November 2023 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the month of November 2023.

Regulatory updates

Release of the draft National Pharmacy Commission Bill, 2023

The Ministry of Health & Family Welfare ("**MOHFW**") has released the preliminary National Pharmacy Commission Bill, 2023, with the intention of revoking the Pharmacy Act of 1948 and substituting the Pharmacy Council of India with a nationwide commission. On November 14, 2023, the MOHFW published the draft bill on its website, inviting feedback from the general public and stakeholders. The proposed legislation seeks to establish a pharmacy education system that enhances the accessibility of quality and cost-effective pharmaceutical education, ensures the presence of sufficient and high-calibre pharmacy professionals across the entire nation, advocates for fair and inclusive healthcare, and facilitates the accessibility of pharmacy professionals' services to all citizens.

Interesting Reads

CDSCO launches an enforcement initiative to tackle inadequate drug manufacturing practices in India.

The Central Drug Standard Control Organisation ("**CDSCO**") in India has launched a significant enforcement campaign to address substandard manufacturing practices, extending measures to include pharmaceutical manufacturers, public testing labs, and clinical research organizations. Recent enforcement actions, prompted by the last risk-based inspection in 2016-17, aim to uphold 'good manufacturing practice (GMP) standards across a variety of medicines. This nationwide effort is a collaborative operation between the central government and state authorities. India, historically a global pharmaceutical manufacturing hub, is now urged by the government to enhance manufacturing process standards to sustain its vital role in meeting global medicinal needs.

'Project Collaboration Agreement' on Traditional & Complementary Medicine Signed by Ministry of Ayush and WHO

The Ministry of Ayush and the World Health Organization ("**WHO**") formalized a 'Project Collaboration Agreement' focused on Traditional and Complementary Medicine. The primary goal of this accord is to standardize traditional and complementary medical systems, incorporate their quality and safety aspects into the National Health System, and promote their dissemination on the global stage. In pursuit of this objective, the WHO, with the support of the Ministry of Ayush, will formulate the Traditional Medicine Global Strategy 2025-34.

India and Netherlands strengthen collaboration on medical product regulation and quality enhancement by signing a Memorandum of Intent

India and the Netherlands have entered into a Memorandum of Intent (MoI) to collaborate on the regulation of medical products, aiming to improve the quality of healthcare services and medical products in both nations. The MoI was formalized during the second World Local Production Forum (WLPF) meeting from November 6 to November 8, 2023, in the Netherlands. The World Local Production Platform, initiated by the WHO, focuses on enhancing access to medicines and other health technologies.

Establishment of "US FDA - Telangana DCA Regulatory Forum" for future collaborative strategies

In a landmark move to strengthen pharmaceutical regulation, the United States Food and Drug Administration (US FDA) recently held a meeting with officials from the Drug Control Administration (DCA) in Telangana, India. The 2 (two) regulatory bodies discussed various initiatives aimed at upholding stringent standards for the production and quality of drugs and medicines across the pharmaceutical, biotechnology, and allied industries. Representatives from the US FDA India Office proposed the establishment of a "US FDA – Telangana DCA Regulatory Forum" to foster ongoing collaboration and strategic partnerships. The primary objective of this proposed forum would be to delve into the intricacies of observed inspections, enabling DCA Telangana inspectors to participate as observers in US FDA-led inspections.

Renaming of Ayush Bharat Health and Wellness Centres

The central government has opted to rechristen the current Ayushman Bharat Health and Wellness Centres (AB-HWCs) as 'Ayushman Arogya Mandir,' accompanied by the tagline 'Arogyam Parmam Dhanam.' In a communication to all States and Union Territories, the Ministry of Health has requested prompt completion of the rebranding initiative by the conclusion of 2023.

Case laws

Drugs (Price Control) Order limited to price monitoring mechanism for non-scheduled formulations

The High Court of Delhi in the recent of ***Union of India and Another v. Bharat Serums and Vaccines Limited***[1] addressed several key points related to the Drug Price Control Order ("**DPCO**") of 2013. It held that the DPCO of 2013 applies to drug formulations, not bulk drugs. It establishes a price control mechanism for scheduled drug formulations and a price monitoring mechanism for non-scheduled formulations and that non-scheduled formulations are not part of the price control regime but fall under the price monitoring mechanism as per the National Pharmaceutical Pricing Policy (NPPP) of 2012. It also held that the price monitoring mechanism for non-scheduled formulations prioritizes public/consumer interest, aligning with the objective of ensuring equitable distribution of drugs at fair prices.

Medical Representatives are considered to be "workmen" under Industrial Disputes Act

In a landmark decision, the Allahabad High Court in the case of ***M/S Nicholas Piramal India Ltd. And Ors Vs Presiding Officer Labour Court Lko. And Ors***[2]***.*** affirmed the status of medical representatives as "workmen" under the Industrial Disputes Act, 1947 ("**Act**"). This ruling overturned a previous contention that medical representatives were not

[1]LPA 118/2023 & C.M. No. 7868/2023, C.M. No. 7871/2023 (Delhi HC)
[2] Writ – C No. – 1004529 of 2007 (Allahabad HC)

considered "workmen" under the Act. The court upheld a Labour Court's decision that a medical representative's dismissal, based on allegations of submitting false call reports, was unfair and illegal. The court's decision clarified that medical representatives are entitled to the same protections under the Act as other workers.

Incentive marks for COVID-duty service

The Madras High Court in the case of ***Dr. D. Hariharan and Others v. UOI and Others and connected matters***[3] upheld Tamil Nadu government's decision to grant incentive marks to doctors serving in COVID-19 duties for regular government appointments. The court dismissed petitions by doctors challenging the order, stating that COVID-19 pandemic warranted special consideration. It emphasized the laudable service of government doctors, justifying the classification for incentive marks. The court disagreed with excluding postgraduate students, allowing them to seek a COVID duty certificate for consideration within ten days. Overall, the decision supports recognizing and incentivizing medical professionals during the pandemic.

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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[3] W.P. Nos. 25827, 25785 and 27568 of 2023 (Madras HC)

Chambers TOP RANKED Asia-Pacific 2023 JSA	The LEGAL 500	asialaw OUTSTANDING FIRM 2023-24
17 Practices and 24 Ranked Lawyers	16 Practices and 11 Ranked Lawyers	19 Practices and 19 Ranked Lawyers
IFLR 1000 TOP TIER FIRM 2023	INDIA BUSINESS LAW JOURNAL BEST OVERALL LAW FIRMS 2023 LAW ASIA	ALB EMPLOYER OF CHOICE 2021 THOMSON REUTERS
11 Practices and 39 Ranked Partners **IFLR1000 APAC Rankings 2022** --- 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 9 Ranked Practices --- 11 winning Deals in IBLJ Deals of the Year --- 10 A List Lawyers in IBLJ Top 100 Lawyer List	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
BENCHMARK LITIGATION	vahura	
7 Practices and 2 Ranked Lawyers	**Ranked #1** **The Vahura Best Law Firms to Work Report, 2022** --- Top 10 Best Law Firms for Women in 2022	

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