September-October 2025 Edition

The National Health Authority ("**NHA**") recently, at the Central Vigilance Commission workshop as part of Vigilance Awareness Week 2025, showcased the use of artificial intelligence ("**AI**") to strengthen transparency and integrity in India's digital health ecosystem. Dr. Sunil Kumar Barnwal, IAS, CEO, (NHA) shared his insights on the integration of AI within India's digital health ecosystem, particularly through flagship initiatives such as the Ayushman Bharat Digital Mission and Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana. He further focused on "Fraud Detection in Government Health Schemes using AI" highlighting NHA's innovative use of AI and machine learning to identify, prevent and address fraudulent activities in real time. AI and machine learning are revolutionising the world's largest public health assurance scheme, shifting the paradigm from reactive fraud detection to proactive integrity management.

Further, India recently signed a Memorandum of Understanding ("**MoU**") with Australia in the area of food safety. The MoU will strengthen cooperation in the field of food safety, through the exchange of best practices, knowledge sharing, import procedures and other technical collaboration including capacity-building initiatives.

This edition of the JSA healthcare Newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem during September and October 2025.

Regulatory updates

Amendment to the Uniform Code for Marketing Practices in Medical Devices 2024

The Department of Pharmaceuticals ("**DoP**"), *vide* notification dated September 1, 2025, has notified amendments to the Uniform Code for Marketing Practices in Medical Devices ("**UCMPMD**") 2024 ("**Code**"). The amendments aim to simplify disclosure requirements, streamline reporting and provide clarity on the sample evaluation process. Some of the key amendments are as follows:

1. clarifications have been inserted with respect to the disclosure of marketing expenditure in relation to the method of arriving at the value of free evaluation samples distributed to healthcare professionals:

   (a) in case the company is a manufacturer of such samples, the samples should be valued on a per unit basis, i.e., per device/vial/ml etc., and its value should be the price charged to the stockist or immediate customer on a per unit basis for the same make, brand, product variant and value of the medical device; and

   (b) in case the company has purchased such samples from another supplier, the purchase price should be used for determining the monetary value of free evaluation samples under the Code. The price of such free samples should be recorded as the average price charged to the stockist or immediate customer, or the average price paid for the purchase of the medical device for the same make, brand, product variant and value on annual basis.

2. a new UCMPMD portal has been introduced for compliance purposes under the Code;
3. the Chief Executive Officer of the company is now responsible for adherence to the Code. Disclosure of marketing expenditure must be submitted by the executive head of the company within 2 (two) months of the end of every financial year or be uploaded on the website of the association of which the company is a member. In case the company is a member of more than 1 (one) association, it must, submit the disclosure to any 1 (one) association of which it is a member, while informing the other association(s) of such disclosure being made; and
4. with respect to data security, associations must now have a system in place to ensure that data disclosed by its members is stored securely and is adequately protected and must be retained for a minimum period of 5 (five) years or for such longer period as may be necessary for the purpose of facilitating inquiry.

Guidelines for Promotion of Research and Innovation in Pharma MedTech Sector Scheme

DoP, *vide* notification dated October 1, 2025, has notified the Guidelines for Promotion of Research and Innovation in Pharma MedTech ("**PRIP**") Sector Scheme ("**Guidelines**"). The Guidelines aim to encourage industry investment in research and development in pharmaceutical and medical technology sectors, to foster quality research and nurture a pool of scientists in the country, and promote industry-academia linkage, for leading India to a sustained global competitive advantage. Some of the key aspects are as follows:

1. Centres of Excellence ("**CoEs**") established at the National Institutes of Pharmaceutical Education and Research (NIPERs) will help in building specific research capacities in the identified priority areas in a focused time-bound programme;
2. Government academic and research institutions eligible for collaboration have been prescribed; and
3. Institutes must ensure the following in respect of the CoEs:

(a) the proposing institute will furnish an undertaking that: (i) no expenditure will be incurred from the financial assistance provided under the Scheme towards the salary and allowances payable to any regular employee; (ii) it will bear expenditure incurred on any employees engaged for the CoE for the period beyond the Scheme period; and (iii) it will ensure that the CoE achieves self-sufficiency within the Scheme period;

(b) the institute will delineate the precise allocation and utilisation of funds and provide a detailed breakup of the financial resources deployed. Such breakup will outline the allocation for essential activities, such as development of research infrastructure, procurement of equipment and operations;

(c) the institute will ensure prudent fiscal management and effective resource utilisation aligned with the objectives of the Scheme; and

(d) in carrying out the activities of the CoE, the institute will adhere to the provisions of the General Financial Rules, 2017 and related instructions issued by the Ministry of Finance.

Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations

The Central Drugs Standard Control Organisation ("**CDSCO**"), *vide* notification dated October 7, 2025, has reiterated the critical importance of the testing of raw materials, including the excipients, before its use in the manufacturing of pharmaceutical formulations. As per Rule 74 (c) and Rule 78 (c) (ii) of the Drugs Rules, 1945, the licensee must either in their own laboratory or in any laboratory approved by the licensing authority: (a) test each batch or lot of the raw material used by them for the manufacture of their product; and (b) test each batch of the final product, and must maintain records or registers showing the particulars in respect of such tests as specified in Schedule U of the Drugs Rules, 1945. The CDSCO has requested all the State/ Union Territory drug controllers to take measures to ensure

testing before the manufacture and release of a product batch to the market. Further, it must also be ensured that the manufacturers have robust vendor qualification systems in place and use raw materials, including excipients, from reliable approved vendors only.

Withdrawal of permissions for use of the term "ORS" along with brand names

The Food Safety and Standards Authority of India ("**FSSAI**"), *vide* notification dated October 14, 2025, has stated that all the previous permissions allowing the use of the term "ORS" (Oral Rehydration Salts) alongside brand names on food labels will be revoked. The earlier permissions, issued through orders dated July 14, 2022, and February 2, 2024, had allowed such use with a disclaimer stating that the product was not an ORS formula as recommended by the World Health Organization.

Further, FSSAI, *vide* notification dated October 14, 2025, issued a clarification on withdrawal of permissions for use of the term "ORS" along with brand names. It clarified that the use of the term "ORS" in the trademarked name or in the naming of any food product otherwise-whether fruit-based, non-carbonated, or ready-to-drink beverages even when accompanied by a prefix or suffix, constitutes a violation of the provisions of the Food Safety and Standards Act, 2006 and the regulations made thereunder. Such practices are misleading to consumers by way of false, deceptive, ambiguous, and erroneous names/ label declarations, and are in contravention of Sections 23 and 24 of the Food Safety and Standards Act, 2006, Sub-regulation 4(3) of the Food Safety and Standards (Labelling and Display) Regulations, 2020, Sub-regulation 5(1) of the Food Safety and Standards (Labelling and Display) Regulations, 2020 and Sub-regulations 4(1) and 4(13) of the Food Safety and Standards (Advertising & Claims) Regulations, 2018, and is liable for punishment under Sections 52 and 53 of the Food Safety and Standards Act, 2006.

Further, all food business operators have been directed to remove the word "ORS" from their food products, irrespective of its use as a standalone term or in combination with any prefix/suffix or as part of the trademark with prefix/suffix in the product name, and ensure strict compliance with the labelling and advertisement requirements prescribed under the Food Safety and Standards Act, 2006 and the regulations framed thereunder.

Draft guidance document on conduct of medical device software under the Medical Devices Rules, 2017

CDSCO, *vide* notification dated October 21, 2025, has issued a draft guidance document on conduct of medical device software under the Medical Devices Rules, 2017, addressing specific regulatory requirements for medical device software and to align the requirements with globally harmonised practices. It aims to provide guidance to Indian manufacturers and importers for the submission of an application to the licensing authority for obtaining license/permission for the manufacturing or import of medical device software (including *in vitro* diagnostic medical device software) under the Medical Devices Rules, 2017. It provides the scope, definition, classification, standards, requirements of technical documents and quality management system applicable for medical device software.

Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high risk solvents

CDSCO, *vide* notification dated October 22, 2025, acknowledging the safety concerns arising from the contamination of cough syrups with diethylene glycol. has directed the establishment of a digital monitoring system on the ONDLS portal for monitoring the supply chain as well as quality of the high risk solvents including propylene glycol. The CDSCO has upgraded the ONDLS portal for addressing this issue. All State/ Union Territory drug controllers to direct all the manufacturers of pharma grade solvents to obtain a manufacturing licence through the ONDLS portal. In case the manufacturer already holds the manufacturing licence, he must register on the ONDLS portal and submit the data through "Old Licence Management" under ONDLS. Further, the solvent manufacturers must also upload details on the

ONDLS portal regarding each batch manufactured and details of the vendors to whom the solvents are sold from time to time.

Case laws

Delhi High Court dismisses Dr. Reddy's Laboratories petition against FSSAI

The High Court of Delhi, in its order dated October 31, 2025, in the case of ***Dr. Reddys Laboratories Limited & Ors. vs. Union of India & Anr.***[1], dismissed the petition against the decision of FSSAI banning ORS labelling on drink beverages. The Court stated that is not inclined to interdict with the impugned order passed by FSSAI. This is particularly in light of the deleterious effect and adverse health outcomes caused by the consumption of fruit-based or non-carbonated or ready-to-drink beverages by consumers who are in medical need of an ORS formulation. The petitioner had submitted that the stock which is already in the supply chain be allowed to be sold to prevent monetary loss. However, the Court, ruling to the contrary,stated its reluctance in ruling over a measure taken by the regulatory body i.e., FSSAI on public health considerations. Accordingly, the Court dismissed the petition, while directing the FSSAI to consider and address through a reasoned order the irreparable loss caused by the ban pleaded by the petitioner, if a representation is made by the petitioner in this regard.

[1] 2025:DHC:9592

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:

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41 Ranked Lawyers

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21 Ranked Lawyers

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