Pharma & Healthcare Update

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MID-YEAR UPDATE: DIGITAL HEALTH IN INDIA

INTRODUCTION

As the momentum to digitize the healthcare system in India continues to grow, the Government has been keeping up pace to catalyse the transition. The Ayushman Bharat Digital Health Mission ("**ABDM**")[1] remains on top of the list in the transformation of the digital healthcare landscape and has seen even more progress in its implementation this year. Over 21 crores of health IDs have been issued under the ABDM till date.[2] In January 2022, with the launch of the ABDM Unified Health Interface, digital health companies and other participating entities have been given the green signal to build their services on top of it.

A snapshot of the key developments from the first half of 2022 in the digital health space is captured below.

DRAFT HEALTH DATA RETENTION POLICY UNDER ABDM

In December 2021, the National Health Authority ("**NHA**") released a Consultation Paper on Proposed Health Data Retention Policy[3] to govern the processing of personal data and sensitive data within the National Digital Health Ecosystem ("**NDHE**") under the ABDM. In pursuance of the comments received from the industry and public [*our comments are accessible here*], in April 2022, the NHA released a Draft Health Data Retention Policy ("**HDRP**")[4] for further consultation.

The HDRP largely retains the essence of the proposed governance structure envisaged in the original consultation paper. It seeks to create uniform principles for the retention, use, storage and accessibility of health data in line with international best practices. At the present, the HDRP only proposes to govern the data fiduciaries, data processors, Health Information Providers, Health Information Users and repositories to operate in the NDHE.

Once operational, the HDRP will serve as a guidance document for ABDM operators and should be read in consonance with general laws on data protection including the Information Technology, 2000 and Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011. The current version of the HDRP is also largely aligned with the proposed framework for data protection- the Draft Data Protection Bill, 2021. However, the HDRP addresses certain key industry-specific aspects with respect to health data such as sharing of de-identified or anonymised health data for health and clinical research; privacy by design for maintenance of electronic health records; obtaining consent through health information manager (consent manager under ABDM) etc.

CONSULTATION PAPER ON DRUG REGISTRY UNDER ABDM

In March 2022, the NHA released a Consultation Paper on Drug Registry[5] ("**Consultation Paper**") under the ABDM. The Proposed Drug Registry is intended to be a single, up-to-date, centralized repository of all the drugs across all systems of medicine (although initially only applicable for allopathic drugs) within the NDHE. The Drug Registry application is proposed be designed using open-source technologies and will be interoperable.

The concept of the Drug Registry was originally introduced through the National Digital Health Mission Blueprint in 2019.[6] The Drug Registry will be a one-stop shop for data on generic drugs, branded drugs and individual units of drugs. The data proposed to be disseminated through this application includes composition details, dosage, manufacturer's name, license details, package details, classification and schedule of drugs (as per the Drugs and Cosmetics Act, 1940 framework). Initially this the Drug Registry will be populated by data from sources like government hospitals, regulators, databases (SUGAM, IPDMS etc.), and eventually by private parties. This data will be used to aid the issue of prescriptions, insurance companies to cross-check claims and pharmacies track logistics. It would also enable the public to verify details of drug prescriptions through a public portal.

At the present, the Consultation Paper does not clarify whether medical devices data is to be included in the proposed Registry.

RAJYA SABHA ON E-COMMERCE IN PHARMACEUTICAL INDUSTRY

In June 2022, the Parliamentary Standing Committee on Commerce submitted its Report on Promotion and Regulation of E-Commerce in India, 2022[7] ("**E-Commerce Report**"). While noting the growth of the e-pharmacies in India, the Report expresses concern over possible misuse of such avenues for distribution of illegal or unethical medicines or outdated, substituted, or counterfeit medications amid the absence of regulations.

In 2018, an amendment to the Drugs and Cosmetics Rules, 1945 ("**Draft E-pharmacy Rules**") were published to

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introduce specific regulations for e-pharmacies in India. Subsequently, the COVID-19 pandemic took over and the Draft E-Pharmacy Rules took a setback. However, the Draft E-pharmacy Rules have not been finalised till date. At the present, the E-Commerce Report notes that such undue delay is not conducive for the fast pace digital markets and that the Draft E-Pharmacy Rules should be finalised and implemented without further delay.

E-SANJEEVANI AND ABDM INTEGRATED

Recently, the NHA announced the integration of eSanjeevani - India's National Telemedicine Service launched by the Ministry of Health and Family Welfare ("**MoHFW**") ABDM.[8] It enables the existing users of eSanjeevani to create their Ayushman Bharat Health Account ("**ABHA**") and link it to their existing health records. This is a positive step in collating and digitizing health data of individuals in India. The users would also be able to share their health records with doctors on eSanjeevani which will help in better clinical decision making and ensuring the continuity of care.

CONCLUSION

The Indian digital health market continues to command the favour of the Government. The ABDM presents a multitude of opportunities for emerging and established industry players. Even in the absence of sector-specific laws, the existing laws can be harnessed to adequately regulate this space. While the policies and systems introduced under the ABDM have limited scope today, industry-wide enforcement may be reasonably anticipated, and therefore the ABDM serves as the forerunner to tomorrow's digital health laws.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

[1] An overview of developments in ABDM in 2021 is provided here:

https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Digital_Health_in_India.pdf (Last

accessed on June 24, 2022).

[2] Press Release Dated April 5, 2022, accessible at:

https://pib.gov.in/PressReleasePage.aspx?PRID=1813660 (Last accessed on June 24, 2022).

[3] Accessible here:

https://abdm.gov.in:8081/uploads/Consultation_Paper_on_Health_Data_Retention_Policy_21_28557f9a6a.pdf

[4] Accessible here:

https://abdm.gov.in:8081/uploads/Draft_HDM_Policy_April2022_e38c82eee5.pdf (Last accessed on June 24, 2022).

[5] Accessible here:

https://abdm.gov.in:8081/uploads/Drug_Registry_Consultation_Paper_092e75a15e.pdf (Last accessed on June 24, 2022).

[6] Accessible at:

https://main.mohfw.gov.in/sites/default/files/Final%20NDHB%20report_0.pdf (Last accessed on June 24, 2022).

[7] Accessible at:

https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/159/172_2022_6_14.pdf (Last accessed on June 24, 2022).

[8] Accessible at: https://pib.gov.in/PressReleasePage.aspx?PRID=1830743 (Last accessed on June 24, 2022).

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