



August 2023 Edition

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

Regulatory updates

Exemption to medical devices from the E-Waste (Management) Rules, 2022

The Ministry of Environment, Forest and Climate Change *vide* the [E-Waste \(Management\) Second Amendment Rules, 2023](#) exempts certain medical devices and monitoring and control instruments (including laboratory equipment) from application of Rule 16 (1) of the E-Waste (Management) Rules, 2022. Rule 16 (1) prescribes a threshold for use of hazardous substances in the manufacture of electrical and electronic equipment and their components or consumables or parts or spares, during production.

National Medical Commission puts Registered Medical Practitioner (Professional Conduct) Regulations, 2023 on hold

The National Medical Commission issued a [notification on August 23, 2023](#) suspending the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 with immediate effect. Instead, the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002 will be enforced. This decision is in accordance with the powers vested under the National Medical Commission Act, 2019.

Department-Related Parliamentary Standing Committee on Health and Family Welfare release its 146th Committee Report

The Department-Related Parliamentary Standing Committee on Health and Family Welfare (“**Committee**”) prepared the 146th report on the ‘Action Taken by the Government on the Recommendations/ Observations contained in the 138th Report on Medical Devices: Regulations and Control’ pertaining to the Department of Health & Family Welfare, Ministry of Health & Family Welfare. The said report was laid before the Lok Sabha on August 4, 2023. The 138th report contained 49 (forty nine) recommendations of which 9 (nine) recommendations were accepted.

Avoidance of sale of certain over the counter (OTC) drugs

The Drugs Control Department, Government of New Delhi has issued an [advisory on July 19, 2023](#) advising all retail chemists to not undertake any over the counter sale of drugs such as aspirin, ibuprofen and diclonofenac group of medicines owing to increase in dengue and chikungunya cases. Such drugs may only be sold with a prescription issued

by a registered medical practitioner. Retail chemists have also been instructed to keep a register of recording the stock of pain killer drugs falling under the said category.

Approval of the National Research Foundation (NRF) Bill, 2023

The Ministry of Science and Technology has issued a [press release dated June 28, 2023](#) with respect to grant of approval by the Union Government for the introduction of National Research Foundation (NRF) Bill, 2023 in the Parliament. This legislation will enable the establishment of the NRF, which aims to initiate, nurture, and advance research and development (R&D) activities, while fostering a culture of research and innovation across universities, colleges, research institutions, and R&D laboratories throughout India.

Issuance of test license for veterinary drugs

The Central Drugs Standard Control Organisation (“CDSCO”) has issued a [circular dated July 19, 2023](#) indicating that all applications for issuance of Form 11 (test license) for veterinary drugs is now to be submitted online on the SUGAM portal (an e-governance initiative implemented by CDSCO) and that physical applications would no longer be accepted.

Pharmacists registered under Jammu and Kashmir Pharmacy Act, 2011, deemed to be registered under the Pharmacy Act, 1948

The Lok Sabha passed the Pharmacy (Amendment) Bill, 2023 (“**Amendment**”) on August 7, 2023 allowing persons qualified or registered under the Jammu and Kashmir Pharmacy Act, 2011, to be registered as pharmacists under the Pharmacy Act, 1948. The Amendment proposes to remove the ambiguity with respect to the 2 (two) legislations. Upon enactment, persons whose name has been entered in the register of pharmacists maintained under the Jammu and Kashmir Act, 2011 will be deemed entered in the registry of pharmacists prepared and maintained under Chapter IV of the Pharmacy Act, 1948.

Interesting Reads

Request to reconsider the New Drugs, Medical Devices and Cosmetics Bill, 2022 by the Association of Indian Medical Device Industry

The Association of Indian Medical Device Industry (“**AIMED**”) has expressed its disapproval of the Centre's intention to present the New Drugs, Medical Devices and Cosmetics Bill, 2022 in the upcoming monsoon session of Parliament. AIMED oppose the decision to introduce and pass the legislation without engaging in any consultations with significant stakeholders, as it aims to amend and consolidate the legislation concerning the import, production, distribution, and commercialization of drugs, cosmetics and medical devices.

Case laws

Suspension of doctor's license

The Supreme Court in the case of *Gostho Behari Das v Dipak Kumar Sanyal and Ors.*¹ has held that a doctor's license to practice cannot be suspended as penalty under the Contempt of Court Act, 1961. The court went on to observe that a medical practitioner guilty of contempt of Court may also be so for professional misconduct but the same would depend on the gravity/nature of the contemptuous conduct of the person in question. The court further held that they are, however, offences separate and distinct from each other. The former is regulated by the Contempt of Court Act, 1971 and the latter is under the jurisdiction of the National Medical Commission Act, 2019.

¹Civil Appeal No. 4725/2023 (SC)

Prohibition of an individual registered with the Alternate Medical Council from utilizing the prefix 'Doctor'.

The Calcutta High Court in the case of *Dhirarastra Dutta v State of West Bengal and Ors.*² has restrained an individual registered with the Alternate Medical Council, Kolkata from using the prefix 'Doctor.'

Additionally, the court has directed the West Bengal Medical Council to launch an investigation into the matter concerning the unauthorized issuance of certificates for 'registered medical practitioners.' The court held that individuals cannot be certified as 'registered medical practitioners' outside the rules prescribed by the Indian Medical Council. A person who does not possess the requisite qualification in terms of the Indian Medical Council Act, 1956, and whose name does not appear in the register of medical practitioner as contemplated in the aforementioned act, is not entitled to use the prefix doctor, or 'Dr.'

Issuance of directive for compliance under Mental Healthcare Act 2017

The Kerala High Court in a recent ruling of *XXX v State of Kerala*³ instructed the state police chief to take necessary measures in sensitizing all police officers regarding the relevant provisions outlined in the Mental Healthcare Act of 2017. The court took into account the suggestion put forth by the amicus curiae during the proceedings that competent authorities must ensure that police officers receive appropriate training under the said legislation.

The objective behind this directive is to ensure prompt, proper and effective compliance by the police force with the provisions, which would pave way for ameliorating the grievances of mentally ill persons.

² WPA(P)/21/2023 (Calcutta HC)

³ CrI.MC No. 428 of 2023 (Kerala HC)

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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17 Practices and
24 Ranked Lawyers



16 Practices and
11 Ranked Lawyers



7 Practices and
2 Ranked Lawyers



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



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Firm of the Year 2022

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Year (Premium) 2022

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