July 2022 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem. In July, several guidelines were issued dealing with In-Vitro Diagnostic Medical Devices. The Ministry of Health and Family Welfare ("**Ministry**") has introduced draft standards for accessibility of the healthcare system to all, especially persons with disabilities. The Ministry has also sought stakeholders' suggestions on the draft Medial Devices and Cosmetics Bill, 2022.

Draft Accessibility Standards for Healthcare

On June 2, 2022, the Ministry released the Draft Accessibility Standards for Healthcare, 2022 ("**Accessibility Standards**") with an intent to ensure that healthcare and public spaces remain accessible to all, especially to persons with disabilities. It aims to ensure that individuals with physical, auditory, speech, visual, cognitive, and mental disabilities have equal and seamless access to healthcare facilities.

The Accessibility Standards comprehensively deal with potential barriers to access healthcare in an egalitarian manner and attempts to address these barriers by devising detailed frameworks for delivering accessible healthcare. Broadly, it includes measures for creating accessible facilities, such as: (a) accessible outdoor patient and emergency department; (b) accessible indoor patient department; and (c) accessible medical equipment and furniture.

Guidance on performance evaluation / external evaluation of in vitro diagnostic medical devices

On July 7, 2022, the Central Drugs Standard Control Organisation ("**CDSCO**"), Directorate General of Health Services, Ministry, Government of India, released a Guidance Document on Performance Evaluation / External Evaluation of In Vitro Diagnostic Medical Devices ("**IVD Guidance Document**") for public comments. The objective of the IVD Guidance Document is to facilitate the manufacturers/ importers / testing laboratories (*to whom the guidance document applies*) of in vitro diagnostics medical devices ("**IVD MDs**") in India and sensitize them regarding performance evaluation / external evaluation of IVD MDs.

The IVD Guidance Document deals with evaluation of IVD MDs, utilized to conduct diagnostic tests to ascertain specific details about a person's health, or possible ailments. It comprehensively deals with the standards to be followed for testing, safety, dispatch, storage, recording of result, disposal of samples and storage of results.

Guidance on stability studies of in-vitro diagnostic medical device

On July 7, 2022, the CDSCO released a Guidance document on stability studies of in-vitro diagnostic medical device ("**SS Guidance Document**") for public comments. The SS Guidance Document provides instructions and guidelines for manufacturers and importers of IVD MDs, specifically with respect to shelf life, and the in-use stability of the IVD MDs.

The CDSCO strongly encourages manufacturers to follow the SS Guidance Document when submitting Class C and Class D IVDMD license applications and post approval change applications. Based on the purpose for which they are used, IVD MDs are classified as (i) low risk- Class A; (ii) low moderate risk- Class B; (iii) moderate high risk- Class C; and (iv) high risk- Class D. The SS Guidance Document contains an array of mechanisms to ensure and ascertain the stability of the IVD MDs.

Guidance on post-market surveillance of in-vitro diagnostic medical device

On July 7, 2022, the CDSCO released a Guidance document on post-market surveillance of in-vitro diagnostic medical devices ("**Surveillance Guidance Document**") for public comments. The Surveillance Guidance Document seeks to ensure that after having put the IVD MDs into the marketplace, their safety features and adequate functionality are complied with. This would be relevant for all persons who import, distribute, manufacture or use IVD MDs.

The Surveillance Guidance Document provides an in-depth analysis as to which complaints may be identified, detailed guidance into the types of tests that may be carried out, along with standards of harm or detriment to those undergoing such tests. This ensures compliance with rigorous standards of post-market success of the IVD MDs. It also provides checklists for the ascertaining of incorrect test results, standards of adverse events, incorrect manufacturer instructions, responsibilities of manufacturers, and other such specifications to ensure adherence to quality checks.

The Drugs, Medical Devices and Cosmetics Bill, 2022

On July 8, 2022, the Ministry released a draft of the Drugs, Medical Devices and Cosmetics Bill, 2022 ("**Bill**"). The Bill seeks to overhaul the existing Drugs and Cosmetics Act, 1940, which is the primary legislation dealing with the regulation of drugs, medical devices and cosmetics in India.

The Bill has been drafted on the basis of recommendations of an eight-member panel headed by the Drugs Controller General of India with the stated objective of "*consolidating all laws relating to the import, manufacture, distribution and sale of drugs, medical devices and cosmetics to ensure their quality, safety, efficacy, performance and clinical trial of new drugs and clinical investigation of investigational medical devices….*".

It has been published for public comments to be given until August 22, 2022. For detailed analysis of the Bill, please refer to the JSA Prism of July 15, 2022.

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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23 Ranked Lawyers

15 Practices and
18 Ranked Lawyers

7 Practices and
2 Ranked Lawyers

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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
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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

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