August 2022 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments in the Indian healthcare ecosystem.

Guidelines for healthcare institutions for the implementation of the Ayushman Bharat Digital Mission

On August 22, 2022, the National Health Authority had issued hardware guidelines for healthcare institutions like hospitals, clinics and health and wellness centres to promote digitisation in hospitals (the "**Digitisation Guidelines**"). The Digitisation Guidelines provide a basic framework to states/union territories for planning, assessing and procuring of information technology hardware (including specifications of various hardware equipment) to operate applications compliant with the Ayushman Bharat Digital Mission. The Digitisation Guidelines are recommendary in nature, and the local governments have the flexibility to modify them based on local requirements and circumstances.

The use of Ayushman Bharat Digital Mission in healthcare institutions offers many advantages. The latest technologies will replace the time-consuming and laborious manual approach, which results in a highly coordinated and organised treatment process. Patients' data is also secured on systems which are always recoverable. The organised process further enables healthcare workers to provide better and more efficient care to patients. Moreover, medical errors due to manual data entry will get eliminated with the adoption of a digital healthcare ecosystem.

The digital ecosystem will also enable a host of other facilities like teleconsultation, paperless health records, QR code-based outpatient department registrations, etc. The Digitisation Guidelines are available at https://abdm.gov.in:8081/uploads/Hardware_Guidelines_ABDM_e162cf7a7b.pdf.

Guidance Document for Implementing Laboratory Services

On August 5, 2022, the MoHFW, had issued the guidelines for implementing laboratory services (the "**Guidance Document**"). For the effective implementation of the services, its components, such as the list of tests provided at health facilities, gap analysis of existing equipment, operational model, supply chain, procurement, human resources, quality control and data management are required to be robust. The Guidance Document recommends an expanded range of diagnostics at all levels of public health facilities providing for a minimum set of essential diagnostic tests in accordance with the essential diagnostic list. The guidelines issued therein pertain to the '*Free Diagnostics Service Initiative*' ("**FDSI**") programme under the National Health Mission launched in July 2015 with the aim to provide accessible and affordable pathological and radiological diagnostics services closer to the community which in turn reduces out-of-pocket expenditure.

Under the National Heath Mission, FDSI is delivered through various modes such as (a) in-house; (b) public private partnership; and (c) hybrid mode by the States/UTs across the country. Free laboratory services are operational in 33 (thirty-three) states/union territories, out of which 11 (eleven) states/ union territories provide the services via the in-house mode. Similarly, free tele-radiology service is operational in 11 (eleven) states/union territories via the in-

house mode. The Guidance Document is available at https://www.nhm.gov.in/New_Updates_2018/NHM_Components/Health_System_Stregthening/Comprehensive_primary_health_care/letter/Guidance_document_for_Free_Laboratory_Services.pdf.

Revised Guidelines for the Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices

On August 18, 2022, the Department of Pharmaceuticals, Ministry of Chemical and Fertilizers revised the guidelines for the Production Linked Incentive ("**PLI**") Scheme for Medical Devices (the "**Revised PLI Scheme**") originally issued on July 21, 2020 (and thereafter revised on October 29, 2020). The Revised PLI Scheme provides for a financial incentive to approved medical device manufacturers to help boost domestic manufacturing and attract large-scale investment in medical device segments.

As part of the Revised PLI Scheme, applications have been invited for the medical devices classified into 2 (two) categories i.e., Category A and Category B. Category A products comprise of rotational cobalt machine, linear accelerator (LINAC), CT scan, MRI, dialyzer, anesthesia unit ventilators, heart valves, stents, etc. On the other hand, Category B products include brachytherapy systems, radiotherapy simulation systems, cyclotrons, needles-anesthesia, syringes-anesthesia, anesthesia kits, cochlear implants, spinal and neuro-surgical implants, etc. The classification of eligible products under both the categories (i.e., Category A and Category B) is made based on the 4 (four) segments they cater to. These are: (a) cancer care / radiotherapy medical devices; (b) radiology and imaging medical devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices; (c) anesthetics and cardiorespiratory medical devices including catheters of cardio respiratory category and renal care medical; and (d) all implants including implantable electronic devices.

Any application either under Category A or category B can be made by a global manufacturing company. Differing turnover thresholds are prescribed for the 2 (two) aforementioned categories which are as follows: (a) for applicants to be eligible under Category A, the company and/or the group company's turnover for the financial year ended 2018-19 must be INR 60,00,00,000 (Indian Rupees sixty crore) or above; and (b) in order to be eligible to apply for under Category B, the turnover of the company and/or the group company for the financial year ended 2018-19 must be INR 20,00,00,000 (Indian Rupees twenty crore).

For applicants eligible to apply under Category B of the Revised PLI Scheme, the applications can be filed between September 1, 2022 and October 31, 2022.

The Revised PLI Scheme is available at https://pharmaceuticals.gov.in/sites/default/files/Revised%20Guidelines%20of%20PLI%20Medical%20Devices%20dated%2018.08.2022.pdf

Acknowledgment of the Success of AI-based technologies Deployed Under Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana

On August 2, 2022, the MoHFW in a press release unfolded its zero-tolerance approach to any kind of fraud under the Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana ("**AB-PMJAY**"). The Government of India adopts a pro-active approach towards dealing with fraud and abuse. MoHFW has underscored several countervailing strategies that have been employed under the AB-PMJAY to address various types of fraud and further, acknowledges the success of the artificial intelligence-based technologies deployed under the scheme.

The National Health Authority is the implementing the agency of AB-PMJAY which has issued a comprehensive set of anti-fraud guidelines. The feature of Aadhar-based biometric verification of beneficiary at the time of admission and discharge has been launched at all private hospitals. The MoHFW noted that the use of artificial intelligence and machine learning has provided a comprehensive fraud analytics solution to detect fraud pro-actively, develop algorithms that can be used on large volume of data to identify suspect transactions and entities and risk scoring of hospitals and claims.

Healthcare Practice

JSA provides a full range of transactional and advisory services in the healthcare sector. We represent clients in the entire spectrum of the health care system, including, hospital networks and individual hospitals, managed care organisations, health insurers, pharmaceutical and biotechnology companies, medical device manufacturers; and major financial investors in the sector. These include domestic as well multinational clients. Our clients in the sector range from start-ups to industry leaders. We also represent the leading trade associations representing these industries, namely, Centre for Scientific & Industrial Research, Centre for DNA finger printing & Diagnostics, Institute of Microbial Technology, All India Institute of Medical Science-Department of Biotechnology, National Institute of Health & Family Welfare, etc.

JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

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14 Practices and
23 Ranked Lawyers

15 Practices and
18 Ranked Lawyers

7 Practices and
2 Ranked Lawyers

IFLR1000 India Awards 2021

10 Practices and
34 Ranked Partners

Banking & Finance Team
of the Year

Fintech Team of the Year

Restructuring & Insolvency
Team of the Year

Among Top 7 Best Overall
Law Firms in India and
10 Ranked Practices

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13 winning Deals in
IBLJ Deals of the Year

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6 A List Lawyers in
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Banking & Financial Services
Law Firm of the Year 2022

Dispute Resolution Law
Firm of the Year 2022

Equity Market Deal of the
Year (Premium) 2022

Energy Law Firm of the Year 2021

Ranked #1
The Vahura Best Law Firms to
Work Report, 2022

Top 10 Best Law Firms for Women
in 2022

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