
March-April 2025 Edition

Healthcare is one of the key focus areas of the Government of India. Recently, the Government has issued a press release with an update on the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana ("**AB PM-JAY**"). It states that the Economic Survey 2024-25 highlights the impact of AB PM-JAY in reducing out-of-pocket expenditure through increased social security and primary health spending, with recorded savings over INR 1.25 lakh crore (Indian Rupees one point two five lakh crore). The survey also states that the Government-supported insurance schemes like AB PM-JAY, Rashtriya Swasthya Bima Yojana, and State-specific programs contribute 2.63% to healthcare financing and the rise in government health spending has significantly reduced financial hardship for households. As on March 24, 2025, more than 36.9 crore (thirty-six point nine crore) 'Ayushman cards' have been created under the scheme.

This edition of the JSA healthcare newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem in March and April 2025.

## Regulatory updates

### Online application for extension of time to comply with revised Schedule M of the Drugs and Cosmetics Act, 1940

On March 24, 2025, the Central Drugs Standard Control Organisation ("**CDSCO**") has issued a circular informing that it has developed an online system for submission of applications for applicants/manufacturers seeking an extension of time to comply with the revised Schedule M (*dealing with good manufacturing practices for pharmaceutical manufacturing*) of the Drugs and Cosmetics Act, 1940, through the ONDLS Portal. No hard copy of the application for seeking extension of the timeline for implementation will be considered.

### Exemption of sampling and testing of orphan drugs at COSCO port offices

On March 26, 2025, CDSCO has issued an office memorandum streamlining the procedure for release of orphan drugs. It has been decided that such consignments must be released by the COSCO port offices on the basis of legal undertaking to be submitted by the importer stating that required quantity of sample will be forwarded to the concerned laboratory and the test report will be submitted to the respective port office within 15 (fifteen) days of receiving it from the laboratory.

## Reclassification of point related to food grade packaging material as critical to food safety under inspection checklist

On April 3, 2025, the Food Safety and Standards Authority of India ("**FSSAI**") has issued an order reclassifying the point related to food grade packaging material. Considering its critical role in ensuring food safety, FSSAI has decided to reclassify the point related to food packaging material as critical in the inspection checklist related to general manufacturing, milk and milk product processing, meat processing, fish and fish products processing and catering. The packaging material used must be food grade, in sound condition and must have certificate of conformity issued by the National Accreditation Board for Testing and Calibration Laboratories, accredited laboratory against the Food Safety and Standard (Packaging) Regulations, 2018 (*previously, the criteria for packaging materials was limited to it being of food grade and in sound condition*). The scoring is revised to 4 (four) (*previously, it was 2*) for all items.

## Transfer of drugs from special economic zone to domestic tariff area

On April 8, 2025, CDSCO has issued a circular streamlining the procedure for transfer of drugs manufactured in a Special Economic Zone ("**SEZ**") to Domestic Tariff Area ("**DTA**") for sale and distribution. It has been decided that the prescribed procedure should be followed to ensure that the drugs meet quality, safety and efficacy requirements as per the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945. Some of the key aspects are as follows:

1. banned drugs manufactured at an SEZ for export purpose are not allowed for transfer to DTA for any purpose;
2. in case of unapproved and approved new drugs manufactured in an SEZ, the requirements specified for manufacturing of new drugs under the New Drugs and Clinical Trials Rules, 2019 and the Drug Rules 1945 are required to be complied with;
3. in case the drugs manufactured in an SEZ do not fall under the category (a) and (b) above, requirements specified for manufacturing of drugs under the Drugs Rules 1945 are required to be complied with;
4. in case an Active Pharmaceutical Ingredient ("**API**") is imported to SEZ for manufacturing of its formulation and the formulation is proposed to be diverted to DTA for sale and distribution, registration certificate and import license are required for that API; and
5. APl/semi-finished/finished dosage forms in bulk packs imported without registration certificate and import license will not be permitted for sale and distribution to DTA

## Provision for auto-generated market standing certificate and non-conviction certificate for licensed medical device

On April 9, 2025, CDSCO has issued a notice regarding auto-generation of Market Standing Certificate ("**MSC**") and Non-Conviction Certificate ("**NCC**") for licenced medical device. To promote ease of doing business and to simplify the regulatory procedure, the current online application workflow for grant of MSC and NCC for medical devices licensed by the Central Licensing Authority is upgraded in the online system for medical devices with a new workflow for auto-generated MSC and NCC.

## Use of chlorpheniramine maleate and phenylephrine hydrochloride

On April 15, 2025, the Ministry of Health and Family Welfare, Government of India ("**MOHFW**") has issued a notification stating that the use of the drug fixed dose combination of chlorpheniramine maleate + phenylephrine hydrochloride is likely to involve risk to children below 4 (four) years of age. Therefore, the Government has restricted the manufacture, sale or distribution of all formulations of fixed dose combination of chlorpheniramine maleate + phenylephrine hydrochloride subject to the condition that the manufacturers must mention the warning "*fixed dose*

*combination must not be used in children below four years of age*" on the label and package insert or the promotional literature of the drug.

### Drugs and Cosmetics (Compounding of Offences) Rules, 2025

On April 24, 2025, MOHFW has issued the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 ("**Rules**"). The Rules aim to provide a framework for resolving certain drug-related offences outside of traditional prosecution, potentially leading to quicker resolutions while still ensuring compliance and accountability within the pharmaceutical sector. The Rules prescribe the following:

1. procedure for appointment of compounding authority;
2. application procedure and the respective forms to be filed with the compounding authority for compounding of the offence;
3. procedure for compounding;
4. powers of compounding authority to grant immunity from prosecution; and
5. withdrawal of immunity from prosecution under prescribed conditions.

### Introduction of tooltips for legal forms in SUGAM and medical device online portals to assist stakeholders

On April 28, 2025, CDSCO issued a circular introducing tooltips for legal forms on the SUGAM and medical device online portals. These tooltips are designed to provide helpful guidance on the specific requirements for each field in the various application forms submitted to CDSCO for approval. This feature aims to improve the user experience, facilitate the quality of submission of data in applications and minimise errors .

### FSSAI empowers consumers to report misleading claims on food products

On April 30, 2025, FSSAI has issued a press release introducing a new digital utility that enables consumers to directly report misleading claims made on food product labels. Consumers can now lodge complaints regarding misleading or false claims displayed on packaged food items through the Food Safety Connect mobile application or via Food Safety Compliance System.

## Case law

### Supreme Court: Licence of hospital will be suspended if it is involved in child trafficking

The Supreme Court of India, in the case of ***Pinki vs. State of Uttar Pradesh and Anr.***[1], has observed that if any newborn infant is trafficked from any hospital, the immediate action against the hospital should be suspension of licence to run the hospital over and above other actions in accordance with law. When any lady comes to deliver her baby in any hospital, it is the responsibility of the administration of the hospital to protect the newborn infant in all respects.

[1] 2025 INSC 482

## Interesting Read

### All India Institute of Medical Sciences, New Delhi and Society for Applied Microwave Electronics Engineering and Research sign memorandum of understanding to enhance innovation in medical electronics and healthcare technology

The Press Information Bureau released a press release dated March 28, 2025 announcing that the Society for Applied Microwave Electronics Engineering and Research and All India Institute of Medical Sciences, New Delhi have signed a Memorandum of Understanding ("**MoU**") for collaborative research on medical devices, This MoU enables both institutions work collaboratively to develop high field/low field magnetic resonance imaging/ nuclear magnetic resonance systems and promote research in radio frequency, rf, microwave systems and allied areas for the medical applications.

## 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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41 Ranked Lawyers

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21 Ranked Lawyers

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