



March 2026

India's healthcare sector continues to focus on digital integration, infrastructure expansion, and regulatory adjustments to existing schemes. During the Budget 2026, the Hon'ble Finance Minister announced a series of landmark initiatives to expand education, research, quality assurance, global leadership, medical value tourism, and skilled workforce development under the Ministry of Ayush. These measures reinforce India's aspiration to position traditional medicine as a key driver of preventive healthcare, economic growth, and global leadership in wellness.

Keeping with the theme of revitalizing India's rich Ayurvedic tapestry, 3 (three) new All India Institutes of Ayurveda to expand high-quality undergraduate and postgraduate education, advanced research, and tertiary care services have been proposed to be established. Building on the success of existing national institutes, these institutions are expected to elevate academic standards and strengthen evidence-based integrative care across the country and serve as the foundation for Ayurvedic healthcare. The Budget also proposed upgrading Ayush pharmacies and drug testing laboratories to meet higher certification standards. This move is expected to enhance product quality, consumer confidence, and export readiness and will also support farmers cultivating medicinal plants and Micro, Small, and Medium Enterprises engaged in processing and manufacturing.

The Union Minister for Health and Family Welfare launched 2 (two) revolutionary digital health initiatives: SAHI (Strategy for Artificial Intelligence in Healthcare for India) and BODH (Benchmarking Open Data Platform for Health AI) during the India AI Impact Summit 2026. This marks a significant milestone in advancing safe, ethical, and evidence-based deployment of Artificial Intelligence (AI) in India's healthcare ecosystem.

This edition of the JSA healthcare Newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem during January and February 2026.

Regulatory updates

Legal Metrology (General) Amendment Rules, 2026

The Ministry of Consumer Affairs, Food and Public Distribution, *vide notification* dated January 7, 2026, has amended the Legal Metrology (General) Rules, 2011. Amendments are made to Part VII-A of the Eighth Schedule by including comprehensive requirements for non-invasive, non-automated sphygmomanometers (blood pressure monitors). Provisions detailing scope, terminology, instrument description, units of measurement, metrological accuracy limits, technical specifications, safety standards, marking requirements, and manufacturer obligations have been included.

Draft New Drugs and Clinical Trials (Amendment) Rules, 2025

The Ministry of Health and Family Welfare ("MoHFW"), *vide notification* dated January 20, 2026, has proposed an amendment to Paragraph 4.2 of Table 2 of the Second Schedule of the New Drugs and Clinical Trials Rules, 2019, in

relation to intravenous infusion and injectables, to exempt certain clinical studies for those injectables where the test product's excipients are qualitatively and quantitatively identical to the reference product.

New Drugs and Clinical Trials (Amendment) Rules, 2026

MoHFW, *vide* [notification](#) dated January 20, 2026, has amended the New Drugs and Clinical Trials Rules, 2019. Some of the key amendments are as follows:

1. in case of manufacture of a new drug or investigational new drug for analytical and non-clinical testing, an online application in Form CT-10 can be submitted as prior intimation to the Central Licencing Authority; and
2. reduction in the review period for applications seeking permission to manufacture a new drug or an investigational new drug for clinical trials, or to conduct bioavailability/bioequivalence studies from 90 (ninety) days to 45 (forty-five) days.

New Drugs and Clinical Trials (Second Amendment) Rules, 2026

MoHFW, *vide* [notification](#) dated January 21, 2026, has amended the New Drugs and Clinical Trials Rules, 2019. Key amendments include:

1. in case of single-dose, two-period, two-sequence, two-treatment, bioavailability or bioequivalence studies in normal healthy adult human volunteers (for export purpose), of oral dosage form of a drug (other than drugs of cytotoxic, hormone, narcotic and psychotropic substances categories and not a drug of Narrow Therapeutic Index or a drug having highly variable pharmacokinetics) already approved in India or any one of the United States of America, European Union, Japan, Australia, Canada and United Kingdom, the studies may be conducted after submission of an online application as prior intimation in Form CT-05 and its acknowledgement by the Central Licensing Authority, subject to the following conditions:
 - a) the application of the prior intimation is required to be appended with approval of the ethics committee registered with the Central Licensing Authority; and
 - b) the ethics committee maintaining a separate record of review and approval of such bioavailability or bioequivalence studies being conducted on the basis of the acknowledgement of prior intimation, which will be reviewed by the Central Licensing Authority at the time of renewal of the registration of the ethics committee; and
2. to expedite clinical research, the requirement of obtaining prior permission for certain categories of low-risk bioavailability/ bioequivalence studies has been dispensed with, and such studies may now be conducted by submitting an online application in Form CT-05.

Draft amendments to Drugs Rules, 1945

MoHFW, *vide* [notification](#) dated January 21, 2026, has proposed an amendment to the Drugs Rules, 1945 (“**Drug Rules**”). It is proposed that antimicrobial drugs and their preparations must bear a conspicuous blue vertical strip on the left side running throughout the body of the label without disturbing the other conditions printed on the label.

Further, *vide* another [notification](#) dated January 21, 2026, MoHFW has proposed an amendment to Schedule V of the Drugs Rules, which deals with standards for patent or proprietary medicines for adults, infants less than 1 (one) year and children above 1 (one) year up to adults. It is proposed to rectify the strength of folic acid with respect to the unit of measurement by substituting "mg" with "mcg".

Guidance on import of in-vitro diagnostic medical device

On January 30, 2026, the Central Drugs Standard Control Organization (“CDSCO”) issued a [guidance document](#) on import of in-vitro diagnostics medical devices. It serves as guidance for importers for submitting product licence applications to CDSCO through the ‘cdscomdonline’ and ‘NSWS’ portal. It outlines the applicable regulatory framework, procedural steps, documentation requirements, and compliance obligations that are required to be fulfilled in accordance with the Medical Devices Rules, 2017.

Draft amendments to New Drugs and Clinical Trials Rules, 2019

MoHFW, *vide* [notification](#) dated February 2, 2026, has proposed an amendment to the New Drugs and Clinical Trials Rules, 2019. It is proposed that on receipt of application in Form CT-01 under Rule 17(1), the authority designated must scrutinise the documents and information, and if satisfied that the requirements of these rules have been complied with, grant final registration to Ethics Committee in Form CT-03; or if not satisfied, reject the application, for reasons to be recorded in writing.

Legal Metrology (General) Second Amendment Rules, 2026

The Ministry of Consumer Affairs, Food and Public Distribution, *vide* [notification](#) dated February 11, 2026, has amended the Legal Metrology (General) Rules, 2011. Part D is inserted to Schedule Eight Part VI specifying metrological and technical requirements for clinical electrical thermometers for continuous measurement. Provisions detailing scope, terminology, description, metrological requirements and technical requirements are included.

Revised implementation and migration plan for second edition NABH entry-level certification standards for hospitals

The National Accreditation Board for Hospitals and Healthcare Providers (“NABH”), *vide* [notification](#) dated February 13, 2026, has issued a revised implementation and migration plan for the second edition of the NABH entry-level certification standards for hospitals. All applications under the NABH entry-level certification programme for hospitals, must be applied through the new portal (<https://nabh.qcin.org>). All applicants and certified hospitals are required to follow the implementation and migration plan as per the prescribed protocol. The NABH entry-level certification standards for hospitals is structured into 3 (three) categories: core, commitment and excellence. This structure is intended to support a phased, progressive, and outcome-oriented quality journey for hospitals, in alignment with the hospital’s bed strength, applicant category, and certification cycle.

Transplantation of Human Organs and Tissues Rules, 2026

MoHFW, *vide* [notification](#) dated February 18, 2026, has amended Rule 31(4)(c) of the Transplantation of Human Organs and Tissues Rules, 2014, in relation to the procedure for notifying and coordinating the retrieval of organs or tissues from a deceased person after obtaining consent for the same. The allocation of the organ to be shared is to be decided by the State networking organisation (e.g., in Delhi, previously, the National Organ and Tissue Transplant Organization was bestowed with this power).

Drugs (Amendment) Rules, 2026

MoHFW, *vide* a [notification](#) dated February 16, 2026, has amended Drugs Rules, 1945. Some of the key amendments are as follows:

1. Amendment of Rule 121A in relation to the test for bacterial endotoxins-pyrogens or the test for pyrogens (*where justified or authorised*). A solution of substances intended for parenteral administration (as well as water or any other aqueous solvent supplied along with such substance) must comply with such tests and be carried out as per the current edition of Indian pharmacopeia (*earlier this was mandated for parenteral administration in large volumes of 10 ml. or more at a time*); and
2. amendments to Forms 20B, 20G and 21B providing for the personal supervision of a named competent person for conducting the sale of drugs is conducted. Further, the licensees are mandated to report any change in the competent person to the licensing authority within 1 (one) month of such a change.

Testing of drugs for grant of permissions for import/manufacture of new drugs and issuance of registration certificate for import of drugs

CDSCO, *vide* [circular](#) dated February 23, 2026, has expedited the processing of applications for import/manufacture of new drug for sale or for distribution and issuance of registration certificate for import of drugs, providing for the issuance of a No Objection Certificate for testing of drug samples at designated laboratories (IPC, Ghaziabad; CDTL, Mumbai; CDL at CRI, Kasauli; or NIB, Noida) immediately upon receipt of applications in the concerned division. Applicants are required to submit their finalised regulatory specifications on the basis of the prevailing pharmacopoeia standards and the product specific quality management system. The circular will be effective from June 1, 2026.

Office Memorandum on revision of MRP of life saving drugs exempted from custom duty

The Department of Pharmaceuticals (“DoP”), *vide* [notification](#) dated February 10, 2026, has directed manufacturers and marketing companies selling prescribed life saving drugs/ formulations to revise the MRP of drugs/ formulations on account of exemption of custom duty. The information about the revision is required to be submitted through Form V of Drugs (Prices Control) Order, 2013 and the manufacturers are required to issue a price list or supplementary price list to the dealers, State Drugs Controllers and the Government indicating such changes.

CDSCO mandates manufacturers to incorporate potential side effects of Doxycycline and Carbimazole

CDSCO, *vide* circulars dated February 17, 2026, has requested all States/Union Territories Licensing Authorities to direct manufacturers of [Doxycycline](#) and [Carbimazole](#) formulations to mention “*CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, and Dizziness) for Doxycycline*” and “*agranulocytosis for Carbimazole*” as adverse drug reactions in the caution section of package insert/promotional literature of the drug.

Modification in the operational guidelines of sub-scheme ‘Medical Device Clinical Studies Support Scheme’

DoP, *vide* a [corrigendum](#)/addendum dated February 23, 2026, has amended paragraphs 5.4 and 5.11 of Chapter V (*Medical Device Clinical Studies Support Scheme*) under the Scheme for Strengthening of Medical Device Industry. DoP provides financial support in conducting clinical investigation/ clinical performance evaluation/ post market follow-up study/ animal studies to the eligible applicants in the form of grant on re-imbursment basis the prescribed criteria. Pursuant to the amendment, applicants who have an average turnover of not more than INR 10,00,00,000 (Indian Rupees Ten Crore) in the preceding 2 (two) financial years, will be provided financial support of INR 5,00,00,000 (Indian Rupees five crore) or 70% (seventy percent) of the expenditure incurred, whichever is less.

Case laws

Supreme Court: Stem cell therapy for autism spectrum disorder cannot be offered by medical practitioners for commercial clinical treatment

The Supreme Court of India (“**Supreme Court**”), in its [Judgement](#) dated January 30, 2026, in the case of ***Yash Charitable Trust and Ors. v. Union of India and Ors.***¹, held that therapeutic use of stem cells cannot be offered by medical practitioners as a clinical service outside an approved and monitored clinical trial/research setting, since autism spectrum disorder is not recognised as ‘a sound and relevant medical practice’. The Supreme Court directed the Secretary, MoHFW, to solve for and ensure that patients are able to continue receiving the therapy till the time they can be re-routed to the institutions that are conducting clinical trials. A period of 4 (four) weeks was granted to file submissions in compliance with this direction.

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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¹ 2026 INSC 96



19 Practices and
40 Ranked Lawyers



8 Ranked Practices,
22 Ranked Lawyers



15 Practices and
20 Ranked Lawyers



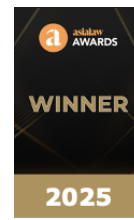
13 Practices and
49 Ranked Lawyers



20 Practices and
24 Ranked Lawyers



8 Practices and
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