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The digital health and medical device revolution in India

With the introduction of new regulations and initiatives such as the Startup India campaign, and more recently the new Medical Device Rules 2017 (GSR 78E) - set to take effect from January 2018 - the Indian Government has made significant steps towards streamlining the development processes that impact digital health. Dr Milind Antani, of Nishith Desai Associates, provides his analysis of the changes taking place, and the impact that they will have going forward.

"I see technology as a means to empower and as a tool that bridges the distance between hope and opportunity. We must ensure that technology is accessible, affordable and adds value," - Shri Narendra Modi, Prime Minister of India.

The Indian healthcare market has been growing at a very healthy pace, and is forecast to grow from $100 billion today to $280 billion by 2020[1]. By then, India is pegged to be the third largest healthcare market in the world[2]. This leap to third place will not be possible without the assistance of two very promising sectors - the advent of digital technologies in healthcare and the development of the medical device sector.

Being a populous nation, access to affordable and quality healthcare in India has always been a challenge. How does one deliver quality services to 1.3 billion people, while also ensuring that those services remain affordable?

Digital technology promises to address this challenge. Economical telecommunication services coupled with increasing smartphone accessibility and adoption has led to connectivity like never before, and is only expected to increase exponentially in the future[3].

The opportunities that digital access has provided has led to innovations that have practically reduced the need to have a physical service provider in many instances, even in areas of healthcare. Riding strong on the wave of this digital revolution is telemedicine, which has been able to utilise the growing network of connected individuals to bring healthcare services closer to home.

Telemedicine in India now offers possibilities far beyond the originally intended video conferencing service. For individuals residing in lesser developed areas without a doctor for miles around, dreaded journeys to the nearest city to visit a clinic have been

significantly reduced, thanks to a more developed telemedicine platform.

From the comfort of one's home, it is now possible to access doctor profiles, book appointments, connect with medical professionals and even be provided with customised services at the patient's residence. The development of technology in the mobile space has even allowed doctors to record and access vital health parameters of a patient without the patient having to visit a clinic. Preliminary advice and investigations take place over the telemedicine platform, and a patient need only visit the doctor physically in case of follow-up treatments where required.

Another emerging area in the technology space is the online pharmacy model, where patients are able to procure medication by uploading a copy of their prescription, the pharmacy then delivers the same to the patient's home. These services have become viable due to

scalability and because they involve less of the costs that usually come with having multiple physical stores.

With the Government's push for innovation through new policies such as the National Intellectual Property Rights Policy of 2016, coupled with incentives for startups such as through the 'Startup India' policy, numerous players have made their debut in the digital healthcare industry. There are many prominent players in the digital healthcare market. Due to the promising nature of these players, the digital health space has also seen large scale investor interest, with companies being provided adequate funding at various stages to scale up their business.

As with most industries, the development of the digital health space is outpacing the growth of its regulatory framework. The legal and regulatory scenario in India is yet to specifically address the nuances and legalities surrounding these digital services. India currently does not have specific legislation that addresses this new area, requiring stakeholders to comply with multiple applicable existing laws, to the extent possible. Certain legislation was drafted at a time when such services were not envisaged as the technology was not yet available.

This is a concern for the digital health industry as compliance with multiple pieces of legislation is a practical difficulty. For instance, telemedicine offers the opportunity to practice across different states in the country, but the official position on the possibility of cross-state practice of medicine is still unclear, as regulators at the state and central level have divergent views. There has also been some debate on the legal validity of prescriptions when scanned and uploaded online, and consequently the legality of dispensing prescription medications on the basis of such prescriptions.

According to the current legal framework, for prescriptions to be considered a valid document when they are transferred electronically - as is the case with

the uploading of a prescription to an online pharmacy - they must comply with the provisions of the Information Technology Act 2000 ('IT Act') and the Drugs and Cosmetics Act 1940 ('D&C Act'). Prescriptions are required by the D&C Act to be signed, while the IT Act requires that electronic documents are authenticated by means of a digital signature, where a law requires for such documents to be signed.

Despite these issues, the industry continues to grow strongly, with more than 200 startups having set up their business in the sector since 2014. Fortunately, the Government has also taken note of the growth of the industry and the need for addressing the regulatory framework to promote this space. In furtherance of this, the Government published guidelines dealing with electronic health record standards[4] in 2016 in an attempt to establish uniform standards for health records across the industry that would also provide interoperability.

The standards also lay down formats for discharge and treatment summaries, and state that patient data stored by a healthcare provider are owned by the patient and held in trust on his or her behalf. These guidelines do not have legal force, and are hence recommendatory in nature. However, the Government is reportedly working on a law to regulate electronic health data which proposes to adopt and enforce these standards.

The Government is also contemplating the setting up of a dedicated authority - the National eHealth Authority ('NeHA') - which, it is proposed, will be entrusted with the development of an integrated health information system, setting eHealth related standards and acting as a nodal authority for enforcing the laws relating to the privacy of the patient[5]. With respect to online pharmacies, the Government constituted a sub-committee to examine the issue of regulating the sale of drugs over the internet. In its report, the sub-committee noted that e-prescriptions could be beneficial for Indian patients, and also recommended the setting up of a national portal to route online

transactions and e-prescriptions, for use by registered retailers and wholesalers. The West Bengal Government has also actively been utilising e-prescriptions using a system of unique registration numbers for patients. Hospitals in West Bengal have reportedly issued over 3 million prescriptions electronically.

India's makeover in the healthcare space does not stop there. The medical device industry has also had a very eventful and progressive year. Presently valued at $5.2 billion in India, it is expected to grow to $50 billion by 2050[6]. As certain medical devices were placed in the same category as pharmaceutical products, the sector faced regulatory difficulties due to this lack of a separate set of regulations to specifically govern such products. However, this is set to change with the introduction of the new Medical Device Rules 2017 (the 'Rules')[7], which are slated to take effect from 1 January 2018.

The new Rules will bring necessary clarity to the medical device industry, promoting the ease of doing business in India. The Rules contemplate the creation of a risk-based classification system, ranging from low risk (Class A) to high risk (Class D). The classification of the medical device makes a material difference, as the compliance requirements increase the higher the risk of the device. Many previously unregulated devices are expected to be regulated under the new Rules in some way. Apart from the device itself, the Rules also intend to regulate certain software that is used in the device. While certain countries allow for medical device manufacturers to self-classify, the Indian regulatory authorities have opted to classify the medical device products for the industry.

To further ease compliance, the new Rules provide for a single window system of clearance through an online portal intended to be set up by the central Government. There will also be more clarity in relation to the standards to be followed, with the new Rules allowing for compliance with specified international standards, the manufacturer's own validated standards in certain cases,

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and standards issued by the Bureau of Indian Standards. Another improvement that would ease the burdens on business in India is the rationalisation of timelines. Fixed timelines have been prescribed, and where changes in licensed particulars are identified and not responded to within the specified timeframe, they will be deemed granted. This ensures that decisions on licence applications are made in a timely manner, allowing for better business planning.

The regulatory scheme for clinical trials for medical devices will also be overhauled, with the new Rules providing a separate framework for regulating the clinical investigation of medical devices in India. Pilot and pivotal studies will now be introduced, along with clinical performance evaluation of In-Vitro Diagnostic devices.

The Rules are a great respite for the industry, which had previously made multiple calls for separate regulations for medical devices. As with much nascent legislation, the new Rules do suffer from certain imperfections however. The transition from the current regulatory framework to the new one may not be an entirely smooth process as there is no clarity on how pending applications will be dealt with when the implementation date of the new Rules kicks in. Licences granted under the current regulatory framework will continue to be in force for a period of 18 months or until the licence expires, whichever is earlier. However, it is unclear how applications made while

the current framework is applicable but pending the implementation of the new Rules will be dealt with.

With the introduction of the new Rules, all devices that fall within the Rules will also be subject to price control. This will be bittersweet for players in the industry, as the prices of their products may be capped, but it also brings certainty in regards to the manner in which prices are fixed for medical devices. Recently, the Government has come down hard on manufacturers of coronary stents[8] and knee implants[9], placing price caps on both the cost as well as the amount of permissible trade margin on these medical devices, which are currently deemed to be drugs under the current regulatory framework. While there has been fallout to these actions, the Rules will bring about more certainty and structure to the process of price fixation for medical devices.

While the Rules are expected to come into effect from the start of next year, it remains to be seen if this will be possible in practice. The process of risk-based classification is still ongoing, and the regulators are currently discussing draft classifications with the industry[10]. While the timely implementation of the new Rules is expected, there is the possibility that the implementation of the Rules may be deferred. However, most industry players have begun their preparations for adoption and compliance with the new Rules, in the hope of a smooth and seamless transition.

Once the Rules come into force, they are expected to change the face of the medical device industry in India. The Government is also pushing for local manufacturing of medical devices, with multiple medical device parks being set up around the country offering incentives for medical devices to be manufactured in those locations. These incentives, along with the larger 'Make in India' movement, have made local manufacturing a lucrative option for new and existing players to set up their manufacturing plants within India. This will help in reducing India's dependence on imported medical devices, and will also bring down the costs of those devices. The ultimate beneficiary of all of these reforms will effectively be the patient. With reduced costs, critical medical devices will be accessible to a larger number of patients.

With the 'Digital India' and 'Make in India' initiatives, along with multiple other positive policies and regulatory reforms that have been introduced in the recent past, it is clear that India's evolution will benefit all industries, including the digital health and medical device industries. In the coming year, a lot of development in both spaces is expected. All stakeholders, from patients to manufacturers, are eagerly hoping that the healthcare revolution continues its momentum in the coming year. With multiple reforms in the pipeline, 2018 promises to be an exciting time for both the digital health and medical device sectors in India.

1. India Brand Equity Foundation, Healthcare Industry in India, Sectoral Report: September 2017, https://www.ibef.org/industry/healthcare-india.aspx

2. Make in India, Sector overview: Pharmaceuticals, http://www.makeinindia.com/sector/pharmaceuticals

3. Livemint, Number of Internet users in India could cross 450 million by June: Report (2 March 2017), http://www.livemint.com/Industry/QWzIOYEsfQJknXhC3HiuVI/Number-of-Internet-users-in-India-could-cross-450-million-by.html

4. Ministry of Health and Family Welfare Circular Electronic Health Record (EHR) Standards (30 December 2016), https://www.nhp.gov.in/NHPfiles/EHR-Standards-2016-MoHFW.pdf

5. National Health Portal: National eHealth Authority (NeHA), https://www.nhp.gov.in/national_eHealth_authority_neha_mtl

6. Make in India: Sector Survey: Medical Devices, http://www.makeinindia.com/article/-/v/sector-survey-medical-devices

7. Ministry of Health And Family Welfare, G.S.R. 78(E) (31 January 2017), http://egazette.nic.in/WriteReadData/2017/173925.pdf

8. National Pharmaceuticals Pricing Authority, Order S.O 412(E) (14 February 2017), http://www.nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf

9. National Pharmaceuticals Pricing Authority, Order S.O 2668(E) (16 August 2017), http://www.nppaindia.nic.in/order/order_knee_160817.pdf

10. Central Drugs Standard Control Organization, Notice (29 June 2017), http://www.cdsco.nic.in/writereaddata/notice%2029_6_2017.pdf