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Indian industry and regulators embrace the digital wave

A number of initiatives and developments signify that the Indian Government is keen to be involved in pushing the health sector towards going 'digital'; for instance the National Pharmaceutical Pricing Authority ('NPPA') has released the Pharma Sahi Daam app, which assists the public in accessing information about drug pricing in India. Darren Punnen, Anay Shukla and Dr Milind Antani of Nishith Desai Associates describe how Indian patients, industry and regulators are embracing digital.

With reports stating that 75% of patients expect to use digital services in the future, the future of healthcare is in the online space. Given the significantly increasing digital footprint of the patient population, neither pharmaceutical companies nor regulators can afford to be on the sidelines while this fast-evolving digital revolution unfurls.

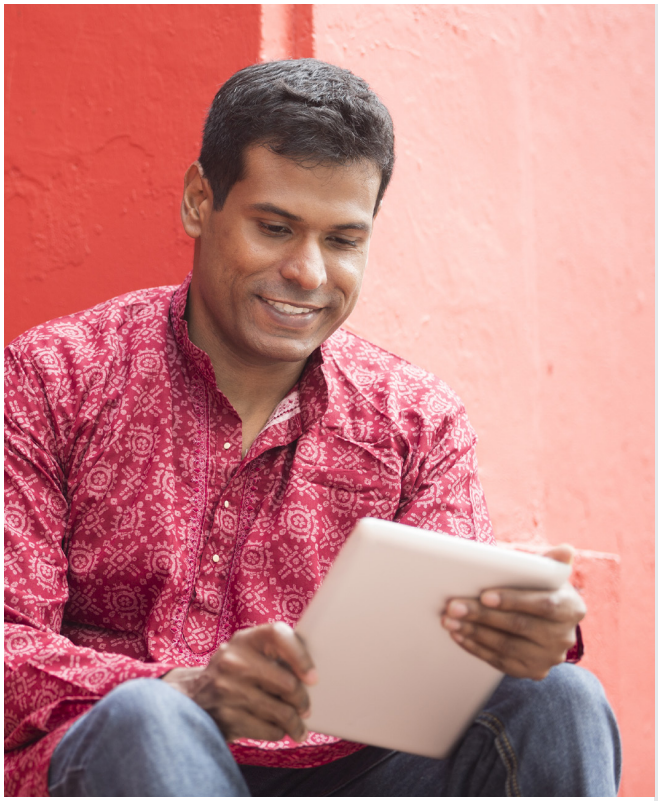
'Pharma Sahi Daam' by the NPPA - the apex authority that regulates the price of medicines in India - was a step in the right direction. This app is an extension of the web platform set up to bring about awareness and access to the price of scheduled drugs in India. While the platform was very useful to the public, especially in the early stages of the implementation of revised ceiling prices of drugs, the app will go a long way to increase the accessibility of this information. Essentially, a patient can now cross-check the price of drugs from within the pharmacy on his/her mobile phone, and simultaneously report cases of overcharging from within the app. The app is not only useful for patients, but also to the distributors and retailers who are able to easily report cases of denial of supply of pharmaceuticals, which is a contravention under the current Drugs (Price Control) Order 2013. While the app is currently available only on Android, an iOS version is expected soon.

The NPPA has also implemented an Integrated Pharmaceutical Database Management System, which provides for the online submission of applications and forms to the regulator. This becomes essential in the case of pharmaceuticals under price control, as the NPPA is now able to determine average market prices of drugs on a real-time basis and with more comprehensive data, which becomes necessary with the Drug Price Control Order ('DPCO') having moved from a cost-based pricing model to a market-based price control model.

The much-needed push to go online has come from multiple Government initiatives, including the 'Digital India' initiative by the Ministry of Electronics and Information Technology, with a vision to "transform India into a digitally empowered society and knowledge economy." Various Government departments are already working on ensuring that e-governance becomes a reality in India. Government initiatives have sought to further their ultimate objectives, which are to provide access to quality healthcare to all members of the public. One such major initiative is the proposal to set up a National e-Health Authority ('NeHA'). NeHA is proposed to be a promotional, regulatory and standards-setting organisation to guide and support India's journey in eHealth and its consequent realisation of the benefits that come with the use of ICT. The Authority is also involved in drafting certain legislation that is required to take the Indian healthcare sector digital. Along with this, NeHA is also working towards the harmonisation of the Electronic Health Record Standards, in order to ensure its interoperability as well as confidentiality and privacy.

State governments are also playing an active role. The Gujarat Government has started 'E-Olakh' - the primary aim is to maintain a database of birth and death records and issue birth and death certificates. The Chhattisgarh Government, with the help of the Indian Space Research Organisation ('ISRO'), has linked Government medical colleges at Raipur and Bilaspur, which have in turn been linked with premier hospitals across the country, creating a state-wide network. 30 such nodes have also been set up in Karnataka in collaboration with the ISRO. The ISRO is also deploying telemedicine nodes under the 'gramsat scheme.' Along with various state governments, the ISRO has managed to establish a vast telemedicine network of 225 hospitals that are connected to 40 super specialty hospitals.

For pharma, the opportunities are immense. Apart from the ease of doing business that going online inherently provides, convenience seems to be one substantial selling point. Regulatory authorities such as the Central Drugs Standard Control Organisation ('CDSCO') have initiated the process of allowing clinical trial submissions to be made online. Paperless applications are also envisaged in the draft Medical Devices Rules 2016 - the proposed legislation that will govern medical devices in India - wherein all applications and forms will be done purely on an online basis. Making use of the current trends in the market could also help companies achieve better data collection and analytics. For example, wearable technology that can monitor the vitals of a patient can help researchers understand the effect of their products better, as they are now able to monitor and collect medical



information of the patient on a real-time basis and for extended durations, such as changes that occur while the patient is sleeping. Access to comprehensive data is one of the biggest advantages that is available to the pharma sector, helping with efficiency and costs in the long-run.

The overlap of benefits for patients as well as the healthcare and pharmaceutical industry can clearly be seen with the various eHealth applications that are being introduced into the market, with telemedicine turning out to be an emerging space. Patients who would generally not have access to quality healthcare due to location constraints are now able to consult with specialists from within their own homes. At the same time, the patient pool that is accessing healthcare facilities will see a boom, and with it opportunities for pharma and healthcare companies to expand and fill the upcoming deficit. The scope of services are also constantly expanding with developments in technology, with new facilities such as robotic surgery, self-monitoring healthcare devices, electronic health records, etc.

It is up to players in the pharma sector to hitch themselves onto the digital bandwagon to create a strong presence in the area. Both regulators and companies have already initiated the process, with some areas having grown in leaps and bounds. Patients have already made it amply clear that they are willing to move online, so the ball is now in the service provider's court.

European Commission launches consultation on Health Technology Assessments

The European Commission launched a public consultation on strengthening cooperation on Health Technology Assessments ('HTAs') across EU Member States on 21 October 2016, which aims to gather stakeholder views on the approach proposed in the Inception Impact Assessment. The Commission's consultation is part of the broader ongoing challenge facing healthcare globally concerning access to new medical technologies and medicines, set against the need to control healthcare costs.

HTAs are seen as a key tool for EU Member States to ensure the sustainability of national health systems and access for patients to medical technologies, and they also create an incentive for companies to innovate by rewarding technologies with high 'added value' against criteria underlying health technology assessments on cost-effectiveness. An additional complexity faced in the EU - which the Commission seeks to address - is the fact that the methodology for HTAs varies as the healthcare systems in the EU/EEA are not harmonised, which often results in divergent HTA evaluations and ultimately impacts patient access to innovative health technologies.

"There have been ongoing discussions since the early 2000s at an EU level to identify the path forward to harmonise the approach to HTAs applied by various national authorities so that EU patients can have equal access to new medicines and new medical technologies," explains Dr Lincoln Tsang, Partner at Arnold & Porter. "This consultation seeks to engage a broader group of stakeholders to solicit their views on whether there is an opportunity to harmonise the approach to HTAs, i.e. the added value of a new technology for it to be accessed. The consultation does not seek to interfere with the national competence to regulate pricing and reimbursement policy which remain national and should be governed by national laws or policies under the so-called 'subsidiarity' principles."

There is already exchange of HTA methodologies and outcomes through EUnetHTA and the HTA Network under the Joint Action EUnetHTA. However, the lack of 'binding mechanisms for mutual recognition of joint assessments' is seen as one of the major shortcomings of EUnetHTA. "Although it is unclear at the moment what role, if any, the UK, outside of the EU, will have in future HTA cooperation at the EU level, there is a growing recognition of the significant benefits of HTA cooperation at international level. The World Health Organisation has urged its members to develop and apply HTA and to strengthen inter-country collaboration to obtain efficiencies," said Helen Cline, Legal Director at Pinsent Masons LLP. "Closer cooperation on HTA across Europe and internationally would reduce duplication of efforts for HTA bodies and industry and lead to convergence in HTA procedures and methodologies. A rebalancing of the current fragmented HTA system is also needed to promote the best possible outcomes for patients."