



December 2023 Edition

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

Regulatory updates

CDSCO issues advisory to uphold drug quality through strict manufacturing standards

The Central Drugs Standard Control Organisation (“CDSCO”) issued an [advisory guideline on December 5, 2023](#), alerting drug manufacturers to comply strictly with good manufacturing practices and licensing conditions. Emphasizing the critical role of excipients and active pharmaceutical ingredients (APIs) in ensuring drug quality, safety, and efficacy, the advisory urges the use of pharmaceutical-grade excipients in cough syrup production to prevent contamination, especially during increased usage in winters. Stakeholders are directed to ensure adherence to quality standards.

NMC issues a public notice banning e-cigarettes and heated tobacco products (HTPs)

The National Medical Commission (NMC) issued a [public notice on December 15, 2023](#), notifying healthcare professionals about the ban on e-cigarettes and heated tobacco products (HTPs) under the Prohibition of Electronic Cigarettes (Production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Act, (PECA), 2019. Affiliated professionals must refrain from researching or engaging in related activities without prior approvals from Directorate General of Health Services (Dte.GHS) and Ministry of Health and Family Welfare (MoHFW). The public notice also provides that healthcare professionals affiliated with National Medical Commission must comply with [D.O. letter H.11013/03/2021-TC](#) dated December 8, 2023.

CDSCO directs updating of label for a fixed-dose combination

The CDSCO issued a [circular on December 18, 2023](#), addressing concerns over unapproved promotion of an anti-cold drug formulation for infants. The committee's recommendation suggests restricting the use of fixed-dose combination (FDC) of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml for children below 4 (four) years. Manufacturers are directed to update labels and promotional literature accordingly. All stakeholders are urged to notify action taken on such matter to the office.

Interesting Reads

e-pharmacies face backlash from the Madhya Pradesh Chemists' Association

The Madhya Pradesh Chemists' Association, in its annual meeting has called for action to be taken against the sale of online drugs, alleging that such e-pharmacies often sell adulterated and spurious drugs online. The President of the Association noted that as no mechanism was in place for regulation of e-pharmacies, no quality checks were in place to ensure the quality of the medicines being sold online and went on to urge other state associations as well as the Government of India, to address this concern at the earliest.

Rules of origin for medical sector

The rules of origin for the medical sector continues to remain a sticking point in ongoing discussions between the Governments of India and the United Kingdom in relation to the proposed Free Trade Agreement between the 2 (two) countries. Under this provision, the United Kingdom would not be able to dump goods from some third country in the Indian market by just putting a label on such goods and would have to undertake certain prescribed value addition in that product to export the product to India.

Healthcare advertisements most violative

In its half-yearly assessment of complaints, the Advertising Standards Council of India ("ASCI"), has reported that advertisements in the healthcare sector have been the most violative. The ASCI has concluded that the violations are largely owing to advertisements over social media, and often such advertisements have been violative of the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

Gujarat becomes first state to issue online licenses of medicines

Gujarat has become the first state to issue online licenses to allopathic medicines through its newly launched FDCA-mDMLA mobile app. The mobile app will merge all the online platforms at one place for faster, real time access towards verification of the status of the application, as well as issue of the license. An Assistant Commissioner from the Gujarat Food and Drugs Control Administration will oversee the functioning of the mobile app and governance system.

Government of India mulls regulator for healthcare sector to facilitate insurance for all

The Government of India is considering setting up a regulator for the healthcare sector to facilitate affordable insurance coverage. Discussions between all stakeholders including the Ministries of Finance and Health, insurance companies, the IRDAI amongst others are envisaged in the near future

Case laws

Framing of policy for e-pharmacies

The High Court of Delhi in its recent order in *Dr. Zaheer Ahmed v Preeti Sudan, Secretary, Union of India and Ors*¹ has directed the Government of India to formulate a policy for sale of medicines by e-pharmacies within a period of 8 (eight) weeks, while acknowledging the delay in formulation and implementation of such a policy. The Court has also required the Joint Secretary dealing with such a policy to appear before the court if such policy has not been framed before the next date of hearing, being March 4, 2024.

¹ Cont. Cas(C)355/2019 & C.M.Nos. 12361-12362/2023, 44233/2023 (Delhi HC)

Budgetary allocation and vacancy concerns in Maharashtra healthcare system

The High Court of Bombay, in the case of *Khalil Ahmad Hasanmiya Wasta v. State of Maharashtra and Ors.*², raised concerns regarding the underutilization of healthcare budget allocations and substantial staff vacancies in medical departments. The court highlighted the need to expedite recruitment processes to fill vacancies, emphasizing the adverse impact on healthcare facilities due to high number of unfilled positions. Additionally, the court requested detailed affidavits from authorities regarding past budgetary lapses and plans to address vacancies.

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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² Public Interest Litigation Stamp No. 16 of 2021 (Bombay HC)

		
<p>17 Practices and 24 Ranked Lawyers</p>	<p>16 Practices and 11 Ranked Lawyers</p>	<p>19 Practices and 19 Ranked Lawyers</p>
		
<p>11 Practices and 39 Ranked Partners IFLR1000 APAC Rankings 2022</p> <p>-----</p> <p>Banking & Finance Team of the Year</p> <p>-----</p> <p>Fintech Team of the Year</p> <p>-----</p> <p>Restructuring & Insolvency Team of the Year</p>	<p>Among Top 7 Best Overall Law Firms in India and 9 Ranked Practices</p> <p>-----</p> <p>11 winning Deals in IBLJ Deals of the Year</p> <p>-----</p> <p>10 A List Lawyers in IBLJ Top 100 Lawyer List</p>	<p>Banking & Financial Services Law Firm of the Year 2022</p> <p>-----</p> <p>Dispute Resolution Law Firm of the Year 2022</p> <p>-----</p> <p>Equity Market Deal of the Year (Premium) 2022</p> <p>-----</p> <p>Energy Law Firm of the Year 2021</p>
		
<p>7 Practices and 2 Ranked Lawyers</p>	<p>Ranked #1 The Vahura Best Law Firms to Work Report, 2022</p> <p>-----</p> <p>Top 10 Best Law Firms for Women in 2022</p>	

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