March – April 2024 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the months of March and April 2024.

Regulatory updates

Central Drugs Standards Control Organization ("CDSCO") mandates online safety reporting for medical devices

The CDSCO has issued a circular dated March 19, 2024, mandating all manufacturers of medical Devices/ in-vitro devices to submit periodic safety update reports only on the online portal. The circular further provides that offline mode of submission of application will not be accepted with effect from April 1, 2024.

CDSCO - Notice to all stakeholders for strengthening of Private Medical Devices Testing Laboratory

The CDSCO has issued a public notice dated April 3, 2024, inviting applications from existing private labs to register for testing specific medical devices. Applications are invited from private labs that have the facilities to perform various medical device tests that include physical, chemical, microbiological, mechanical, and electrical examinations to expedite the testing process for medical devices. Eligible and interested private labs can submit their applications through Form MD-39, along with the requisite fees, for registration with the CDSCO.

The Department of Pharmaceuticals issues Uniform Code for Pharmaceutical Marketing Practices, 2024

A new Uniform Code for Pharmaceutical Marketing Practices, 2024 has been notified by the Department of Pharmaceuticals on March 12, 2024, as a replacement to the Uniform Code for Pharmaceutical Marketing Practices, 2014 bringing changes to the regulatory framework on pharmaceutical marketing practices.

For further details, please refer to the JSA Prism of April 12, 2024.

The Ministry of Health and Family Welfare ("MOHFW") amends the pack size rule for retail sale of drugs

The MOHFW issued a notification dated March 18, 2024, regarding a modification in the retail pack size rule under Rule 105 of the Drug Rules, 1945 which applies to packaging of tablets (coated or uncoated) and capsules (hard or soft gelatine). This notification has been issued after consultation with the Drugs Technical Advisory Board. The

amendment permits the packaging of drugs meant for retail sale in multiples of 7 (seven) when the minimum pack size is greater than 10 (ten) units (in addition to retail sale in multiples of 5 (five)).

MOHFW amends punitive clauses under the Drugs and Cosmetics Act, 1940 ("D&C Act")

The MOHFW, through the Department of Health and Family Welfare, *vide* notification dated March 28, 2024, notified the effective date of amendments introduced by the Jan Vishwas (Amendment of Provisions) Act, 2023. These amendments alter penalties and punishments outlined in Sections 29, 30, and 32(B) of the D&C Act. The maximum leviable penalty has been raised to INR 1,00,000 (Indian Rupees one lakh), a significant increase from the previous limit of INR 5,000 (Indian Rupees five thousand). Further, subsequent offences involving the use of a government analyst's report for advertising of any drug or cosmetic, now carry an extended imprisonment period of up to 2 (two) years and/or a fine of up to INR 5,00,000 (Indian Rupees five lakh). Additionally, Section 32B of the D&C Act now allows compounding of offences under Sections 27(d) and 27A(ii) of the D&C Act, which set out the offence of manufacture and sale of drugs and cosmetics in contravention of the D&C Act. These amendments are set to come into force from December 31, 2024.

E-Commerce platforms advised to ensure appropriate categorization of food products sold on their websites

The Food Safety and Standards Authority of India ("**FSSAI**") has observed that food products categorized under 'Proprietary Food', specifically dairy based beverage mix, cereal based beverage mix, or malt based beverage, are being marketed on e-commerce platforms as 'Health Drink' or 'Energy Drink', which is misleading consumers**.** Additionally, there is no definition or standardized category for 'Health Drink' under the Food Safety and Standards Act 2006 or its related regulations**.** Therefore, FSSAI has issued a clarification dated March 28, 2024 for all e-commerce food business operators to remove or de-link such beverages from the 'Health Drink' and 'Energy Drink' sections and place the products in appropriate categories as provided under the existing laws**.**

National Commission for Indian System of Medicine ("NCISM") notifies regulations setting minimum standards and rating of undergraduate ayurveda, and siddha colleges and attached hospitals

The NCISM *vide* notification dated April 26, 2024, has published the National Commission for Indian System of Medicine (Minimum Essential Standards, Assessment and Rating for Undergraduate Siddha Colleges and Attached Teaching Hospitals) Regulations, 2024 ("**NCISM Regulations**") to ensure quality education and infrastructure for aspiring siddha practitioners. The NCISM Regulations establish a comprehensive framework for ensuring the quality and consistency of siddha medical education in India. Key provisions include:

1. **Minimum essential standard requirements**: The NCISM Regulations define the basic infrastructure such as the admission capacity, land requirement, minimum constructed area, faculty, equipment, and facilities required for Siddha colleges and their attached teaching hospitals to operate.
2. **Assessment Criteria**: Detailed guidelines for the assessment of colleges are provided. These include the evaluation of academic processes, clinical training, research activities, and the overall educational environment.
3. **Financial transparency**: Separate bank accounts are mandatory for colleges and attached hospitals (non-government institutions).
4. **Technology integration**: An IT cell must be established to manage all information technology needs.
5. **Establishing cells and committees**: Institutions must establish various cells including a student council, grievance redressal cell, pharmacovigilance cell, committee against sexual harassment of women, internal quality

assurance cell, human resources cell, and a research innovation and entrepreneurship development cell overseen by the chairperson, along with an academic committee.

Further, the NCISM Regulations supersedes (a) the Indian Medicine Central Council (Requirements of Minimum Standard for Under-graduate siddha colleges and attached hospitals) Regulations, 2016 and (b) the Establishment of New Medical College, Opening of new or Higher Course of Study or Training and Increase of Admission Capacity by a Medical College Regulations, 2019.

Interesting Reads

Parliamentary Standing Committee report for promotion of medical device industry

The Parliamentary Standing Committee on Chemicals and Fertilizers ("**Committee**"), in a recent report titled 'Promotion of Medical Device Industry' on February 8, 2024, has highlighted various impediments that are holding the healthcare manufacturing sector behind. The report stresses on how India's current central medical device regulations i.e. Medical Devices Rules, 2017 do not regulate second-hand medical devices. The Committee has recommended framing policy to ensure its quality and safety, as well as introducing possible restrictions on import of secondhand or refurbished medical devices into India. The Committee also highlighted issues of dependency on import of high-end devices (such as electronic equipment, advanced surgical instruments, and diagnostic products), low beneficiaries under production-linked incentive (PLI) schemes, high goods and services tax (GST) and customs duty on medical devices, and inconsistent price regulation.

National Disaster Management Authority and Union Health Ministry issue joint advisories for prevention of hospital fires.

In response to the increasing threat of hospital fires during the summer, the Union Health Ministry and the National Disaster Management Authority (NDMA) have together issued a joint advisory to all States and union territories providing measures to prevent such incidents. This involves obtaining valid fire no-objection certificates (NOC) from the respective state fire departments, correcting electrical load capacity problems, and conducting comprehensive inspections of hospitals to guarantee fire safety compliance. Chief Secretaries of all States and union territories have received detailed guidelines to distribute to accredited hospitals. These guidelines include procedures for routine upkeep of firefighting systems, audits of electrical loads, oxygen safety precautions, installation of smoke detectors and fire alarms, management of combustible materials and compliance with the National Building Code. Additionally, emphasis is placed on staff training, evacuation plans, and follow-up reviews to ensure the implementation of such safety measures.

The Central Government pushes deadline for constitution of State Allied and Healthcare Councils

The MOHFW *vide* an order dated March 20, 2024, has extended the timeline in the establishment of State Allied and Healthcare Councils ("**Council**"). The order clarifies that every state government and union territory is expected to establish councils under the National Commission for Allied and Healthcare Professionals Act, 2021 ("**Act**"). MOHFW has allowed 3 (three) years and 6 (six) months to implement such councils from the date of commencement of the Act in 2021. Such order essentially provides an extension of 3 (three) years to the originally stipulated 6 (six) month period for the establishment of Councils under Section 22(1) of the Act.

Case laws

Supreme Court orders presence of company director and endorser in contempt proceedings over misleading advertisements

In the case of ***Indian Medical Association & Anr v. Union of India***[1], the Supreme Court has ordered both the director of the company and the endorser of the offending advertisement to appear for contempt proceedings concerning misleading advertisements. The business in question is a major Indian ayurvedic medicine manufacturer caught in the crosshairs for advertising false claims. The Court was prima facie of the opinion that the endorser, along with the director, had violated provisions under Section 3 and 4 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, read with Rule 6 of the corresponding rules. The Court had previously granted three weeks for the Director to respond to the contempt notice, which went unanswered. Following this lack of response, a notice was ordered to be issued against the endorser to show cause as to why contempt proceedings should not be initiated against him.

Supreme Court agrees to hear plea against fixed rate for hospitals and seeks response from the Central Government

The Supreme Court has sought a reply from the Central Government after it agreed to hear a plea by an association of doctors and hospitals that questioned Government's move to prescribe uniform fee for private hospitals. The matter is now stated for hearing on September 10, 2024. The Hospital associations have said that standardised rates for medical procedures should not be implemented without a proper analysis of costing, requirements and expertise of doctors.

Cognizance of offence under the Drugs and Cosmetics Act, 1940 cannot be taken based on a police inspector's complaint

The Supreme Court its recent order in ***Rakesh Kumar v. The State of Bihar & Anr.***[2], held the proceedings against the appellant under the Drugs and Cosmetics Act, 1940, initiated based on the Police Inspector's complaint, have been deemed legally invalid. The court has also reversed and set aside the order of the Patna High Court which had refused to quash the proceedings against the accused.

Punjab and Haryana High Court rules implanting poor quality pacemaker as 'Cheating'

The High Court of Punjab and Haryana, in the case of ***Max Super Speciality Hospital and another V. State of Punjab and another.***[3], ruled that the incident goes beyond gross medical negligence. The court highlighted that the petitioners conspired to commit cheating by implanting a pacemaker costing INR 45,000 (Indian Rupees forty-five thousand) instead of one costing INR 4,50,000 (Indian Rupees four lakhs fifty thousand) as consented by the patient's family.

Jharkhand High Court emphasizes quality over pricing, while assigning tenders of medical devices

The High Court of Jharkhand, in the case of ***Hosco Pvt. Ltd. V. Jharkhand Medical & Health Infrastructure Development & Procurement Corporation Ltd and Ors.***[4], dismissed the writ application. The court emphasized that the price of a product such as defibrillators, alone cannot be the determining criteria in awarding a tender, as the quality of the product in addition to meeting other specification as per the respective tender documents, should be taken into consideration while making such selection. Additionally, the court ruled that a tenderer without technical

[1] Writ Petition (Civil) No. 645/2022
[2] 2024 LiveLaw (SC) 264
[3] 2024 LiveLaw (PH) 80
[4] 2024 LiveLaw (Jha) 41

qualifications cannot challenge the tender process. The judgment highlighted the importance of product quality and adherence to tender specifications.

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:

Ayisha Mansoor
Partner

Prakriti Jaiswal
Partner

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19 Practices and 19 Ranked Lawyers	12 Practices and 42 Ranked Partners **IFLR1000 APAC Rankings 2023** --- 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 --- 12 A List Lawyers in IBLJ Top 100 Lawyer List
Innovative Technologies Law Firm of the Year 2023 --- 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 --- Employer of Choice 2021	7 Ranked Practices, 16 Ranked Lawyers --- Elite – Band 1 - Corporate/ M&A Practice --- 3 Band 1 Practices --- 4 Band 1 Lawyers,1 Eminent Practitioner	**Ranked #1** **The Vahura Best Law Firms to Work Report, 2022** --- Top 10 Best Law Firms for Women in 2022 7 Practices and 2 Ranked Lawyers

For more details, please contact km@jsalaw.com

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