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A quarterly update on the pharmaceutical, life sciences and healthcare industry

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Dear Readers,

The new year brings with it an opportunity to reflect on the first quarter of 2026, a period marked by sweeping regulatory reform, landmark judicial pronouncements, and robust deal-making activity across India's pharmaceutical, healthcare, and life sciences ecosystem. From the Union Budget's ambitious healthcare agenda to transformative recommendations by the DTAB, and from the Supreme Court's first-ever passive euthanasia order to a wave of significant transactions, this edition of *Synapse* captures a quarter that has set a purposeful tone for the year ahead.

Significant regulatory developments between January and March 2026 reflect a concerted push towards modernisation, international harmonisation, and enhanced compliance infrastructure. Building on this agenda, the MoH&FW notified two amendments to the New Drugs and Clinical Trials Rules, introducing a prior intimation pathway for analytical and non-clinical testing and streamlining bioequivalence study approvals for export-oriented drugs, while a further proposed amendment introduced a three-tiered change management framework covering major, moderate, and minor post-approval changes for drug manufacturing processes. Complementing these reforms, the MoH&FW also proposed rationalisation of duplicate viral testing requirements for blood products in alignment with international pharmacopoeial standards. On the pricing front, the NPPA fixed retail prices for 36 new drug formulations and directed revision of MRPs for 17 life-saving drugs following customs duty exemptions, ensuring that the benefit of duty relief is passed on to consumers. Reinforcing environmental compliance, the MoEFCC notified the Solid Waste Management Rules, 2026, introducing a four-stream waste segregation mandate and an Extended Bulk Waste Generator Responsibility framework, and exempted Common Effluent Treatment Plants from mandatory prior environmental clearance.

Turning to news and policy developments, this quarter was anchored by the Union Budget 2026–27, which underscored the Government's focus on strengthening India's pharmaceutical, healthcare, and life sciences ecosystem. The proposed INR 10,000 crore Biopharma Shakti programme seeks to address challenges in scaling biologics manufacturing and regulatory approval timelines; a scheme for establishing five regional medical tourism hubs in partnership with the private sector was announced; and basic customs duty was proposed to be removed on 17 high-cost cancer drugs, with expanded exemptions for rare disease patients. The DTAB, at its 93rd meeting, made significant recommendations including the inclusion of all antimicrobials under the definition of "New Drug", conferring legal sanctity upon Good Distribution Practices, and restricting advertisement of drugs listed under Schedules H, H1, and X. On the trade front, the India–EU Free Trade Agreement is expected to significantly expand the reach of India's traditional medicine sector across European markets, with wide-ranging implications for Ayush practitioners, intellectual property, and regulatory cooperation.

Complementing these developments, the Union health minister launched SAHI and BODH at the India-AI Impact Summit 2026, establishing India's governance framework for responsible and accountable AI in healthcare.

In another significant area of development, the litigation space witnessed landmark judicial activity across constitutional, regulatory, and patient rights domains. The Supreme Court passed its first-ever order permitting passive euthanasia, applying the framework laid down in *Common Cause v. Union of India* (2018) and directing the withdrawal of life-sustaining treatment in a case involving a patient in a Permanent Vegetative State. The Court further held that the right to menstrual health forms an integral part of the right to life under Article 21 of the Constitution. It also issued notice on a PIL seeking the exclusion of medical professionals from the ambit of the Consumer Protection Act, 2019. The Apex Court also held that offering stem cell therapy for autism spectrum disorder as a routine clinical service amounts to malpractice. At the High Court level, the Delhi High Court restored the Central Government's ban on two FDCs comprising Glimepiride, Pioglitazone, and Metformin, the Madras High Court held non-compete, non-solicitation, and confidentiality clauses in hospital–doctor agreements void *ab initio* and opposed to public policy. The Kerala High Court upheld the entitlement of physiotherapists and occupational therapists to use the "Dr." prefix under the National Commission for Allied and Healthcare Professions Act, 2021.

This quarter also saw several significant developments on the transactions and investments front, reflecting the evolving dynamics of the healthcare and life sciences sector. This edition of *Synapse* captures some of these key updates.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated pharmaceuticals, healthcare, and life sciences practice. Our class-leading practice specialists are always on top of the latest developments in the sector. This latest issue of Synapse is our effort to keep you abreast with the latest developments in this dynamic sector. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback, and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blogs at https://corporate.cyrilamarchandblogs.com for more articles on matters of interest in the Indian pharmaceutical, life sciences, and healthcare spaces. We hope you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and healthy.

Regards,

CYRIL SHROFF
Managing Partner
Cyril Amarchand Mangaldas

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Regulatory Updates

1. Key Ministry of Health and Family Welfare (MoH&FW) updates

a. *MoH&FW notifies the New Drugs and Clinical Trials (Amendment) Rules, 2026, providing for changes in test license requirements under the New Drugs and Clinical Trial Rules, 2019 (**NDCT Rules 2019**)*[1]

The MoH&FW, *vide* notification G.S.R. 46(E) dated January 20, 2026, has notified the New Drugs and Clinical Trials (Amendment) Rules, 2026 (**NDCT Amendment 1**), to amend the NDCT Rules. The NDCT Amendment 1 introduced a prior intimation pathway for the manufacture and procurement of new drugs or investigational new drugs for analytical and non-clinical testing (excluding sex hormones, cytotoxic, beta lactam, biologics with live microorganisms, and narcotics and psychotropic drugs), commencing upon acknowledgement of an online application in the relevant Form, without the need for formal permission. It has also halved the statutory timelines under Rules 53 and 60 from 90 (ninety) to 45 (forty-five) working days, with consequential amendments to Rules 54 through 66 and the relevant Forms ensuring parity of regulatory oversight across the prior intimation and permission pathways.

b. *MoH&FW notifies the New Drugs and Clinical Trials (Second Amendment) Rules, 2026*[2]

The MoH&FW, *vide* notification G.S.R. 50(E) dated January 21, 2026, notified the New Drugs and Clinical Trials (Second Amendment) Rules, 2026 (**NDCT Amendment 2**). The NDCT Amendment 2 introduced a prior intimation pathway, distinct from the existing permission route, for conducting single-dose, two-period, two-sequence, two-treatment BA/BE studies on normal healthy adult human volunteers, limited to oral dosage forms of drugs approved in India or in specified reference countries (United States, European Union, Japan, Australia, Canada, or the United Kingdom), solely for export purposes, and excluding cytotoxic, hormone, narcotic, psychotropic, narrow therapeutic index drugs, and highly variable pharmacokinetic drugs. Under this pathway, sponsors may commence studies upon submission of an online application in Form CT-05 and acknowledgement by the Central Licensing Authority (**CLA**), subject to Ethics Committee approval and a minimum sample size of 18 (eighteen).

c. *MoH&FW proposes correction to unit of measurement for folic acid under Schedule V of the Drugs Rules, 1945 (**Drugs Rules**)*[3]

The MoH&FW, *vide* draft notification G.S.R. 53(E) dated January 21, 2026, issued a draft amendment to the Drugs Rules. The amendment proposed a correction to Schedule V of the Drugs Rules, substituting the unit of measurement for folic acid from "mg" to "mcg" in the Table under Schedule V.

d. *MoH&FW proposes inclusion of Pregabalin and its drugs formulations in Schedule H1 of Drugs Rules*[4]

The MoH&FW, *vide* draft notification G.S.R. 54(E) dated January 21, 2026, issued a draft amendment to the Drugs Rules. The amendment proposed the insertion of a new serial number 51 in Schedule H1 of the Drugs Rules, adding "Pregabalin" to the list of regulated drugs.

e. *MoH&FW proposes inclusion of warning caution in blue vertical strip on labels for antimicrobials* [5]

The MoH&FW, *vide* notification G.S.R. 51(E) dated January 21, 2026, has notified draft amendment to the Drugs Rules. Proposing the insertion of a new clause (xiv) in sub-rule (1) of Rule 96 of the Drugs Rules, the amendment mandates that all antimicrobial drugs and their preparations bear a conspicuous blue vertical strip to the left of the label, running throughout the body of the label without disturbing the other conditions printed thereon.

f. *MoH&FW notifies draft amendment for waiver of sub-acute animal toxicity studies under the NDCT Rules*[6]

The MoH&FW, *vide* draft notification G.S.R. 45(E) dated January 20, 2026, notified draft rule amendments to the NDCT Rules. The amendments provide that the requirement for in vivo bioequivalence studies for intravenous infusions and injectables shall not apply

[1] https://egazette.gov.in/WriteReadData/2026/269489.pdf.
[2] https://egazette.gov.in/WriteReadData/2026/269595.pdf.
[3] https://egazette.gov.in/WriteReadData/2026/269588.pdf.
[4] https://egazette.gov.in/WriteReadData/2026/269587.pdf.
[5] https://egazette.gov.in/WriteReadData/2026/269542.pdf.
[6] https://egazette.gov.in/WriteReadData/2026/269566.pdf.

where the test product, in respect of its excipients, is qualitatively and quantitatively the same as the reference product.

g. *MoH&FW proposes change in management framework for NDCT Rules 2019*[7]

The MoH&FW, *vide* notification G.S.R. 97(E) dated February 2, 2026, published the Draft New Drugs and Clinical Trials (Amendment) Rules, 2026, proposing amendments to the NDCT Rules, with key highlights as follows:

i. New clauses were proposed under Rules 77 and 82 of the NDCT Rules, requiring manufacturers to notify the licensing authority of any change in manufacturing process, excipients, packaging, shelf life, specifications, testing, or documentation.

ii. The amendments also introduced a three-tiered change management framework:

a. *Level I (Major Quality Changes)*: Requiring prior approval from the licensing authority before implementation.

b. *Level II (Moderate Quality Changes)*: Requiring prior approval from the licensing authority before implementation.

c. *Level III (Minor Quality Changes)*: May be implemented without prior approval, subject to annual submission to the licensing authority by the first quarter of each calendar year.

The draft rules were published for information of all persons likely to be affected, with objections and suggestions invited within 30 (thirty) days from the date of publication in the Official Gazette.

h. *MoH&FW amends Drugs Rules on bacterial endotoxins test, licence forms, and Schedule H*[8]

The MoH&FW, *vide* notification G.S.R. 135(E) dated February 16, 2026, notified the Drugs (Amendment) Rules, 2026, to further amend the Drugs Rules. The amendments substituted Rule 121A to require solutions intended for parenteral administration to comply with a test for bacterial endotoxins or, with the test for pyrogens, as per the current edition of the Indian Pharmacopoeia (I.P.). Provisions in Forms 20B, 20G, and 21B under Schedule A were also inserted, requiring that sale be conducted under the personal supervision of a named competent person and that any change in competent person be reported to the licensing authority within one month. Additionally, a new entry 6 was inserted in the footnote to Schedule H, clarifying that drugs listed at serial number 15 of Schedule K shall not be covered under Schedule H."

i. *MoH&FW proposes inclusion of Navi Mumbai International Airport as authorised drug import gateway*[9]

The MoH&FW, *vide* draft notification G.S.R. 66(E) dated January 28, 2026, proposed amending Rule 43A of the Drugs Rules to include Navi Mumbai International Airport (NMIA), Raigad, Maharashtra, as an authorised port, by replacing the words "Cochin and Thiruvananthapuram" with "Cochin, Thiruvananthapuram, and Navi Mumbai International Airport (**NMIA**) in Raigad, Maharashtra." The draft rules were published after consultation with the Drugs Technical Advisory Board (**DTAB**), under Sections 12(1) and 33(1) of the Drugs and Cosmetics Act, 1940 (**Drugs Act**). The draft notification invited public comments for a 30 (thirty)-day period following its publication in the Official Gazette.

j. *MoH&FW issues draft notification regarding blood product testing*[10]

The MoH&FW, *vide* draft notification G.S.R. 164(E) dated March 9, 2026, invited public comments on a draft amendment to the Drugs Rules, proposing to remove duplicate viral testing requirements for blood products under Schedule F, Part XII C. Specifically, the amendment seeks to omit the requirement for finished blood products to be tested for HIV I and II antibodies, Hepatitis B surface antigen, and Hepatitis C virus antibody at the final product stage, given that plasma pools are already subjected to identical screening prior to fractionation under international pharmacopoeial standards. It seeks to rationalise testing requirements, reduce avoidable compliance burden, and harmonise India's regulatory framework with international norms without compromising patient safety, with stakeholders invited to submit comments within the stipulated period.[11]

[7] https://egazette.gov.in/WriteReadData/2026/269818.pdf
[8] https://egazette.gov.in/WriteReadData/2026/270343.pdf
[9] https://egazette.gov.in/WriteReadData/2026/269655.pdf
[10] https://egazette.gov.in/WriteReadData/2026/270812.pdf
[11] https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=2237960&reg=3&lang=1

k. *MoH&FW issues draft notification regarding post-approval changes in drug manufacturing processes*[12]

The MoH&FW, *vide* draft notification G.S.R. 173(E) dated March 9, 2026, invited public comments on a proposed amendment to the Drugs Rules, aimed at regulating and classifying post-approval changes in drug manufacturing processes. The amendment, issued under the Drugs Act, following consultation with the DTAB, mandates drug manufacturers to notify the licensing authority of any changes in manufacturing process, raw materials, packaging, shelf life, specifications, testing, or documentation. The draft introduces three categories of quality changes. Major changes (Level I) and moderate changes (Level II), both require prior approval from the licensing authority given their potential significant or moderate impact on drug identity, strength, quality, purity, or potency, whereas minor changes (Level III) may be implemented without prior approval, but must be reported through annual submissions. In certain cases, manufacturers must additionally notify the licensing authority within 30 (thirty) days of implementing specific changes. The proposed framework seeks to strengthen regulatory oversight while allowing operational flexibility for minor modifications, with stakeholders invited to submit objections or suggestions within 30 (thirty) days to the Drugs Division of the MoH&FW.

2. Key Central Drugs Standard Control Organisation (CDSCO) updates

a. *CDSCO releases Standard Operating Procedure for processing applications for compounding of offences under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025*[13]

The CDSCO, *vide* Standard Operating Procedure document no. Legal Cell-GNL-000 (Revision 00), released a Standard Operating Procedure for processing compounding applications under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, applicable to offences under Section 32B of the Drugs Act. Applications are to be submitted physically under Rule 4, following which the Compounding Authority (Additional Director General of Health Services) will call for a report from the Reporting Authority (Drugs Controller General of India), with prescribed timelines of 5 (five) days for seeking zonal reports, 10 (ten) days for forwarding, and one month overall for submission of the final report. The Compounding Authority may then either allow the application, fixing the compounding amount and granting immunity from prosecution, or reject it after a mandatory personal hearing. The compounding amount, once paid within 30 (thirty) days of the order, is non-refundable except where a court rejects the immunity. This immunity may be withdrawn if later discovered that the applicant concealed material particulars or furnished false evidence.

[12] https://egazette.gov.in/WriteReadData/2026/270856.pdf
[13] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM3NjI=

b. *CDSCO has released Frequently Asked Questions (FAQs) on Drugs and Cosmetics (Compounding of Offences) Rules, 2025*[14]

The CDSCO, *vide* Doc No. CDSCO/FAQ/CA/01/2025, released a Frequently Asked Questions document on the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, intended solely for public awareness purposes and not for legal or professional use. The Rules provide a legal mechanism to settle certain offences under the Drugs Act, without full court prosecution, laying out the procedure, authorities, forms, and conditions for compounding, having come into force on April 24, 2025. The FAQs clarify that an application for compounding may be made either before or after the institution of prosecution. It also emphasises that compounding is not a right of the applicant but is entirely at the compounding authority's discretion and that the compounding amount is fixed based on the facts of the case. Immunity from prosecution may be granted where the applicant has fully cooperated and made a full and true disclosure of facts. Such immunity stands automatically withdrawn if the applicant fails to pay the compounding amount or comply with conditions and may also be withdrawn if the applicant concealed material facts or gave false evidence, with prosecution thereafter proceeding as though immunity was never granted.

c. *CDSCO publishes final risk classification list of medical devices pertaining to Oncology under Medical Devices Rules, 2017*[15]

The CDSCO, *vide* File No. MED-16014(12)/1/2024-eoffice dated January 2, 2026, published the final risk classification list of medical devices pertaining to Oncology. The list, placed in Appendix A, classifies 77 oncology-related medical devices across risk classes A through D, with the general intended use specified against each device serving as guidance for applicants seeking manufacturing or import licenses under the Medical Devices Rules, 2017 (**MD Rules**). The list is dynamic and subject to revision from time to time. The classified devices span a wide range of oncological applications, including radiation therapy accessories (accelerator system chairs – Class C; quality assurance devices – Class C), alternating electric field antimitotic cancer treatment systems (Class D), computer vision/machine learning-aided software for cancer detection (Class C), embolisation particles (Class D), microwave and radiofrequency ablation systems (Class C), high intensity focused ultrasound (**HIFU**) ablation systems (Class C), and stereotactic radiosurgery systems for the central nervous system (Class D), among others.

d. *CDSCO directs manufacturers to incorporate agranulocytosis as adverse drug reaction in Carbimazole PILs*[16]

The CDSCO, *vide* File No. PSUR-13011(14)/1/2025-eoffice-Part (2) dated February 11, 2026, directed all State and Union Territory Licensing Authorities to require manufacturers of Carbimazole formulations to incorporate *"agranulocytosis"* as an adverse drug reaction (**ADR**) in the corresponding Prescribing Information Leaflet (PIL) and promotional literature of the drug. The directive arose from recommendations of the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (**IPC**), Ghaziabad, which assessed ADR reports pertaining to Carbimazole formulations at the 26th Signal Review Panel meeting held on March 24, 2025, evaluating Patient Population Incidence – Adverse Drug Reactions (**PPIs-ADR**) based on Individual Case Safety Reports (**ICSR**). The recommendations of the NCC-PvPI were subsequently reviewed and endorsed by the Subject Expert Committee (**SEC**) on Endocrinology and Metabolism at its meeting held on January 6, 2026, at CDSCO-HQ, New Delhi.

e. *CDSCO releases draft guidance for import of In Vitro Diagnostic Medical Devices for stakeholder comments*[17]

The CDSCO, *vide* No. CDSCO/IVD/GD/DRAFT/IMP/01/2026, released a draft guidance document titled "Guidance for Import of In Vitro Diagnostic Medical Devices" (**Draft IVD Import Guidance**), intended to assist importers in submitting product licence applications through the Online System for Medical Devices (cdscomdonline.gov.in) and National Single Window System (**NSWS**) portals. The Draft IVD Import Guidance applies to the import of In Vitro Diagnostic Medical Devices (IVDs) and serves as a consolidated reference

[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM3NTk=
[15] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM3NTM=
[16] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM4NzA=
[17] https://cdsco.mohfw.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Draft%20Guidance%20document%20for%20Import%20of%20In-vitro%20diagnostic%20Medical%20device%20for%20stakeholders%20comment.pdf

document outlining the applicable regulatory framework, procedural steps, documentation requirements, and compliance obligations under the MD Rules. Under MD Rules, the CLA, CDSCO, under the Directorate General of Health Services, is the competent authority for issuing import licences for all classes of IVDs. IVDs are classified into four risk-based classes: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk). The Draft IVD Import Guidance has been placed in the public domain for comments and suggestions from relevant stakeholders, with all stakeholders requested to provide their responses within 15 (fifteen) days from the date of publication.

f. CDSCO implements prior intimation system for analytical and non-clinical testing applications[18]

The CDSCO, *vide* Circular No. IT/MISC/001/2026 dated March 6, 2026, directed all stakeholders to implement the prior intimation system for Forms CT-10, CT-12, and CT-13, in pursuance of Gazette Notification G.S.R. 46(E) dated January 20, 2026, which introduced amendments to the NDCT Rules establishing the system. Accordingly, all stakeholders are required to submit applications for analytical and non-clinical testing in Forms CT-10, CT-12, and CT-13, as applicable, through the NSWS portal (www.nsws.gov.in) for the purposes of prior intimation. The prior intimation system shall not apply to the following categories: sex hormones, cytotoxic drugs, *beta lactam* drugs, biologics containing live microorganisms, and narcotic and psychotropic substances. Upon submission of the application in the requisite form at the NSWS portal, the acknowledgement of submission received from the portal or via email shall be treated as prior intimation. For all other purposes or categories not covered under the amended rules, the system of prior approval shall remain applicable.

3. Key National Pharmaceutical Pricing Authority (NPPA) updates

a. NPPA fixes retail prices for 36 new drug formulations[19]

The NPPA, *vide* notification S.O. 449(E) dated January 30, 2026, notified retail price fixation orders under the Drugs (Prices Control) Order, 2013 (**DPCO 2013**). The maximum retail price (**MRP**), excluding Goods and Services Tax (**GST**), was fixed for 36 (thirty-six) new drug formulations across various therapeutic categories, including antihyperlipidemic combinations (Atorvastatin and Ezetimibe), nutritional supplements (Calcium Citrate, Vitamin D3, Methylcobalamin, Pyridoxine HCL, and Folic Acid), antimicrobials (Cefuroxime Axetil and Potassium Clavulanate; Ciprofloxacin and Tinidazole; Clarithromycin, Esomeprazole, and Amoxicillin combikit), oncology infusions (Gemcitabine Hydrochloride injection, ready-to-use infusion bags in three strengths), etc., manufactured by specified pharmaceutical companies.

b. NPPA fixes retail prices for 20 new drug formulations[20]

The NPPA, *vide* notification S.O. 1085(E) dated February 27, 2026, notified retail price fixation orders under the DPCO 2013. It fixed the MRP, excluding GST, for 20 (twenty) new drug formulations, including Atorvastatin and Clopidogrel capsules, Cetirizine ophthalmic solution, Ivermectin & Albendazole tablets, Rosuvastatin and Clopidogrel tablets by specified pharmaceutical companies.

c. NPPA directs revision of MRP for 17 life-saving drugs following customs duty exemption[21]

The NPPA, vide Office Memorandum File No. 12(24)/ 2021/ DP/NPPA/Div.II(Vol.II)-Part(1) dated February 10, 2026, directed all manufacturers and marketing companies to revise the MRP of 17 (seventeen) life-saving drugs / formulations following the Department of Revenue, Ministry of Finance Notification No. 02/2026-Customs dated February 1, 2026, which exempted 17 (seventeen) life-saving drugs from customs duty. In accordance with the DPCO 2013, the MRP of drugs and formulations is inclusive of all applicable taxes and duties. Accordingly, any downward revision in duties and taxes must be reflected in the MRP, with the benefit of nil duty or reduction in duties and taxes passed on to consumers. All manufacturers and marketing companies selling the drugs and formulations covered under the aforesaid customs notification are required to revise the MRP on account of the Custom Duty exemption, submit information regarding such revision through Form V, and issue a revised price list or supplementary price list to

[18] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM5NDM=
[19] https://egazette.gov.in/WriteReadData/2026/269671.pdf.
[20] https://egazette.gov.in/WriteReadData/2026/270554.pdf.
[21] https://nppa.gov.in/uploads/tender/bb04e36ca9c300868e764ca319bb4c56.pdf

dealers, State Drugs Controllers, and the Government indicating the changes.

4. Key Ministry of Environment, Forest, and Climate Change (MoEFCC) pharma and environmental regulatory updates

a. *MoEFCC notifies Solid Waste Management Rules, 2026*[22]

The MoEFCC, *vide* notification S.O. 388(E) dated January 27, 2026, notified the Solid Waste Management Rules, 2026 (**SWM Rules**), superseding the Solid Waste Management Rules, 2016. The SWM Rules shall come into force on April 1, 2026, and apply to all urban and rural local bodies, special economic zones, airports, defence establishments, railway stations, and all other residential, commercial and institutional waste generators. The rules mandate four-stream segregation of waste at source into wet, dry, sanitary, and special care waste, and introduce an Extended Bulk Waste Generator Responsibility (**EBWGR**) framework requiring bulk waste generators to register on a centralised online portal, process wet waste through decentralised composting or biomethanation facilities, and procure EBWGR certificates from local bodies for solid waste collected, transported, and processed. The rules establish a multitiered implementation framework, assigning specific duties to local bodies, state and central pollution control boards, and several central ministries including the Ministries of Housing and Urban Affairs, Drinking Water and Sanitation, Power, New and Renewable Energy, and Petroleum and Natural Gas, and establish centralised and state-level monitoring committees to oversee implementation, compliance, and annual reporting.

b. *MoEFCC exempts common effluent treatment plants from prior environmental clearance requirements*[23]

The MoEFCC, *vide* notification S.O. 389(E) dated January 28, 2026, amended the Environment Impact Assessment Notification, 2006, exempting all Common Effluent Treatment Plants (CETPs) from mandatory prior environmental clearance by omitting CETPs from the Schedule under "Physical Infrastructure including Environmental Services". The exemption, recommended by the Expert Appraisal Committee and endorsed by the Expert Advisory Committee, recognises the technological advancements achieved, robust compliance mechanisms in place, and the demonstrable shift towards sustainable water management practices, while ensuring that environmental safeguards remain enforced through State Pollution Control Boards or Pollution Control Committees via the consent mechanism under the Water

[22] https://egazette.gov.in/WriteReadData/2026/269620.pdf.
[23] https://egazette.gov.in/WriteReadData/2026/269611.pdf.

(Prevention and Control of Pollution) Act, 1974 (**Water Act**) and the Air (Prevention and Control of Pollution) Act, 1981 (**Air Act**).

c. *MoEFCC notifies Control of Air Pollution (Grant, Refusal or Cancellation of Consent) Amendment Guidelines, 2026*[24] *and Control of Water Pollution (Grant, Refusal or Cancellation of Consent) Amendment Guidelines, 2026*[25]

The MoEFCC, *vide* notification G.S.R. 62(E) and G.S.R. 63(E), both dated January 23, 2026, notified the Control of Air Pollution Amendment Guidelines, 2026, and the Water Pollution Amendment Guidelines, 2026. The amendments provide for a perpetual consent to operate, which, once granted, shall remain valid until cancelled, doing away with the previous framework of periodic renewal. These also introduce a Registered Environment Auditor mechanism, whereby project proponents may, as an alternative to inspection by a State Board officer, engage a Registered Environment Auditor to visit premises, verify particulars, and obtain information relevant to consent applications. Micro and small units located in industrial estates or areas notified by the State Government, Union Territory Administration, or local body are granted deemed consent to establish upon submission of a self-certified application in Form-I. The amendments mandate a unified online consent and authorisation management portal, through which all applications for grant, verification, inspection, refusal, or cancellation of consent shall exclusively be processed once operational. The Central Board is empowered to charge 5 per cent of the consent fee as service charges to be credited to the Central Pollution Control Board fund.

5. Key Food Safety and Standards Authority of India (FSSAI) updates

a. *FSSAI proposes amendments to Food Business Licensing and Registration Regulations, 2011, to mandate daily production records and FIFO/FEFO storage practices*[26]

The FSSAI, *vide* notification F. No. REG-11013/1/2026-Regulation-FSSAI dated January 23, 2026, published draft amendments to the Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011. The proposed amendments mandate food business operators to maintain daily records of production and raw material utilisation separately, with a carve-out exempting non-manufacturing food businesses from this requirement. Further, the said amendments provide that the storage of raw materials, ingredients, work-in-progress, and processed, cooked, or packaged food products shall be subject to FIFO (First In First Out) and FEFO (First Expire First Out) principles, with a carve-out exempting retailers from this requirement.

b. *FSSAI proposes amendments to Food Safety and Standards (Packaging) Regulations to introduce new definitions*[27]

The FSSAI, *vide* notification F. No. SS-T0FA(NOTI)/7/2025-Standard-FSSAI dated February 26, 2026, published the Draft Food Safety and Standards (Packaging) Amendment Regulations, 2026, to further amend the Food Safety and Standards (Packaging) Regulations, 2018 (Packaging Regulations), with objections and suggestions invited within 60 (sixty) days from the date on which copies of the Gazette containing the notification are made available to the public. The proposed amendments seek to insert six new definitions under Regulation 2(1) of the Packaging Regulations, namely: "food contact material", "food grade contact material", "modified atmosphere packaging", "food packaging", "non-intentionally added substances (**NIAS**)", and "aseptic packaging".

[24] https://egazette.gov.in/WriteReadData/2026/269608.pdf.
[25] https://egazette.gov.in/WriteReadData/2026/269603.pdf.
[26] https://egazette.gov.in/WriteReadData/2026/269606.pdf.
[27] https://egazette.gov.in/WriteReadData/2026/270529.pdf

News Updates

1. Union Budget 2026–27: Key pharma and healthcare sector highlights[28]

The Finance Bill 2026–27 underscores the Government's continued focus on strengthening India's pharmaceutical, healthcare, and life sciences ecosystem through targeted policy interventions, fiscal support, and regulatory reforms, with an emphasis on innovation, domestic manufacturing, research and development, and access to affordable healthcare.

a. *Biopharma Shakti proposed to strengthen the biopharmaceutical industry*

India's bioeconomy has grown from USD 10 billion in 2014 to USD 165.7 billion in 2024, with a target of USD 300 billion by 2030. To address challenges in scaling biologics manufacturing, regulatory approval timelines, and specialised infrastructure, the Budget proposed Biopharma Shakti, the five (5)-year initiative with a INR 10,000-crore outlay aimed at boosting innovation and manufacturing of biologic products and biosimilars. Key measures include the strengthening of CDSCO by introducing scientific committees to support regulatory decision-making, establishment of three (3) new National Institutes of Pharmaceutical Education and Research (NIPERs), the upgradation of seven (7) existing institutions, and the creation of a network of 1,000 (one thousand) clinical trial sites to address capacity and quality gaps in clinical research.

b. *Scheme proposed for establishment of medical tourism hubs*

The medical tourism market in India is projected to reach between USD 13 billion and USD 16.2 billion by 2026–30. Under the Budget, a scheme was proposed to support states in establishing five (5) regional medical tourism hubs in partnership with the private sector, envisaging the development of large-scale integrated healthcare destinations combining advanced hospital infrastructure, diagnostics, post-treatment care, rehabilitation services, and AYUSH systems under a single framework.

c. *Budget impetus for scaling traditional medicine*

The Budget provided a strong impetus to India's AYUSH sector through a multipronged institutional and infrastructure-led approach, including the establishment of five (5) medical hubs with integrated AYUSH centres and diagnostics infrastructure, and the setting up of three (3) new All India Institutes of Ayurveda to support education, research, and clinical services. The Budget also provided for the upgradation of existing AYUSH

[28] https://www.indiabudget.gov.in/doc/budget_speech.pdf

pharmacies and drug testing laboratories across the country and proposed National Skills Qualifications Framework (NSQF)-aligned training programmes for multiskilled caregivers, combining core healthcare with allied skills such as wellness, yoga, and assistive devices.

d. *Mental healthcare infrastructure expansion with new institutes and second NIMHANS campus*

The Budget announced the establishment of two (2) new national mental health institutes in Ranchi and Tezpur, envisaged as national-level centres for specialised treatment, academic training, and research, and the establishment of a second campus of the National Institute of Mental Health and Neurosciences (NIMHANS) in North India, modelled on the Bengaluru-based institution.

e. *Customs duty relief for more cancer drugs, rare diseases*

In India, patients suffering from cancer and rare diseases have faced significant affordability challenges due to high import duties on critical medicines and specialised medical nutrition. The Budget proposed removing basic customs duty on 17 (seventeen) high-cost cancer drugs and expanded the list of rare diseases eligible for customs duty exemption on personal imports by adding seven (7) more conditions, extending relief to patients requiring specialised drugs, medicines, and medical food not readily available domestically.

2. DTAB Updates

The DTAB, headed by Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (**DCGI**), in its 93rd meeting held on February 16, 2026, made the following recommendations.[29]

a. *DTAB recommends inclusion of antimicrobials under "New Drug"*

The DTAB recommended the inclusion of all antimicrobials under the definition of "New Drug" under the NDCT Rules to strengthen regulatory oversight on antimicrobial resistance. The recommendation applies prospectively and existing licensees have been permitted to continue operations without additional requirements.

b. *DTAB recommends legal sanctity for Good Distribution Practices*

The DTAB recommended amending the Drugs Rules to confer legal sanctity upon Good Distribution Practices (**GDP**), making GDP mandatory for all firms involved in manufacturing, selling, stocking, or distributing drugs.

c. *DTAB recommends revision of microbial limits in Schedule M*

The DTAB recommended revising microbial limits within Schedule M in alignment with WHO Technical Report Series 1044, with exemptions applicable to medical gases, empty gelatin capsules, and disinfectant fluids.

d. *DTAB recommends issuance of licences for marketers and wholesalers*

The DTAB recommended amending the Drugs Rules to provide for issuance of licences to marketers of drugs and a separate licence form for wholesale distribution of bulk drugs, with prescribed qualification requirements for competent persons.

e. *DTAB recommends restrictions on advertisement of drugs*

The DTAB recommended prohibiting advertisement of drugs listed under Schedules H, H1, and X without prior sanction of the Central Government, and transferring all Schedule G drugs to Schedule H.

f. *Additional recommendations*

The DTAB additionally recommended amending Rule 64 of the Drugs Rules, in respect of qualification requirements for the competent person, creation of a separate licence form for wholesale distribution of bulk drugs, and prohibiting the manufacture and sale of animal health products containing Carboxypenicillins and Phosphonic acid derivatives used for growth promotion. It also recommended restricting Nicotine replacement products to flavoured Nicotine gums of 2mg with a ban on sale to minors, exempting import of drugs for analytical testing from CDSCO permission requirements (except narcotics), and prohibiting sale of Fixed-Dose Combinations (**FDCs**) containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride to children aged four years and under.

3. India-EU Free Trade Agreement: Implications for Ayush, traditional medicine, and regulatory cooperation[30] [31]

The India–EU Free Trade Agreement (**FTA**), announced on January 27, 2026, is expected to significantly expand the

[29] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjkyMg==
[30] https://www.commerce.gov.in/wp-content/uploads/2026/01/Factsheet-on-India-EU-trade-deal-27.1.2026.pdf
[31] https://www.pharmabiz.com/NewsDetails.aspx?aid=183828&sid=1

reach of India's traditional medicine sector across European markets, offering long-term regulatory certainty for Indian Ayush businesses and practitioners seeking a European presence. The FTA reinforces intellectual property protections, introduces enhanced regulatory cooperation on sanitary, phytosanitary, and technical barriers to trade matters, and strengthens regulatory predictability for exporters through digitisation, information sharing, and adherence to international standards. The EU represents a significant and growing market opportunity for Indian Ayush exports, with the European herbal medicine market valued at USD 69.20 billion in 2021. Moreover, total Ayush exports to the EU have grown at 8.36 per cent during 2017–21, with Germany, Italy, France, and the Netherlands as key markets.

Key highlights of the FTA for the Ayush and traditional medicine sector include:[32]

a. In EU Member States where domestic regulations do not exist, Ayush practitioners will be permitted to offer services on the basis of professional qualifications obtained in India.

b. The FTA locks in the openness of the EU for the establishment of Ayush wellness centres and clinics across Member States and envisages greater bilateral exchange to facilitate trade in Indian Traditional Medicine services.

c. India's Traditional Knowledge Digital Library (**TKDL**) is specifically recognised under the FTA as a key initiative in protecting traditional knowledge.

d. The IPR chapter provides for exchange of views and information on technology transfer, including measures to facilitate information flows and business partnerships.

e. Enhanced cooperation on Sanitary and Phytosanitary (**SPS**) matters enables recognition of conformity assessment results, equivalence on SPS measures based on technical justification, and localised responses to pest and disease outbreaks.

f. Enhanced cooperation on Technical Barriers to Trade (**TBT**) matters facilitates smoother market access and regulatory alignment between India and EU Member States.

4. Indian Pharmacopoeia Commission releases 10th edition of Indian Pharmacopoeia to update National Drug Standards[33]

The Indian Pharmacopoeia Commission, under the MoH&FW, has released the *Indian Pharmacopoeia 2026* (**IP 2026**) on January 2, 2026, marking the 10th edition of India's official compendium of legally enforceable drug quality standards under the Drugs Act. IP 2026 supersedes its preceding edition and prescribes binding standards for drugs manufactured, distributed, and marketed in India. Monographs not included in this edition will remain valid unless specifically withdrawn. The edition introduces 121 new monographs spanning drug substances, pharmaceutical dosage forms, biological and biotechnology-derived products, vaccines, immunosera, radiopharmaceuticals, and herbal products. It also marks the first-time inclusion of monographs for blood and blood component products in compliance with the Drugs Rules, introducing detailed standards to strengthen quality assurance in transfusion-related articles. Structured across four volumes consolidating general notices, monographs, and reference data, IP 2026 reflects India's continued efforts towards harmonisation of domestic drug standards with international pharmacopoeial practices. It also plays a central role in licensing, inspection, quality control, and regulatory enforcement, underscoring the Central Government's commitment to aligning pharmaceutical quality standards with evolving scientific advances and public health needs.

5. NPPA's Multidisciplinary Committee defers decision on separate price cap for cementless knee implants[34]

NPPA's Multidisciplinary Committee (**MDC**) has deferred its decision on requests from knee implant manufacturers and importers seeking the creation of a separate price category for cementless knee implants, directing that subject experts and applicant companies be invited for detailed discussions at its next meeting. The matter has been under deliberation since the 68th MDC meeting (June 3, 2025), during which the Committee had sought studies and published literature in support of applicants' claims, DCGI approval copies, MRP data for both cemented and cementless knee implants as sold in other countries, and data on landed cost, Price to Dealer, Price to Hospital, Price to Retailer, and MRP of

[32] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2219406&reg=3&lang=1
[33] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2210754&reg=3&lang=1
[34] https://medicaldialogues.in/news/industry/medical-devices/nppa-panel-defers-decision-on-separate-price-cap-for-cementless-knee-implants-164954

cemented and uncemented hip implants. NPPA had previously fixed ceiling prices for knee implants under Para 19 of the DPCO 2013. The MDC had reiterated that all manufacturers must comply with notified ceiling prices irrespective of implant type and noted that manufacturers of uncemented implants may approach NPPA with supporting documents for fixation of a separate ceiling price. At its most recent deliberation, the MDC noted that most applicant companies had submitted documents, with the exception of hip implant data from M/s. Meril Life Sciences Pvt. Ltd.. The company had subsequently requested withdrawal of its application for a 3D-printed uncemented knee implant, stating that its product had already been launched within the ceiling price prescribed by NPPA.

6. CDSCO to replace SUGAM Portal with new open-architecture digital platform[35]

The CDSCO will replace its decade-old SUGAM portal with a new open-architecture digital platform, following final approval from the Department of Expenditure, Government of India. The DCGI stated that the existing SUGAM portal has completed its lifecycle and that the CDSCO plans to launch the new platform within 18 (eighteen) months from the start of development, with the Request for Proposal (**RFP**) currently under preparation and tenders to be floated shortly. The new portal aims to integrate the entire regulatory value chain under one digital umbrella, bringing together State drug approvals, CDSCO approvals, sale licence processes, laboratories, Pharmacopoeial bodies, and research and testing institutions. Key institutions including the IPC, the National Institute of Biologicals (**NIB**), and the Indian Council of Medical Research (**ICMR**). The DCGI noted that the regulatory system has already achieved more than 97 (ninety-seven) per cent digitisation, and that the transition to the new portal is aimed at improving interoperability, transparency, efficiency, and data-driven decision-making, with the new portal based on open architecture to encourage broader participation in its development.

7. CDSCO to engage QCI-certified notified bodies to augment drug regulatory audit capacity[36]

The CDSCO is set to expand its drug regulatory audit capacity by formally engaging competent notified bodies certified by the Quality Council of India (**QCI**). The DCGI stated that the move has received agreement from the government in principle and that discussions with the QCI are in the final stages. The DCGI noted that until now, audits were conducted by CDSCO drug inspectors or State drug regulatory authorities and that regulatory audits had not been conducted in certain categories of drugs at all due to manpower shortages and structural constraints. The proposed framework aims to bridge these gaps by onboarding competent third-party notified bodies accredited by QCI, The DCGI further flagged structural gaps in CDSCO's internal scientific review framework, noting the absence of a dedicated in-house scientific cadre for reviewing clinical and bioequivalence protocols, with the organisation currently relying heavily on external subject expert committees for technical and clinical evaluations. To address these gaps, the CDSCO plans to recruit approximately 1,500 (fifteen hundred) personnel to strengthen internal scientific review capacity, particularly for clinical site evaluations and regulatory approvals.

8. CDSCO introduces SHRESTH Index to improve performance of State Drug Regulatory Authorities[37]

The CDSCO has proposed the State Health Regulatory Excellence (**SHRESTH**) Index, aimed at driving improvements in state drug regulatory authority performance to ensure drug safety and quality standards are consistently met. State Regulators have been provided with a framework for self-scoring on 27 parameters encompassing regulatory

[35] https://www.digitalhealthnews.com/cdsco-to-replace-sugam-portal-with-new-open-architecture-digital-platform
[36] https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/cdsco-to-outsource-gmp-audits-add-1500-experts-to-strengthen-scientific-capacity
[37] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2155722&reg=3&lang=2

processes, system compliances, education, and actions for non-compliances. SHRESTH provides 27 indices for manufacturing states across five themes of human resources, infrastructure, licensing, surveillance, and responsiveness, and 23 indices for primarily distribution states. States must submit data on predefined metrics by the 25th of every month, shared with all states and Union Territories on the 1st of the following month. As per reports, SHRESTH will help harmonise regulatory processes across the country. The Index is not a scorecard but a roadmap for states to ensure safe and effective drugs and medical devices.

9. CDSCO orders label changes for Carbimazole and Doxycycline following PvPI adverse drug reaction signals[38]

The CDSCO has directed all State and Union Territory Licensing Authorities to require manufacturers to update Prescribing Information Leaflets for Carbimazole and Doxycycline, incorporating agranulocytosis as an adverse drug reaction (**ADR**) for Carbimazole, and CNS side effects including restlessness, anxiety, irritability, nervousness, and dizziness as ADRs for Doxycycline. The directive follows recommendations of the Pharmacovigilance Programme of India (**PvPI**). The recommendations of the National Coordination Centre for PvPI (**NCC-PvPI**), IPC, Ghaziabad, were discussed at the 26th Signal Review Panel meeting held on March 24, 2025, and subsequently reviewed by the Subject Expert Committees on Endocrinology and Metabolism and on Antimicrobial and Antiparasitic at their meetings held on January 6, 2026, at CDSCO Headquarters, New Delhi.

10. MoH&FW issues comprehensive Drug Procurement Policy for Central Government Health Scheme[39]

The MoH&FW has issued a comprehensive Drug Procurement Policy (**DP Policy**) for the Central Government Health Scheme (**CGHS**), replacing the previous approach to medicine sourcing and supply across all CGHS establishments, and covering 4.2 million beneficiaries across 81 cities through 350 wellness centres. The DP Policy standardises procurement through detailed procedures covering drug selection, the CGHS formulary, and eligibility criteria, mandating bulk procurement exclusively through central agencies such as the Medical Stores Organisation and the Pharmaceuticals and Medical Devices Bureau of India, maintenance of buffer stocks, and compliance with IP 2026 standards and WHO Good Manufacturing Practices. To ensure uniform implementation, the MoH&FW has directed the Directorate of CGHS to issue subsequent operational orders and guidelines applicable across all CGHS dispensaries.

11. DoP modifies incentive criteria for clinical investigations under MDCSS scheme[40]

The DoP revised the incentive criteria for clinical investigations conducted under the Medical Device Clinical Studies Support (**MDCSS**) sub-scheme of the Scheme for Strengthening of Medical Device Industry (SMDI), based on a decision taken at the first meeting of the Scheme Steering Committee (**SSC**) held on November 21, 2025. Under the revised criteria, applicants with an average turnover of not more than INR 10 crore in the preceding 2 (two) financial years shall be eligible to receive INR 5 crore or 70 per cent of the expenditure incurred, whichever is less, as grant on reimbursement basis for clinical investigations. The existing criterion of INR 5 crore or 25 per cent of the expenditure incurred, whichever is less, will continue to apply to all other eligible applicants. All other incentive criteria under the MDCSS sub-scheme, including for pre-clinical studies and post-market clinical follow-up and performance evaluation of new IVDs, remain unchanged.

12. ICMR releases Guidelines on HRD Scheme for health research[41]

The ICMR released Guidelines on the Human Resource Development (**HRD**) Scheme for Health Research for the 15th Finance Commission Period (2021–22 to 2025–26). The HRD Scheme, created by the Department of Health Research, aims to establish a pool of trained health research personnel by upgrading the skills of faculty of medical colleges and institutes, mid-career scientists, and medical and non-medical students through specialised training in priority areas of health research at leading national and international institutions. The Scheme was initially

[38] https://www.thehindu.com/news/cities/puducherry/drug-manufacturers-directed-to-revise-safety-risk-labelling-information-for-two-drug-formulations/article70652072.ece
[39] https://www.cghs.mohfw.gov.in/CGHSGrievance/FormFlowXACTION?hmode=ftpFileDownload&fileName=15012026205256_MoHFW%20OM%20dated%2015012026_New%20Drug%20Procurement%20Policy-1.pdf&folderName=Circular&isGlobal=1
[40] https://pharma-dept.gov.in/sites/default/files/Corrigendum%20for%20revised%20operational%20guidelines%20of%20sub-scheme%20Medical%20Device_0.pdf
[41] https://schemes.dhr.gov.in/staticweb/pdf/DHR/Downloads/HRD/HRD%20AMENDED%20GUIDELINES%20DATED%2020.05.2025.pdf

approved by the Cabinet Committee on Economic Affairs (CCEA) on February 28, 2014, at a total estimated cost of INR 597 crore, subsequently extended through 2020–21, and thereafter approved for the 15th Finance Commission period with the approval of the Expenditure Finance Committee (EFC) at its meeting held on March 18, 2021.

13. ICMR seeks public comments on Draft Operational Guidelines for Single Ethics Review of Multicentre Research[42]

The ICMR Bioethics Unit released the Draft Operational Guidelines for Single Ethics Review of Multicentre Research in India for public consultation. The Draft Guidelines seek to address systemic challenges arising from the existing ethics review process for multicentre research in India, wherein ethics approval is required from the Ethics Committee (EC) at each participating site, resulting in duplication of effort, inconsistent decisions, and delays in study initiation. Under the proposed single ethics review mechanism, a single EC, identified from among the participating sites, would undertake a comprehensive ethics review of the complete multicentre research protocol, including all core and site-specific documents, and upon completion of its review, issue a consolidated ethics approval applicable to all participating sites. The proposed mechanism builds upon earlier streamlining efforts by ICMR, including the common ethics review approach introduced under the ICMR National Ethical Guidelines (2017) and the joint ethics review approach proposed under the ICMR Joint Ethics Review Guidelines (2023).

14. ICMR deploys AI-enabled tool under National One Health Mission to predict pandemics[43]

The ICMR is set to deploy an AI-enabled pathogen surveillance tool under the National One Health Mission (NOHM), having invited Expressions of Interest (EoI) from eligible organisations to develop the tool, with the aim of enabling early detection of emerging and novel pathogens across zoonotic, viral, bacterial, and parasitic disease categories, including diseases such as Zika, Nipah, Coronavirus, anthrax, plague, and kala azar. The initiative seeks to shift India's pandemic response from a reactive to a predictive model by integrating data streams from humans, animals, and the environment to identify unusual patterns and assess environmental causes of disease at an early stage, before cases escalate into outbreaks.

15. ICMR mandates clinical trials to focus on Indian demography and lifestyle to address rising burden of lifestyle diseases[44]

The ICMR has issued a mandate to prioritise clinical trials based on Indian body types, genetics, and diets, with the aim of generating homegrown medical evidence better suited to addressing India's rising burden of lifestyle diseases. The mandate is driven by a concerning 2024 ICMR analysis that linked nearly 56.4 per cent of India's total disease burden to unhealthy diets and poor lifestyle choices, over 61 percent of all deaths in India to non-communicable diseases. The mandate also reflects the recognition that many Indians carry higher visceral fat despite a normal BMI, rendering them more vulnerable to diabetes and heart disease, often a decade earlier than their counterparts in developed nations. Under the mandate, multicentre clinical trials across at least five hospitals will be encouraged, with each study eligible for government funding of up to INR 8 crore.

16. Union Health Minister launches SAHI and BODH initiatives to advance responsible AI in healthcare at India AI Impact Summit 2026[45]

Union Minister for Health and Family Welfare, Jagat Prakash Nadda, launched SAHI (Strategy for Artificial Intelligence in Healthcare for India) and BODH (Benchmarking Open Data Platform for Health AI) at the India AI Impact Summit 2026. SAHI serves as a governance framework and national roadmap for the responsible, ethical, and accountable use of AI in healthcare, ensuring that AI tools meet rigorous standards of safety, efficacy, and ethical compliance prior to large-scale adoption. BODH, developed by IIT Kanpur in collaboration with the National Health Authority (NHA), enables systematic evaluation of AI models for performance, robustness, bias, and generalisability using anonymised real-world health datasets before population-scale deployment. Dr. Catharina Boehme, Officer-in-Charge of the WHO South-East Asia Regional Office, commended India as among the first countries to adopt a national AI strategy for health, describing its whole-of-government approach as setting an important global benchmark.

[42] https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1770696642_icmr_singleethicsreviewformulticentreresearch.pdf
[43] https://www.indiatoday.in/health/story/icmr-deploys-ai-tool-under-national-one-health-mission-to-predict-pandemics-2866441-2026-02-11
[44] https://www.business-standard.com/health/icmr-mandates-india-centric-clinical-trials-demography-lifestyle-126021200548_1.html
[45] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2229226&reg=3&lang=1

17. Ministry of AYUSH showcases Ayush Grid and AI Initiatives at India–AI Impact Summit 2026[46]

The Ministry of AYUSH participated in the India-AI Impact Summit 2026, the first global AI summit hosted in the Global South, held under the theme "Sarvajana Hitaya, Sarvajana Sukhaya – Welfare for All, Happiness for All." At the summit, the ministry presented the architecture of the Ayush Grid, India's digital public health platform for traditional medicine, and the My Ayush Integrated Services Portal (MAISP), which integrates healthcare services, capacity building, medicinal plants research, Ayush drug administration, and education on a single platform. The pavilion also showcased AI-enabled technologies under development for Ayush systems, including AI-powered chatbots, clinical decision-making tools, research analytics, and a Yoga Posture AI solution enabling users to check and correct yoga asanas.

18. Indian medical device makers raise alarm over potential relaxation of refurbished medical equipment import policy[47]

The Association of Indian Medical Device Industry (AiMeD), a leading medical industry body has strongly opposed any relaxation of restrictions on the import of refurbished or pre-owned medical equipment, citing risks to patient safety arising from unknown device histories, inconsistent performance, and limited traceability that cannot be addressed through *post facto* checks alone. AiMeD's concerns are heightened by the MoH&FW's constitution of a committee to examine the regulation of refurbished medical devices, and by the possibility of low or zero-duty imports of such devices from the United States under ongoing bilateral trade negotiations. The industry body has urged that refurbished devices be subject to the same calibration, testing, and recall standards as new equipment. It also called for prioritisation of indigenously manufactured devices under the Make in India and Atmanirbhar Bharat frameworks and noted that several countries including China, Brazil, and Indonesia entirely prohibit such imports.

19. Karnataka Health Department proposes QR Codes on medicine packaging to support visually impaired patients[48]

The Karnataka Health Department has proposed the introduction of QR codes on medicine strips to enable visually impaired users to access essential drug information, including dosage, composition, manufacturing date, and expiry date, via smartphone. The proposal, announced by State Health Minister Dinesh Gundu Rao, seeks to promote equitable healthcare and independent living for persons with visual disabilities. This initiative is grounded in data collected from 500 visually impaired individuals across Karnataka, Kerala, Andhra Pradesh, and Telangana under the IMPACT-VIP project (Initiative for Medication Practices and Accessibility through QR Code Technology for the Visually Impaired Persons), supported by the Japan International Cooperation Agency. The proposed QR codes will incorporate tactile indentations to assist users in locating and scanning them. The Karnataka Health Department intends to submit the proposal to the Central Government for standardisation and potential national rollout, with officials noting that the initiative could additionally benefit elderly users, persons with literacy or language barriers, and visually impaired pharmacists.

[46] https://www.expresspharma.in/ministry-of-ayush-showcases-ayush-grid-and-ai-initiatives-at-india-ai-impact-summit-2026/
[47] https://www.fortuneindia.com/business-news/indian-medical-device-makers-worried-about-policy-on-refurbished-medical-equipment-imports/130353
[48] https://timesofindia.indiatimes.com/city/bengaluru/karnataka-health-dept-moots-qr-codes-on-medicine-packaging/articleshow/127868771.cms

Litigation Updates

1. Supreme Court passes first-ever order permitting passive euthanasia[49]

The Supreme Court (**SC**), in Misc. Application No. 2238 of 2025 in SLP (Civil) No. 18225 of 2024, *vide* judgment dated March 11, 2026, passed its first-ever order permitting passive euthanasia in application of the framework laid down in *Common Cause v. Union of India* (2018), as modified in 2023, recognising the fundamental right to die with dignity. The judgment arose in respect of the miscellaneous application filed by Harish Rana through his parents in an SLP that the Apex Court had earlier disposed of on November 8, 2024. It had ensured adequate care and necessary treatment including home care at the Respondents' expense and granted liberty to seek further directions. The High Court of Delhi (**Delhi HC**) had earlier dismissed the writ petition on July 2, 2024, on the ground that the Petitioner was not being kept alive mechanically and could sustain himself without external medical aid.

During the course of the proceedings, the SC directed the constitution of a Primary Medical Board and thereafter a Secondary Medical Board at AIIMS, both of which reported that Harish had suffered irreversible, non-progressive brain damage and fulfilled the criteria of Permanent Vegetative State for approximately 13 years, with Clinically Assisted Nutrition and Hydration (**CANH**) required for survival but incapable of improving or repairing the underlying brain damage. In its judgment, the SC held that:

- CANH, including nutrition administered through a surgically installed PEG tube even at home, constituted "medical treatment" governed by the same legal principles as other life-sustaining interventions and was amenable to lawful withholding or withdrawal under the Common Cause framework.
- Applying the "best interests" principle and relying on the unanimous opinions of both Medical Boards and the considered position of the family, the SC concluded that continued CANH was no longer in Harish's best interests and that treatment ought not to be prolonged further. It further held that where both Boards concur in certifying withdrawal or withholding of life support, court intervention was generally not required and the decision may ordinarily be implemented upon the Secondary Board's concurrence.
- The SC accordingly directed the withdrawal and withholding of all medical treatment including CANH and waived the 30 (thirty)-day reconsideration period given the unanimity of all stakeholders. It also directed AIIMS to admit Harish to its Palliative Care department and facilitate his shifting from residence and directed

[49] Harish Rana v. Union of India, Judgment dated March 11, 2026, in MA No. 2238 of 2025 in SLP (Civil) No. 18225 of 2024

carrying out the withdrawal under a robust palliative and end-of-life care plan to manage symptoms and preserve dignity. The SC further directed all High Courts to issue directions to Judicial Magistrates to receive intimations from hospitals where both Boards unanimously decide to withdraw or withhold life support. It also directed the Union of India to ensure that Chief Medical Officers in all districts maintain updated panels of qualified Registered Medical Practitioners for nomination to Secondary Medical Boards.

The matter has been listed for compliance reporting after one month, in respect of the directions concerning Harish Rana, and in August 2026, in respect of the systemic directions.

2. SC holds that right to menstrual health forms part of right to life under Article 21[50]

The SC, in W.P. (Civil) No. 1000 of 2022, *vide* judgment dated January 30, 2026, held that the right to menstrual health forms an integral part of the right to life and human dignity guaranteed under Article 21 of the Constitution of India, and that the right to education under Article 21A is a *"multiplier right"* enabling the exercise of other human rights, such that inaccessibility of menstrual hygiene management measures undermines the dignity of a girl child and her ability to participate in education in a meaningful and non-discriminatory manner. The judgment arose in the context of a writ petition preferred by a social worker seeking directions to provide free sanitary pads to female students of classes 6 to 12, separate toilets in all government-aided and residential schools, and other consequential reliefs.

The SC observed that the lack of menstrual hygiene management in schools contributes to both absenteeism and complete dropout, and issued comprehensive directions requiring all States and Union Territories to ensure functional gender-segregated toilets with hand washing facilities, provision of oxo-biodegradable sanitary napkins free of cost, establishment of Menstrual Hygiene Management corners, and safe disposal mechanisms in compliance with the SWM Rules. The SC further directed NCERT and State Councils of Educational Research and Training to incorporate gender-responsive curricula on menstruation and puberty, directed training and sensitisation of teachers. It also directed the District Education Officer to conduct periodic inspections and seek anonymous student feedback and requested NCPCR and SCPCRs to oversee implementation. The SC issued a continuing *mandamus* and clarified that its directions, read alongside the Union's Menstrual Hygiene Policy for School Girls, shall operate as mandatory standards alongside existing State policies and programmes.

3. SC issues notice on PIL to exclude doctors from Consumer Protection Act[51]

The SC, in W.P. (Civil) No. 110 of 2026, *vide* order dated February 10, 2026, issued notice to the Union Ministries of Health and Family Welfare and Consumer Affairs and the National Medical Commission (**NMC**) on a Public Interest Litigation (**PIL**) seeking a declaration that medical professionals do not fall within the ambit of the Consumer Protection Act, 2019 (**CP Act**). The PIL was filed by the Association of Healthcare Providers (India) and Dr. Alexander Thomas under Article 32 of the Constitution, seeking a writ of *mandamus* to exclude medical professionals holding MBBS or higher qualifications from the definition of "service" under Section 2(42) of the CP Act, on the ground that subjecting medical professionals to consumer law has eroded the patient–doctor relationship, encouraged defensive medical practices, and escalated healthcare costs.

The petition relied on the SC's judgment in *Bar of Indian Lawyers v. D.K. Gandhi* (2024), which held that the legislature never intended to bring professionals within the ambit of consumer protection law and observed that its earlier ruling in *Indian Medical Association v. V.P. Shantha* (1995), which brought medical services under consumer law, deserves to be revisited by a larger Bench. The petition further submitted that while advocates have since been exempted from the CP Act, doctors continue to be governed by the 1995 precedent.

4. SC asks FSSAI to consider front-of-pack warning labels on foods high in sugar, salt, and fat[52]

The SC, in Misc. App. No. 1177 of 2025 in W.P. (Civil) No. 437 of 2024, *vide* order dated February 10, 2026, examined the compliance by the FSSAI with directions previously issued by the Court in the disposed of writ petition, which had sought a writ of *mandamus* directing the Union of India to issue appropriate directions or make regulations for Front-of-

[50] Dr. Jaya Thakur v. Government of India, Judgment dated January 30, 2026, in W.P. (Civil) No. 1000 of 2022
[51] Association of Healthcare Providers (India) and Anr. v. Union of India and Ors., Order dated February 10, 2026, in W.P. (Civil) No. 110 of 2026
[52] 3S And Our Health Society vs. Union of India & Anr., Order dated February 10, 2026, in Misc. App. No. 1177 of 2025 in W.P. (Civil) No. 437 of 2024

Package Warning Labels (**FoPNL**) on packaged foods. The SC had disposed of the original writ petition directing the Expert Committee constituted by the FSSAI to prepare its recommendations and submit a report within three months so that the necessary amendments to the Food Safety and Standards (Labelling and Display) Regulations could be given effect.

The SC expressed dissatisfaction with the compliance affidavit filed by the FSSAI, noting that the Expert Committee had flagged concerns among stakeholders regarding the applicability of the algorithm for the Indian Nutrition Rating (**INR**). No consensus had been reached on the INR format draft notified in 2022, with the FSSAI indicating its intention to conduct additional research, consumer surveys, and wider stakeholder consultations before taking any further steps. The SC observed, *prima facie*, that the exercise undertaken so far had not yielded any positive result, took note of the petitioner's suggestion that every pre-packaged food product must carry a warning indicating high sodium, sugar, and saturated fat levels, and directed the FSSAI to take this aspect into consideration and revert within four weeks.

5. SC holds that stem cell therapy for autism spectrum disorder offered as routine clinical service amounts to malpractice[53]

The SC, in W.P. (Civil) No. 369 of 2022, *vide* judgment dated January 30, 2026, held that offering Stem Cell Therapy (**SCT**) as a clinical service for curing Autism Spectrum Disorder (**ASD**) amounts to malpractice, on the ground that SCT as a treatment for ASD lacks scientific support and has not been recognised as a sound medical practice backed by empirical evidence. It also clarified that SCT can be approved for monitored clinical research trials. The judgment arose in context of a writ petition filed by Yash Charitable Trust, Dr. Vibha Krishnamurthy, Forum for Medical Ethics Society, and a parent whose child had received stem cell treatment for ASD, seeking action against the rampant promotion of untested and unproven SCT as a cure for ASD.

The SC observed that the Ethics & Medical Registration Board (NMC) recommendations dated December 6, 2022, read with the applicable ICMR guidelines, indicate that the therapeutic use of stem cells for ASD is not recommended as routine clinical treatment, and held that every use of stem cells outside an approved clinical trial is unethical and constitutes malpractice. It further held that patient autonomy does not enable valid consent to an unproven treatment, as patients may remain under therapeutic misconception, and that proceeding with such treatment amounts to a gross violation of medical ethics. On the regulatory framework, it held that while autologous stem cells may not meet the criteria of a *"new drug"* under the NDCT Rules, they fall within the broader definition of *"drug"* under Section 3(b)(I) of the Drugs Act and that Chapter IV of the NDCT Rules provides the necessary regulatory pathway. The SC directed the MoH&FW, in consultation with AIIMS and

[53] Yash Charitable Trust and Ors. v. Union of India and Ors., Judgment dated January 30, 2026, in W.P. (Civil) No. 369 of 2022.

the NMC, to provide the best possible solution to ensure continuity of treatment for patients already undergoing SCT, granting four weeks for this purpose.

6. Delhi HC issues directions on real-time availability of bed and medical facility information and implementation of NextGen e-Hospital platform[54]

The Delhi HC, in W.P. (Civil) No. 3903 of 2017, *vide* order dated February 13, 2026, observed that integration of hospitals through digital systems can significantly improve patient care and enable faster treatment in emergencies, and issued directions to ensure real-time availability of information on beds and medical facilities across the city. The HC noted that despite the onboarding of 38 hospitals in Delhi to the NextGen e-Hospital platform developed by the National Informatics Centre, admissions and discharges were still partly being handled manually and that a mobile application to provide real-time bed availability information is awaiting final approvals for launch.

The HC directed the Health Secretary of the Delhi Government to ensure mandatory implementation of the NextGen e-Hospital platform for admissions, inpatient and outpatient services, and discharge processes across all onboarded hospitals. It also directed that consultations be held to consider onboarding private hospitals. The HC issued a notice to Google's counsel to assist with technical onboarding issues relating to the mobile application, directed the Delhi HC's IT Officer to provide technical support, and directed the Health Department to provide four additional technical personnel to NIC within one week. The matter has been listed for further hearing on April 16, 2026.

7. Delhi HC restores ban on Type 2 diabetes FDCs[55]

The Delhi HC, in LPA Nos. 671 of 2019, 105 of 2020, and 106 of 2020, *vide* judgment dated January 9, 2026, allowed three Letters Patent Appeal(s) (**LPA**) filed by the Union of India and the All India Drug Action Network (**AIDAN**), setting aside the judgment of the Single Judge and restoring the Central Government's ban on two FDCs comprising Glimepiride, Pioglitazone, and Metformin in two different strengths, prohibited *vide* notifications S.O. 4471(E) and S.O. 4472(E) dated September 7, 2018, under Section 26A of the Drugs Act, which empowers the Central Government to regulate, restrict, or prohibit the manufacture, sale, or distribution of any drug or cosmetic in public interest, on the basis of recommendations of the DTAB Sub-Committee, constituted pursuant to the SC's directions in Union of India v. Pfizer Limited & Ors. (2018). The Single Judge had set aside the notifications on the ground that the Sub-Committee's reasoning was cryptic, internally inconsistent, and failed to explain why regulation or restriction would be insufficient.

The Division Bench reversed the Single Judge, holding that Section 26A operates on a precautionary standard and does not require proof of actual harm, the statutory threshold being satisfied once a drug is shown to be likely to involve risk to human health. The Bench further held that it cannot be presumed that individual drug components behave identically in combination as they do independently and that the Single Judge had erred in examining each of the Sub-Committee's grounds in isolation rather than assessing their cumulative effect.

8. Delhi HC seeks joint decision on veg/non-veg labelling for toothpastes, soaps, and other cosmetics[56]

The Delhi HC, in W.P. (Civil) No. 1989 of 2015, *vide* order dated February 7, 2026, noted a clear contradiction between the mandatory requirement for display of red, brown, or green dots on packaging of soaps, shampoos, toothpastes, and other cosmetics and toiletries under the Legal Metrology (Packaged Commodities) Rules, 2011, and the DTAB's recommendation that such indication be made voluntary, and directed the DCGI and the Director, Legal Metrology to hold a joint meeting with stakeholders and file a joint affidavit arriving at a comprehensive decision on the matter.

The Petitioner had challenged the amendment to Rule 6(8) of the Legal Metrology (Packaged Commodities) Rules, 2011, introduced *vide* notification dated June 16, 2014, contending that the Director, Legal Metrology lacked jurisdiction to prescribe such a requirement for cosmetics, which ought to have been addressed by the DCGI under the Drugs Act. The DTAB, in its meetings held in May 2018 and April 2021, had recommended that such indication be kept voluntary, citing the absence of an established certification system for vegetarian and non-vegetarian ingredients and cautioning that mandatory compliance would add unnecessary regulatory burden. The Delhi HC observed that despite the

[54] Court On Its Own Motion v. Union of India & Ors., Order dated February 13, 2026, in W.P. (Civil) 3903 of 2017 and W.P.(C) 8548/2017order dated February 13, 2026, in W.P. (Civil) 3903 of 2017
[55] All India Drug Action Network v. Lupin Ltd. & Ors., Judgment dated January 9, 2026, in LPA Nos. 671 of 2019, 105 of 2020, and 106 of 2020
[56] Reckitt Benckiser (India) Limited v. Union of India, Order dated February 7, 2026, in W.P. (Civil) No. 1989 of 2015

matter being pending for over a decade, the conflict remained unresolved and impleaded the DCGI as Respondent No. 2. The matter is listed for further proceedings in April 2026.

9. Madras HC holds non-compete, non-solicitation, and confidentiality clauses in hospital-doctor agreements void ab initio and opposed to public policy[57]

The High Court of Madras (**Madras HC**), in Arbitration O.P.(Com. Div.) No. 708 of 2025, *vide* order dated February 23, 2026, held that clauses relating to confidentiality, non-solicitation, and non-compete contained in a professional agreement executed between a hospital and a doctor were void *ab initio*, being in restraint of lawful profession, unenforceable, and opposed to public policy. Accordingly, it dismissed the petition filed by the hospital under Section 11(6) of the Arbitration and Conciliation Act, 1996, with costs of INR 1,00,000 payable to the doctor. The dispute arose from a professional agreement dated September 8, 2022, under which the petitioner hospital had appointed the doctor as a Consultant Cardio Thoracic Surgeon. Following his resignation and subsequent joining of another hospital, the petitioner hospital invoked the liquidated damages clauses and initiated arbitration proceedings.

The HC held that a doctor cannot be construed as an employee of a hospital by virtue of the nature of services rendered, and that a hospital can at best utilise a doctor's services but cannot treat a qualified doctor like a regular employee. It also held that non-solicitation and non-compete clauses in such agreements were squarely hit by Section 23 of the Indian Contract Act, 1872 (**Contract Act**), being unlawful and contrary to public policy. It also violated Section 27 of the Contract Act, which prohibits agreements in restraint of profession. The HC further observed that the doctor had complied with the notice period requirements under the agreement and that there was accordingly no dispute remaining to be referred to arbitration.

10. Jharkhand HC disposes of PIL on biomedical waste management with directions for strict compliance with BMW Rules, 2016[58]

The High Court of Jharkhand (**Jharkhand HC**), in W.P. (PIL) No. 1385 of 2012, *vide* judgment dated February 26, 2026,

disposed of a PIL concerning biomedical waste management with broad directions to ensure effective implementation of the Bio-Medical Waste Management Rules, 2016 (**BMW Rules**), holding that biomedical waste management is intrinsically linked to the protection of public health and the right to a clean and safe environment under Article 21 of the Constitution. The Division Bench held that judicial intervention had been necessitated by administrative inaction and systemic deficiencies. However, considering the progress achieved and the institutional mechanisms now in place, continued judicial supervision was neither warranted nor consistent with the principle that primary responsibility lies with the statutory authorities. The PIL, filed in 2012, had highlighted indiscriminate dumping of hazardous biomedical waste in public spaces, with repeated deficiencies noted including lack of consolidated data, open dumping of infectious waste, and inadequate treatment facilities.

The HC observed that persistent administrative laxity and lack of coordination between agencies had resulted in procedural mandates remaining largely on paper, and referred to the SC's judgment in *Bhopal Municipal Corporation v. Subhash C. Pandey* (2026). The SC had held that the mere introduction of new regulatory frameworks would not improve ground realities unless authorities undertake adequate preparatory measures and infrastructure development prior to their enforcement. The Jharkhand HC accordingly disposed of the petition with detailed directions to the State Government, Pollution Control Board, and healthcare institutions to ensure strict compliance with the

[57] MIOT Hospitals (P) Ltd. v. Balaraman Palaniappan, Order dated February 23, 2026, in Arbitration O.P.(Com. Div.) No. 708 of 2025
[58] Jharkhand Human Rights Conference v. State of Jharkhand, Judgment dated February 26, 2026, in W.P. (PIL) No. 1385 of 2012

BMW Rules, clarifying that such directions shall operate in addition to, and not in derogation of, existing statutory obligations.

11. Kerala HC upholds "Dr" prefix for physiotherapists, occupational therapists[59]

The High Court of Kerala (**Kerala HC**), in W.P. (Civil) No. 41064 of 2025, *vide* judgment dated January 22, 2026, dismissed petitions filed by the Indian Medical Association, the Indian Association of Physical Medicine and Rehabilitation, and its Secretary, holding that the title "Doctor" does not belong exclusively to medical professionals and that physiotherapists and occupational therapists are entitled to use the "Dr." prefix under the National Commission for Allied and Healthcare Professions Act, 2021 (**NCAHP Act**) and the Competency-Based Curriculum for Physiotherapy and Occupational Therapy, which permits usage of the "Dr." prefix along with "PT" and "OT" as suffixes. The petitioners had sought reading down of certain provisions of the NCAHP Act and the Curriculum as being contrary to the NMC Act.

The HC held that the NMC Act does not contain any provision conferring the title "Doctor" exclusively on medical professionals and that Section 40 of the Kerala State Medical Practitioners Act cannot be understood as statutorily entitling qualified medical professionals to prefix "Dr." to their names to the exclusion of others. It further observed that the term "Doctor" was meant for persons who have achieved the highest level of learning and that persons holding higher educational qualifications, such as a PhD, have always been entitled to use the title. The Kerala HC declined to read down the provisions of the NCAHP Act in the absence of any specific challenge to them, noted the overriding effect of the NCAHP Act as a subsequent enactment, and held that it would be inappropriate to intervene with Government policy at the instance of only a few medical professionals.

12. NCDRC holds that prescribing allopathic medicines without a recognised medical qualification constitutes negligence and deficiency in service[60]

The National Consumer Disputes Redressal Commission (**NCDRC**), in Revision Petition No. NC/RP/574/2025, *vide* judgment dated January 30, 2026, held that prescribing allopathic medicines without a recognised medical qualification constitutes deficiency in service and negligence by operation of law, irrespective of the outcome of treatment. It set aside the orders of the fora below and directed the respondent to pay INR 2,00,000 as compensation along with simple interest at 9 per cent per annum from the date of filing of the complaint until realisation and INR 20,000 towards litigation costs. The complaint arose after the complainant developed a severe eye infection following treatment administered by the respondent optical centre on June 10, 2010, which included oral medicines, eye drops, and a handwritten prescription against payment of INR 500 as consultation charges. This had resulted in permanent loss of vision in the complainant's left eye, which could not be reversed despite subsequent specialist treatments.

The NCDRC held that the District Forum had committed a serious error in dismissing the complaint on a preliminary ground of maintainability without adjudicating the substantive issues, and that the State Commission's finding that a diploma holder could prescribe allopathic medicines was contrary to statutory provisions and binding SC precedent. Relying on the SC's decision in *Baharul Islam v. Indian Medical Association* (2023), the NCDRC observed that the practice of modern medicine is governed by the Indian Medical Council Act, 1956, now succeeded by the National Medical NMC Act (2019), which permits prescription and practice only by persons possessing recognised medical qualifications and registration, and that the injury suffered by the complainant was a direct consequence of such illegal practice.

[59] Indian Association of Physical Medicine and Rehabilitation (IAPMR) v. Union of India and Ors., Judgment dated January 22, 2026, W.P. (Civil) No. 41064 of 2025.
[60] Rakesh Kumar Shukla v. Alok Eye Health and Optical Centre, Judgement dated January 30, 2026, in Revision Petition No. NC/RP/574/2025

Transaction Updates

1. Novo Holdings buys significant stake in Surya Hospitals[61]

Novo Holdings, a leading global healthcare and life sciences investor with a long-standing commitment to building scaled, high-quality healthcare platforms in India, has announced a significant minority stake investment in Surya Hospitals, the largest private women and children specialty hospital chain in Western India. Founded in 1984, Surya Hospitals is a widely recognised centre of excellence for women's, neonatal, and paediatric care, operating a network of super specialty hospitals across Mumbai, Pune, and Jaipur. Over the years, it has expanded into a comprehensive super specialty institution delivering advanced care across complex gynaecology, neonatology, paediatrics, and multiple surgical super-specialties. The investment is expected to support Surya's next phase of growth, encompassing expansion of its footprint across Western India, continued development of clinical infrastructure, and strengthening of its specialist medical teams, bringing together Surya's well-established clinical leadership with Novo Holdings long-term, engaged ownership approach and its connectivity across a global healthcare ecosystem.

2. Zenex Animal Health acquires majority stake in Netherlands-based VievePharm[62]

Zenex Animal Health India, a leading Animal healthcare company has announced the acquisition of a majority stake in VievePharm, a Netherlands-based specialist in natural animal nutrition and phytogenic formulations for the livestock, equine, and pet care markets, for an undisclosed consideration. Headquartered in Enter, Netherlands, VievePharm brings with it established expertise in bolus technology used to deliver minerals, vitamins, and udder health support, which will be integrated into Zenex's broader global product offering. The deal provides Zenex with a manufacturing and sales base in Western Europe and expands its portfolio of natural and herbal animal health products, building on the company's 2023 acquisition of Ayurvet. This comes at a time when mounting regulatory pressure on veterinary antibiotic use across the European Union, with the EU's Farm to Fork Strategy targeting a 50 (fifty) per cent reduction in veterinary antibiotic sales by 2030 compared to 2018 levels, is expected to benefit Zenex's combined naturals portfolio. Zenex, which currently operates across Asia, Africa, and parts of the CIS region, intends to use VievePharm's established distribution network to accelerate its entry into Western European markets.

[61] https://novoholdings.dk/news/novo-holdings-invests-in-surya-hospitals-to-strengthen-access-to-high-quality-women-s-and-children-s-healthcare-in-india
[62] https://www.livemint.com/companies/news/zenex-animal-health-acquires-majority-stake-in-natural-nutrition-firm-vievepharm-11772203743365.html

3. Nova IVF picks up majority stake in Kerala's CRAFT Hospitals[63]

Nova IVF Fertility, a leading Bengaluru-based assisted reproductive technology chain owned by Asia Healthcare Holdings and backed by global private equity firm TPG Capital, has announced the acquisition of a majority stake in CRAFT Hospitals, one of Kerala's leading fertility centres, for approximately USD 40 (forty) million. CRAFT Hospitals has, over the years, built a well-regarded clinical legacy in reproductive healthcare in Kerala, and the acquisition marks Nova IVF's formal entry into the state, where it had until now maintained only a single centre in Palakkad. The transaction is expected to address a meaningful gap in Nova IVF's South India footprint, allowing it to build on CRAFT's established patient trust and clinical capabilities while expanding its network of advanced fertility services across a market it has long identified as strategically significant.

4. USV Pharma acquires Wellbeing Nutrition[64]

Mumbai-based pharmaceutical company USV Pharma, founded in 1961 and known for its focus on small-molecule active pharmaceutical ingredients and medicines such as Ecosprin, Tazloc, and OnArmi, has signed an agreement to acquire a 79 (seventy-nine) per cent stake in D2C nutraceutical brand Wellbeing Nutrition for INR 1,583 crore (approximately USD 174.7 million) in an all-cash deal. The majority stake comprises approximately 35 (thirty-five) per cent from founder Avnish Chhabria and around 44 (forty-four) per cent from existing shareholders, with early backers Fireside Ventures and Hindustan Unilever exiting the startup through the transaction. Chhabria will continue to retain a stake with the current management remaining in place to operate the business. Founded in 2019 by Chhabria and Saurabh Kapoor, Wellbeing Nutrition sells vitamins and mineral supplements through its website and retail outlets and has raised total funding over USD 12 (twelve) million to date. The acquisition would enable USV to extend its commitment from prescription-led care to preventive and lifestyle-focused wellness, broadening its portfolio into the fast-growing nutraceuticals segment.

5. BPL Medical Technologies acquires Yozma BMtech to strengthen bone health and diagnostics portfolio[65]

BPL Medical Technologies has announced the acquisition of Yozma BMtech Co., a South Korean company specialising in bone mineral density (**BMD**) diagnostic solutions, adding to its imaging and diagnostics portfolio across preventive healthcare, bone health, and women's health segments. Following the acquisition, BPL has launched BMtech's BMD measuring machines in India and Dubai, with the systems intended to support screening and monitoring for osteoporosis and other bone-related conditions. The devices feature high-speed scanning with high-resolution imaging, low-radiation exposure, and fan-beam technology with multichannel detectors designed to measure BMD across multiple anatomical sites, with certain models also supporting whole-body bone densitometry and body composition analysis. The acquisition aims to address the growing need for preventive diagnostics associated with ageing populations, osteoporosis prevalence, and lifestyle-related risks, and is expected to expand BPL's presence in the women's health segment, where BMD assessment plays an important role in managing post-menopausal health risks.

6. MakeO announces acquisition of Zenyum to build Asia's largest consumer dental tech platform[66]

MakeO, the parent company of Indian clear aligner brand Toothsi, has entered into a definitive agreement to acquire Zenyum, Southeast Asia's leading consumer dental company headquartered in Singapore. This transaction creates Asia's largest consumer dental business spanning India and key markets including Taiwan, Hong Kong, Japan, Singapore, Malaysia, Vietnam, Saudi Arabia, Qatar, and the UAE. The combined entity positions Toothsi as a pan-Asian leader in clear aligner technology, orthodontics, and consumer oral-care products, with India serving as the strategic and manufacturing hub for the combined business. Toothsi's vertically integrated, US FDA-certified clear aligner platform will design, manufacture, and export aligner products across the group's Asian markets, with consumers set to benefit from its patented suite of aligner appliances capable of

[63] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/nova-ivf-picks-up-majority-stake-in-keralas-craft-hospitals-at-40-mn-valuation/articleshow/129395255.cms
[64] https://b2b.economictimes.indiatimes.com/news/entrepreneur/usv-pharma-buys-79-stake-in-wellbeing-nutrition-for-1583-crore/128266697
[65] https://www.expresshealthcare.in/news/bpl-medical-technologies-acquires-yozma-bmtech-to-expand-bone-density-diagnostics/452979/
[66] https://www.biospectrumasia.com/news/27/27182/makeo-announces-acquisition-of-zenyum-to-build-asias-largest-consumer-dental-tech-platform.html

treating the full complexity spectrum of malocclusions across all age groups. The acquisition also brings together Toothsi's clinical expertise with Zenyum's oral-care devices and product portfolio, creating a comprehensive consumer dental offering across the region.

7. Sukino raises USD 31 million in Series B funding[67]

Bengaluru-based healthcare startup Sukino has raised USD 31 million in a Series B funding round led by Bessemer Venture Partners, with participation from Rainmatter, the investment arm of Zerodha. Founded in 2016 by Rajinish Menon and Shalini Menon, Sukino operates post-acute and rehabilitative care centres for patients with chronic and recovery-related healthcare needs, delivering services through both physical centres and at-home care across conditions, such as stroke rehabilitation and other long-term care requirements. The fresh capital will be used to expand Sukino's network of out-of-hospital care centres beyond its current footprint of 11 (eleven) centres across South Indian cities such as Bengaluru, Kochi, and Coimbatore, with the company reporting approximately 64 (sixty-four) per cent year-on-year growth and plans to add up to 22 (twenty-two) centres over the next two years. The investment reflects growing investor confidence in Sukino's model of structured recovery and continuity of care for patients after hospital discharge, a segment increasingly recognised as critical amid quicker hospital turnover and rising demand for specialised post-hospitalisation support.

8. Even Healthcare raises USD 20 million to expand hospital network[68]

Even Healthcare has raised USD 20 million in a fresh funding round from existing investors Lachy Groom and Alpha Wave as well as new investor Sharrp Ventures, among others, bringing its total capital raised to USD 70 (seventy) million to date. This follows a USD 30 million Series A round closed in September 2024 from investors including Khosla Ventures, Founders Fund, and 8VC. The Bengaluru-based startup, founded in 2020 by Mayank Banerjee, Matilde Giglio, and Alessandro Ialongo, offers subscription-based managed care services that provide members with unlimited doctor consultations, diagnostics, and medical guidance through a monthly or annual fee model, replacing per-visit costs with continuous, preventive health management. The fresh capital will be deployed to expand Even's hospital footprint in Bengaluru, following the launch of its first hospital in the city in May 2025, which the company claims achieved operational break-even within six months. Even's core model is designed to function as a proactive health partner, helping members manage conditions early, guide lifestyle changes, and coordinate care, with insurance available as a complementary layer for emergencies and hospitalisation.

9. Pandorum Technologies secures USD 18 million Series B funding[69]

Pandorum Technologies, an India and US-based biotechnology firm founded by Tuhin Bhowmick and Arun Chandru, has raised USD 18 million in a Series B funding round led by Protons Corporate, with participation from Galentic Pharma, Ashish Kacholia, Noblevast Advisory, Avinya Fund, and the Burman Family, among others. Pandorum is engaged in the development of exosome-based therapies that modify disease processes by reprogramming tissue responses, such as inflammation and fibrosis, with an initial clinical focus on ocular surface diseases including Stevens-Johnson Syndrome and Neurotrophic Keratitis. Its lead candidate Kuragenx has received Orphan Drug Designation from the US Food and Drug Administration. The fresh capital will support clinical programmes, manufacturing scale-up, and operations across the United States, Japan, and the Middle East, underpinned by a distributed manufacturing model comprising a partnership with AGC Biologics in Italy for Western markets and a supply agreement with Nucelion Therapeutics, a Bharat Biotech subsidiary, for Asia-Pacific, while the company also expands its platform to address conditions affecting the lung, liver, and nervous system.

10. 4baseCare raises INR 90 crore in Series B funding[70]

Bengaluru-based precision oncology startup 4baseCare has raised INR 90 crore in the first close of its Series B funding round, co-led by marquee investors Ashish Kacholia and Lashit Sanghvi, as the company looks to accelerate growth across India and key international markets. Operating at the intersection of genomics and artificial intelligence, the fresh capital will be deployed across three core priorities,

[67] https://www.bwdisrupt.com/article/healthcare-startup-sukino-raises-31-mn-series-b-from-bessemer-rainmatter-587045
[68] https://www.entrepreneurindia.com/blog/en/news/even-healthcare-raises-usd-20-mn-led-by-lachy-groom-alpha-wave.58616
[69] https://www.businesswire.com/news/home/20260207246124/en/Pandorum-Technologies-Raises-US%2418-Million-in-Series-B-to-Advance-Global-Access-to-Programmable-Tissue-Regenerative-Therapies
[70] https://www.cnbctv18.com/business/startup/4basecare-raises-rs-90-crore-series-b-funding-oncotwin-expansion-precision-oncology-19842546.htm

expanding its hospital-linked lab network, strengthening its AI-driven oncology platform, and deepening its presence in overseas markets. A significant portion of the funding will support the scaling of Oncotwin, the company's flagship product positioned as the world's first oncology digital twin platform, designed to simulate patient-specific cancer outcomes using clinical genomics and AI, and already selected by Memorial Sloan Kettering Cancer Center in the United States for validation on its dataset. The raise will further support an aggressive lab expansion strategy targeting 25 (twenty-five) new hospital-linked lab collaborations over the next 18 (eighteen) months, as 4baseCare continues to build population-specific genomic intelligence aimed at improving treatment decision-making for Indian and similar patient cohorts.

11. Nivaan Care raises USD 7 million to expand pain management clinics[71]

Nivaan Care, a New Delhi-based single-specialty interventional pain management clinic chain founded in 2023, has raised USD 7 (seven) million in a Series A funding round led by Sorin Investments, with participation from existing backers W Health Ventures, Endiya Partners, and Rebright Partners, following a USD 4.25 million seed round closed in February 2025. Nivaan operates single-specialty clinics focused on chronic conditions such as back, knee, and neck pain through a multidisciplinary care model integrating pain physicians, physiotherapists, and care coordinators, currently serving patients across Delhi-NCR, Mumbai, Jaipur, and Lucknow. It has completed over 40,000 (forty thousand) consultations and approximately 5,000 (five thousand) minimally invasive procedures. The company's evidence-led approach addresses the fragmented nature of chronic pain care in India, offering patients a structured alternative to basic physiotherapy or invasive surgery by focusing on non-surgical and minimally invasive interventions. The fresh capital will be deployed to expand Nivaan's clinic network into new cities including Bengaluru, strengthen its clinical and operating infrastructure, and advance its minimally invasive pain management capabilities, as the company continues to build a scalable, patient-centric model tailored to Indian healthcare needs.

12. Zydus Multispecialty and Cancer Hospital acquires VINS Hospital in Vadodara[72]

Zydus Multispecialty and Cancer Hospital, Vadodara, has announced the acquisition of the Vadodara Institute of Neurological Sciences (VINS) Hospital, a 50 (fifty)-bed facility specialising in neurology and neurosurgery, adding a dedicated neurological care centre to its hospital network. Founded approximately two decades ago by Dr. Monish Malhotra, VINS Hospital has been a key provider of neurological services in Vadodara, and its integration is expected to significantly strengthen Zydus's neuro-specialty capabilities by bringing together leading clinical expertise, advanced technology, and comprehensive services under one unified system, enabling patients to access specialised neurological diagnosis, treatment, and surgery closer to home. The combined neuroscience portfolio will support the management of conditions including brain and spinal tumours, aneurysms, movement disorders, stroke, trauma, deep brain stimulation, and epilepsy care, furthering the Zydus Group's vision of building one of India's most comprehensive centres for neuroscience care.

13. Estée Lauder Companies to increase stake in Ayurveda Brand Forest Essentials[73]

US-based beauty giant Estée Lauder Companies has agreed to acquire the remaining stake in Forest Essentials, India's leading luxury Ayurveda beauty brand, expanding a partnership that traces its origins to an initial investment made in 2008 and a subsequent increase to 49 (forty-nine) per cent in 2020, with the latest transaction set to give Estée Lauder full ownership of the brand, subject to regulatory approvals expected to close in the second half of 2026. Founded in 2000 by Mira Kulkarni, Forest Essentials is widely recognised for its premium skincare and beauty products rooted in Ayurvedic tradition, operating nearly 200 (two hundred) standalone stores and having built a strong position in India's luxury skincare segment over the past two and a half decades. Reports suggest that the acquisition reflects Estée Lauder's long-term commitment to India, which it regards as one of its largest and most significant emerging markets, and its conviction in the global resonance of the Forest Essentials brand, with the combined ambition of strengthening the brand's leadership at home while thoughtfully introducing it to a global audience.

[71] https://entrackr.com/snippets/nivaan-care-raises-7-mn-in-series-a-round-led-by-sorin-investments-11032479
[72] https://www.expresshealthcare.in/news/zydus-multispecialty-and-cancer-hospital-acquires-vins-hospital-in-vadodara/452586/
[73] https://brandequity.economictimes.indiatimes.com/news/business-of-brands/estee-lauder-to-acquire-remaining-stake-in-forest-essentials/129133946

List of Contributors

Biplab Lenin
Partner

Akshat Razdan
Principal Associate

Kartik Jain
Principal Associate

Priyam Rajkumar
Senior Associate

Kritika Asawa
Senior Associate

Anam Chowdhary
Associate

Yash Kataria
Associate

Cyril Amarchand Mangaldas
Advocates & Solicitors

100⁺ years of legacy | **1400** Lawyers | **220** Partners

Peninsula Chambers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai – 400 013, India
T +91 22 6660 4455 **F** +91 22 2496 3666 **E** cam.mumbai@cyrilshroff.com **W** www.cyrilshroff.com
Presence in Delhi-NCR | Bengaluru | Ahmedabad | Hyderabad | Chennai | GIFT City | Singapore | Abu Dhabi