May 2026

Recent developments in the Indian healthcare and life sciences industry highlight the Government's continued emphasis on harmonizing the framework with global standards, bolstering enforcement, strengthening quality, improving patient safety, streamlining and digitization of procedures, and boosting the ease of doing business in India.

This edition of the JSA Healthcare Newsletter focuses on the key developments undertaken in the Indian healthcare and life sciences ecosystem during March and April 2026.

Regulatory updates

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

The Department of Pharmaceuticals ("**DoP**"), *vide* notification dated April 30, 2026, amended the Uniform Code for Marketing Practices in Medical Devices, 2024 ("**UCMPMD**") to eliminate the requirement for medical devices companies conducting advanced trainings in foreign locations to obtain prior approval.

Though the general principle is that foreign events should be avoided, the UCMPMD permitted companies to conduct advanced clinical trainings abroad in exceptional circumstances such as non-availability of facilities or expertise in India. In such instances, companies were required to submit an application justifying the reason for conducting the training overseas along with the estimated expenditure at least 3 (three) months prior to the proposed event. However, in the absence of defined timelines for processing the applications, companies faced uncertainty while planning these trainings.

In response to representations from the industry, the DoP has rationalised the requirements for companies conducting advanced clinical trainings or demonstrations overseas. Medical devices companies would no longer be required to obtain prior approval from the DoP, but must share deatails such as justification of the training, details of participants, estimated expenditure for the entire programme, at least 1 (one) month in advance, with their respective industry associations, which will then place it in public domain. This reiterates the DoP's prior initiatives to shift from an oversight-based to a transparency-led approach to governing industry-healthcare provider interactions.

Clarification on trigger for submission of periodic safety update reports for new drugs

The Central Drugs Standard Control Organisation ("**CDSCO**"), *vide* advisory dated April 21, 2026, issued directions to manufacturers and importers of new drugs regarding the submission of Periodic Safety Update Reports ("**PSURs**") for new drugs in cases where a new drug is not placed on the market immediately after the marketing authorisation is granted. The advisory clarifies that in such cases, the reporting timeline for PSURs will commence from the actual date of market launch rather than the date of regulatory approval, in order to ensure accurate capture of post-marketing safety data. Pertinently, this is a deviation from the approach followed by most national regulatory agencies including

in the United States of America, the United Kingdom, European Union, and signals the CDSCO's growing emphasis on pharmacovigilance. The advisory further instructs manufacturers and importers to consolidate all dosage forms, formulations, and indications within a single report while providing separate data presentations where necessary, to avoid duplication and improve the quality of pharmacovigilance reporting in accordance with the New Drugs and Clinical Trials Rules, 2019.

Crackdown on disease awareness campaigns

The CDSCO, *vide* an advisory dated March 10, 2026, reiterated the restrictions on advertising or engaging in promotional activities pertaining to prescription drugs such as GLP-1 drugs under the Drugs Rules, 1945. The advisory specifically alleged that pharmaceutical companies have been engaging in "indirect promotional activities" including disease awareness campaigns, digital media outreach and other communications relating to GLP-1 drugs and similar prescription drugs indicated for obesity and metabolic disorders.

Disease awareness campaigns that do not include any reference to a specific drug have typically been encouraged, since they educate the public about diseases and conditions. However, the CDSCO has stated that disease awareness campaigns "that function as surrogate advertisements" for prescription-only drugs are strictly prohibited, and will be attract strict action under the Drugs and Cosmetics Act, 1940. The CDSCO directed pharmaceutical companies to submit comprehensive risk mitigation plans which shall ensure continued safety monitoring and implementation of risk mitigation measures.

Regulatory surveillance over weight loss drug (GLP-1) supply chain

The CDSCO, *vide* a press release dated March 24, 2026, announced strengthened regulatory surveillance over the supply chain of GLP-1 drugs to curb illegal distribution channels, non-compliant dispensing practices, and misuse of such drugs. This included conducting inspections across wholesalers, retail pharmacies, online platforms, and wellness clinics. The state drug licensing authorities were directed to strengthen the monitoring of the end-to-end supply chain to ensure that the manufacture, import, distribution and wholesale, retail sale and dispensing occur only through authorised channels and in conformity with the approved indications and labelling. Further, the state licensing authorities were also requested to actively monitor print, electronic, digital, social media and outdoor platforms for non-compliant advertisements or surrogate promotional activities relating to GLP-1 drugs, and to initiate appropriate actions where necessary.

National Dental Commission Act, 2023 notified

The Ministry of Health and Family Welfare ("**MoHFW**") *vide* notification dated March 19, 2026, has repealed the Dentists Act, 1948 and dissolved the Dental Council of India. Concurrently, *vide* another notification dated March 19, 2026, has brought into effect the remaining provisions of the National Dental Commission Act, 2023. The National Dental Commission and the three autonomous bodies under the National Dental Commission Act – the Undergraduate and Postgraduate Dental Education Board, the Dental Assessment and Rating Board, and the Ethics and Dental Registration Board were also notified *vide* a third and fourth notification respectively.

This reform is aimed at improving the quality of dental education and practice in India. Pertinently, the regulations enacted under the Dentists Act, 1948 - including the Revised Dentists (Code of Ethics) Regulations, 2014 - shall remain in force till fresh regulations are enacted by the National Dental Commission.

Regulation and mandatory registration of licensed blood centres on the e-*RaktKosh* portal

The CDSCO, *vide* circular dated March 18, 2026, has directed all State Licensing Authorities to ensure mandatory registration and active utilisation of the e-*RaktKosh* portal by all licensed blood centres across States and Union Territories. Following the review meeting held on March 11, 2026, and in continuation of earlier advisories, the directive requires all State Licensing Authorities and CDSCO zonal and sub-zonal offices to coordinate for complete onboarding of blood centres onto the portal and ensure regular updating of blood stock and component availability data. The compliance requirements will now form part of routine regulatory inspection processes, and the inspection checklist for blood centres will be updated accordingly to include verification of e-*RaktKosh* usage. State Licensing Authorities were also required to submit a status report within 30 (thirty) days detailing the total number of licensed blood centres, those registered on the portal, and those pending registration.

Implementation plan of certification standards for emergency departments in hospitals

The National Accreditation Board for Hospitals and Healthcare Providers ("**NABH**"), *vide* circular dated March 5, 2026, has released the second edition of its Certification Standards and Guidebook for Emergency Department in Hospitals. The updated standards are applicable to new certification applications with effect from April 1, 2026, while existing applicants within defined timelines may opt between the first and second editions based on their submission status. The circular clarifies that all re-certification applications submitted after March 31, 2026, will be assessed only under the second edition, and no new or renewal applications under the first edition will be accepted beyond this date. The NABH certification is legally required, but hospitals elect to obtain it as an indicator of their commitment to healthcare quality and patient safety.

Implementation of prior intimation system for Form CT-05 application

CDSCO, *vide* circular dated April 20, 2026, notified the implementation of the Prior Intimation System for Form CT-05 applications for export purposes with effect from April 21, 2026, pursuant to New Drugs and Clinical Trials (Second Amendment) Rules, 2026 dated January 21, 2026. All stakeholders must submit online application (for export purpose only) as prior intimation in Form CT-05 on SUGAM portal. Once the application is submitted, the acknowledgment of application submission received from the portal may be treated as "prior intimation" and the concerned applicant can accordingly use this intimation for further use as required. For all other purposes or categories not covered under the New Drugs and Clinical Trials (Second Amendment) Rules, 2026, the existing system of prior approval is applicable.

Online applications for grant of license and post approval changes with respect to marketing authorisation for r-DNA products

The Central Drugs Standard Control Organisation ("**CDSCO**"), *vide* circular dated March 9, 2026, mandated that all applicants must apply for post approval changes with respect to marketing authorisation for r-DNA products through Online System of SUGAM Portal (www.cdscoonline.gov.in) under "Post Approval Changes - MA". The facility for offline submission of hard copy applications has been discontinued for processing with effect from March 5, 2026.

Further, *vide* circular dated March 10, 2026, CDSCO streamlined the submission procedure for grant of license in Form 28-0/28-DA for r-DNA products. Submission of applications can be made through the Online System of Online National Drugs Licensing System (ONDLS Portal) (https://statedrugs.gov.in). The facility for offline submission of hard copy applications has been discontinued with effect from March 10, 2026.

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Manufacturing and marketing of unapproved drug products- Sodium Hyaluronate Eye Drops 0.3%

CDSCO, *vide* letter dated March 18, 2026, issued a regulatory direction regarding the manufacturing and marketing of unapproved drug products, specifically Sodium Hyaluronate Eye Drops 0.3% weight by volume. The communication highlights that the said product falls under the category of a new drug and cannot be manufactured or marketed in India without prior approval from the licensing authority under the New Drugs and Clinical Trials Rules, 2019. It directs State and Union Territory Drugs Controllers to take immediate action to prevent unauthorised manufacture and sale, including cancellation of any product permissions granted for the subject drug, and to ensure strict compliance with applicable regulatory provisions governing new drug approvals.

Import, manufacturing, sale of medical devices intended for In-Vitro Fertilization

CDSCO, *vide* circular dated March 27, 2026, has clarified that medical devices intended for assisted reproductive technology procedures, including intrauterine insemination kits and centrifuges used for sperm washing, fall under the definition of medical devices regulated under the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017. The circular further directed all State and Union Territory Drug Controllers and Licensing Authorities to ensure that such devices are not imported, manufactured, distributed, or sold without obtaining the necessary licenses from the competent licensing authority.

Proposed amendments

Introduction of rules for post approval changes for drugs

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* draft notification dated March 9, 2026, has proposed the incorporation of a structured framework for post-approval changes under the Drugs Rules, 1945. These include changes relating to manufacturing processes, excipients, packaging, shelf life, specifications, testing, and documentation across various manufacturing licence categories under the Drugs Rules, 1945. In February this year, the MoHFW had released a draft amendment proposing the addition of similar conditions for post approval changes to new drugs under the New Drugs and Clinical Trial Rules, 2019.

The draft rules classify changes into major quality changes (Level I), moderate quality changes (Level II), and minor quality changes (Level III), based on their potential impact on the identity, strength, quality, purity, or potency of a drug product, but does not lay down parameters for determining how the impact should be evaluated. Manufacturers would be required to obtain prior approval from the licensing authority for major and moderate quality changes, while minor changes may be implemented without prior approval, subject to specified exceptions and annual reporting requirements.

Proposal to rationalise screening requirements for blood products

The MoHFW, *vide* draft notification dated March 9, 2026, has proposed an amendment to the testing requirements for blood products such as albumin, plasma protein, fraction, immunoglobins and coagulation factor concentrates manufactured under the Drugs Rules, 1945.

Presently, blood products are required to conform to the applicable standards under Indian Pharmacopoeia, in the absence of which the standards specified under United States Pharmacopoeia or British Pharmacopoeia must be followed. In addition, manufacturers are required to conduct screenings for HIV I and HIV II antibodies, Hepatitis B surface antigen, and Hepatitis C virus antibodies.

The industry contended that the provision was resulting in superfluous testing, and that the relevant monographs in the pharmacopeial standards already specify the screening tests that need to be conducted for a particular blood product. In response to these representations, the Drugs Technical Advisory Board examined the matter, and agreed that the condition for conducting the specified screenings may be omitted, and the draft amendment was subsequently issued for public consultation.

Clarity on the requirement for obtaining test license

The MoHFW, *vide* draft notification dated April 21, 2026, has proposed an amendment to the Drugs Rules, 1945 which would expand the categories of manufacturing license holders who can manufacture drugs for examination, test or analysis without obtaining a separate license under Form 29.

Under the existing rule, any person intending to manufacture drugs for the purpose of examination, test, or analysis is required to obtain a test license in Form 29, unless they already hold a manufacturing license in Form 25 or Form 28 in respect of such drugs. The draft amendment seeks to broaden the scope of the exemption by substituting the reference to "Form 25 and Form 28" with a wider set of licenses, including Forms 25, 25A, 25F, 28, 28A, 28B, 28D, 28DA, and 28F. Pertinently, the exemption from obtaining a separate license is only applicable when the drug to be manufactured for examination, test or analysis is covered under an existing manufacturing license.

Proposed amendment to the Medical Devices Rules

The MoHFW, *vide* notification dated April 10, 2026, has proposed an amendment to the under the Medical Devices Rules, 2017, which would make conformity with quality management systems specified in the Fifth Schedule mandatory for Class A non-sterile and non-measuring ("**NSNM Devices**") devices.

NSNM Devices are considered low-risk, and are only required to obtain a registration on the Online System for Medical Devices portal. The registration number is generated on the basis of the information and self-declarations uploaded by the manufacturer or importer. Presently, the applicant is required to self-certify conformity with the standards specified in the Medical Devices Rules - which would include product standards issued by the Bureau of Indian Standards – but is not required to self-certify conformity with the quality management systems. In order to ensure that certain baseline quality standards are adhered to, the amendment has made such self-certification mandatory for the registration of NSNM Devices.

Separately, the notification has also proposed an amendment to the requirements for importing a medical device which does not have a predicate. Generally, clinical investigations are required to be conducted prior to making an application for import or manufacture of such devices. However, a conditional exemption is provided for devices which have been evaluated and approved by certain national regulatory authorities, and have been marketed in those countries for at least two years. Presently, the national regulatory authorities of the United Kingdom, United States of America, Australia, Canada and Japan have been recognised for this purpose. It has been proposed that the European Union also be included in the list.

In a separate notification dated April 10, 2026, the MoHFW has proposed measures for ensuring accountability in situations where the manufacturer of a sterile medical device outsources the sterilisation activities to the site of

another facility. In such cases, it would be mandatory to declare the license number of the sterilization site as well on the label of the device.

The notification also proposed the standardisation of the fees that may be charged for the testing and evaluation of medical devices, specifying price caps for nearly a dozen types of tests, and the provision for the prices to increase by 5% each year. These prices would be applicable to all medical device testing laboratories, including those that are privately-owned.

Case laws

Supreme Court of India permits withdrawal of life-sustaining treatment in line with patient's best interests and affirms dignified end-of-life care framework

The Supreme Court of India ("**Supreme Court**"), in its judgment dated March 11, 2026, in the case of ***Harish Rana vs. Union of India***.[1], held that medical treatment need not be prolonged where the twin legal requirements for withdrawal of life-sustaining treatment were satisfied, namely that the treatment constituted ongoing medical intervention and that its continuation was no longer in the patient's best interests. Noting the unanimous consensus of the family members and duly constituted medical boards, the Supreme Court permitted the withdrawal/withholding of life-sustaining treatment and directed that the process be carried out under a structured palliative and end-of-life care framework to ensure dignity, comfort, and minimisation of suffering. The Supreme Court further issued comprehensive nationwide directions to streamline end-of-life decision-making, including the maintenance of panels of qualified medical practitioners for constitution of medical boards, timely nominations by Chief Medical Officers, and coordinated oversight by hospitals, High Courts, and State authorities to ensure uniform implementation of established guidelines on end-of-life care.

Supreme Court directs nationwide framework for standardisation and implementation of intensive care unit infrastructure and care guidelines

The Supreme Court, in its order dated April 23, 2026, in the case of ***Asit Baran Mondal & Anr. vs. Dr. Rita Sinha MBBS MS (Obst. Gynae) & Ors***.[2], recorded that a foundational document titled 'Guidelines for Organization and Delivery of Intensive Care Services' had been prepared with consensus of expert stakeholders from leading medical institutions. It directed all Additional Chief Secretaries/Secretaries, heading the Department of Health and Medical Education in States and Union Territories to prepare an action plan for implementation of the guidelines. It further mandated a coordinated process with the Ministry of Health culminating in a consolidated national implementation blueprint to be submitted within 3 (three) weeks.

[1] 2026 INSC 222
[2] M.A. Diary No. 30408/2024 (Item No. 20, Court No. 13, Section XVII-A)

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 is prepared by:

Sidharrth Shankar
Partner

Dhruv Malhotra
Partner

Eshika Phadke
Senior Associate

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