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synapse

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

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Dear Readers,

The third quarter of 2026 brought with it a period of considerable activity across India's healthcare and life sciences landscape, with significant regulatory reform, landmark judicial pronouncements, and notable transactions shaping the sector. The quarter was characterised by a deepening regulatory focus on pharmaceutical and medical device compliance, expanded pricing oversight, and continued enforcement action across food safety and drug regulation. This edition of *Synapse* captures these evolving trends and their implications for India's healthcare ecosystem.

On the regulatory front, the Ministry of Health and Family Welfare (**MoH&FW**) amended the Medical Devices Rules, 2017, covering registration certificates, sterilisation labelling, and testing fees. The MoH&FW also notified debarment rules for false or fabricated drug applications, prohibited the manufacturing and sale of 16 irrational fixed dose combination drugs, moved high-alcohol oral medicines from Schedule K to Schedule H1 and brought cell and gene therapy products under the central licensing framework. In digital health and medical technology space, the CDSCO issued its Guidance Document on Medical Device Software under the MDR-2017 and announced plans to roll out an integrated digital drug regulatory platform within 18 months.

On food and cosmetics regulation, the Food Safety and Standards Authority of India (**FSSAI**) has proposed "High Fat, Sugar, Salt" thresholds for school food regulations, mandated new packaging norms for pan masala, eased front-of-pack labelling norms for coffee-chicory mixtures, and amended licensing rules on record-keeping and FIFO/ FEFO storage. The Central Consumer Protection Authority penalised Stori Foods and Amazon for misleading claims, and FSSAI enforcement action prompted corrective measures by Dabur, Lotte India, and other food business operators.

On the healthcare delivery and life sciences front, the MoH&FW released the revised Draft National Pharmacy Commission Bill, 2026, proposing a comprehensive overhaul of pharmacy regulation, notified the Transplantation of Human Organs and Tissues (Second Amendment) Rules, 2026, and mandated periodic renewal of Assisted Reproductive Technology and surrogacy clinic registrations.

In the news and policy space, Government defended medical service rate standardisation under the Clinical Establishments Rules before the Supreme Court of India, a Parliamentary panel recommended statutory price caps for medical devices, and a government panel upheld the doorstep drug delivery rule for vulnerable patients. In the litigation space, Kerala High Court upheld action

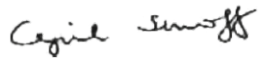
against misleading pharmacy discount boards, the Bombay High Court held that FSSAI licence suspension cannot continue indefinitely once compliance is restored and separately directed automatic revocation of food licence suspensions upon verified compliance.

The quarter also witnessed several notable transactions, including Amneal Pharmaceuticals' acquisition of Kashiv BioSciences for USD 1.1 billion, Piramal Pharma's majority stake acquisition in Yapan Bio, AbbVie's USD 10.9 billion acquisition of Apogee Therapeutics, Cyrix Healthcare's acquisition of Blue Star E&E's MedTech Solutions business, and Novartis India's agreement to acquire Pfizer's hypertension brand Minipress for INR 1,250 crore. Additionally, Warburg Pincus is set to acquire Seacod-maker Universal NutriScience.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated pharmaceuticals, healthcare, and life sciences practice. This latest issue of Synapse is our effort to keep you abreast of the latest developments in this dynamic sector. We hope you find this issue of interest. As always, your feedback helps 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,



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I. Pharmaceutical & Medical Devices

Regulatory Updates

- a. *MoH&FW amends Medical Devices Rules, 2017, covering registration certificates, sterilisation labelling, and testing fees¹*

The Ministry of Health and Family Welfare (**MoH&FW**), vide G.S.R. 743(E), dated August 14, 2026, has notified the Medical Devices (Second Amendment) Rules, 2026, effective from the date of publication. The amendment formally defines Certificate of Registration as the registration certificate issued by the State or Central Licensing Authority in Form MD-2, MD-40, or MD-42. It introduces a new labelling requirement: when a manufacturer outsources sterilisation of a medical device to another licensed facility, that facility's licence number is now required to be stated on the label of the medical device.

- b. *MoH&FW amends Medical Devices Rules, 2017, to introduce QMS self-certification for certain Class A medical devices and recognise EU regulatory approvals²*

The MoH&FW, vide G.S.R. 744(E), dated August 14, 2026, notified the Medical Devices (Third Amendment) Rules, 2026 wherein manufacturers and importers of Class A non-sterile, non-measuring medical devices are required to self-certify compliance with Quality Management System (**QMS**) requirements, in addition to compliance with applicable standards, at the time of registration. It also adds European Union countries, alongside the US, the UK, and Japan for recognition of foreign regulatory approvals.

- c. *MoH&FW notifies debarment rules for false or fabricated drug applications³*

The MoH&FW, vide Notification G.S.R. 706(E), dated July 30, 2026, notified the Drugs (Eleventh Amendment) Rules, 2026, further amending the Drugs Rules, 1945 wherein any applicant who is found to be guilty of submitting misleading, fake, or fabricated documents or information may be debarred by the licensing authority for a duration that it deems fit upon the service of a show-cause notice. The applicant has the right to appeal within 30 days from the date of receipt of the final order.

- d. *MoH&FW includes Pregabalin in Schedule H1 of the Drugs Rules, 1945⁴*

The MoH&FW, vide notification S.O. 3068(E), dated June 11, 2026, has prohibited the manufacture for sale, sale, distribution and supply of 16 identified fixed dose combination (**FDC**) drugs for human use, with immediate effect. The Ministry stated that the 16 combinations were found to lack therapeutic justification and that their continued use was not considered beneficial relative to the risks involved.

- e. *MoH&FW moves high-alcohol oral medicines from Schedule K to H1⁵*

The MoH&FW, vide notification G.S.R. 607(E), dated July 8, 2026, amended the Drugs Rules, 1945, to curb the sale of oral medicines containing high-alcohol-content in larger pack sizes. The amendment removes the exemption under Schedule K for oral formulations, containing more than 12% ethyl alcohol packed and sold in bottles or packings exceeding 30 mL, meaning such products will now require manufacturing and sale licences under the Drugs and Cosmetics Act, 1940 (**D&C Act**). The amendment shall come into force by January 7, 2027.

- f. *MoH&FW brings cell, gene therapy products under central licensing framework⁶*

The MoH&FW, vide notification G.S.R. 530(E), dated June 29, 2026, has notified the Drugs (Eighth Amendment) Rules, 2026, amending the Drugs Rules, 1945 which brings "cell or stem cell derived products, gene therapeutic products, and xenografts" under the Central Licence Approving Authority (**CLAA**) framework, alongside recombinant DNA (r-DNA) derived drugs, vaccines and large volume.

- g. *MoH&FW proposes prior intimation route for import of test-sample drugs via Form 12⁷*

The MoH&FW, vide notification G.S.R. 509(E), dated June 23, 2026, released draft amendments to the Drugs Rules, 1945, proposing a simpler "prior intimation" route in place of a full import licence for drugs imported solely for

¹ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTQ=
² cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTU=
³ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1NzU=
⁴ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1MTk=
⁵ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0NTc=
⁶ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MTc=
⁷ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDk=

analytical and non-clinical testing. This excludes sex hormones, cytotoxic drugs, beta-lactams, biologics with live micro-organisms, and narcotic/ psychotropic drugs.

h. MoH&FW adds four therapeutic categories to Schedule H2⁸

The MoH&FW, vide notification G.S.R. 506(E), dated June 22, 2026, has notified the Drugs (Seventh Amendment) Rules, 2026 which saw the addition of a new Table 2 to Schedule H2 of the Drugs Rules, 1945, bringing four additional therapeutic categories. This includes all vaccines, antimicrobials, narcotic drugs and psychotropic substances under the Narcotic Drugs and Psychotropic Substance Act, 1985 (**NDPS Act**), and all anticancer drugs, within the scope of Schedule H2. The changes will be effective from July 1, 2027, except for antimicrobials, which would come into force a year later, on July 1, 2028.

i. MoH&FW proposes revised Periodic Safety Update Reports filing schedule for new drugs⁹

The MoH&FW, vide draft notification G.S.R. 504(E), dated June 22, 2026, has proposed amending the NDCT Rules by inserting a new proviso to the Fifth Schedule. It would revise the filing schedule for Periodic Safety Update Reports (**PSURs**) for new drugs. For modified or sustained-release formulations, the draft proposes that PSURs be submitted every six months for the first two years after approval, annually for the subsequent two years, and thereafter once every three years until the drug is actually marketed. For vaccines, recombinant DNA (**r-DNA**) derived products, monoclonal antibodies, cell or stem cell derived products, gene therapeutic products and xenografts, which retain new drug status, the draft proposes submitting PSURs every six months for the first two years, and annually thereafter until the drug is marketed.

j. MoH&FW proposes inclusion of four additional drugs in Schedule H1 of the Drugs Rules, 1945¹⁰

The MoH&FW, vide draft notification G.S.R. 745(E), dated August 19, 2026, published draft Drugs (Amendment) Rules, 2026, to amend the Drugs Rules, 1945. The draft proposes adding Flupentixol, Zopiclone, Gabapentin, and Carisoprodol in Schedule H1.

k. MoH&FW prohibits all formulations of FDC containing Chlorpheniramine Maleate and Phenylephrine HCl in children below four¹¹

The MoH&FW, vide notification S.O. 4595(E), dated August 18, 2026, has restricted the manufacture, sale or distribution of all formulations of FDC containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride, subject to the condition that manufacturers mention the warning “Fixed Dose Combination shall not be used in children below four years of age” on the label, package insert and promotional literature of the drug.

l. MoH&FW expands Rules 89 to include exemptions from Form 29 test licence requirements¹²

The MoH&FW, vide notification G.S.R. 713(E), dated August 6, 2026, notified the Drugs (Twelfth Amendment) Rules, 2026, amending Rule 89 of the Drugs Rules, 1945. Rule 89 currently exempts holders of Forms 25 and 28, which broadly cover standard drug manufacturing licences, from obtaining a separate test licence, in Form 29, to manufacture drugs for examination, test, or analysis. This exemption has now been extended to holders of Forms 25A, 25F, 28A, 28B, 28D, 28DA, 28E and 28F, which broadly cover manufacturing licences and loan licences for Schedule X drugs, large volume parenterals/ vaccines/ r-DNA products, blood products, and umbilical cord blood stem cell banking.

m. MoH&FW proposes CCTV surveillance requirement at drug retail premises¹³

The MoH&FW, vide draft notification G.S.R. 791(E), dated September 8, 2026, has proposed the Drugs (Amendment) Rules, 2026, further amending the Drugs Rules, 1945. The draft proposes that the supply of drugs on the prescription of a Registered Medical Practitioner, except in the case of wholesale dealings, be undertaken under a Closed-Circuit Television (**CCTV**) surveillance system installed and maintained at the licensed premises, with recordings preserved for a minimum period of three months.

⁸ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDU=

⁹ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDU=

¹⁰ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0NT=

¹¹ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0NTY=

¹² cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1OTQ=

¹³ <https://gazzettetracker.com/g/CG-DL-E-16092026-276270>



- n. *MoH&FW proposes exemption for emergency contraceptive Levonorgestrel Tablets under Schedule K of the Drugs Rules, 1945*

The MoH&FW, vide draft notification G.S.R. 792(E) dated September 3, 2026, has proposed to amend the Drugs Rules, 1945 to insert Levonorgestrel Tablets 0.75 mg/1.5 mg (emergency contraceptives) under Schedule K. The draft proposes that the packaging and package insert for Levonorgestrel Tablets 0.75 mg/1.5 mg carry boxed warnings.

- o. *MoH&FW proposes prohibition on certain antimicrobials for animal use¹⁴*

The MoH&FW, vide draft notification S.O. 4996(E), dated September 3, 2026, has proposed to prohibit the import, manufacture, sale, and distribution of certain antimicrobials for animal use. The antimicrobials covered are, under the category of antibiotics: (i) Carboxypenicillins and (ii) Phosphonic acid derivatives.

- p. *CDSCO directs withdrawal of Homoeopathic medicines containing Phenolphthalein¹⁵*

The CDSCO, vide circular F.No. AYU-11/15/2024-eoffice, dated July 6, 2026, addressed the manufacturing and marketing of medicines containing Phenolphthalein,

that were being labelled as Homoeopathic medicines. CDSCO noted that such combinations do not meet the criteria for classification as a Homoeopathic medicine Drugs Rules, 1945 and that approval of such combinations compromises patient safety and may lead to adverse drug reactions, warranting withdrawal of manufacturing permission on grounds of statutory non-conformity.

- q. *CDSCO clarifies regarding submission of applications for compounding of offences¹⁶*

The CDSCO, vide circular F. No. Legal-13011(11)/17/2026-eoffice (Comp.37331), dated July 21, 2026, issued a clarification on submission of applications under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025. It clarifies that jurisdiction is determined by the authority whose Drugs Inspector drew the sample. Applications relating to samples drawn by a State/ UT Drugs Inspector are to be filed before the concerned State/ UT Compounding Authority, while those drawn by a CDSCO Drugs Inspector are to be filed before the Central Compounding Authority. Applications filed before an authority lacking jurisdiction are liable to be returned or rejected, and stakeholders have been advised to ascertain the competent authority before submission to avoid delay.

¹⁴ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NmM=

¹⁵ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0Mzk=

¹⁶ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1Mjk=

- r. *CDSCO clarifies regulatory pathway for formulation intermediates, including modified-release granules and pellets*¹⁷

The CDSCO, vide circular F. No. ND-11012(17)/1/2026-eoffice, dated June 24, 2026, has clarified that under Rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules, 2019**), modified or sustained-release dosage forms, including gastro-resistant/ delayed-release (enteric-coated) tablets and capsules, are always deemed 'new drugs'. Consequently, formulation intermediates used in such formulations (bulk SR, ER, PR, DR pellets and granules) will require CDSCO approval, with manufacturers required to submit applications for both the finished formulation and the formulation intermediate together to CDSCO.

- s. *CDSCO mandates online SUGAM submission for vaccine PAC applications*¹⁸

The CDSCO, vide circular F.No. VAC-11014(17)/4/2026-eoffice, dated June 24, 2026, the CDSCO has streamlined the submission of application for Post Approval Changes in Registration Certificates and Import Licences of human vaccines and anti-sera by mandating online submission through the SUGAM portal, in accordance with the CDSCO Guidance for Industry on Post Approval Changes in Biological Products: Quality, Safety and Efficacy Documents, effective from July 1, 2026.

- t. *CDSCO directs action against manufacturing and marketing of unapproved drug products containing Enclomiphene and its combinations*¹⁹

The CDSCO, vide circular F. No. ENFORC-12016(11)/2/2026-office-34479, dated August 10, 2026, has directed all State and Union Territory Drugs Controllers to immediately identify manufacturers, marketers, distributors and retailers dealing in unapproved drug products containing Enclomiphene and its combinations, and initiate regulatory action against them, including cancellation or suspension of manufacturing permissions.

- u. *CDSCO issues circular on indiscriminate use of painkillers and antibiotics, associated risk of chronic kidney disease*²⁰

The CDSCO vide circular F.No. Legal-11017(11)/177/2026 dated September 21, 2026, has addressed the indiscriminate use of Non-Steroidal Anti-Inflammatory Drugs (**NSAIDs**) and antibiotics and the associated risk of chronic kidney disease, and antibiotics and the associated risk of chronic kidney disease. The circular advises the public against the indiscriminate, repeated or prolonged use of NSAIDs and antibiotics without medical advice, including self-medication, sharing prescribed antibiotics and using leftover medicines. Healthcare professionals have been advised to prescribe these medicines only when clinically indicated and follow appropriate dosing and antimicrobial stewardship principles.

- v. *DoP notifies Drugs (Prices Control) Amendment Order, 2026*²¹

The Ministry of Chemicals and Fertilizers, vide notification S.O. 3516(E), dated June 30, 2026, has notified the 13th amendment to the Drugs (Prices Control) Order, 2013 (**DPCO 2013**), effective from the date of publication. The amendment authorises the Government to establish a separate ceiling or retail prices for the same drug based on therapeutic rationale, packaging, pack size or dosage. It also limits manufacturers' liability for overcharging on stock distributed through a specified distributor or retailer, provided they demonstrate compliance with the prescribed price-dissemination requirements, including the circulation of revised price lists, newspaper advertisements, website updates, and stock/ production disclosures. The amendment further exempts an existing manufacturer from seeking fresh price approval when launching the same new drug within twelve months of its price being fixed, requiring instead a launch intimation in a newly introduced Form-IA within one month. It also introduces a seven-year record-retention requirement for sales and production data, with government inspection powers.

¹⁷ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDM=

¹⁸ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDI=

¹⁹ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2MDI=

²⁰ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2ODQ=

²¹ 13th Amendment S.O. 3516 (E) dated 30 June 2026.pdf

w. *NPPA clarifies filing of Form-IA for “new drugs”²²*

The National Pharmaceutical Pricing Authority (**NPPA**), vide an office memorandum dated July 16, 2026, has issued clarifications regarding the filing of Form-IA under Paragraph 15 of the Drugs DPCO 2013. The NPPA has clarified that the amended provisions introduced pursuant to the 13th Amendment to the DPCO 2013 apply only to retail prices notified on or after July 1, 2026. Accordingly, retail prices notified before July 1, 2026, will continue to be governed by the earlier framework.

x. *NPPA reiterates quarterly Form III filing compliance under DPCO 2013²³*

The NPPA, vide office memorandum F No. 15(108)/ 2021/ Div.III/ NPPA Part (1), dated June 26, 2026, has directed all entities falling within the definition of “manufacturer” under the Drugs (Prices Control) Order, 2013, to ensure timely and regular submission of quarterly returns relating to scheduled formulations in Form III, and has also directed manufacturers to submit any Form III returns missed in previous quarters.

y. *NPPA fixes retail prices for 11 new drug formulations under DPCO 2013²⁴*

The NPPA, vide order S.O. 4774(E) dated August 27, 2026, has fixed retail prices for 11 new drug formulations, including combinations of Drotaverine and Mefenamic Acid, Glimepiride, Telmisartan-based tablets, and Dolutegravir, Lamivudine and Tenofovir Alafenamide.

z. *DGFT automates free sale and commerce certificates issuance for pharma exporter²⁵*

The Directorate General of Foreign Trade (**DGFT**), vide Notice No. 24/2026-2027, dated August 31, 2026, has introduced automated issuance of Free Sale and Commerce Certificates (**FSC**) on the DGFT portal. These certificates are issued to exporters, under the Foreign Trade Policy, for items not covered under the D&C Act.

Litigation Updates

a. *J&K&L High Court refuses to quash “Not of Standard Quality” drug complaint against Corona Remedies²⁶*

The Jammu & Kashmir & Ladakh High Court (**J&K&L High Court**), in *Ankur Kirtikumar Mehta & Ors. v. Bharti Bachloo, Drugs Inspector*, vide order CRM(M) No. 237/2019, on August 11, 2026, dismissed a petition by three Directors of M/s Corona Remedies Pvt. Ltd., seeking quashing of the criminal complaint under Section 18(a)(i), read with Section 27(d) of the D&C Act, 1940, arising from a batch of “Locipil Tablets” declared “Not of Standard Quality” by the Government Analyst. The Court held that factual questions such as alleged non-involvement of directors in production and procedural objections on the Government Analyst’s report, are matters for trial and cannot be adjudicated at the quashing stage.

b. *Kerala High Court upholds action against misleading pharmacy discount boards²⁷*

The Kerala High Court (**KHC**), in *Pharmadude Pharmacy v. State of Kerala and Others*, W.P.(C) No. 39706 of 2024 and connected cases (W.P.(C) No. 41978 of 2024 and W.P.(C) No. 1447 of 2025), order dated June 19, 2026, upheld the Drugs Controller’s power to require pharmacies to give an undertaking that they will not display misleading or vague discount boards, dismissing the petitions that challenged the underlying circular and allowing the connected petition that sought its enforcement. The Court clarified that pharmacies remain free to sell drugs below the maximum retail price (**MRP**) and to offer genuine discounts, the circular does not restrict that right. It targets only false or exaggerated discount claims that mislead customers. The Court held that requiring this undertaking as a licensing condition falls within the Drugs Controller’s regulatory powers, since it is aimed at preventing consumer deception rather than restricting legitimate discounting.

²² <https://nppa.gov.in/storage/uploads/tender/om-dated-16072026-16-07-2026.pdf>

²³ Om-dt-230626-23-06-2026.pdf

²⁴ Retail-27-08-2026.pdf

²⁵ Trade notice 27_0001.pdf

²⁶ Ankur Kirtikumar Mehta & Ors. v. Bharti Bachloo, Drugs Inspector, CRM(M) No. 237/2019

²⁷ Pharmadude Pharmacy v. State of Kerala and Others, W.P.(C) No. 39706 of 2024 and connected cases



News Updates

a. Vadodara firm develops India's first homegrown heart-lung machine²⁸

Vadodara-based Mediyant Technologies has developed India's first homegrown heart-lung machine. The device temporarily replicates the functioning of the heart and lungs during open-heart surgery by maintaining blood circulation and oxygen supply. It has received approval from the US FDA and the CDSCO has classified it as a Class C medical device. The heart-lung machine market in India currently sits at a valuation of approximately USD 73.1 million.

b. The Government defends medical service rate standardisation under CER before SC²⁹

The MoH&FW has defended the validity of Rule 9(ii) of the Clinical Establishments (Central Government) Rules, 2012, before the Supreme Court in a challenge filed by the All-India Ophthalmological Society. The provision requires clinical establishments to charge within rate bands fixed by the Centre, in consultation with State Governments. The Centre has submitted that this standardises charges across establishments, prevents price gouging and arbitrary inflation, and protects patients from exploitation, while still allowing establishments to adjust charges within the range based

on infrastructure, service quality and patient demographics.

c. Parliamentary panel recommends statutory price caps for medical devices³⁰

The Parliamentary Standing Committee on Health and Family Welfare, in its 176th Report presented on August 7, 2026, has recommended that the gap between the landing price of a medicine or medical device and its MRP should not exceed 20%. The committee clarified that lower prices should not compromise device quality. It mentioned the 2017 coronary stent price cap as a precedent, noting that it brought prices down from about INR 1.9 lakh to INR 25,000-30,000 and generated estimated annual consumer savings of INR 13,353 crore.

d. NPPA integrates Pharma Jan Samadhan Portal with Pharma Sahi Daam Portal for enhanced citizen services³¹

The NPPA has integrated the Pharma Jan Samadhan portal, which handles medicine-related grievances, with the Pharma Sahi Daam portal, which provides medicine price information, into a single unified platform operating through the Pharma Sahi Daam app and website. Pharma Sahi Daam allows citizens to compare medicine prices and verify whether scheduled drugs are

²⁸ [India's indigenous heart-lung machine gets FDA, CDSCO nod - Medical Buyer](#)

²⁹ [Centre defends Rule 9\(ii\) of CER in SC; pushes for standardizing medical service rates - Medical Buyer](#)

³⁰ [Parliamentary panel calls for statutory price capping for medical devices, including stents - Medical Buyer](#)

³¹ [NPPA Integrates Pharma Jan Samadhan Portal with Pharma Sahi Daam Portal for Enhanced Citizen Services](#)

being sold within government-fixed ceiling prices, while Pharma Jan Samadhan enables consumers to report and seek redressal for issues such as overpricing, sale without price approval, and non-availability of drugs. Post integration, both services are accessible through a single interface, with immediate effect, in line with the government's broader digital governance push.

e. *AYUSH Ministry operationalises Ayush Quality Mark framework*³²

The Ministry of Ayush has entrusted the Ayush Export Promotion Council (**AYUSHEXCIL**) to implement the Ayush Quality Mark, launched in December 2025 as a unified quality-assurance framework for Ayush products and services. The framework covers Ayush medicines, hospitals, clinics, wellness centres, medical value travel facilitators and testing laboratories, with certification aligned with internationally accepted standards of quality, safety and efficacy.

f. *Government Panel upholds Doorstep Drug Delivery Rule for vulnerable patients*³³

A sub-committee constituted by the Drugs Technical Advisory Board (**DTAB**) has recommended retaining the 2020 notification, G.S.R. 220(E), that permitted doorstep delivery of medicines, and rejected the All India Organisation of Chemists and Druggists' request for its withdrawal. The recommendation follows allegations that digital platforms were facilitating medicine deliveries without adequate prescription checks, contrary to the prescription requirements under the Drugs Rules, 1945.

Transaction Updates

a. *Amneal completes USD1.1 billion acquisition of Kashiv BioSciences*³⁴

Amneal Pharmaceuticals and Kashiv BioSciences, in April 2026, announced a definitive agreement for Amneal to acquire Kashiv BioSciences at around USD 1.1 billion. The combination aims to diversify Amneal's long-term growth by addressing the impending loss of exclusivity of biologics worth approximately USD 300 billion, with

plans to build a portfolio of over 12 commercial products and 20 plus additional pipeline assets by 2030.

b. *Piramal Pharma announces majority stake acquisition in Yapan Bio*³⁵

Piramal Pharma acquired over 40 per cent stake in Yapan Bio, a contract development and manufacturing organisation (**CDMO**) specialising in vaccines and biologics, for INR 76 crore. The acquisition integrates Yapan Bio's large-molecule development and manufacturing capabilities with Piramal Pharma Solutions' CDMO offering, including support for its ADCelerate platform for antibody-drug conjugate development.

c. *AbbVie completes \$10.9 billion acquisition of Apogee Therapeutics*³⁶

AbbVie has completed its acquisition of Apogee Therapeutics, Inc. for approximately USD 10.9 billion. The deal brings Apogee's pipeline of novel antibodies targeting inflammatory pathways, including lead asset zumilokibart, into AbbVie's immunology portfolio.

d. *Cyrix Healthcare completes acquisition of Blue Star E&E's MedTech Solutions business*³⁷

Cyrix Healthcare has acquired the MedTech Solutions business of Blue Star E&E, effective September 1, 2026, strengthening its capabilities in medical imaging, CT and MRI equipment sales, installation, maintenance, repairs and refurbishment. The deal also bolsters AURUM, Cyrix's refurbished equipment business, and expands its Total MedTech Management platform across India, the Middle East and Africa.

e. *Novartis India to acquire Pfizer's hypertension brand Minipress for INR 1,250 crore*³⁸

Novartis India has agreed to acquire Pfizer's Minipress trademark, a hypertension therapy, for INR 1,250 crore. Minipress is an off-patent therapy indicated for hypertension and benign prostatic hyperplasia. The sale comes as Pfizer faces multiple loss of exclusivity events and declining COVID-19 vaccine sales.

³² [Implementation of Ayush Quality Mark](#)

³³ [Government Panel Upholds Doorstep Drug Delivery Rule for Vulnerable Patients, ETPharma](#)

³⁴ [Amneal Pharmaceuticals Acquires Kashiv BioSciences for \\$1.1 Billion, ETPharma](#)

³⁵ [Piramal Pharma Acquires Majority Stake in Yapan Bio for ₹76 Crore, ETPharma](#)

³⁶ [AbbVie completes acquisition of Apogee Therapeutics for approximately \\$10.9 billion](#)

³⁷ [Cyrix acquires Blue Star E&E's MedTech Solutions Business, to bolster its capabilities](#)

³⁸ [Novartis India Acquires Pfizer's Minipress Brand for ₹1250 Crore Amidst Pharma Challenges, ETPharma](#)

II. Food, Nutrition & Cosmetics

Regulatory Updates

- a. *FSSAI proposes 'High Fat, Sugar, Salt' thresholds for school food regulations*³⁹

The Food Safety and Standards Authority of India (**FSSAI**), vide notification dated August 7, 2026, released Draft Food Safety and Standards (Safe food and balanced diets for children in school) Amendment Regulations, 2026. The Draft Regulation inserts a new provision that defines the thresholds for food products classified as “*high in added fat, added sugar, or sodium*”, which are aligned with the Indian Council of Medical Research (**ICMR**)’s Dietary Guidelines for Indians.

- b. *FSSAI mandates packaging norms for Pan Masala*⁴⁰

The FSSAI vide notification F. No. RCD-09002/1/2026-Regulatory-FSSAI, dated August 7, 2026, released the Food Safety and Standards (Packaging) Amendment Regulations, 2026, addressing packaging of Pan Masala. Permitted packaging material shall be made of “*paper, paperboard, cellulose, or other naturally derived materials*” that are free from plastic and further provides for compliance under Plastic Waste Management Rules, 2016.

- c. *FSSAI eases front-of-pack labelling norms for Coffee-Chicory Mixture*⁴¹

FSSAI, vide direction dated July 21, 2026 (F. No. 14(12)2020/RIRC/RCD/FSSAI), has addressed the notification of Food Safety Standards (Labelling and Display) First Amendment Regulations, 2025, dated August 8, 2025, which had mandated a front-of-package declaration for Coffee-Chicory Mixture, with enforcement specified as July 1, 2026. FSSAI has approved a simpler labelling option, deciding to keep the earlier notification in abeyance pending formal amendment.

- d. *FSSAI amends licensing rules on record-keeping and FIFO/FEFO storage*⁴²

The FSSAI vide notification F. No. REG-11013/1/2026-Regulation-FSSAI, dated June 23, 2026, notified the Food Safety and Standards (Licensing and Registration of Food Businesses) second Amendment Regulations, 2026. The

amendment makes two changes. It revises the condition requiring licensees to maintain daily records of production and raw material utilisation, clarifying that this condition shall not apply to non-manufacturing food businesses. Separately, the hygienic and sanitary practices requirement on storage of raw materials, ingredients, work-in-progress and processed, cooked or packaged food products has been revised to require storage in accordance with ‘*First In First Out*’ and ‘*First Expire First Out*’ principles, with an express carve-out that this requirement shall not apply to retailers.

Litigation Updates

- a. *Bombay High Court holds FSSAI licence suspension cannot continue indefinitely once compliance is restored*⁴³

The BHC in *Hotel Alankar v. State of Maharashtra and Others*, Writ Petition No. 3806 of 2026, order dated September 8, 2026, addressed the continued suspension of an FSSAI licence following an inspection showing 69% compliance, with deficiencies including unlicensed alcohol sales, improper storage of vegetarian and non-vegetarian food, and improper disposal of used cooking oil. A re-inspection recorded 97% compliance. The Court held that suspension under the under the Food Safety and Standards Act, 2006 (**FSS Act**) is a public-health measure and cannot continue indefinitely once the identified deficiencies are rectified. It revoked the suspension and restored the licence, while directing continued monitoring and an undertaking that the petitioner would not sell products not endorsed on its licence. The Court observed that subsequent violations could be addressed through penalties under Sections 55 and 63 of the FSS Act rather than prolonged suspension.

- b. *J&K&L High Court holds differential MRP restriction applies prospectively*⁴⁴

The J&K&L High Court, in *Hindustan Coco Cola Beverages Pvt. Ltd. v. Assistant Controller, Legal Metrology, Reasi*

³⁹ Draft Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2026.pdf

⁴⁰ Final Food Safety and Standards (Packaging) Amendment Regulations, 2026.pdf

⁴¹ https://www.fssai.gov.in/docs/foodlaw/advisory/6a604e4037173Direction_Coffee%20Chicory.pdf?csrt=2721280565436364715

⁴² <https://www.fssai.gov.in/docs/food-law/notice-comment/6a3c0a8fbaf61273797.pdf?csrt=2721280565436364715>

⁴³ *Hotel Alankar v. State of Maharashtra and Others*, Writ Petition No. 3806 of 2026

⁴⁴ *Hindustan Coco Cola Beverages Pvt. Ltd. v. Assistant Controller, Legal Metrology, Reasi and Another*

and Another, CRMC No. 395 of 2017, on July 3, 2026, held that the restriction preventing manufacturers, packers and importers from declaring different MRPs for identical pre-packaged products was introduced only from January 1, 2018, under Rule 18(2A) of the Legal Metrology (Packaged Commodities) Rules, 2011 (**LMPC Rules 2011**), through G.S.R. 629(E), dated June 23, 2017. Since the alleged conduct occurred in 2016, the Court held that the amended restriction could not be applied to conduct predating its commencement, as doing so would retrospectively criminalise conduct that was not an offence at the time. The Court accordingly quashed the prosecution.

c. *Bombay High Court directs automatic revocation of food licence suspensions upon verified compliance*⁴⁵

The BHC in *Siddharth Agro v. State of Maharashtra and Others*, Writ Petition No. 9946 of 2026, order dated August 28, 2026, addressed a challenge to the suspension of the petitioner's FSSAI licence, issued on July 15, 2026 for non-compliance with the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. The Court directed the authorities to carry out a fresh inspection and furnish the petitioner a copy of the auto-generated compliance report. Noting a recurring pattern across matters before it where suspension or cancellation orders are not revoked even after an establishment cures the deficiencies, forcing avoidable litigation and causing financial harm to the business, its employees and supply chains. The Court directed that once the authorities are satisfied through the auto-generated report that deficiencies have been duly rectified, the suspension or cancellation order shall stand automatically revoked upon issuance of that report, without requiring the establishment to approach the Court again, and applied the same principle to revoke the suspension in this case upon compliance being confirmed.

News Updates

a. *Supreme Court reprimands FSSAI over delay in FOPL implementation*⁴⁶

The Supreme Court recently reprimanded the FSSAI over delays in implementing mandatory front-of-package warning labels on packaged foods, while hearing a public interest litigation seeking directions to the Centre, states and Union Territories. The bench observed that such labels are necessary to protect children from junk food addiction. The Court noted there had been no progress on its earlier order and asked the Centre's counsel whether the government intended to comply on its own or await a binding judicial direction.

b. *FSSAI cracks down on misleading "100%" claims across six food companies*⁴⁷

The FSSAI recently took enforcement action against six food companies, i.e. Amway India, Emami, Bonn Biscuits, Apis India, Juza Foods and MasterChow Foods, over the use of "100%" claims on labels, packaging and advertisements. Following the FSSAI's intervention, all six withdrew such claims from their products. This forms part of the FSSAI's broader crackdown on misleading labels and claims in the food sector.

c. *FSSAI enforcement prompts corrective action by Dabur, Lotte India and others*⁴⁸

The FSSAI observed that several food companies including Dabur, Ferns N Petals, etc., took corrective measures after notices were served for misleading labelling, product classification, and advertising violations. Dabur was asked to correct the classification of an Ayurvedic medicinal oil sold as edible oil, while Lotte India was flagged for "100%" claims. Similar actions have been taken against several other FBOs.

⁴⁵ *Siddharth Agro v. State of Maharashtra and Others*, Writ Petition No. 9946 of 2026 (Bombay High Court, order dated August 28, 2026)

⁴⁶ *Supreme Court Criticizes FSSAI for Delays in Packaged Food Warning Labels*, [ETHealthworld](#)

⁴⁷ *FSSAI cracks down on "100%" claims: Amway India, Emami, Bonn Biscuits withdraw misleading labels*, [ETHealthworld](#)

⁴⁸ *Dabur, Ferns N Petals, Lotte India rectify labelling, advertising lapses after FSSAI notices*, [ETHealthworld](#)



d. FSSAI action prompts six FBOs to correct misleading claims and trademarks⁴⁹

The FSSAI communicated that six FBOs have rectified their labelling defaults. The corrective measures came after the authority had acted against the food companies for misleading claims, along with directions to update the packaging of the products. Corrective measures included changing deceptive trademarks, withdrawing “vegan and healthy” claims, halting non-compliant production, and delisting a product.

e. CCPA penalises Amazon for misleading “Ram Mandir Prasad” advertisements⁵⁰

The CCPA imposed INR 1 lakh penalty on Amazon Seller Services Pvt. Ltd. for publishing misleading advertisements. It permitted listing of ordinary commercial sweets falsely labelled as ‘Shri Ram Mandir Ayodhya Prasad’, without authorisation from the Shri Ram Janmabhoomi Teerth Kshetra Trust. The Authority found the listings especially egregious as they appeared just before the January 22, 2024, Pran Pratishtha ceremony and held Amazon liable under Section 21(4) of

the Consumer Protection Act, 2019. Amazon was directed to ensure verifiable proof of authorisation before listing prasad-type products linked to ten (10) named religious institutions, and prominently display seller details per the E-Commerce Rules, 2020.

Transaction Update

a. Warburg Pincus to acquire Seacod-maker Universal NutriScience⁵¹

Warburg Pincus, a US-based private equity firm, is leading the acquisition of Universal NutriScience, the Indian Seacod liver oil capsule-maker, for approximately INR 2,700-2,800 crore, marking its fourth acquisition in India’s healthcare, supplements and preventive health sector within months. Through this transaction, all existing investors in UNS will exit. Official announcements are awaited as discussions are still private. The market is projected to grow to nearly USD 55-57 billion by 2030.

⁴⁹ Food Companies Rectified Claims: FSSAI Forces Six Food Companies to Correct Misleading Labels and Claims, ETHealthworld

⁵⁰ CCPA Fines Amazon ₹1 Lakh For Permitting Sale Of Regular Sweets Under False Label Of ‘Shri Ram Mandir Ayodhya Prasad’

⁵¹ Hindustan Unilever: Warburg Pincus Leads Acquisition of Seacod-Maker Universal NutriScience for ₹2800 Crore, ETPharma

III. Digital Health & Med-Technology

Regulatory Update

- a. *CDSCO issues Guidance Document on Medical Device Software under MDR-2017*⁵²

The CDSCO, vide circular F. No. MED-16028/2/2025-eoffice, dated July 21, 2026, has issued the final Guidance Document on Medical Device Software (**MDSW**) under the Medical Devices Rules, 2017 (**MD Rules 2017**), following the draft version that was circulated on October 21, 2025. The guidance clarifies regulatory expectations for MDSW, covering the applicable framework, classification principles, safety and performance requirements, documentation expectations, quality management considerations, and post-market obligations. It clarifies that standalone software, software embedded in or driving a hardware device, and technologies such as mobile apps, AI/ML tools and cloud-based platforms are all classified as MDSW, where they serve a medical purpose. It also provides examples of what is and is not regulated.

News Update

- a. *CDSCO to roll out integrated digital drug regulatory platform within 18 months*⁵³

CDSCO has announced plans to operationalise the first phase of an integrated, end-to-end digital drugs regulatory system within 18 months. The platform is intended to streamline regulatory processes through digitalisation, improve coordination among stakeholders and support more efficient, data-driven oversight of the pharmaceutical sector. The announcement was made by the Drugs Controller General of India at the Global Drug Regulatory Conclave 2026.

Litigation Update

- a. *Supreme Court says laser imagers used with diagnostic equipment are not diagnostic apparatus*⁵⁴

The Supreme Court, in *M/s. Carestream Health India Pvt. Ltd. v. Commissioner of Customs*, Civil Appeal No. 3440 of 2025, on August 12, 2026, upheld the classification of imported laser imagers under Customs Tariff Heading, rejecting their classification as diagnostic apparatus. The Court reasoned that imagers merely reproduce images generated by MRI, CT, X-ray and other diagnostic machines and do not independently perform, assist in, or contribute to the diagnostic process. It held that the device's ability to produce high-quality medical images does not make it a diagnostic instrument, as diagnosis is undertaken by the primary imaging equipment and medical professionals.

Transaction Update

- a. *Temple acquires London longevity clinic LongeVus*⁵⁵

Temple, the wearable technology startup, has acquired LongeVus, a London-based longevity medicine practice, as it builds clinical and scientific capabilities ahead of a wider product launch. Financial terms were not disclosed. LongeVus will continue to operate as part of Temple, with its founders continuing to serve its existing clients. The acquisition supports validation of Temple's wearable device worn on the temple and designed to track physiological signals, including a proprietary "Entropy" metric ahead of its product launch.

⁵² cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1MTM=

⁵³ [Digital Drug Regulation: CDSCO to Introduce Integrated Compliance Platform in 18 Months](#)

⁵⁴ *M/s. Carestream Health India Pvt. Ltd. v. Commissioner of Customs*, Civil Appeal No. 3440 of 2025

⁵⁵ [Deepinder Goyal's Temple acquires London longevity clinic LongeVus | India Business News - The Times of India](#)

IV. Healthcare Delivery, Clinical Trials & Life Sciences

Regulatory Update

- a. *CDSCO restricts of In-Vitro Fertilization media, reagents and related consumables used in Assisted Reproductive Technology procedures*⁵⁶

The CDSCO, vide circular File No. MED/71/2026-eOffice, dated June 23, 2026, issued a circular on sale of In-Vitro Fertilization (IVF) media, reagents and related consumables used in Assisted Reproductive Technology (ART) procedures meant for use by ART clinics and banks registered under the Assisted Reproductive Technology (Regulation) Act, 2021 (ART Act). The circular clarifies that media, reagents and similar products intended for use in ART procedures such as IVF and cryopreservation are covered under the MD Rules, 2017, and a licence is required to import or manufacture such products. Accordingly, all stakeholders, including manufacturers, importers and distributors, have been directed to ensure that supply of such products is made only to centres registered under the ART and Surrogacy Acts.

- b. *CDSCO clarifies processing route for new drugs undergoing global Phase III trials with Indian subjects*⁵⁷

The CDSCO, vide circular dated August 10, 2026, bearing reference F. No. ND-11011(13)/2/2026-eoffice, has issued a clarification on processing of applications seeking permission to import and market new drugs not approved anywhere in the world, where Phase III Global Clinical Trials are ongoing or have been completed with participation of Indian subjects under the NDCT 2019. CDSCO had observed a rise in such applications from companies whose drugs were either still under review by foreign regulators or had completed Phase III global trials involving Indian subjects. All such applications shall be examined and processed by the CDSCO. Applicants have been directed to submit their application to the CDSCO.

- c. *MoH&FW releases Transplantation of Human Organs and Tissues Second Amendment Rules 2026*

The MoH&FW, vide notification G.S.R. 630(E), dated July 15, 2026, has notified the Transplantation of Human Organs and Tissues (Second Amendment) Rules, 2026,

effective from the date of publication. The amendment notifies that an order of the Authorisation Committee, which approves or rejects an organ or tissue donation/transplant, can now be appealed within thirty days to the State Government, or to the concerned Government or Administrator in Union Territories.

- d. *MoH&FW releases revised Draft National Pharmacy Commission Bill, 2026, proposing overhaul of pharmacy regulation*⁵⁸

The MoH&FW has released the second version of the Draft National Pharmacy Commission Bill, 2026, following stakeholder consultations, proposing to replace the Pharmacy Act, 1948, with a new framework for regulating pharmacy education, professional registration and practice. The revised draft proposes a live, publicly accessible National Register of Pharmacy Professionals electronically synchronised with State Registers, alongside a dedicated Pharmacy Ethics and Registration Board. The Bill also provides transitional protections to existing registered pharmacists and students already enrolled before commencement.

- e. *MoH&FW mandates periodic renewal of ART and surrogacy clinic registrations*⁵⁹

The MoH&FW, through the Assisted Reproductive Technology (Regulation) Amendment Rules, 2026, and Surrogacy (Regulation) Amendment Rules, 2026, has introduced mandatory periodic renewal of registrations. ART clinics and ART banks must renew their registrations every five years, while surrogacy clinics must renew theirs every three years, by applying through the National Registry Portal at least 60 days before expiry. Renewal is subject to regulatory scrutiny and inspection, with delayed applications attracting higher fees.

- f. *MoH&FW and NMC restrict stem cell therapy to approved indications*⁶⁰

The National Medical Commission (NMC), vide advisory R-13014/28/2022-Ethics, dated September 5, 2026, referred to the Supreme Court's order dated January 30,

⁵⁶ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDE=

⁵⁷ cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ10TG=

⁵⁸ e09761311aa45a6e996226aa33b2d87f.pdf

⁵⁹ <https://gazettetracker.com/g/CG-DL-E-18062026-273565>

⁶⁰ MoH&FW Advisory & NMC Advisory



2026 in *Yash Charitable Trust & Ors. v. Union of India & Ors.*, W.P. (C) No. 369 of 2022 and reiterated that stem cell therapy may be offered as standard clinical care only for disease conditions or indications approved by the MoH&FW, and that unauthorised administration, prescription, promotion or advertisement beyond such indications constitutes professional misconduct. State Medical Councils have been directed to examine alleged violations and take disciplinary action where misconduct by a Registered Medical Practitioner is established after due process. Outside the approved indications, stem cell therapy may be undertaken only as part of an approved clinical trial in accordance with the applicable regulatory framework.

Litigation Updates

- a. *Punjab & Haryana High Court holds continued listing of doctor's name on PCPNDT registration insufficient for criminal liability*⁶¹

The Punjab and Haryana High Court, in *Dr. Shyam Bihari v. State of Haryana*, CRR-3912-2018 (O&M), on July 3, 2026, held that a medical practitioner cannot be prosecuted under the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (**PCPNDT Act**), read with rules, merely because his/her

name continued to appear on the registration panel of a diagnostic centre where an illegal prenatal sex determination operation was conducted. The Court observed that criminal liability requires substantive material demonstrating the doctor's active involvement in the alleged offence, and that administrative omissions or delays in updating registration records cannot, by themselves, establish participation in illegal sex determination activities.

- b. *Orissa High Court holds PCPNDT Rules do not bar qualified radiologists from practising at clinics in different districts*⁶²

The Orissa High Court, in *Jagabandhu Barik v. State of Odisha & Ors.*, W.P.(C) No. 14988 of 2026, held that the PCPNDT Act, read with rules do not prohibit a qualified radiologist from conducting ultrasonography at clinics situated in two different districts. The Court clarified that the restriction limiting registration at a maximum of two clinics within a district does not extend to an inter-district prohibition. It further held that the District Advisory Committee cannot deny permission to the radiologist, particularly if his government employer had issued a no-objection certificate for practice beyond duty hours. The Court accordingly set aside the prohibition order and directed the authorities to grant permission, subject to there being no other legal impediment.

⁶¹ Dr. Shyam Bihari vs. State of Haryana, CRR-3912-2018

⁶² Jagabandhu Barik v. State of Odisha & Ors., W.P.(C) No. 14988 of 2026

- c. *Allahabad High Court holds surrogacy age restrictions inapplicable to pre-existing frozen embryos*⁶³

The Allahabad High Court, in *A v. Union of India & Anr*, Writ-C No. 6292 of 2026, held on July 7, 2026, that age restrictions under the Surrogacy (Regulation) Act, 2021, cannot be mechanically applied to intending couples who had created and cryopreserved embryos before the legislation came into force. The Court reasoned that applying the statutory age bar retrospectively would unfairly deprive such couples of the benefit of a surrogacy process lawfully initiated under the earlier legal framework. It further observed that a rigid application of the restriction would infringe the right to reproductive autonomy, recognised as part of personal liberty under Article 21 of the Constitution of India.

- d. *Kerala High Court holds Electro-Homeopathy practice subject to statutory registration*⁶⁴

The KHC, in *The Travancore-Cochin Medical Council v. Rajesh K. and Others*, W.A. No. 1737 of 2020; 2026:KER:42984, on June 17, 2026, held that the practice of Electro-Homeopathy is regulated under the Travancore-Cochin Medical Practitioners Act, 1953, and the Kerala State Medical Practitioners Act, 2021, as applicable. The Court held that a person cannot lawfully practise Electro-Homeopathy without requisite registration and inclusion in the statutory register of practitioners. It rejected the contention that the absence of an express prohibition makes such practice unregulated, observing that the right to practise a profession is subject to laws governing professional qualifications and conduct, particularly where public health and patient safety are involved. The Court accordingly allowed the appeal and dismissed the writ petition.

News Update

- a. *Kerala directs all government hospitals to display doctors' names and OP timings*⁶⁵

The Kerala Health Ministry has directed government healthcare institutions to display doctors' names, outpatient days and timings, sanctioned posts, vacancies, and vigilance contact details, allowing patients to report doctor absenteeism. The directive covers all government facilities, from primary health centres to taluk headquarters hospitals, with action to follow against doctors found violating duty norms.

Transaction Updates

- a. *Tenet Diagnostics raises USD 30 million from Tata Capital and Blue Earth Capital*⁶⁶

Tenet Diagnostics has raised approximately USD 30 million from Tata Capital Healthcare Fund III and Swiss impact investor Blue Earth Capital. The investment will support the expansion of Tenet's diagnostic centre and B2B laboratory network across India, as well as potential strategic acquisitions. Tenet currently operates over 35 diagnostic centres across 14 states, offering radiology, pathology and nuclear medicine services.

- b. *Advent International acquires Yatharth Hospitals*⁶⁷

Advent International invest approximately INR 3,150 crore in Yatharth Hospitals, acquiring a 24.9% stake in the hospital chain. The investment will support Yatharth's expansion, including the development of new hospitals and strengthening of its existing healthcare network. The transaction marks Advent International's entry into India's hospital sector.

⁶³ A v. Union of India & Anr Writ-C No. 6292 of 2026

⁶⁴ Travancore-Cochin Medical Council v. Rajesh K. and Others, W.A. No. 1737 of 2020

⁶⁵ All govt hospitals to display doctors' names, OP timings, ETHealthworld

⁶⁶ Tenet Diagnostics Gets USD 30 Million Boost From Tata Capital

⁶⁷ Advent International joins India's hospital gold rush with Rs 3,150 crore Yatharth bet - The Economic Times

V. Allied Sectors

Regulatory Updates

- a. *Ministry of Fisheries, Animal Husbandry and Dairying notifies draft rules for prevention and control of contagious diseases in animals*⁶⁸

The Ministry of Fisheries, Animal Husbandry and Dairying (Department of Animal Husbandry and Dairying), vide notification G.S.R. 723(E) dated August 11, 2026, published the draft Prevention and Control of Infectious and Contagious Diseases in Animals Rules, 2026. The draft introduces digital reporting of disease outbreaks, vaccinations and post-mortem findings through the Bharat Pashudhan portal, along with procedures for carcass disposal and post-mortem examinations. It also provides for a complaint and penalty mechanism before an adjudicating officer, with a right of appeal, and directs recovered penalties to the Animal Welfare Board of India for disease prevention and control activities.

- b. *MoA&FW notifies Insecticides Third (Amendment) Rules, 2026, permitting import of insecticides for non-insecticidal use*

The Ministry of Agriculture and Farmers Welfare (**MoA&FW**), vide notification G.S.R. 597(E) dated July 8, 2026, notified the Insecticides Third (Amendment) Rules, 2026, amending the Insecticides Rules, 1971. The amendment empowers the Registration Committee to grant import permits for insecticides intended for non-insecticidal use and prescribes the procedure for such imports. Applications are required to be made in the newly prescribed Form IA with a fee of INR 5,000. The Registration Committee is required to decide applications preferably within 45 days, extendable by a further 15 days. The import permit will be valid for one year, or three years where the applicant already holds a registration certificate for the concerned pesticide.

- c. *MoA&FW notifies Plant Quarantine (Fifth Amendment) Order, 2026, permitting Durian import from Vietnam*

The MoA&FW, vide notification S.O. 3828(E) dated July 9, 2026, notified the Plant Quarantine (Regulation of Import

into India) (Fifth Amendment) Order, 2026, under Section 3(1) of the Destructive Insects and Pests Act, 1914, with effect from the date of publication. The amendment permits the import of *Durio zibethinus* (Durian) fruits from Vietnam for consumption, without prescribing any additional phytosanitary declarations or special import conditions.

- d. *MoA&FW notifies Plant Quarantine (Seventh Amendment) Order, 2026, adding wood species from Bhutan*⁶⁹

The MoA&FW, vide notification S.O. 4770(E) dated August 25, 2026, notified the Plant Quarantine (Regulation of Import into India) (Seventh Amendment) Order, 2026, amending Schedule VI of the 2003 Order under the Destructive Insects and Pests Act, 1914, with effect from the date of publication. The amendment permits the import of wood from several plant species from Bhutan, including *Alnus nepalensis*, *Lagerstroemia parviflora* and *Acacia catechu*, along with 14 additional species. Each entry prescribes treatment requirements, including methyl bromide fumigation or heat treatment, which must be certified in the phytosanitary certificate issued by the exporting country.

- e. *CPCB clarifies distinction between biodegradable and compostable plastics*⁷⁰

The Central Pollution Control Board (**CPCB**), vide public notice dated September 8, 2026, clarified the distinction between “biodegradable” and “compostable” plastics, noting their misuse and misrepresentation by manufacturers, producers, importers and brand owners in product labelling, advertisements and marketing communications. The CPCB reiterated that compostable plastics must conform to IS/ISO 17088:2021 and biodegradable plastics must conform to IS 17899 T:2022 and obtain CPCB certification before being marketed or sold.

⁶⁸ <https://gazettetracker.com/g/CG-DL-E-17082026-275499>

⁶⁹ <https://gazettetracker.com/g/CG-DL-E-27082026-275827>

⁷⁰ CPCB Clarification

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