious liability does not apply to criminal prosecutions. This would mean that the institutions/online platforms that provide the e-Health services would not be criminally liable for the acts of its employees.

56. Jacob Mathew v. State of Punjab and Anr. (2005) 6 SCC 1

57. Id.

8. e-Health in Foreign Jurisdictions

In most jurisdictions around the world, regulators are still working on addressing e-Health technology and services from a legal standpoint. One of the first questions that invariably arises is whether such technology should be fit into the current legal framework meant for conventional healthcare devices and services, or whether there is a need to address it with more individualized and comprehensive regulations. The progress and outlook of various countries towards e-Health have been discussed below.

I. United States of America

Various states in the United States of America ("**USA**") have passed telemedicine specific regulations. The District of Columbia, for example, has come out with proposed rules to incorporate telemedicine into its municipal regulations.[58] The proposed rules place obligations on the physicians such as obtaining patient consent for the telemedicine services, archival and retrieval of patient records and implementing quality oversight mechanisms. The rules also propose to amend certain definitions in order to integrate and recognize telemedicine services into the municipal code.

Actions at the state level have addressed some concerns that arise from the practice of telemedicine. Some of these have been discussed below:

A. Cross-State Licensing

Licensing of medical practitioners in USA is state-bound, which requires a medical practitioner to apply for a separate license in order to practice in another state. This becomes an issue when the patient is located in one state while the medical practitioner is located in another. In order to address this, some state medical boards such as Alabama have been permitted to issue 'special purpose licenses' to practice medicine across states and provide telemedicine services.[59] In certain other states, doctors are required to be licensed in the state where the patient is located, with limited exceptions for consultations. While representations for a better system have already been initiated, it may take some time before a system catering specifically to e-Health services is set up.

B. Reimbursements

The American Telemedicine Association ("**ATA**") - a leading not-for-profit organization helping to transform healthcare by improving the quality, equity and affordability of healthcare throughout the world – has been one of the biggest proponents of integrating telemedicine into the existing healthcare systems that are in place in USA. One of the major pushbacks that USA is dealing with currently for better adoption of the technology is the lack of coverage of such services in insurance policies. Certain policies go to the extent of specifically excluding e-Health services such as telemedicine from its coverage. The ATA along with other organizations have been pushing for states in USA to pass parity laws that will allow for private insurance coverage of telemedicine.[60] More than 30 states have passed such enactments, while some other states have introduced bills for the same. This would go a long way in ensuring better adoption of e-Health services, since insurance coverage is a major consideration in USA.

58. D.C Municipal Regulations and D.C Register; Notice of Proposed Rulemaking - Establishing rules on telemedicine; available at http://www.dcregs.dc.gov/Gateway/NoticeHome.aspx?noticeid=5881612

59. The Federation of State Medical Boards; Telemedicine Licensure; available at: www.fsmb.org/pdf/GRPOL_Telemedicine_Licensure.pdf

60. American Telemedicine Association; State Legislative & Regulatory Trackers; available at: http://www.americantelemed.org/main/policy-page/state-policy-resource-center

C. Patient privacy and confidentiality

In terms of patient privacy and confidentiality, sharing of information and other critical aspects have been covered under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act. Amendments to federal privacy and security laws in 2013 now requires all subcontractors having access to protected health information must now be compliant with all applicable laws, which ensures that sensitive data is accorded the same level of protection regardless of where the data is transferred.

D. Online prescriptions

States have come up with regulations which either list the medicines that are permitted to be prescribed over telemedicine or list medicines that are prohibited from being prescribed over such platforms. Some states require prescriptions to be issued only after an actual physical examination is conducted on the patient. The state of Minnesota, for example, requires referring practitioners to have performed an in-person examination of the patient before a medicine can be prescribed.[61]

E. m-Health

In the m-Health and telemedicine space, the USFDA has been playing an active role in addressing the new technology.[62] The USFDA has divided mobile applications into three categories - mobile applications that are considered medical devices and subject to USFDA regulations, mobile applications that may be considered medical devices, but which the FDA does not currently intend to regulate, and mobile applications that could be used in a health care environment, but are not considered medical devices.

USA still has some regulatory overlaps that it needs to iron out, but regulators have understood and acknowledged the importance of e-Health and it's potential, and are working towards adapting the current legal framework to fit these new requirements.

II. European Union (EU)

The EU has been studying e-Health in its various forms from as early as 2008, with its European Patients Smart Open Services Project. It has been working towards improving citizens' health and increasing healthcare quality and access by making e-Health part of the health policy and coordinating EU countries' political, financial and technical strategies.

Over the years, the EU has come out with multiple recommendations, guidelines and suggestions for cross border e-Health services. Aspects such as insurance, data privacy, competition, electronic health records and integration of e-Health services have been examined extensively. In 2014, a report was published with an overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border e-Health services.[63] The report contained recommendations such as the content to be included in health records, placing legal obligations on doctors to update health records, safeguards for accessing health data and the interoperability of health records.

61. 2016 Minnesota statutes, Chapter 151, section 151.37; available at: https://www.revisor.mn.gov/statutes/?id=151.37

62. FDA, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, Sept. 25, 2013.

63. Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services; available at: http://ec.europa.eu/health/ehealth/docs/laws_report_recommendations_en.pdf

III. Australia

The Australian government has a dedicated arm for digital health – the Australian Digital Health Agency ("**ADHA**").[64] Standards Australia, a government-recognized standard setting organization in Australia, has laid down an exhaustive set of standards for various aspects of e-Health, covering communications, data security, health concept representation, health record interoperability, patient administration messaging, prescription messaging and tele-health.[65]

The ADHA has set up a "My Health Record" System, with healthcare practitioners and organizations registering onto the platform in order to be placed into the Healthcare Identifiers Service and to obtain a Public Key Infrastructure Certificate to access the My Health Record System. My Health Record is a centralized, secure online summary of patient health information. Patients are able to control what goes into it, and who is allowed to access it by choosing to share health information with specific doctors, hospitals and other healthcare providers.[66] While registration is not mandatory, organizations and doctors will not be able to have full access to the My Health Record System unless registered.

IV. China

The National Health and Family Planning Commission of the People's Republic of China ("**NHPC**") in 2014 came out with a set of interpretations and associated guidelines (titled "Opinions of the National Health and Family Planning Commission Regarding Promoting Medical Institutions' Telemedicine Services") related to telemedicine services in China. The guidelines actively promote the use and development of telemedicine services in China, while also covering essential points such as the need to ensure quality and efficiency as well as supervision and oversight in the performance of such services.

64. Australian Digital Health Agency, Australian Government; more information available at: http://www.digitalhealth.gov.au/

65. List of standards available at: http://www.e-Health.standards.org.au/Home/Publications.aspx

66. My Health Record, Australian Digital Health Agency; more information available at: https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/content/home

9. Current Issues and Considerations

I. General Considerations

A. Cross-State and Cross-Border Tele-Consultations

There seems to be some dichotomy with regard to the extent to which a license to practice medicine applies. The MCI Act states that a person whose name is a part of the Indian Medical Register, which is a central register maintained by the MCI, is entitled to practice as a medical practitioner in any part of India, subject to any other conditions laid down under the MCI Act. However, certain state medical council legislations expressly prohibit the practice of medicine within the state unless the medical practitioner is registered with the relevant state medical council.

One concern that state medical councils may have would be in relation to which council would be required to try a violation by a medical practitioner – the state in which the practitioner is registered or the place in which the violation took place. However, the Supreme Court in the case of *Malay Ganguly v. Medical Council of India and Ors.*[67] had considered the question of liability when a medical practitioner commits an offence while practicing in an area that is outside of the jurisdiction of the relevant state from which he/she received registration. The question was sent to the MCI for deliberation, and in the meeting of the ethics committee held from 26th to 28th August, 2004, the matter was taken up for consideration. The ethics committee observed "as such there is no necessity of registration in more than one State Medical Council because any doctor who is registered with any State Medical Council is automatically borne on the strength of the Indian Medical Register and also by virtue of Section 27 of the MCI Act, a person who is borne in the Indian Medical Register can practice anywhere in India". The committee also laid down how complaints against a medical practitioner were to be dealt with when the medical practitioner was registered with more than one state. Unfortunately, the ambiguity regarding registration was not conclusively put to rest.

Since the ambit of a telemedicine practice would be to provide medical services that are not restricted to the location of the patient, it is unclear whether a doctor registered with a state medical council would be permitted to provide medical services to patients residing in another state, and whether such doctors would be required to obtain multiple state registrations in order to be entitled to practice.

Regulators may consider adopting some of the practices being followed by USA in terms of special licensing for the purpose of telemedicine, which would bring some clarity and aid medical practitioners and healthcare institutions in being compliant with regulatory requirements.

B. Prescribing Drugs

Doctors must exercise caution while prescribing drugs through a telemedicine platform. Apart from IT Act requirements relating to the validity of a prescription (discussed under the e-Pharmacies section), Indian courts have stated that prescriptions should not ordinarily be given to a patient without actual examination. They have also observed that the tendency to give prescriptions over the telephone should be avoided, except in cases of emergency.[68]

C. Delivery of drugs

Home delivery of medication may face challenges from a pharmacy regulation perspective. The Pharmacy Practice Regulations, 2015 (**"PPR Regulations"**) – which regulates the practice of pharmacy by registered pharmacists

67. 2004 (1) SCC 305

68. Martin F. D'Souza v. Mohd. Ishfaq; (2009) 3 SCC 1

in India - state that prescription drugs are to be handed over to the patient or his caretaker directly by a registered pharmacist. Thus, it becomes practically challenging in an online set-up to have pharmacists deliver medication directly to patients.

D. Jurisdictional issues

Since e-Health services are not location-specific, service recipients are distributed around the country. This becomes an issue in the case of an untoward event which leads to a suit being filed in a civil, criminal or consumer court. The plaintiff – the aggrieved patient in this case – is entitled to institute a suit at a forum where he or she is situated, which requires the provider of the service to have to travel to the location in which the suit has been instituted. This also acts as a deterring factor for practitioners who are on the fence regarding the adoption of e-Health services in their practice, as there is a constant risk of having to travel to any part of the country to appear before the relevant forum if a case is instituted.

II. Model-specific Considerations

e-Health being a very broad concept, the legal considerations for each model are diverse. This paper focuses the legal and regulatory framework of three major models that are picking up momentum in India – telemedicine, m-Health and e-Pharmacies.

A. Telemedicine

The most common form of telemedicine seen today is tele-consultation. Doctors sitting in one state are able to provide consultation to patients residing in the most remote locations. The barriers that once restricted access to quality healthcare have now been reduced significantly with the help of telemedicine services. While there are many services popping up around the country, care must be taken that the services provided are in compliance with the legal and regulatory requirements.

Annexure A provides a schematic representation of a few telemedicine scenarios.

In a typical telemedicine setup, there would be exchange of patient information, interaction between a doctor and a patient and the involvement of an intermediary in certain cases. Each of these components have their own legal considerations under various legislations.

i. Informed Consent

Consent while handling SPDI is one of the most essential compliance requirements under Data Protection law. The SPDI of patients that is collected, stored, transferred or processed must be in accordance with the Data Protection Rules. Informed consent of the patient/user is an essential requirement before such data is collected or processed.

ii. Privacy Policy and Due Diligence Requirements

The service provider is also required to have a privacy policy in place in accordance with the Data Protection Rules. In case the service provider is an intermediary, there is also a requirement of a terms of use and compliance with certain due diligence requirements in order to be protected from violations of the IT Act and its rules by users of the service.

iii. OSP Registration

Telemedicine services have specifically been covered under the OSP Regulations. While there are no express penalties for non-compliance with the regulations, there is still a legal requirement to register the service. Applications for registration under the OSP Regulations are to be made with the Department of Telecommunications.

B. m-Health

With the number of smartphone users on the rise, m-Health applications have a lot of potential. However, service providers utilizing this model must keep certain considerations in mind.

SPDI of users are collected on a real-time basis, which makes protection of such data a challenge. Users would also rely heavily on these applications and the information it provides, which makes accuracy an essential element. Service providers may face inevitable issues such as server downtime, inability to communicate with the device, etc. To protect both the user as well as the service provider, certain disclaimers must be put in place that informs the user of the accuracy of the information provided and the possibility of errors, mechanical or otherwise.

C. e-Pharmacies

e-Pharmacies in India were not received well by existing brick and mortar set ups. The All India Organisation of Chemists & Druggists ("**AIOCD**"), called for a nation-wide strike in protest against online pharmacies in order to "protect the general health of the public and interest of its members".[69] The strike saw 8.5 lakh chemists from all across India closing their shops for the entire day, demanding action from the government. The Maharashtra Food and Drug Administration had also raided 27 online pharmacies and filed a First Information Report against a popular e-commerce platform and it's CEO.[70]

The D&C Act requires that all drugs must be sold under a license. Thus, general retailers in India cannot sell drugs, except for a limited class of medicines such as gripe water, which can be sold without a license. The concept of e-Pharmacies were not envisaged by law makers when the act and its rules were drafted. Schedule N of the D&C Rules lay down the requirements to be met before running a pharmacy. The requirements were designed for traditional brick and mortar stores, and hence it becomes difficult for even legitimate e-Pharmacies to comply with the current regulatory requirements. It remains to be seen how the law will evolve to accommodate such services as well.

Other regulatory issues for e-Pharmacies would include having to satisfy the requirement of dispensing prescription medication only on the production of a valid prescription. Measures must also be put in place whereby a prescription drug is not dispensed more than once against the same prescription. For a prescription to be considered valid when it is transferred electronically - as in the case of uploading a prescription to an online pharmacy - it must comply with the provisions of the IT Act as well as the D&C Act and Rules.

The D&C Rules require a prescription to be in writing and signed by a registered medical practitioner. Under the IT Act, a document that is required by law to be in writing would be deemed to be in compliance of such law if the same is made available in an electronic form and accessible in a way that it can be used for future references.[71] Hence a prescription uploaded online would fulfill the first requirement of a valid prescription under the D&C Rules. However, the IT Act further states that where a law requires for a document to be signed, it would be deemed to be in compliance only if such information or matter is authenticated by means of an electronic signature.[72] Affixing an electronic signature to any document thus becomes essential for it to fulfil a legal obligation mandating a regular signature. This would imply that uploading a scanned copy of a prescription may not be recognized as valid under law.

In the wake of the ongoing battle against e-Pharmacies, the Drug Controller General of India ("**DCGI**") had set up a sub-committee under the

69. '72,000 chemists in Maharashtra to shut shops on Oct 14 against e-pharmacy; FDA asks chemist assns to call off strike'; available at http://www.pharmabiz.com/NewsDetails.aspx?aid=91092&sid=1

70. 'Online medicine sales: Are you aware?'; available at http://www.pharmabiz.com/ArticleDetails.aspx?aid=90368&sid=9

71. Section 4 of the IT Act

72. Section 5 of the IT Act

chairmanship of Maharashtra Food & Drugs Administration commissioner Dr. Harshdeep Kamble to look into the issue.[73] The sub-committee has invited experts from various relevant fields to get holistic feedback, and while the committee deliberates on the issue, the DCGI has directed all state drug controllers to keep a strict vigil on online pharmacies to ensure that they are not in violation of the current regulations. The committee has reportedly submitted its recommendations to the office of the DCGI, which will in turn submit its recommendations to the Ministry of Health and Family Welfare after review. The drug regulator is also proposing to set up a centralized online portal which will utilize new technologies to effectively deliver medicines in a regulated manner.[74]

In terms of medicines being prescribed through telemedicine services, service providers are exercising caution while prescribing prescription drugs due to the uncertain regulatory framework. Taking a leaf out of USA's law books, it would greatly help the industry if Indian regulators could also develop a comprehensive list of medicines that would be permitted to be dispensed via an online platform, or alternatively come up with a negative list which prohibits the sale of certain medicines through such platforms. It would also help for regulators to clarify whether medicines can be prescribed without an in-person examination of the patient, or the class of drugs that would be permitted to be prescribed without such examination.

73. http://www.cdsco.nic.in/writereaddata/Online-Sale-dec-2015.pdf

74. Shardul Nautiyal, Pharmabiz; CDSCO plans to launch centralised portal towards regulating online pharmacy; available at: http://www.pharmabiz.com/PrintArticle.aspx?aid=98607&sid=1; last accessed on November 14 2016

10. Government initiatives

I. National e-Health Authority ("NeHA")

NeHA, which is the brainchild of the Ministry of Health and Family Welfare, is a proposed authority that is intended to be responsible for the development of an integrated health information system in India. It will be the nodal authority that will develop an integrated health information system along with the application of telemedicine and mobile health by collaborating with various stakeholders. Apart from this, it will also be responsible for enforcing the laws and regulations relating to the privacy and security of the patients' health and information records.

NeHA is proposed to be a promotional, regulatory and standards setting organization to guide and support India's journey in e-Health and consequent realization of benefits of ICT intervention in the health sector in an orderly way. It also spells out the proposed functions and governance mechanism of NeHA.[75]

II. State Initiatives

The Gujarat government has started the initiative 'E-Olakh', which is developed for recording and registering births, deaths, and compilation of records. The primary aim is to maintain a database of birth and death records and issue birth and death certificates. [76]

The Chhattisgarh government, with the help of the Indian Space Research Organisation ("**ISRO**"), has linked government medical colleges at Raipur and Bilaspur which have in turn been linked with premier hospitals across the country creating a statewide network.[77] 30 such nodes have also been set up in Karnataka in collaboration with ISRO.

The ISRO is also deploying telemedicine nodes under the 'gramsat scheme'. Along with various state governments, the ISRO has managed to establish a vast telemedicine network that consists of 225 hospitals that are connected to 40 super specialty hospitals. The Andaman and Nicobar Islands are also now linked through satellite connectivity. [78]

III. Proposed Legislation

The Ministry of Health and Family Welfare is reportedly working on preparing a legislation that will address the one of the critical concerns in the e-Health space – data privacy and protection of health information. The ministry has assigned the National Law School of India University with the task of drafting the first draft of the "Electronic Health Data Privacy, Confidentiality and Security Act", which will also formally establish NeHA as well as heath information exchanges in India.[79] The proposed legislation intends to provide regulation and standardization for electronic health records, as well as consequences for data breaches. The legislation would also clarify areas such as the ownership of electronic health records and the transfer and access of such information.

75. NeHA concept note, available at http://mohfw.nic.in/showfile.php?lid=3099

76. http://www.nhp.gov.in/e-Health-initiatives-in-gujarat-_pg

77. Central Bureau of Health Intelligence; Telemedicine Project, Chattisgarh; available at http://www.cbhi-hsprod.nic.in/searnum.asp?PNum=210

78. Prof. S K Mishra; E health Initiatives in India; available at http://stbmi.ac.in/matter/international%20pub/35_e-%20Health%20Initiatives%20in%20India_skmishra.pdf

79. Prathiba Raju, Express Healthcare; 'We are working in the direction of citizen empowerment through information dissemination'; available at: http://www.expressbpd.com/healthcare/it-healthcare/we-are-working-in-the-direction-of-citizen-empowerment-through-information-dissemination/377474/

IV. National Intellectual Property Rights Policy ("NIPR")

The Department of Industrial Policy and Promotion ("**DIPP**") released the NIPR on May 12 2016, after receiving approval from the cabinet ministry. The NIPR, themed 'Creative India; Innovative India', focuses on creating awareness on the importance of IPR as a marketable financial asset and economic tool and lays down seven broad objectives ranging from awareness creation to strengthening the enforcement and adjudication mechanisms for combating infringement.

The NIPR recognizes the potential for innovation that exists in new and emerging technologies like nano-technology, biotechnology, agri-biotech, life sciences, green technologies, telecommunications, new materials, space technologies, etc.[80] The policy also talks about developing novel technology platforms in order to ensure enhanced access to affordable medicines and other healthcare solutions .[81]

80. Objective 5 of the NIPR

81. Objective 5.8 of the NIPR

11. Recommendations

The uncertain environment in which e-Health players are currently operating has made it difficult to effectively perform such services. At the same time, it also acts as a deterring factor for new entrants to venture into this field. It has become abundantly clear that the large scale adoption of e-Health is the need of the hour in a country whose population is in need of better access to healthcare.

Some of the policy changes that would go a long way in ensuring the smooth adoption of e-Health services in India include addressing conventional jurisdictional issues in cross-state and cross-border activities as well as developing a solid framework within which services can function. For cross-state telemedicine consultations, an efficient solution could be the implementation of a central level special licensing system for medical practitioners administered by the MCI, which would be in addition to the state medical council registration. Such licensing could have pre-requisites such as certification in telemedicine issued by a notified certification agency. The issuance of a special license at the central level would enable medical practitioners to practice across state borders, which is a fundamental element in the provision of services such as telemedicine.

The government could also engage in discussions with foreign jurisdictions to come up with a framework in which Indian qualified doctors can provide medical services to patients situated outside of India. In this way, India could help other countries that are currently in need of healthcare services, as well as allow for the provision of such services by foreign practitioners to patients situated in India.

In terms of e-Pharmacies, the regulatory authority could develop a list of medicines that would be allowed to be dispensed over such platforms, taking into account the various nuances and complications that such a platform brings, as compared to traditional pharmacy models.

Standards could also be laid down for e-Prescriptions and the manner in which such documents are required to be maintained in order for it to be considered valid. In certain countries, it has been found that the use of e-prescriptions have in fact reduced the misuse of prescriptions by patients, since there would be definitive records of dispensations against a prescription. These methods, while still in early stages of implementation, seem to have benefitted jurisdictions such as USA, and may be able to address some of the issues the Indian e-Health industry is facing today.

12. Conclusion

The e-Health market presents a lot of opportunities, but with every opportunity, there are bound to be risks involved. Innovation in this sector is yet to reach a saturation point, with new products frequently being introduced in the market. The legislative framework to protect and regulate such developments will remain one step behind, as it is yet to be seen how the industry will mature. Regardless, regulators have taken note of the restrictions and in many cases, the absence, of the law and are striving to formulate forward looking policies and legislations. The NIPR is only one such example.

The Ministry of Health and Family Welfare recently set up ten panels led by the top brass of the DCGI's office. They have been entrusted with the revision of the drug regulations in order to bring about ease in compliance and adopting to the progressive changes in the industry.[82]

In a country where access to affordable healthcare is still a looming issue, the public stands to gain immensely from the development of the e-Health industry. With the public interest in the minds of both the regulators as well as the innovators, it remains to be seen if the developing legal and regulatory framework of the nation will impede or ignite its growth. While there is a long way to go, it is hoped that the overall positive outlook and support that the industry is receiving will continue and sustain itself in the future.

82. Suja Nair Shirodkar; Health ministry sets up 10 panels with top officials from DCGI office, SLAs to revise D&C Rules; available at http://www.pharmabiz.com/NewsDetails.aspx?aid=96214&sid=1

ANNEXURE A

Telemedicine Scenarios

I. Important Components of the Process of Telemedicine

a. **Patient**: The individual who requires Tele-consultation.

b. **Primary Doctor:** The registered medical practitioner who has physical access to the Patient. The Primary Doctor will be available at the TCC (defined below).

c. **Specialist:** The registered medical practitioner who provides medical consultation to the Patient from over a distance. A Specialist is located at Telemedicine Specialty Centre.

d. **Telemedicine System:** The system / technology created in order to store, transmit and control all the information / data of the patient [(e.g. the Electronic Medical Record ("**EMR**") from the Patient to the Specialist, via TCC and TSC (defined below)].

e. **Telemedicine Consultancy Centre ("TCC"):** The medical facility where the patient is present. The TCC will be equipped with basic technology required for exchange of medical information and medical consultation.

f. **Telemedicine Specialty Centre ("TSC"):** The medical facility where the Specialist is present. Like the Telemedicine Consultancy Center, this facility will be equipped with basic technology required for exchange of medical information and medical consultation. The specialist will provide Tele-consultancy from the TSC.

g. **Tele-consultation:** The delivery of health care services using information and communication technology over a distance.

II. Scenarios

A. Telemedicine between Patient and Specialist via the Primary Doctor

i. The patient goes to the TCC to receive expert advice of the Specialist who is located at the TSC.

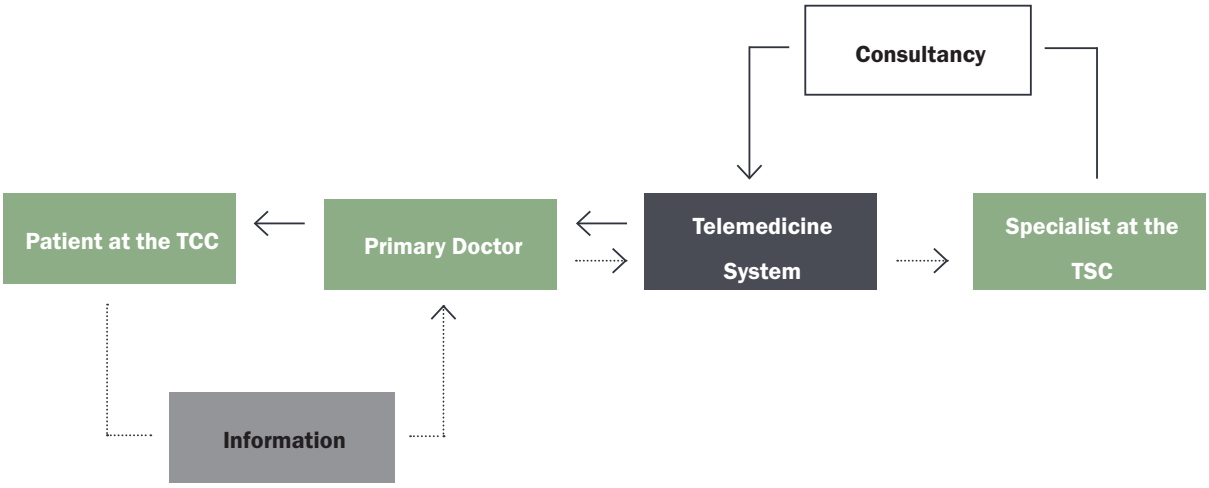
ii. The TCC houses a Primary Doctor who examines the Patient and sends report of his examination to the TSC.

iii. The health information of the patient is shared real time (synchronously) or in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.

iv. The specialist present at the TSC examines the health information and gives his or her expert consultation/advice.

v. The expert advice is relayed real time (synchronously) or in a specific format (Doctor Opinion) to the TCC, via the Telemedicine System. In either event, it is stored permanently in the Telemedicine System.

vi. The Primary Doctor at TCC receives the expert advice and treats the Patient accordingly.



B. Telemedicine between Patient and Specialist without the Primary Doctor

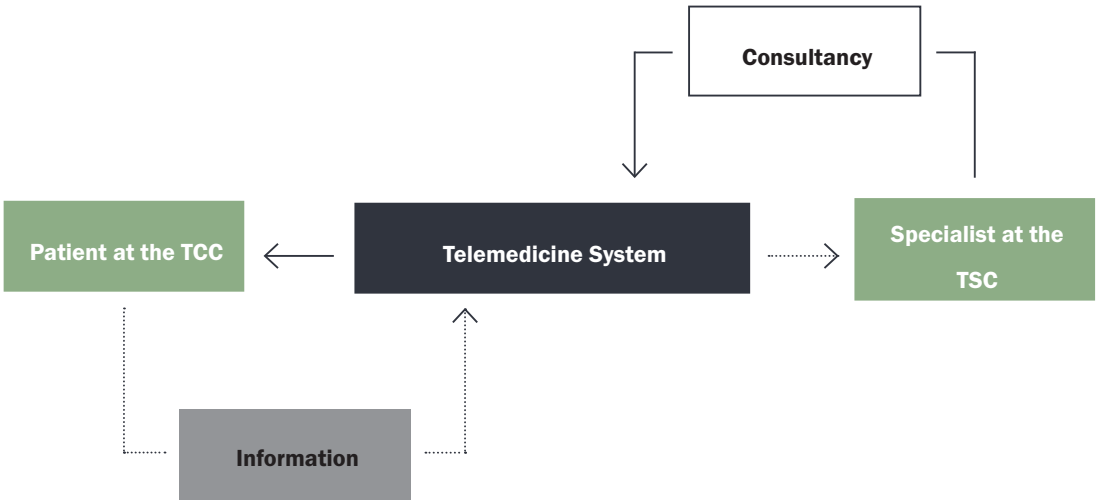
i. The patient goes to the TCC to receive expert advice of the Specialist who is located at the TSC.

ii. The health information of the patient is shared real time (synchronously) or in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.

iii. The specialist present at the TSC examines the health information and gives his or her expert consultation/advice.

iv. The expert advice is relayed real time (synchronously) or in a specific format (Doctor Opinion) to the TCC, via the Telemedicine System. In either event, it is stored permanently at the Telemedicine System.

v. The patient is directly treated by the Specialist.

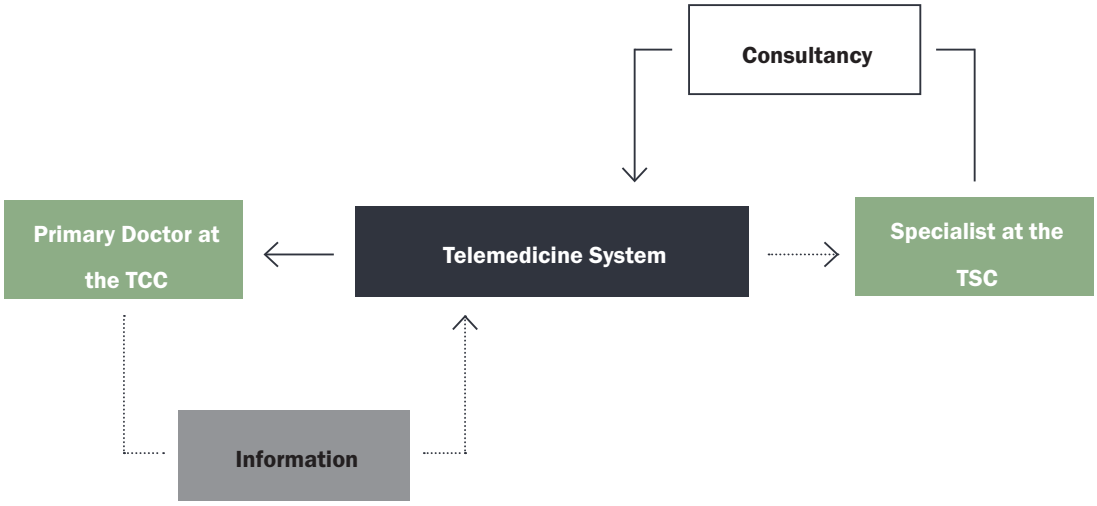


C. Telemedicine between the Doctors

i. The health information of the patient is shared in a specific format (asynchronously, e.g. EMR), to the TSC via a Telemedicine System. The Telemedicine System permanently stores all health related information.

ii. The Specialist present at the TSC examines the health information and gives his or her expert consultation/advice.

iii. The expert advice is relayed in a specific format (Doctor's Opinion) to the TCC, via the Telemedicine System. It is stored permanently at the Telemedicine System.



About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. We provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner.

As a firm of specialists, we work with select clients in select verticals on very complex and innovative transactions and disputes.

Our forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and Medical Devices and Nanotechnology.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automobile, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprises of marquee Fortune 500 corporations.

Our ability to innovate is endorsed through the numerous accolades gained over the years. We are happy to say, we are consistently, ranked amongst the world's Most Innovative Law Firms. We have recently unveiled, a state-of-the-art campus *'Imaginarium Aligunjan*- at Alibaug near Mumbai'. This is meant to be a platform for unifying, developing and distilling ideas and thought. 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. In doing so, we will co-create solutions to the diverse and complex problems confounding the world today. Ultimately, AliGunjan will be a private place for public good – an instrument of change for a better world.

NDA was ranked the 'Most Innovative Asia Pacific Law Firm in 2016' by the *Financial Times - RSG Consulting Group* in its prestigious **FT Innovative Lawyers Asia-Pacific 2016** Awards. While this recognition marks NDA's ingress as an innovator among the globe's best law firms, NDA has previously won the award for the 'Most Innovative Indian Law Firm' four years in a row from 2014-2017.

As a research-centric firm, we strongly believe in constant knowledge expansion enabled through our dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs. Our constant output through Webinars, Nishith.TV and 'Hotlines' also serves as effective platforms for cross pollination of ideas and latest trends.

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 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 Behaviour to Create Competitive Advantage' in the September 2009 issue of Global Business and Organizational Excellence (GBOE).

A brief below chronicles our firm's global acclaim for its achievements and prowess through the years.

- **IDEX Legal Awards:** In 2015, NDA 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". Nishith Desai was also recognized as the 'Managing Partner of the Year' in 2014.
- **Merger Market:** has recognized NDA as the fastest growing M&A law firm in India for the year 2015.
- **Legal 500** has ranked us in Tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014, 2017, 2018). We have also been ranked in Tier 1 for Dispute Resolution, Labour & Employment and Investment Funds (2018)
- **International Financial Law Review (a Euromoney publication)** in its **IFLR1000,** has placed Nishith Desai Associates in Tier 1 for Private Equity (2014, 2017, 2018). For three consecutive years, **IFLR** recognized us as the Indian "Firm of the Year" (2010-2013) and has placed us in Tier 1 category in 2018 for our Technology - Media - Telecom (TMT) practice.
- **Chambers and Partners** has ranked us #1 for Tax and Technology-Media-Telecom (2013, 2014, 2015, 2017, 2018); #1 in Employment Law (2015, 2017, 2018); #1 in Private Equity (2013, 2017); #1 for Tax, TMT and Real Estate – FDI (2011); and #1 in Labour and Employment (2018)
- **India Business Law Journal (IBLJ)** has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015
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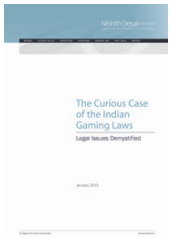

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Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

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.

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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.

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