May-June 2025 Edition

This edition of the JSA healthcare newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem during May and June 2025. Some of the key developments incorporated in this edition include the addendum to the operational guidelines of sub-scheme 'Capacity Building and Skill Development for Medical Devices' under the scheme 'Strengthening of Medical Device Industry', the Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2025, and advisory to all Food Business Operators ("**FBOs**") to discontinue the usage of the term "100%" on food product labels, packaging and promotional content.

Regulatory updates

States to intensify inspections and carry out drives to curb use of illegal ripening agents and synthetic coatings on fruits

On May 20, 2025, the Food Safety and Standards Authority of India ("**FSSAI**") issued a press release urging all States and Union Territories to intensify inspections and carry out special enforcement drives to curb the illegal use of non-permitted fruit ripening agents, as well as colouring and coating of fruits with synthetic colours or non-permitted wax. As part of the enforcement drive, inspection of go-downs and storage facilities, particularly those suspected of using substances like calcium carbide for ripening, may be carried out. In this regard, it is pertinent to note that calcium carbide is strictly prohibited for the artificial ripening of fruits under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011. Accordingly, per the press release, the presence of calcium carbide on the premises or stored alongside crates of fruits is to be treated as circumstantial evidence against the FBO, potentially leading to prosecution under the Food Safety and Standards Act, 2006 ("**FSS Act**").

Guidelines for acceptance of recycled polyethylene terephthalate as food contact material

On May 23, 2025, the Ministry of Health and Family Welfare ("**MoHFW**") issued guidelines for acceptance of recycled Polyethylene Terephthalate ("**PET**") as Food Contact Material ("**FCM-rPET**"). These guidelines pertain only to the recycling process/operation of transforming post-consumer PET used for food applications into recycled PET as FCM-rPET resins suitable for making food contact materials using recycling technology approved by FSSAI. It does not apply to production of resins for non-food grade consumer applications.

Guidance document on disposal of expired/unused drugs

On May 26, 2025, the Central Drugs Standard Control Organisation issued guidelines on disposal of expired and unused drugs. The objective of the guidance document is to provide clear and comprehensive instructions in accordance with the Drugs and Cosmetics Act, 1940, the rules thereunder and other laws as applicable for the safe disposal of expired and unused drugs. It establishes procedures for collection, storage and transportation of the expired/unused drugs and their disposal, thereby protecting the environment and safeguarding the public health.

Discontinuation of the term "100%" on food product labels and promotional materials

On May 28, 2025, FSSAI issued an advisory to all FBOs to discontinue the usage of the term "100%" on food product labels, packaging and promotional content as this terminology is ambiguous and usage of the term "100%" in isolation or conjunction with other descriptions is likely to convey a false sense of absolute purity or superiority. Further, the advisory notes that:

1. the term "100%" is not defined or referenced in any manner under the Food Safety and Standards (Advertising and Claims) Regulations, 2018, the FSS Act or any rules or regulations made thereunder; and
2. Regulation 10 (7) of the Food Safety and Standards (Advertising and Claims) Regulations, 2018 strictly prohibits any advertisement or claim that undermines other manufacturers or influence consumer perception in a misleading manner.

Modification in the operational guidelines under the scheme 'Strengthening of Medical Device Industry'

On June 9, 2025, the Department of Pharmaceuticals ("**DoP**") issued an addendum to modify the notified amendments to the operational guidelines of sub-scheme 'Capacity Building and Skill Development for Medical Devices' under the scheme 'Strengthening of Medical Device Industry'. Some of the key amendments are as follows:

1. DoP will provide up to 75% of the cost of the course or INR 21,00,00,000 (Indian Rupees twenty one crore), whichever is lower, on reimbursement basis as and when expenditure is incurred; *This is in connection with the financial assistance to be provided to Center Government Universities/Institutes for running multidisciplinary post-graduate courses in medical device.*
2. financial support based on the number of students will be provided on quarterly reimbursement basis to the trainee institute for the number of students enrolled; and *This is connection with the financial assistance to be provided to the Central/State Government universities/institutes and approved private institutions for running diploma, certificate and short- term training courses for existing workforce.*
3. expenditure incurred and claimed towards non-recurring expenses is not required to be refunded. *This relates to grant paid by the DoP being refunded by the institution as and when the programme is discontinued midway or the detailed conditions as laid down and approved by the DoP are not followed.*

Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2025

On June 20, 2025, MoHFW notified the Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2025 to amend the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018 ("**Alcoholic Beverages Rules**"). Some of the key amendments are as follows:

1. the term 'alcoholic ready-to–drink beverages' has been inserted to mean, flavoured beverages having more than 0.5 and up to 15.0% of alcohol by volume, made from spirit or the mixture of spirit or any alcoholic beverage as base by adding natural or nature identical or artificial flavours and food additives permitted under the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, or a combination thereof, and fruit or vegetable juice or herbs or spices, or a combination thereof, with or without added sugar or caloric sweeteners or salt and with or without carbonation. In case of carbonated alcoholic ready-to-drink beverages, they are required to be carbonated with carbon dioxide, which must have a minimum of one volume of carbon dioxide and should conform to the requirements of TABLE-4 of the Alcoholic Beverages Rules;
2. the term 'honey wine or mead' has been inserted to mean a wine produced from the fermentation of an aqueous solution of honey by yeasts without addition of any other carbohydrate source. It may contain herbs, spices or natural flavourings and is required to conform to the requirements provided under Table-2 of the Alcoholic Beverages Rules except ethyl alcohol content which may vary between 4% to 15.5%; and
3. provisions relating to country liquors and Indian liquors have been introduced. Country liquors/Indian liquors are specified under the following types: (i) 'Plain country liquor' or 'Plain Indian liquor' is defined as alcoholic distillates obtained from fermented molasses, jaggery, cereals, potato, cassava, fruits, coconut and palm tree sap, mahua flowers, or other agricultural carbohydrates; and (ii) 'Blended country liquor' or 'Blended Indian liquor' is defined as a blend of alcoholic distillates, rectified spirit, or neutral spirit. These definitions aim to standardise the production and classification of these beverages.

These rules will come into force on January 1, 2026.

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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18 Practices and
41 Ranked Lawyers

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21 Ranked Lawyers

14 Practices and
12 Ranked Lawyers

12 Practices and 50 Ranked Lawyers

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