September-October 2023 Edition

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

Regulatory updates

Inclusion of additional medical devices under the licensing regime

The Central Drugs Standard Control Organisation ("**CDSCO**") has issued a circular on October 12, 2023 regulating Class C and D medical devices under a licensing regime, effective from October 1, 2023. Existing importer/manufacturers who submitted applications for grant of import/manufacturing license under the provisions of Medical Devices Rules, 2017 prior to such regulation will be held valid and can continue to import/manufacture for up to 6 (six) months from the date of issue of the said circular.

Classification of In-vitro Diagnostic Medical Devices under MDR, 2017

The CDSCO, in consultation with Drugs Technical Advisory Board *vide* circular on October 25, 2023, has classified in-vitro diagnostic medical devices under Rule 4(2) of the Medical Devices Rules, 2017. The said medical devices were previously regulated under the Drugs and Cosmetics Act, 1940 and the rules thereunder. The updated list of in-vitro diagnostic medical devices is available in annexure A of the said circular.

NMC releases notification for the maintenance of standards of medical education

The National Medical Council ("**NMC**") issued a gazette notification on September 19, 2023 outlining regulations for medical education to maintain standards and streamline compliance processes. The key highlights of the notification include mandatory annual disclosure by medical institutions and oversight process through individual and joint evaluations by the respective governing board of medical education.

PCI releases circular seeking implementation of the Jan Vishwas Act, 2023

The Pharmacy Council of India ("**PCI**") issued a circular on October 25, 2023 to all the State Governments, Pharmacy Councils and approved institutions for the implementation of the Jan Vishwas (Amendment Provisions) Act, 2023 ("**Act**"). The Act amended certain punitive provisions of the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948, included inquiry and appeal related provisions, increased fine amounts, and increased authority for the State Councils Presidents to adjudicate violations.

For further details on the Jan Vishwas (Amendment of Provisions) Act, 2023 proposing revisions to the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948, please refer to the JSA Prism of August 11, 2023.

Interesting Reads

India marks 10th October as Good Manufacturing Practice Day

The Government of India along with the Indian Drugs Manufacturers' Association celebrated October 10th as National Good Manufacturing Practice ("**GMP**") Day. The rules for GMP in India align with the standards set by the World Health Organization ("**WHO**"). It is the first time that such a day has been celebrated in India and it aims at ensuring a system that focuses on improving quality of many Indian drugs.

Notice to Government of India and Drugs Controller General of India ("DCGI")

The National Human Rights Commission ("**NHRC**") has issued notices to the Ministry of Health and Family Welfare ("**MoHFW**") and the DCGI over the alleged marketing and circulation of falsified liver drug Defitalio and cancer drug Adcetris after taking suo motu cognizance of a news report that referred to an alert from WHO about circulation of certain falsified drugs in India. MoHFW and DCGI are required to submit their responses to the NHRC providing a detailed report on the present status of implementation of relevant laws to check the supply and sale of such falsified life-saving drugs.

Proposal to audit raw material suppliers

The CDSCO has proposed an annual audit to be undertaken by all pharmaceutical companies, of their raw material suppliers as a means to ensure compliance with GMP under the Drugs and Cosmetics Act, 1940, and is expected to formulate guidelines soon.

Case Laws

Doctor must reveal possible side effects of medication, manufacturer not liable

The Supreme Court of India ("**Supreme Court**") in the case of ***Prakash Bang v. Glaxo SmithKline Pharma Ltd***.[1], has upheld the order of National Consumer Disputes Redressal Commission ("**NCDRC**") citing a lack of mention of side-effects on the packaging and subsequent damage in the form of myositis as an adverse reaction to the vaccine 'Energix-B'. The Supreme Court held that it is the duty of the doctor who prescribes such a drug to reveal the side effects.

High degree of evidence needed to prove negligence by medical professionals

The Supreme Court ruled in ***Mrs. Kalyani Rajan v. Indraprastha Apollo Hospital & Ors.[2],*** that there was a lack of evidence regarding the heart attack and the actual treatment, thus missing out on the causal effect. The court considered the evidences and the decision of the NCDRC was upheld in the matter reiterating that the doctor cannot be held liable for medical negligence.

Lack of desired result does not lead to liability on doctors, in case of appropriate treatment being prescribed

The Supreme Court in the case of ***M.A. Bivji v. Sunita & Ors.***[3], set aside the order passed by the NCDRC to pay compensation for a complainant who had suffered permanent damage to her respiratory tract and voice loss, due to

[1] Civil Appeal No. 6791 OF 2013 (SC)
[2] Civil Appeal No. 10347 OF 2010 (SC)
[3] Civil Appeal No. 4847 OF 2018 (SC)

medical negligence during Nasotracheal Intubation (NI). The Supreme Court considered the opinions of all treating doctors and found no adverse link to the prescribed treatment route. The Supreme Court also held that there was no causal link between the NI procedure and the medical complications. Therefore, the subsequent injury cannot be attributable to medical negligence by the doctors.

To read further details, please refer to the JSA Prism of November 3, 2023.

Compensation in HIV medical negligence case

The Supreme Court in the case of ***CPL Ashish Kumar Chauhan v Commanding Officer and Others***[4], ordered the Indian Air Force to pay compensation of INR 1,60,00,000 (Indian Rupees one crore sixty lakh) to the retired officer, he having contracted the human immunodeficiency virus during a blood transfusion at a military hospital. The Supreme Court observed that only superficial attention was paid during the blood transfusion and that there was lack of adherence to or breach of relevant standards of care, as may be reasonably expected from a medical establishment. The Supreme Court went on to hold the Indian Army and the Indian Air Force vicariously liable for the conditions in the medical establishment and directed that in addition to the compensation, these institutions were directed to bear all expenses incurred by the person during any visit for bi-monthly check-ups.

Delhi High Court upholds MoHFW's notifications, categorising all medical devices as 'drugs'

The Delhi High Court in the case of ***Surgical Manufacturers and Traders Association v Union of India***[5], has held that the MoHFW's decision to bring all medical devices within the ambit of the expression "drug" is a clear policy matter and that no fault can be found with the 2020 Notification, whereby all medical devices were brought within the purview of the expression "drug". The Delhi High Court went on to observe that the MoHFW's reasons for doing so are manifold and include the desire to align itself with the international regulatory regime and to further the interest of patients.

[4] 2023 SCC Online SC 1220
[5] 2023 SCC Online Del 5443

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.

This Newsletter has been prepared by:

Sidharrth Shankar
Partner

Ayisha Mansoor
Partner

Arjun Krishnamoorthy
Principal Associate

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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
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For more details, please contact km@jsalaw.com

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