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Research

Digital Health in India

August 2024

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Introduction

> *"There are two areas that are changing — these are information technology and medical technology. Those are the things that indicate that the world will be very different twenty years from how we know it today."*
>
> Bill Gates

When the internet was first created in the 1980s, the primary objective was to get computers to speak the same language to enable data to travel across any network.[1] Over a period of time, internet has transformed communication, business, education and governments. One of the toughest and most distinctive penetrations of internet is into the healthcare sector. Traditionally, healthcare is perceived as the improvement and maintenance of health through diagnosis, treatment and prevention of ailments through the application of knowledge and skill of healthcare professionals. Today, in the advent of digital technologies in healthcare, healthcare delivery has become personalized and precise and need not necessarily involve the direct intervention of a healthcare professional.

The term "Digital Health" is all encompassing and includes all applications emerging from the intersection of healthcare and technology. The World Health Organisation defines digital health as *"a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence."*[2]

Digital Health technology has emerged as a pivotal pillar in the delivery of healthcare. In the recent past, the world has witnessed a boom in the health technology market for products such as wearables, telemedicine, e-pharmacies, etc. In addition, there has been tremendous research and development in the integration of technologies such as robotics, artificial intelligence, blockchain and virtual reality with pharmaceuticals and healthcare where the sector is experiencing gamification of non-game activities to promote better health management. Accurate delivery of healthcare through technologies and traditional means is also being bridged through the incorporation of ambient computing techniques. The use and scale up of digital health solutions can revolutionize how people worldwide achieve higher standards of health, and access services to promote and protect their health and well-being.[3]

In recognition of this impact, the Government of India launched the flagship programme Digital India Campaign in 2015 which included public health initiatives geared towards adoption of digital technologies for penetration of healthcare services in rural areas. Subsequently, the National Health Policy in 2017 envisioned a fully digitized healthcare system in India which culminated in the commencement of the Digital Health Mission in India (now known as the Ayushman Bharat Digital Health Mission).

1 Ben Tarnoff, How Internet Was Invented? , The Guardian, available at: https://www.theguardian.com/technology/2016/jul/15/how-the-internet-was-invented-1976-arpa-kahn-cerf.

2 WHO Guideline on Recommendations on Digital Interventions for Health System Strengthening, World Health Organisation, available at: https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1.

3 Digital Health, World Health Organisation, available at: https://www.who.int/health-topics/digital-health#tab=tab_1.

This increased focus and endorsement of digital health by the Government makes India a conducive market for innovation in healthcare and creates numerous opportunities for investment.

In the absence of a specific Digital Health law, this paper seeks to knit together existing laws and regulations into what may be called an "ad-hoc" legal framework for Digital Health in India. It is being written for those who are already invested in Digital Health as workforce or capital contributors as well as those who are still testing the waters. Since this is a research paper, it also seeks to raise questions and take positions which are yet to be tested with the hope that it would set the tone for legal discussions on larger platforms.

Applications of Digital Health

The term **"Digital Health"** represents a broad range of applications. Any use of information technology and communications to manage health and wellness falls within the ambit of digital health. Few key applications have been discussed below:

A. Telemedicine

Telemedicine is the use of telecommunications technology to provide healthcare. While telemedicine is not a separate specialty, it stands out in the use of various technologies in providing traditional healthcare services remotely.

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. Telemedicine can be a particularly useful tool to improve treatment outcomes in India as over 75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.[1] Telemedicine could effectively bridge the gap between the patient and the doctor and enable greater access to healthcare to the masses.

B. Point-of-Care Diagnostics

Point-of-care Diagnostics **("POCD")** is an emerging trend in the medical device industry and encompasses a broad range of products which enables accurate diagnostics in resource limited setting by patients themselves or healthcare practitioners. It facilitates disease management, monitoring and real-time diagnosis of multiple conditions. In the recent past multiple applications such as biosensors, portable x rays, handheld ultrasounds and smartphone based POCD have been developed.

Conventional clinical diagnostic procedures which generally require expensive and sizeable instruments have been simplified into software or portable POCD devices which can be used at the site of the patient as opposed to a hospital or a laboratory. POCD devices are generally automated technologies which run on artificial intelligence and/or machine learning algorithms which enable the simplification of complex diagnostic procedures to provide immediate test/ diagnosis results. These results can be used by the patient to approach a healthcare professional for further accurate diagnosis and treatment plans. Additionally, implantables such a bio-sensors help with continuous monitoring of a particular health condition. They have the potential to provide real-time and accurate results and therefore are useful for point-of-care analysis. This enables tracking, monitoring and management of the disease which can directly aid medical decision making of the patient and prognosis of physicians since it generates large data sets of minute health changes.

1 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.

Alternately, it is also beneficial in countries such as India where high-grade medical facilities and infrastructure is deficient in rural areas. POCD will enable physicians to provide telehealth services after diagnosis through POCD devices without requiring patients to physically travel and undergo diagnostic tests at medical facilities.

C. m-Health

Mobile health, or m-Health, is the provision of Digital Health services on a mobile platform. India is home to the 2nd largest smartphone market in the world, which makes m-Health a very lucrative option[2]. Providing access to such applications on smartphones is easily achievable, given that the country is expecting to reach 1412 million mobile internet users by 2024, given that the number of smartphone users and internet users are nearly the same.[3] The convenience of Digital Health coupled with the mobility of m-Health opens the arena for a lot more players to actively take part in the revolution.

D. Medical Virtual Assistants

Medical Virtual Assistants **("MVAs")** is an emerging trend in the m-Health landscape. Virtual health assistants and chatbots bridge the gap between patients and physicians and tend to the needs of the patients in between physical appointments through services such as prompting prescription refills, providing information on medical conditions, appointment scheduling, maintain health records and other administrative tasks. MVAs generally run on AI based software to enable the processing of large data sets and provide personalised advice and perform individual specific functions. MVAs are also advantageous for performing administrative tasks at hospitals and other healthcare institutions.

E. 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 manoeuvre more precisely and with smaller incisions.[4] This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient. Going forward we may also witness the use of microbots (also called micro-robots) for diagnosis and treatment of diseases. One such procedure called capsule endoscopy, in which the patient swallows a tiny camera so that the healthcare provider can take pictures of the digestive tract, has already been approved by the United States Food and Drugs Administration (US FDA - the apex regulatory body governing drugs and medical devices in the United States of America).[5] Other applications in the future may include removing plaque from arteries, taking tissue biopsies, attacking cancerous tumors directly and delivering targeted medication in the human body.

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2 India is now the second largest smartphone market in the world, surpassing the U.S., available at: https://mashable.com/article/india-smartphone-market/.

3 Number of internet users in India, available at: https:// www.statista.com/statistics/255146/number-of-internet-us- ers-in-india/.

4 Johns Hopkins Medicine; Types of Minimally Invasive Surgery; available at: http://www.hopkinsmedicine.org/minimally_invasive_robotic_surgery/types.html.

5 The Growing Emergence of Robots in Healthcare: Key Opportunities & Benefits, available at: https://Hitconsultant.net/2019/12/05/The-Growing-Emergence-Of-Robots-In-Health-Care-Key-Opportunitiesbenefits/#.Xpngs8gzbiv.

Microbots are far less likely to cause tissue damage than conventional medical interventions, such as surgical incisions and catheter insertions. By aiming for specific destinations in the body, microrobots could drastically reduce the side effects of pharmaceuticals.[6] Further, 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.[7]

F. 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, blood pressure, glucose levels,[8] posture, diet and exercise.[9] 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.

G. Electronic Health Records ("EHR")

An EHR is a digital version of a patient's health records. EHRs help eliminate the problems associated 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.[10] 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 to manage costs.

H. 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 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 other patients to make an informed decision.

6 Tumbling Microbots for Future Medicine, available at: https://www.americanscientist.org/article/tumbling-microrobots-for-future-medicine.

7 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.

8 Manav Teli, Digital health technologies in India: transforming the medical device industry, TOI, June 16, 2023, accessible at: https://timesofindia.indiatimes.com/blogs/voices/digital-health-technologies-in-india-transforming-the-medical-device-industry/.

9 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/.

10 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/.

I. Big Data in Healthcare

Raw data is collected from the use of various Digital Health services. EHRs in itself generate 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")**[11], 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.

J. Blockchain in Healthcare

Blockchain has been a buzzword across the data industry in the recent years. It is reforming the modes of storage, access, sharing and privacy of data online. Given that the healthcare industry is reliant on massive volumes of data, blockchain enabled technologies present an opportunity to enable the transition to a value-based healthcare system from the traditional volume-based system. Specifically, introduction of blockchain interventions can make health data management and information exchange more seamless and integrated across the various stakeholders. Other potential uses also include health profiling, medication management and insurance management.

K. 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.[12] 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, the correct approach may be difficult to ascertain.

L. e-Pharmacies

India has experienced a rise in e-pharmacies or online pharmacies in the last couple of years. An e-pharmacy or online pharmacy is a pharmacy that operates over the internet and fulfils the orders through mail, courier or delivery persons. 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. While the legal status of online pharmacies remains to be in the grey area, judicial interpretation may pave the way ahead for legal recognition of this advancement.

11 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/.

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

M. e-Learning in the healthcare sector

Continuous Professional Development is a mandatory requirement under the regulation governing doctors and is necessary so that doctors can 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 and is accessible from anywhere, enabling greater access to information to doctors throughout the country and enables uniform knowledge sharing.

Ayushman Bharat Digital Mission

In pursuance of the National Health Policy, 2017, a Committee under the chairmanship of Shri J. Satyanarayana was constituted to develop an implementation framework. This Committee produced the National Digital Health Blueprint, 2019 **("NDHB")**, laying out the building blocks and an action plan to comprehensively and holistically implement digital health in India.

Based upon the NDHB, the Ministry of Health and Family Welfare **("MoHFW")** introduced the National Digital Health Mission **("NDHM")** on August 15, 2020 to create a digital health ecosystem. The NDHM commenced as a pilot initiative across six union territories. A year after its implementation, it has been renamed as Ayushman Bharat Digital Mission **("ABDM")** and is now applicable nationwide. Presently, participation in the ABDM is voluntary.

The ABDM aims to establish a federated health information architecture, health information exchanges, and a national health information network by 2025. Once fully operational, the healthcare system will be a secure interoperable health system which will enable the accessibility and portability of health records across public and private healthcare institutions. The ABDM is based upon these main components:

i. Health ID: Creation of a Digital Health ID for all citizens to enable easy storage, access and sharing of health data. This Health ID may be linked to the Aadhar and/or the mobile number of the individual. The Health ID will enable the individual to store all health-related information and records electronically and be accessed anywhere and at any time. Additionally, sharing credentials of the Health ID will allow healthcare professionals to easily access the health data and past records of the individual with consent.

ii. Health Facility Registry: Participating entities of the ABDM must register as a healthcare provider. Both public and private health facilities, such as hospitals, clinics, diagnostic laboratories and imaging centres, pharmacies can register under the ABDM. Upon registration, the policies under the ABDM shall be binding and the Health Facility shall digitise their systems accordingly. The list of registered facilities is stored in a Repository[1] to help individuals find health services digitally and with ease.

iii. Healthcare Professionals Registry: In addition to registration of facilities, individual healthcare providers may register themselves under the ABDM.[2] Professionals involved in healthcare services, both modern and traditional, can get more online presence and visibility. The healthcare professionals who sign up to ABDM's registry can view patient records online as well as treat them online.

iv. Health Records: The Health Records have been executed as a mobile application system to let individuals add and maintain their health data. The users can also share the data with whom they wish to, such as doctors, healthcare facilities and others.

v. Consent Manager: The exchange of health information is enabled by the consent manager and gateway which supports health data access requests and manages the consent preferences of users of the ABDM interfaces. The new data law i.e. the Digital Personal Data Protection Act, 2023 **("DPDP Act")** proposes the appointment of consent managers by the data fiduciaries to act as intermediaries between the data principals and the fiduciaries for grievance redressal.[3]

1 ABDM Health Facility Registry, available at: https://facility.ndhm.gov.in/.

2 ABDM Healthcare Professionals Registry, available at: https://hpr.ndhm.gov.in/en#:~:text=Healthcare%20Professionals%20Registry%20is%20a,to%20India's%20digital%20health%20ecosystem.

3 Section 13 of the Digital Personal Data Protection Act, 2023.

The interplay of the roles and responsibilities of the consent managers under the two interfaces i.e. the ABDM and the data law interface is yet to be determined.

In addition to these, there are several entities in the ecosystem—ABDM Sandbox,[4] Health Information Providers, Health Information User, Health Repository Provider and Health Lockers[5] which are integral to this proposed digital health ecosystem to integrate Digital Health services. Entities performing such services are also eligible to enrol under the ABDM.

A. Health Data Management

The Health Data Management Policy, 2020 **("HDM")**[6] lays down the framework for security by design for the digital health ecosystem under ABDM. As per the HDM, three separate Health IDs-for patients (Health ID), medical practitioners (Health Practitioner ID) and clinical establishments (Health Facility ID) will be created. Each ID comes with its own set of data access rights and privileges. The HDM Policy also gives the patient complete ownership over the health data and lays down a framework for how this data may be utilized. Once fully functional, the ABDM will link all patient data with a single Health ID making it easier for both patients and healthcare practitioners to access their medical history when making clinical decisions. The data may also be utilized in an anonymized form to better understand trends in public health and assist the government in making data-driven policy decisions in the healthcare space.

B. Sandbox

The ABDM Sandbox[7] is a framework that will allow technologies or products to be tested in the contained environment in compliance with NDHM standards and judge the consumer and market reactions to the same before introducing it on a larger scale. All products and services and the technology will be tested under this framework. The target applicants for the ABDM Sandbox are healthcare or health-tech service providers, including public health programs at the central and state level, software providers, hospitals, laboratories, healthcare aggregators, and health tech companies.[8] The primary objective of introducing a Sandbox under the ABDM is to foster integration of current systems and IT platforms in healthcare to be integrated with the ABDM building blocks, and also enable responsible innovation in health-tech services, promote efficiency and bring benefit to consumers.

Only firms or entities incorporated or registered in India or licensed to operate in India can enter the sandbox after demonstrating compliance with applicable laws on data protection and privacy including. If the entity is unable to fully comply with the relevant requirements or fails to achieve the intended purpose, the Sandbox will be terminated.

4 National Digital Health Mission Sandbox Enabling Framework dated August 18, 2020; available at: https://ndhm.gov.in/publications/sandbox_guidelines.

5 Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Health Lockers, available at: https://abdm.gov.in/publications/policies_regulations/hip_hiu_Policy.

6 Health Data Management Policy, 2020, available at: https://abdm.gov.in:8081/uploads/health_data_management_policy_455613409c.pdf.

7 NDHM Sandbox Enabling Framework, available at: https://ndhm.gov.in/documents/sandbox_guidelines.

8 Medianama, Summary: The National Digital Health Mission's Sandbox Framework, available at: https://www.medianama.com/2020/08/223-national-digital-health-mission-sandbox/.

The benefit of enrolling in the Sandbox is to test the product without a large-scale roll out and allows for experimentation of products on a wider range of consumers. However, it must be noted that the Sandbox is not a legal waiver and the entity will still be liable to consumers and for any violation of applicable regulations.

C. Unified Health Interface

In January 2022, the National Health Authority **("NHA")** launched the Unified Health Interface **("UHI")**[9] a digital healthcare service platform under the ABDM. Policy guidelines on the governance of the system are yet to follow.

Previously, in July 2021, the NHA had released a consultation paper on UHI[10] to invite comments on the design and functionality of this proposed system under the ABDM. The consultation paper envisioned an open network UHI system which will standardize the technology pathways of digital health services to create an efficient digital framework for patients and health service providers. It outlines the proposed design, scope and functions of UHI to provide for the interoperability of health services across the country.

ABDM will manage the UHI Gateway which will enable all participating entities of the ABDM to connect and communicate using standard protocols. Through UHI, health service providers including hospitals, healthcare professionals, pharmacies etc. and patients will be able to connect for bookings, consultations, e- prescriptions, etc. and also securely transfer medical records.

In December 2022, the ABDM released a Consultation Paper on Operationalising UHI[11] to seek public comment on the different elements of the UHI functions and the operational aspects.

Some key services which the UHI seeks to automate are:

- Discovery and booking of doctors for Tele-Consultations
- Discovering availability of doctor
- Discovery of closest labs with the required tests
- Discovery and booking nearest ambulance service, etc.[12]

A major aspect of the UHI is to execute a patient-centric healthcare service system. It intends to promote transparent pricing and health service providers will be required to display prices for services including consultations, scans, tests etc. which will help individuals make a conscious decision in availing these services through the online platform. Further, a feature will assist individuals to monitor drug stocks in pharmacies near their location and even place orders for home delivery with pharmacies which provide this facility. Additionally, UHI also intends to bring ambulance service providers under its ambit for quicker emergency response and care. Registered ambulance operators can receive patient requests through this interface.

9 ABDM Unified Health Interface Initiative, available at: https://abdm.gov.in/collaborative-development.

10 Consultation Paper on UHI, July 2021, accessible at: https://abdm.gov.in:8081/uploads/UHI_Consultation_Paper_60a9201c1d.pdf.

11 Consultation Paper on Operationalising UHI, December, accessible at: https://abdm.gov.in:8081/uploads/Consultation_Paper_on_Operationalising_Unified_Health_Interface_UHI_in_India_b6e1b6279f.pdf.

12 Para 3.2, Consultation Paper on Unified Health Interface, available at: https://ndhm.gov.in/assets/uploads/consultation_papersDocs/UHI_Consultation_Paper.pdf.

D. Proposed Health Data Retention Policy

The NHA invited comments from the public on its Consultation Paper on proposed Health Data Retention Policy **("HDRP Consultation Paper")** released on November 23, 2021. It proposes the health data retention framework for the ABDM architecture. The HDRP Consultation Paper also considers the applicability of the proposed health data retention policy to the entire healthcare system. The passage of a health data retention policy would create uniform principles for the retention, use, storage and accessibility of health data in line with international best practices.

Investment in Digital 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. Digital Health tools such as telemedicine and online pharmacies are considered to be potential 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, for example, on x-rays of patients in the hospital. Many hospitals have also adopted the public-private partnership route to render services through telemedicine. Some investment options are discussed below:

A. 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 for Promotion of Industry and Internal Trade **("DPIIT")**.

The provisions pertaining to FDI are laid down in Regulation 16 of FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2017.[1] While the DPIIT 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 2020.

As per the Consolidated FDI Policy, 100% FDI is permitted in most sectors under the automatic route, i.e., where prior approval of the government, is not required. Generally, there are no restrictions prescribed for Digital Health services, and therefore FDI up to 100% should be permitted without government approval. It must be noted that for the pharmaceutical and healthcare sector, 100% FDI is allowed under the automatic route in Greenfield investments[2] and while 100% FDI is allowed under Brownfield investments,[3] only up to 74% investment is allowed under the automatic route and any investment beyond 74% would require the prior approval of the Government. Greenfield projects are new projects that are coming up in India while Brownfield projects are existing projects in India.

Further, 100% FDI is permitted for e-commerce activities.[4] However, it must be noted that only marketplace entities engaging in B2C model of business are eligible for FDI.

A marketplace-based model of e-commerce means providing of an information technology platform by an e-commerce entity on a digital & electronic network to act as a facilitator between buyer and seller.

1 Consolidated FDI Policy, Government of India, Ministry of Commerce & Industry, Department for Promotion of Industry and Internal Trade, available at : https://Dipp.gov.in/Sites/Default/Files/Cfpc_2017_final_released_28.8.17.Pdf.

2 5.2.27.1, Consolidated FDI Policy 2020.

3 5.2.27.2, Consolidated FDI Policy 2020.

4 5.2.15.2, Consolidated FDI Policy 2020.

B. 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[5], 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 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.[6] 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").**[7]

5 SEBI (Foreign Venture Capital Investor) Regulations, 2000.

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

7 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.

Legal and Regulatory Framework

There is no specific legislation which governs Digital Health in India. The laws that broadly cover Digital Health services are discussed in brief:

A. Drugs and Cosmetics Act 1940 read with Drugs Rules 1945 and Draft E-Pharmacy Rules, 2018

The Drugs and Cosmetics Act, 1940 **("DCA")** read with Drugs Rules, 1945 **("DR")** is the primary regulatory framework which governs manufacture, sale, import and distribution of drugs in India. The Central Government and the State Governments are responsible for the enforcement of the DCA. The Central Drugs Standard Control Organization **("CDSCO")**, headed by the Drug Controller General of India **("DCGI")** is primarily responsible for coordinating the activities of the State Drugs Control Organization, formulating policies, and ensuring uniform implementation of the DCA throughout India. Additionally, there are State Licensing Authorities **("SLA")** which govern the implementation of the DCA in individual states.

The DCA requires that all drugs must be sold under a license issued by the licensing authority. The DR clearly lays down the list of drugs which can only be sold on the production of a prescription issued by a registered doctor, in accordance with the provisions of the DR[1] which implies that there is a distinction between prescription and non-prescription drugs. Drugs which can be sold only on a prescription are stated in Schedules H, H1, and X of the DR.

The DCA 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 DR, to be sold by persons who do not have such a license. Hence, non-prescription drugs are only those drugs that are specified under schedule K. These broadly include drugs not intended for medical use, quinine and other antimalaria 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.

For a prescription to be considered valid it must be in writing, signed and dated by the doctor issuing the prescription. 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.[2]

Broadly, the online services pertaining to pharmaceuticals in India will have to be compliant with the DCA and DR framework. Although the DCA does not specifically recognise any form of online services or product deliveries, the ambit of the regulation is broad and is understood to be applicable to brick and mortar business models as well.

E-pharmacies are regulated on the basis of this principle in India. Accordingly, to operate an e-pharmacy, a license must be obtained from the respective SLA. However, unlike a physical pharmacy, which has a geographical limitation and can function only in a single state at a given point of time, an online pharmacy can operate pan India simultaneously. Additionally, there were several other issues associated with e-pharmacies such as acceptability of scan/ photograph of prescription, prohibition on storage of drugs by courier

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

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

carriers without license, obligation of registered pharmacist to hand over drugs to patient etc. To clarify these aspects, Draft E-pharmacy Rules, 2018 **("Draft Rules")** were published.

Subsequently, on October 31, 2018, the High Court of Madras[3] asked the Central Government to ensure that no prescription medicine is sold online without a license. The Delhi High Court,[4] on the other hand, passed an interim order injuncting certain online pharmacies from selling medicines online without a license. In November, the DCGI issued an order to drug controllers across India to ensure that the interim order of the Delhi High Court is enforced. These orders do not prohibit the online selling of drugs but rather require the drug controllers to ensure that drugs are not sold online without a license.

In its most recent order, the Delhi High Court directed the Central Drugs Standards Control Organisation **("CDSCO")** to report the outcome of the stakeholder consultations held for the Draft Rules in 2018. The Delhi High Court further directed CDSCO to report the final decision on the regulation of e-pharmacies, the hearing for the said matter has been scheduled for November 2023. Separately, the Delhi High Court also clarified that the pendency of the matter will not come in the way of the Government taking action against the persons who are violating the interim order issued in 2018 prohibiting the sale of drugs online without a valid license.

B. The National Medical Commission Act, 2019 and The National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023

The National Medical Commission Act, 2019 **("NMC Act")** which is administered by the National Medical Commission **("NMC")** regulates the medical education and medical profession in India. The NMC Act provides that only those persons who have a recognized degree in medicine and having passed the National Exit Test will be eligible to enrol with the State or National Registers to obtain a license for practising medicine in India **("Registered Medical Practitioners/ RMPs")**.

The NMC notified the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 **("NMC Code")** to supersede the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 **("MCI Code")** issued by the erstwhile Medical Council of India. The NMC Code was out in abeyance on August 23, 2023, pursuant to representations made by various stakeholders. The NMC Code lays down professional and ethical standards to be followed by doctors in their interaction with patients, pharmaceutical companies and within the industry.

The MCI Code continues to remain applicable on the interactions between doctors, their patients and pharmaceutical companies. The MCI Code also specifies that efforts are to be made to computerize medical records so that they can be retrieved quickly.[5] Doctors are bound by the MCI Code and are required to submit a declaration to that effect.[6]

The provisions of the NMC Act and the MCI Code are applicable to digital health applications to the extent that the services involve the delivery of healthcare by a physician to Indian patients.

3 The Tamil Nadu Chemists and Druggists Association vs. Union of India & Ors, W.P. No. 28716 of 2018.

4 Dr. Zaheer Ahmed v. The Union of India & Ors., W.P.(C) No. 11711 of 2018.

5 Regulation 1.3.4 of the MCI Code.

6 Regulation 1.A of the MCI Code.

C. Telemedicine Practice Guidelines, 2020

The Board of Governors instituted by the Central Government for regulating medical education and the medical profession in India (in supersession of the Medical Council of India), issued the Telemedicine Practice Guidelines, 2020 **("Telemedicine Guidelines")** in partnership with the NITI Aayog. These guidelines have been made part of the MCI Code and are therefore binding on medical practitioners practicing allopathic medicine. The Telemedicine Guidelines enable medical practitioners to practice telemedicine in any part of the country, provide guidance on the nature of care that may be provided and the manner of providing such care. For instance, it provides guidance on which mode of communication (audio/video/text) to use for which types of consultation (emergency/non-emergency/medical practitioner to medical practitioner). The Telemedicine Guidelines also categorize medicines in List O, List A, List B and Prohibited List and specify which medicines can be prescribed in which situations.

In August 2023, the NMC issued the Registered Medical Practitioner (Professional Conduct) Regulations, 2023 **("NMC Code")** in supersession of the MCI Code. The NMC Code also included the 'Guidelines for Practice of Telemedicine in India', which would replace the 2020 version of the Telemedicine Practice Guidelines. However, the NMC Code was subsequently put in abeyance and, pending its re-notification, the MCI Code prevails.

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

The DMRA was enacted in 1954 to curb advertisements of drugs and remedies alleged to possess magic qualities. The DMRA prohibits persons from taking part in the publication of an advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

a. the procurement of miscarriage in women or prevention of conception in women; or

b. the maintenance or improvement of the capacity of human beings for sexual pleasure; or

c. the correction of menstrual disorder in women; or

d. the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule to the DMRA.

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.

The MoHFW, on February 03, 2020, published a draft amendment to the DMRA to amend the definition of 'advertisement' under the DMRA to specifically include advertisements made over an online/ electronic medium, increase penalties for violation of the DMRA and expands the list of diseases, disorders or conditions in the schedule to the DMRA. However, the proposed amendment does not substantially alter the existing regulation as advertisements over electronic media were already within the purview of the DMRA. However, the proposed amendment does not substantially alter the existing regulation as advertisements over electronic media were already within the purview of the DMRA.

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

Establishments falling under the definition of a 'clinical establishment' under the Clinical Establishments (Registration and Regulation) Act, 2010 **("CE 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, Himachal Pradesh, Mizoram, Sikkim, Bihar, Rajasthan, Uttar Pradesh, Uttarakhand, Jharkhand, Assam, Haryana and all Union Territories except the NCT of Delhi. Certain states such as Maharashtra and Karnataka have their own state clinical establishment legislations.

F. Telecom Commercial Communication Customer Preference Regulations, 2018 ("TCCP Regulations")

Sending unsolicited commercial communications over voice or SMS are prohibited under the TCCP Regulations and TCCP Regulations. Promotional messages may only be sent to subscribers who have opted in for receiving such communications once registered with an access provider. However, there is no legal bar over sending transactional messages or voice calls. A transactional message is one which is triggered by a transaction performed by the receiver of the message provided the receiver is a customer of the sender and the message is sent within 30 minutes of the transaction being performed and is directly related to it. For example, any information sent for OTP or purchase of goods and services would be identified as a transactional message. All other messages (even though directly connected with the delivery of goods) may only be sent as per a format registered with the access provider after obtaining the consent of the receiver.

G. Consumer Protection Act, 2019 and Consumer Protection (E-commerce) Rules, 2020

The Consumer Protection Act, 2019 **("CPA")** is the provides for protection of consumer's interest and establishes a redressal mechanism. It imposes multiple responsibilities upon sellers and service providers including prohibition of unfair trade practices, misleading advertisements and establishes product liability regime. Central Consumer Protection Authority **("CCPA")** is the regulatory body under the CPA which presides over the administration of CPA and issues penalties. Parallelly, there is also a three-tier consumer disputes redressal mechanism through which a consumer may directly file complaints for violations of CPA.

Additionally, the Consumer Protection (E-commerce) Rules, 2020 **("E-commerce Rules")** have been issued under the CPA to regulate the marketing, sale and purchase of goods and services online. The E-Commerce Rules also incorporate requirements under the Legal Metrology Rules, 2011, IT Act and other applicable laws for sale of goods online. It also distinguishes between the responsibilities of marketplace, inventory entities and sellers.

The E-commerce Rules also govern entities that are not established in India but systematically offer goods or services to consumers. Such entities will need to establish a presence a India through:

a. a company incorporated in India, or

b. a company incorporated outside India which has a place of business in India, including through electronic mode, and conducts any business activity in India, or

c. an office/branch/agency outside India owned or controlled by a person resident in India. E-commerce entities must also appoint an Indian resident as a nodal person of contact to ensure compliance with the CPA 2019.[7]

H. Proposed Law

The Indian Government is in the process of introducing reforms in the regulations applicable to pharmaceutical, medical devices and healthcare industries. The key developments to keep in mind are discussed below.

I. Revamp of DCA Framework

In July 2022, the Government released a draft of the Drugs, Medical Devices and Cosmetics Bill, 2022 **("Proposed Drug Law")**[8] which proposes to overhaul the existing DCA to introduce a comprehensive regime for governing all drugs, medical devices, indigenous drugs and devices (AYUSH), clinical trials and marketing approvals and cosmetics in India. It also seeks to regulate online pharmacies. It is anticipated that the Proposed Drug Law may be enacted in 2023. The key aspects of the Proposed Drug Law have been analysed in our hotline **here**.[9]

Importantly, in terms of impact on digital health applications, the Drug Law mandates that a license be obtained for sale of drugs and medical devices through online mode.

7 Rule 4(1), E-Commerce Rules.

8 Draft Drugs, Medical Devices and Cosmetics Bill, 2022; available at: https://main.mohfw.gov.in/sites/default/files/Drugs%2C%20Medical%20Devices%20and%20Cosmetics%20Bill.pdf (Last accessed on May 11, 2023).

9 Draft Drugs, Medical Devices and Cosmetics Bill, 2022: Dawn of a New Era?, available at: https://www.nishithdesai.com/SectionCategory/33/PharmaHealthcare-Update/12/67/PharmaHealthcareUpdate/6264/1.html.

Data Protection

A. The Information Technology Act, 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011 (together the "Data Protection Rules") and the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021

Digital Health involves a constant exchange of information between the patient and the service provider including the patient's personal information, such as medical history and physiological conditions. At present, the patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information6 **("SPDI")** under the Data Protection Rules. When a body corporate[1] collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

The data protection framework is in the process of transformation given that the Digital Personal Data Protection Act, 2023 **("DPDPA")** was passed by the legislature in August 2023 and is proposed to be brought into force in a phased manned followed by the specific rules for the purpose of implementation of the DPDPA. Once the provisions under the DPDPA are brought in force, it will replace the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011. Our detailed analysis of the DPDPA is accessible **here**.[2]

Broadly, the DPDPA provides specific compliance requirements to be undertaken by any entity processing digital personal data pertaining to an individual. The DPDPA unlike the existing Data Protection Rules does not envisage sub-categories of personal data, pursuant to which the compliances under the DPDPA apply to all forms of data and applies to the processing of all digital personal data in India. Consent is one of the major requirements under the DPDPA. 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 upon providing a notice in compliance with the conditions prescribed under the DPDPA in this regard.[3] The rules are likely to provide further clarity on the form and manner of obtaining such consent in compliance with the DPDPA.

Further, if a body corporate is collecting, storing and processing personal data on behalf of another entity then it may avail the safe harbour provision provided under Section 79 of the IT Act. In order to avail this, it must follow the extensive requirements provided for under the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021 **("Intermediaries Rules")**.

1 Section 43A of the IT Act defines "body corporate" to mean any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities.

2 https://www.nishithdesai.com/NewsDetails/10703.

3 Section 5 and 6 of DPDPA.

These requirements include having a grievance redressal mechanism,[4] displaying privacy policy and usage of personal data,[5] removal of unethical[6] and obscene information,[7] monthly compliance report,[8]implement reasonable security practices[9] etc.

B. The Clinical Establishments (Registration and Regulation) Act, 2010, Clinical Establishments Rules, 2012, and Electronic Health Record Standards, 2016

The Clinical Establishments Rules, 2012 **("CER")** which is issued under the Clinical Establishments (Registration and Regulation) Act, 2010 **("CE Act")** requires clinical establishments to maintain Electronic Health Records **("EHRs")** in accordance with standards determined by the Central Government. The Electronic Health Record Standards, 2016 **("EHR Standards")** has been formulated for the creation of a uniform standard-based system for EHRs in India. The EHR standards will be applicable to Digital Health Entities which fall within the ambit of the CE Act.

The EHR Standards provide the measures for maintenance of health data records to be adopted by clinical establishments. It recommends the data and security measures to be adopted by clinical establishments. Additionally, it also lays down that the ownership of the data shall vest with the individual and the healthcare provider holds such medical data in trust for the individual. It also provides guidance on consent, clinical information systems, interoperability, clinical informatics standards, data privacy and security aspects.

C. Health Data Management Policy, 2020 ("HDM Policy")

The HDM Policy is applicable to entities participating in the ABDM. It is the framework for management of digital health data privacy of individuals who have been issued a Heath ID, registered healthcare professionals and participating entities under the ABDM. It sets out the minimum standards for data privacy protection that should be followed in order to ensure compliance with relevant and applicable laws, rules and regulations.

The HDM Policy adopts definitions and principles from the 2018 version of the Data Protection Bill, which prescribed that data fiduciaries can collect or process personal data or sensitive personal data only with the consent of the data principal and for the purpose the consent was sought for. The notified version of the DPDP Act has brought all data within the ambit of 'digital personal data' and has done away with the concept of sensitive personal data. The DPDP Act retains the compliance requirement with transparency, accountability, and reasonable security practices and procedures. A data fiduciary is also required to execute confidentiality and non-disclosure agreements with data processors covering data protection and privacy responsibilities. Data principles have been assigned rights over their personal data such as confirmation and access, correction and erasure.

4 Rule 3(2), Intermediaries Rules.
5 Rule 3(1)(a), Intermediaries Rules.
6 Rule 3(1)(d), Intermediaries Rules.
7 Rule 3(2)(b), Intermediaries Rules.
8 Rule 3(1)(d), Intermediaries Rules.
9 Rule 3(1)(i), Intermediaries Rules.

Sharing of personal data and sensitive personal data is permitted in two instances under the HDM Policy. First, personal data processed by a data fiduciary may be shared with a Health Information User **("HIU")** only upon the request made by such HIU after obtaining consent of the data principal.

Secondly, Data fiduciaries may make anonymised or de-identified data in an aggregated form available for the purpose of facilitating health and clinical research, academic research, archiving, statistical analysis, policy formulation, the development and promotion of diagnostic solutions and such other purposes as may be specified by the NHA.

D. Data Security Council of India Privacy Guide for Healthcare, 2021

The Data Security Council of India **("DSCI")** is a non-profit industrial body on data protection in India set-up by NASSCOM India. The DSCI Sectoral Privacy Project to create sector specific guidance material to enable organizations to understand and implement privacy controls. As a part of this initiative, DSCI has formulated the DSCI Privacy Guide for Healthcare **("DSCI Guidance")**. The DSCI Guidance is not binding, however, it's adoption can help organisations to better position themselves to attract new business opportunities and demonstrate compliance to the regulators.

The DSCI Guidance identifies demographic data, administrative data, health risk information and health status as Personal Health Data or Information **("PHI").**[10] PHI may be collected either through provision of traditional healthcare or through ancillary modes such as payment and social support services, remote health services, and daily activities.[11] All healthcare service providers including healthcare professionals, institutions, insurers, pharmaceutical companies and third-party aggregators have been identified as entities required to be in compliance with health data privacy norms.

Recommendations for implementation of regulatory requirements such as proportional data collection, consent management, use and disclosures of health data, security measures and anonymity of personal data have been laid down. In the context of Digital Health, where there are multiple channels of data collection and distribution, the DSCI Guidance aids in visualizing potential scenarios of data breaches and liability under the applicable laws.

10 Page 16, Data Security Council of India Privacy Guide for Healthcare, 2021.

11 Page 13, Data Security Council of India Privacy Guide for Healthcare, 2021.

Intellectual Property

The Digital 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 Digital 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.

A. 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 fulfil three criterion – novelty, non-obviousness and utility. Apart from meeting these requirements, the inventions must also not be specifically excluded from being considered as 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 Digital 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. The Indian Patent Office, however, in its 'Guidelines for Examination of Computer Related Inventions **("CRI Guidelines")**' in 2017, 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 CRI Guidelines. Patents for software programs have been issued in the past where it involves a hardware component as well. If the technology/software fulfils 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[1] 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).

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

B. 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 prima facie 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.

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.

C. 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'.[2]

In terms of Digital 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 has 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.

2 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.

D. 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".[3] 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 trademarks. India follows the NICE Classification of Goods and Services[4], 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 computer software and computer programs".

The 'mark' of a Digital 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 being devoid of distinctive character or marks or indications which have become customary in the current language or established practice of trade[5].

E. Trade Secrets

In a nascent industry such as Digital 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.

3 Section 2(M) of the TM Act.

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

5 Section 9 of the TM Act.

Taxation Regime

The power to levy direct and indirect taxes in India are distributed between the central and state governments. The applicable taxes to Digital Health in India are discussed below:

A. Direct Taxes

The taxation of income in India is governed under the Income Tax Act, 1961 **("ITA")** read with the annual Finance Act. Under the ITA, residents are subject to tax in India on their worldwide income, whereas non-residents are taxed only on Indian source income i.e. income that accrues or arises in India, is deemed to accrue or arise in India or which is received or is deemed to be received in India. A company is said to be resident in India if it is incorporated in India or its place of effective management **("POEM")** is located in India. In this regard, the Central Board of Direct Taxes **("CBDT")** recently released the final guidelines for determination of POEM.

"Capital gains" are considered to have their source in India and are taxable in India if they arise directly or indirectly, through the transfer of a capital asset situated in India. Similarly, the "business income" of a non-resident is taxable in India only if it accrues or arises, directly or indirectly, through or from any business connection in India. The Indian tax rates applicable to non-residents could be up to 40% (all tax rates provided herein are exclusion of surcharge and cess discussed below) on taxable business income and capital gains.[1]

If the taxpayer is situated in a country with which India has a double tax avoidance agreement **("Indian Tax Treaty")**, the provisions of the ITA apply only to the extent that they are more beneficial to the taxpayer.

Resident companies are taxed at the rate of 30% , while non-resident companies are taxed at the rate of 40%. A minimum alternative tax is payable by resident, and in certain circumstances, non-resident companies at the rate of around 15%. The corporate tax rate for domestic companies whose total turnover or gross receipts does not exceed INR 400 million (approx. USD 5.5 million) is 25%.

On December 12, 2019, the Government enacted promulgated the Taxation Laws (Amendment) Act 2019, **("Amendment Act")** by virtue of which domestic companies may choose to be taxed at the effective rate of 25.17% under the newly introduced Section 115BAA of the ITA subject to certain conditions such as (i) total income is computed without claiming certain specified deductions and exemptions under the ITA **('Deductions')**; (ii) the company shall not be allowed to set off any carried forward losses from earlier assessment years if such loss is attributable to the Deductions; (iii) the company claims depreciation in the manner prescribed barring any depreciation in respect of plant and machinery; (iv) once exercised, the option to be taxed under this provision cannot be withdrawn and will continue to apply for subsequent assessment years etc. Further, as per Section115BAB (also introduced through the Amendment Act), a company engaged in the business of manufacture / production of any article or thing and research / distribution of such article or thing **("Manufacturing Company (ies)")** that has been set up and registered on or after October 1, 2019 opts for being taxed at such lower rate provided all the aforementioned prescribed conditions are satisfied.

1 Section 9(1), ITA.

Minimum alternate tax **("MAT")** at the rate of 15% (excluding surcharge and education cess) is also payable on the book profits of a company, if the company's income due to exemptions is less than 15% of its book profits. The MAT rate was reduced from 18.5% to 15%, effective from April 1, 2019, by virtue of the Act. Importantly, the Ordinance also provides that no MAT shall be applicable in case of companies opting to be taxed under section 115BAA.

With respect to 'eligible start-ups' meeting certain specified criteria, a 100% tax holiday for any 3 consecutive assessment years out of a block of 10 years beginning from the year in which such start up is set up has been provided for.

B. Indirect Taxes

The Goods and Services Tax Act 2017 **("GST")** is the primary legislation imposing indirect tax. Earlier, indirect taxes were split between multiple legislations at the central and state levels. The GST has subsumed, inter alia, the following taxes:

a. Service tax,

b. Additional Customs Duty commonly known as Countervailing Duty (CVD),

c. Special Additional Duty of Customs (SAD),

d. Central Sales Tax, and

e. Value Added Tax.

The GST prescribes four tax slabs i.e. 5%, 12%, 18% and 28%.[2] However, health care services provided by a clinical establishment, an authorized medical practitioner or para-medics are exempt from GST.[3]

"Health care services" have been defined as "any service by way of diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicines in India..." However, health care services do not include hair transplant or cosmetic or plastic surgery unless it is undertaken to restore or reconstruct anatomy or functions of body functions affected due to congenital defects, developmental abnormalities, injury or trauma.

The Central GST and the State GST are levied simultaneously on every transaction of supply of goods and services except on exempted goods and services, goods which are outside the purview of GST and the transactions which are below the prescribed threshold limits.

The Additional Duty of Excise or CVD and the Special Additional Duty or SAD earlier being levied on imports have been subsumed under GST. As per explanation to clause (1) of article 269A of the Constitution, Integrated GST **("IGST")** will be levied on all imports into the territory of India.

2 Central Board of Excise and Customs, GST Rates, available at: https://cbic-gst.gov.in/gst-goods-services-rates.html, (Last accessed on May 11, 2023).

3 Department of Revenue, Ministry of Finance Notification NO.12/2017- Central Tax (Rate) available at: http://Cbic.gov.in/Resources//Htdocscbec/Gst/Consolidated_notification_cgst_12.Pdf;Jsessionid=7e8ef98f76eac9c0d2b46bc6a10bb90a., (Last accessed on May 11, 2023).

C. Structuring investments

Foreign enterprises could make investments into the Indian companies through an intermediate holding company set up in a tax friendly jurisdiction i.e. a jurisdiction which has signed an Indian Tax Treaty. 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 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.In the aftermath of the 2008 financial crisis, the Organization for Economic Co-operation and Development **('OECD')** along with the G20 had launched the Base Erosion and Profit Shifting **('BEPS')** project. The primary aim of the BEPS project was to align taxation of income with economic activities that generate them.

As part of the BEPS project, in 2013 the OECD Committee on Fiscal Affairs **('OECD CFA')** released the BEPS Action Plans to counter base erosion and profit shifting, i.e. *'tax planning strategies that exploit gaps and mismatches in tax rules to artificially shift profits to low or no tax jurisdictions where there is little or no economic activity, resulting in little or no overall corporate tax being paid'.* [4]

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

4 OECD (2013), Action Plan on Base Erosion and Profit Shifting, OECD Publishing: http://dx.doi.org/10.1787/9789264202719-en.

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.

A. Suits before a Civil Court

Civil suits could arise out of a breach of contractual obligations between the Digital 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).

Suits may also be brought before civil courts in cases of negligence, which has been explained by the Supreme Court has explained 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."[1] 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 Digital 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."[2] There is no limit to the amount that can be claimed as damages in such cases, provided the damages claimed are consequential in nature.

B. Vicarious Liability

In the provision of Digital 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.

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

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

C. Liability under CPA

CPA provides for the protection of consumer interests and establishes the consumer dispute redressal mechanism. 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. Additionally, the CCPA is empowered to take up consumer cases on its own without the institution of a complaint by a consumer.

The CPA 2019 does not mention healthcare explicitly in the definition of services.[3] The ambiguity arises because even though healthcare is not explicitly included as a service under CPA 2019, it is also not explicitly excluded. The definition of services under CPA 2019 also includes services not explicitly listed out in the definition.

In the past, it has been held that medical services would fall within the ambit of the CPA, provided the patient is being charged for the service[4] therefore making it applicable to Digital Health as well. However, one of the essential elements to a claim under CPA 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[5] 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 commissions, 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[6] have been granted in medical negligence cases.

D. Disciplinary Action by the NMC

A consumer is entitled to raise a complaint with the state medical council of the relevant state against a doctor for ethical or professional misconduct. Consumers or doctors who are aggrieved by the decision of the state medical council also have the right to appeal to the Ethics and Medical Registration Board of the Commission within sixty days of communication of such decision.[7] If aggrieved by the decision of the Ethics and Medical Registration Board, a further appeal to the NMC may be made within sixty days of communication of such decision.

3 PRS Legislative Research, Consumer Protection Bill 2019, available at: https://www.prsindia.org/billtrack/consumer-PROTECTION-BILL-2019, (Last accessed on January 18, 2022).

4 Indian Medical Association v. V. P. Shantha And Ors ,AIR 1996 SC 550.

5 Indian Medical Association v. V. P. Shantha And Ors ,AIR 1996 SC 550.

6 INR 5.9 Crore plus interest; Balram Prasad v. Kunal Saha; (2014) 1 SCC 384.

7 Regulation 8.8 of the MCI Code.

Instances of professional misconduct are specified in the NMC Code, such as non-maintenance of medical records,[8] refusing treatment on religious grounds, performing operations without written consent,[9] 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.

E. 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 Digital 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,[10] act endangering life or personal safety of others,[11] causing hurt by an act endangering life or personal safety of others[12] and causing grievous hurt by an act endangering the life or personal safety of others.[13] 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, 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."[14] 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".[15]

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

8 Regulation 7.2 of the MCI Code.
9 Regulation 7.16 of the MCI Code.
10 Section 304-A of the IPC.
11 Section 336 of the IPC.
12 Section 337 of the IPC.
13 Section 338 of the IPC.
14 Jacob Mathew v. State of Punjab and Anr. (2005) 6 SCC 1.
15 Id.

Current Issues and Considerations

Digital 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. The COVID-19 pandemic has popularized telemedicine and many platforms have emerged in the recent past to enable doctors to render remote healthcare services.

I. Informed Consent

Consent while handling personal data of individuals is one of the most essential compliance requirements under Data Protection law. The personal data of patients that is collected, stored, transferred or processed must be in accordance with the Data Protection law and rules introduced thereunder. The informed consent of the patient/user is an essential requirement before such data is collected or processed by the physician/ telemedicine platform.

II. Reasonable Security Practices and Due Diligence Requirements

The service provider is also required to have a privacy policy and reasonable security practices in place in accordance with the Data Protection law. 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 the Intermediaries Rules.

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. Further, data collected from m-Health applications also has the potential to be used for assessments and research purposes. Therefore, compliance with Data Protection Rules and in the future, the DPB is essential. The privacy policy and terms of use must be aligned accordingly.

Further, 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.

Further, some m-health applications may take form of networking platforms and enable users to interact and share information. In such scenarios, the Intermediaries Rules would become applicable. Along with general compliances to be adopted by intermediaries, networking platforms if considered to be a significant social media intermediary, will have to observe some additional due diligence to maintain status of intermediary to be protected under the IT Act.

C. e-Pharmacies

Regulation of e-pharmacies has been hotly debated. There are multiple challenges to dispensing drugs online under the current framework. In its current form, the D&C Act requires that all drugs must be sold under a license. While there is no specific legal guidance in the context of license for e-pharmacies, the selling, stocking, exhibiting, offering for sale and distribution of drugs requires a valid license as per the D&C Act and Rules. Moreover, a drug can only be dispensed by a registered pharmacist to either the patient or his/her caretaker as per the Pharmacy Act, 1948. These requirements make it difficult for e-pharmacy vendors to dispense drugs.

Additionally, 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.[1] Hence a prescription uploaded online would fulfil 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.[2] 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.

While there is no legal guidance the above-mentioned issues, the Doorstep Delivery Notification provides temporary clarity on this subject. The notification states that drugs may be dispensed "based on receipt of prescription physically or through e-mail" thereby making it easier for online pharmacies to dispense drugs even if the prescription has not been digitally signed.

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.

In August 2018, the Ministry of Health and Family Welfare published draft rules to regulate e-pharmacies under the D&C Rules **("Proposed Rules")**. The proposed amendment will introduce a licensing system for e-pharmacies and permit them to function on par with traditional pharmacies by granting them legal recognition. It also imposes conditions on e-pharmacies, such as requiring them to maintain a confidential

1 Section 4 of the IT Act.

2 Section 5 of the IT Act.

record of prescriptions as well as details of the drugs. E-pharmacies are also required to establish a 24/7 customer support and grievance redressal mechanism, in order to address consumer complaints.

Consumers are empowered to submit complaints with the regulator for violation of the license requirements (including with respect to the quality of drugs dispensed). The regulator can cancel the license of the e-pharmacy if a violation is found, in addition to other penalties prescribed.

After the release of the draft rules, both the Madras and Delhi High Court had passed orders banning online sale of medicines. However, the Madras High Court has since then lifted the ban and directed the Government to notify the draft rules expeditiously. e-Pharmacies in India have not been 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".[3] 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 its CEO.[4] The Madras High Court e-pharmacy case mentioned above was also instituted by the Tamil Nadu Chemists and Druggists Association to prevent e-pharmacies from functioning in the state.

D. MVAs

MVAs are increasingly being adopted to provide health information, guidance, news, first aid and other medical communications. Generally, MVAs may either (i) assist the physician or the hospitals with functions or (ii) aid in the disease management of patients.

In scenario (i), some primary legal issues to be considered is data privacy and protection, consent of the patient for the usage of automated mechanisms in rendering diagnosis and healthcare services and tort law liability for negligence.

In the case of scenario (ii), in addition to the requirements mentioned for (i), compliance with the Telemedicine Practice Guidelines is necessary. As per the Telemedicine Practice Guidelines, only a RMP under the NMC Act is qualified to render telemedicine services. The use of automated means such as AI/ML to directly counsel or prescribe medications is not permitted. Therefore, MVA models aimed at disease management and interim care services must ensure that the final prescription and diagnosis is always rendered through a RMP and the MVA assists with the prognosis and collection of data to facilitate the RMP to arrive at a final decision.

3 '72,000 chemists in Maharashtra to shut shops on Oct 14 against e-pharmacy; FDA asks chemist associations to call off strike'; available at: http://www.pharmabiz.com/NewsDetails.ASPX?AID=91092&SID=1, (Last accessed on May 11, 2023).

4 'Online medicine sales: Are you aware?'; available at: http://www.pharmabiz.com/ArticleDetails.aspx?aid=90368&sid=9, (Last accessed on May 11, 2023).

Recommendations

Digital Health models in India must currently focus on three legal principles- data privacy, compliance with existing regulations and conformity with medical ethics. The COVID-19 pandemic has accelerated the adoption of technologies at an astonishing rate and have therefore necessitated specific laws. However, the difficulty in the enactment of a comprehensive Digital Health specific law in India is the lack of clarity on the potential of the emerging technologies itself. At the present, the inter-disciplinary nature of Digital Health applications will require restructuring of multiple legislations. Some key considerations in this respect:

A. EHR System

The need of the hour is for India to implement a nation-wide framework for the adoption of EHRs. Ancillary services such as telemedicine, e-pharmacies and even the use of big data in healthcare can be put in place once a robust EHR system is in place. Additionally, there is also a need for specific legislations to regulate telemedicine and online pharmacies. The Telemedicine Practice Guidelines are only binding on the healthcare providers practicing allopathic medicine while online pharmacies are operating in the gaps of the law, neither legal nor illegal. Regulating these spaces can encourage stakeholders to make full use of available technologies and ensure that the maximum number of patients are able to benefit from them. 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.

B. E-Prescriptions

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 Digital Health industry is facing today.

C. Technical Reliability and Appropriateness

There are multiple challenges rooted within the technologies itself. Considerations of safety and standardisation of hardware and software is necessary. This will aid in understanding legal aspects of liability and implementation of a licensing system.

D. Ascertaining Role of Patients

Until now, the underlying legal assumption is that healthcare professionals being service providers and patients as consumers. However, in the digital revolution, these lines are blurred and m-health applications, self-diagnostics etc. in fact make patients co-deliverers of healthcare services. In this process, patients may commit errors in reporting data, interpreting advice or may even accidentally interfere with automated measures and transmissions. This can directly contribute to negative outcomes. Hence, the reliability on traditional approaches to liability cannot be imported in this context. Hence, the law must look into aspects of usage standardisation and the conditions of absolving liability of the Digital Health entities in such scenarios.

E. Role of Healthcare Professionals

Currently the MCI Code focuses on the responsibilities which are foreseen in the light of standard consultation and treatment scenarios. However, the ambit of these must be extended to perceive any duties which may arise through the use of digital interventions in standard healthcare. Aspects such as patient informatics, promotion, consent, confidentiality etc. must be legally re-configured to suit the Digital Health Ecosystem.

Conclusion

We are currently in the midst of an "information age" envisaged by Alvin Toffler[1] which is a form of industrialization in which information, expertise, and technology is critical to every industry's growth and success. The present-day digital world is populated by various forms of technologies which contribute to the advancement of the global society. This situation benefits humanity enormously, particularly in the health sector with the advancement of therapies, tests, and new medicines that improve our quality of life and extend our life expectancy, among other things.

The Digital 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 to anticipate and ensure that in the absence of specific laws, how existing laws can be harnessed to adequately regulate emerging technologies.

In a country where access to affordable healthcare is still a looming issue, the public stands to gain immensely from the development of the Digital Health industry. The ABDM is a one-of-a-kind strategy to unify the healthcare system in India and promote innovation in the industry. With the public interest in the minds of both the Government as well as the innovators, it remains to be seen how Digital Health will be perceived in law.

While there is a long way to go, Digital Health has gained a strong foothold in India over the past year and we foresee a promising future for the industry.

1 Alvin Toffler, The Third Wave, 1980.

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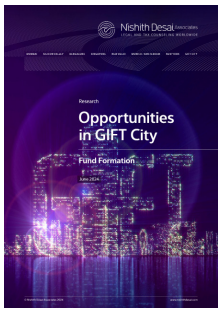

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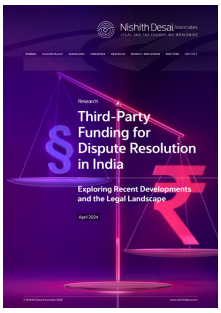

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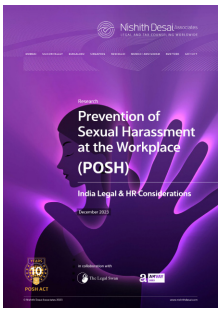

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