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Knowledge Management

Semi-Annual Healthcare Sector Compendium 2025

January – June 2025

Semi-Annual Healthcare Sector Compendium 2025

Introduction

Healthcare is one of the key focus areas of the Government of India and this year, in the Union Budget 2025-26, the Finance Minister announced some key initiatives to boost the Indian healthcare sector:

1. Gig workers of online platforms will be provided healthcare under PM Jan Arogya Yojana. This measure is likely to assist nearly 1,00,00,000 (one crore) gig-workers.
2. The Government has added almost 1,10,000 (one lakh ten thousand) undergraduate and postgraduate medical education seats in 10 (ten) years, an increase of 130%. In the next year, 10,000 (ten thousand) additional seats will be added in medical colleges and hospitals, towards the goal of adding 75,000 (seventy five) seats in the next 5 (five) years.
3. The Government has proposed to facilitate setting up of day care cancer centres in all district hospitals in the next 3 (three) years. 200 (two hundred) centres will be established in 2025-26.
4. Medical tourism and 'Heal in India' will be promoted in partnership with the private sector along with capacity building and easier visa norms.
5. To provide relief to patients, particularly those suffering from cancer, rare diseases and other severe chronic diseases, 36 (thirty six) lifesaving drugs and medicines will be added to the list of medicines fully exempted from basic customs duty. Further, 6 (six) lifesaving medicines will be added to the list attracting concessional customs duty of 5%. Full exemption and concessional duty will also respectively apply on the bulk drugs for manufacture of the above.
6. Specified drugs and medicines under patient assistance programmes run by pharmaceutical companies are fully exempt from basic customs duty, provided the medicines are supplied free of cost to patients and 37 (thirty-seven) more medicines along with 13 (thirteen) new patient assistance programmes will be added.

Further, the Government issued a press release dated March 28, 2025, 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 programmes 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 Compendium consolidates all key developments, notifications, judicial precedents and other updates in the healthcare sector, which were circulated as JSA Newsletters during the calendar period from January 2025 till June 2025.

Regulatory updates

Department of Pharmaceuticals

Compliance of the provisions of Para 24 and 25 of Drugs (Prices Control) Order,2013

On February 4, 2025, the Department of Pharmaceuticals ("**DoP**") issued an office memorandum directing all the retailers and dealers including online pharmacies carrying on business of purchase or sale of drugs through physical mode as well as online mode i.e., through website/online portal/mobile app/e-commerce platforms or any other online mode, to display the current price list issued by manufacturer/marketer to ensure compliance to Para 24 and 25 of Drugs (Prices Control) Order,2013 ("**DPCO, 2013**"). Further, it may be noted that violation of Para 24 and 25 of DPCO, 2013 is punishable under Section 7 of the Essential Commodities Act, 1955.

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

On June 9, 2025, 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 Central 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 (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); and
3. expenditure incurred and claimed towards non-recurring expenses is not required to be refunded (this relates to grant paid by 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).

Ministry of Health and Family Welfare

Drugs Amendment Rules, 2025

On February 11, 2025, the Ministry of Health and Family Welfare ("**MoHFW**") notified the Drugs Amendment Rules, 2025, allowing small and medium manufacturers (having turnover ≤ 250 crores (Indian rupees two hundred fifty crores)) to seek extension of time to comply with the revised Schedule M (Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products) of the Drugs Rules, 1945. Small and medium

manufacturers with turnover less than INR 250 crores (Indian rupees two hundred fifty crores) may seek an extension of the timeline for compliance by making an application to the Central Licence Approving Authority in Form 'A', within a period of 3 (three) months from the date of publication of this notification (i.e., February 11, 2025), along with a plan of upgradation. If approved, the deadline for compliance will be extended to December 31, 2025 (earlier this was December 28, 2024).

Use of chlorpheniramine maleate and phenylephrine hydrochloride

On April 15, 2025, MoHFW 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 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.

Guidelines for acceptance of recycled polyethylene terephthalate as food contact material

On May 23, 2025, 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 the Food Safety and Standards Authority of India ("**FSSAI**"). It does not apply to production of resins for non-food grade consumer applications.

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 amendments will come into force on January 1, 2026.

Insurance Regulatory and Development Authority of India

One-time mandate for blocking the amount towards premium through unified payments interface for issuance of life and health insurance policies

On February 18, 2025, the Insurance Regulatory and Development Authority of India, issued a circular to facilitate smooth transactions of payment of premium, a facility of the unified payments interface one time mandate is enabled to be used by insurers. This feature allows users to block funds in their bank accounts for specific transactions, ensuring availability of funds while deferring actual payments. Insurers are mandated to offer Bima Applications Supported by Blocked Amount ("**Bima – ASBA**") facility to its prospects for life and health insurance policies. At present, the facility of Bima-ASBA is extended to individual policyholders. All insurers must go live and offer Bima-ASBA facility to the prospect or customer on or before March 1, 2025.

Food Safety and Standards Authority of India

Adherence to National Accreditation Board for Testing and Calibration Laboratories scope of accreditation for testing of referral samples

On February 25, 2025, FSSAI, issued an advisory to all the referral laboratories stating that they must strictly adhere to their National Accreditation Board for Testing and Calibration Laboratories ("**NABL**") scope of accreditation as per ISO 17025, while testing referral samples. The laboratories must test food products and parameters explicitly covered under their NABL scope of accreditation to ensure compliance with quality and regulatory standards. In this regard, all FSSAI notified referral laboratories under 43(2) of Food Safety and Standards Act, 2006 ("**FSS Act**") are also hereby

informed and instructed to test only the test parameters specified by the designated officers/authorised officers in Form VIA.

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

On April 3, 2025, FSSAI 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 NABL, 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.

FSSAI empowers consumers to report misleading claims on food products

On April 30, 2025, FSSAI 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.

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

On May 20, 2025, 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, the presence of calcium carbide on the premises or stored alongside crates of fruits is to be treated as circumstantial evidence against the Food Business Operator ("**FBO**"), potentially leading to prosecution under the FSS Act.

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.

Central Drugs Standard Control Organisation

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**") 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 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.

Transfer of drugs from special economic zone to domestic tariff area

On April 8, 2025, CDSCO 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. API/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 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

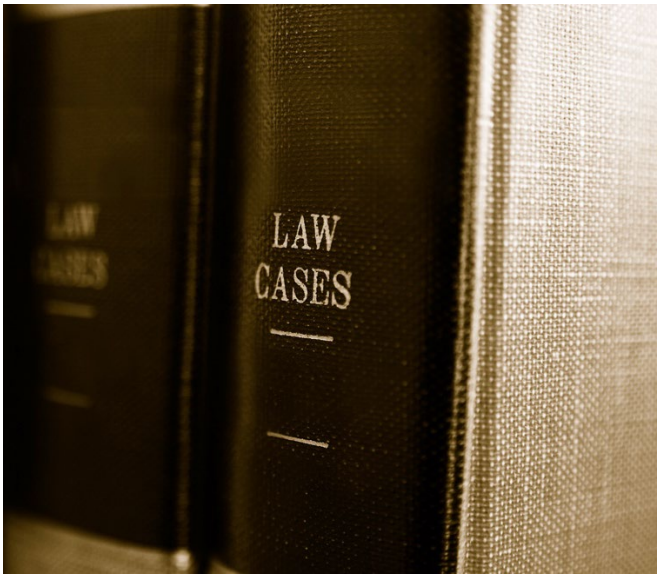
Authority is upgraded in the online system for medical devices with a new workflow for auto-generated MSC and NCC.

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.

Guidance document on disposal of expired/unused drugs

On May 26, 2025, CDSCO 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.



Case laws

Supreme Court of India: 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.

Karnataka High Court: Right to health and right to medical-care is a fundamental right, which stands enforced through corresponding Constitutional obligation on part of the State to create medical facilities

The Karnataka High Court, in the case of ***The Registrar General vs. Union of India***[2], has stated that when right to health and right to medical-care is treated as fundamental right, it stands enforced only with corresponding Constitutional obligation on part of the State to create medical facilities. Further, the court stated thar for effective enjoyment of this right, the creation of medical cadre, adequate medical personnel, setting up of infrastructure, availability of medicines in sufficient quantity and without interruption, as also establishment of primary health centres in the rural area, are the concomitants as they become inseparable necessities for enjoyment of right to health and right to medicare at all levels from urban to semi-urban to rural areas of the State, the medical facility, medical infrastructure and medical personnel have to be made available by the welfare state. The court has issued the following directions:

1. the Department of Health and Family Welfare, State of Karnataka, must constitute a 3 (three) member committee headed by the Secretary, Department of Health, to continuously oversee and implement the mechanism to ensure the providence of medical facility and medical infrastructure including the medical and para-

[1] 2025 INSC 482

[2] Writ Petition No. 797 Of 2024 (Gm-Res-Pil)

medical personnel at all levels-city, district and rural;

2. the committee as above must every 6 (six) months collect and assess the relevant details from deterrent districts about the number of vacancies of medical staff in different categories, the need for upgrading or further extending the medical infrastructure and medical facilities including medicines to the various government hospitals and primary health centres run by the Government;
3. the committee must gather the information about the medical staff vacancies in the Government hospitals and primary health centres and take steps for filling up the vacant posts. This exercise must be undertaken every 6 (six) months;
4. the committees at the district level for the above purposes, must be constituted under the headship of collector/deputy commissioner which must collect the details relating to the medical staff vacancies, medical infrastructure and medical facilities at district and taluka levels to provide such details to the committee as prescribed above, every 6 (six) months and must function in aid and in coordination;
5. the State Government must periodically and preferably every 6 (six) months undertake the survey of the primary health centres in the rural areas of the State for the purpose of upgradation of such centres in terms of medical facilities to be catered by them and also decide about establishing additional primary health centres on need basis in the villages;
6. the Health and Family Welfare Department must evolve and set up a mechanism to see that there is proper co-ordination and supervision in implementing different health schemes of the Central Government and the State Government, as also the health-related strategies; and
7. the budgeting provision for the purpose must be properly and adequately made and there must be ensured purpose-serving spending of the budgetary allocations.

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

7 Ranked Practices,
21 Ranked Lawyers

14 Practices and
12 Ranked Lawyers

12 Practices and 50 Ranked Lawyers

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