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

Volume IX | Issue I | October - December 2025

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Dear Readers,

The new year brings with it an opportunity to reflect on the final quarter of 2025, a period marked by intensified regulatory reforms and heightened judicial scrutiny across India's healthcare ecosystem. The quarter witnessed significant amendments to medical device regulations, drug pricing frameworks, and food safety standards, alongside landmark judicial pronouncements on organ transplantation, clinical establishment regulation, and pharmaceutical marketing practices. These developments underscore a sector navigating the complex interplay between innovation, accessibility, and regulatory compliance while adapting to evolving public health priorities. This edition of *Synapse* captures these evolving trends and their influence on India's healthcare and life sciences landscape.

Significant regulatory developments between October and December 2025 reflect India's continued transformation of its healthcare regulatory landscape, with comprehensive reforms spanning medical device manufacturing, pharmaceutical pricing controls, environmental compliance, and food safety standards. The Ministry of Health and Family Welfare published draft amendments to the Medical Devices Rules, introducing provisions for Class A (Non-Sterile and Non-Measuring) Medical Devices to display registration numbers on labels instead of manufacturing licence numbers, while making registration certificates and licences valid in perpetuity, subject to payment of retention fees. Further amendments to the Drugs Rules, categorised critical therapeutic drug formulations requiring enhanced regulatory oversight, inserted new debarment provisions empowering licensing authorities to debar applicants found guilty of submitting misleading, fake, or fabricated documents, and revised sample size requirements for bioavailability and bioequivalence studies. Significantly, the Health Ministry prohibited the manufacture, sale, and distribution of all oral formulations containing "Nimesulide" above specified dosage in immediate release form, determining that such formulations posed risks and that safer alternatives were available. On the environmental front, Common Effluent Treatment Plants and Common Municipal Solid Waste Management Facilities were exempted from mandatory prior environmental clearance, recognising technological advancements, robust compliance mechanisms, and sustainable waste management practices. Food safety enhancements included FSSAI's withdrawal of permissions for usage of the term "ORS" in brand names, streamlining of laboratory analysis procedures for imported food products, amendments to alcoholic beverages regulations for enhanced labelling and product standards, revision of ester content limits, and directive against use of industrial dye Auramine in food products.

In the news and policy updates space, the Parliamentary Panel on Health and Family Welfare's report outlined comprehensive recommendations for healthcare

and medical devices sector reform, including establishment of an independent Industry Advisory Board, complete digitisation and automation of the licensing process to expedite approvals and innovation, and higher health budget allocation with need-driven financial planning towards achieving the national goal as per the National Health Policy, 2017. Separately, the Parliamentary Panel on Chemicals and Fertilisers called for price control and monitoring of stents to prevent overcharging, noting that prices of Bare Metal Stents and Drug-Eluting Stents have risen significantly since NPPA fixed ceiling prices, while expressing concern over unchecked trade margins in non-scheduled formulations. The Drugs Consultative Committee's meeting considered proposals for issuance of licence to marketers under the Drugs Rules, amendments regarding advertisement of prescription-only and potent drugs, issues related to contraceptives, and use of brand name extensions by pharmaceutical firms. This edition of *Synapse* covers many more such developments, including the launch of the *MedTech Mitra In Vitro Diagnostic Innovators Handbook*, IPC's plans to create standards for medical devices in partnership with BIS, the release of the new edition of *Indian Pharmacopoeia* (**IP**) and its recognition as a book of standards in multiple countries, WHO's new framework to tackle drug resistance and launch of the Global Clinical Trials Forum, NPPA's monitoring of drug prices to prevent overpricing of loose medicines, quality standards for drug samples, and elimination of test licence requirement for pre-human clinical drug trials.

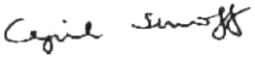
In the litigation space, the Supreme Court issued a notice in a petition challenging the constitutional validity of provisions of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018, with medical bodies contending that the Act does not define expressions such as "fee rate" and "package rate", rendering compliance arbitrary and called for the formulation of a national policy to address inconsistencies in organ transplantation. In another matter, the Court emphasised the need for consumer-centric complaint mechanisms under the UCPMP 2024 and questioned whether binding legislation is required. It also issued contempt notices to multiple jurisdictions for non-compliance with earlier directives on ICU establishment and staffing standards and a notice in a PIL seeking structured procedures for criminal prosecution in medical negligence cases. At the Delhi High Court, the GST Council was directed to convene at the earliest and consider reducing GST on air purifiers and HEPA filters from 18 per cent to 5 per cent, observing that air purifiers fall within the definition of medical device under the 2020 Notification issued by the MoH&FW and that considering Delhi's air quality situation, the concessional rate applicable to medical devices should be extended to air purifiers. The Court also upheld FSSAI's prohibition on "ORS" branding in food products, ruling that public health imperatives override commercial hardship and trademark rights, and separately declined an interim stay on non-patent-territory exports of a contested Semaglutide formulation. Meanwhile, the Madras High Court ordered a neutral expert panel to evaluate contested safety-efficacy claims for diabetes drugs, even as the Kerala High Court treated arbitrary denial of health insurance claims without hearing as justifying writ intervention.

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,



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Regulatory Updates

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

a. *MoH&FW proposes draft amendment to MD Rules*[1]

The MoH&FW, *vide* notification G.S.R. 883(E) dated December 4, 2025, published the Draft Medical Devices (Amendment) Rules, 2024, to amend the Medical Devices Rules, 2017 (**MD Rules**). The proposed amendments introduced provisions for Class A (Non-Sterile and Non-Measuring) Medical Devices to display registration numbers on labels and packaging instead of manufacturing licence numbers. Registration certificates and licences were made valid in perpetuity, subject to payment of retention fees, replacing the previous renewal requirements. A new Form MD-44 was inserted, mandating registered medical device-testing laboratories to furnish comprehensive test and evaluation reports, including physical, chemical, biological, and microbiological assessments.

b. *MoH&FW prescribes qualifications for medical device inspectors and government analysts*[2]

The MoH&FW, *vide* notification G.S.R. 748(E) dated October 10, 2025, notified draft amendments to the MD Rules. The proposed amendments inserted new Rule 18A prescribing mandatory qualifications for inspectors (medical devices) and Rule 18B establishing qualifications for Government analysts.

c. *MoH&FW introduces Table 2 to Schedule H2 for enhanced drug regulation*[3]

The MoH&FW, *vide* notification G.S.R. 757(E) dated October 16, 2025, notified draft amendments to the Drugs Rules, 1945 (**Drugs Rules**). The proposed amendments inserted Table 2 under Schedule H2, categorising four critical therapeutic drug formulations requiring enhanced regulatory oversight: all vaccines, all antimicrobials, all narcotic and psychotropic substances listed under the Narcotic and Psychotropic Drugs Act, 1985 (**NDPS Act**), and all anti-cancer drugs. Additionally, the existing schedule content was redesignated as Table 1 to accommodate the new classification structure.

d. *MoH&FW introduces debarment Provisions for Fraudulent Licence Applications*[4]

The MoH&FW, *vide* notification G.S.R. 756(E) dated October 16, 2025, notified draft amendments to the Drugs Rules. The proposed amendments inserted new debarment provisions across multiple parts, empowering licensing authorities to debar applicants found guilty of submitting misleading, fake, or fabricated documents or information for such period as deemed fit, following natural justice principles. Aggrieved applicants may appeal to the Government within 30 (thirty) days from receipt of debarment orders, whereupon appropriate orders shall be passed after enquiry and hearing.

e. *MoH&FW regulates high-alcohol oral formulations under Schedule H1*[5]

The MoH&FW, *vide* notification G.S.R. 760(E) dated October 16, 2025, notified draft amendments to the Drugs Rules. The proposed amendments removed exemptions under Schedule K for oral formulations containing more than 12 per cent alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles exceeding 30 millilitres from Chapter IV (Import, Manufacture, Sale, and Distribution of Drugs and Cosmetic) provisions of the Drugs and Cosmetics Act, 1940 (**Drugs Act**). Correspondingly, it inserted such high-alcohol oral formulations as entries 51 under Schedule H1, subjecting them to enhanced regulatory controls applicable to prescription drugs.

f. *MoH&FW expands regulatory scope for advanced therapeutic products*[6]

The MoH&FW, *vide* notification G.S.R. 758(E) dated October 16, 2025, notified draft amendments to the Drugs Rules. The proposed amendments expanded the regulatory framework beyond recombinant DNA (r-DNA) derived drugs to encompass cell or stem cell–derived products, gene therapeutic products, and xenografts across multiple provisions including Rules 75, 75A, 76, and 76A, as well as Forms 27D, 27DA, 28D, and 28DA.

[1] https://egazette.gov.in/WriteReadData/2025/268478.pdf.
[2] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?nu m_id=MTM0OTA=.
[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?nu m_id=MTM1MTg=.
[4] https://egazette.gov.in/WriteReadData/2025/267026.pdf.
[5] https://egazette.gov.in/WriteReadData/2025/267030.pdf.
[6] https://egazette.gov.in/WriteReadData/2025/267029.pdf.

g. *MoH&FW bifurcates liquid antiseptics by usage category*[7]

The MoH&FW, *vide* notification G.S.R. 759(E) dated October 16, 2025, notified draft amendments to the Drugs Rules, substituting Serial Number 39 in Schedule K. It bifurcated liquid antiseptics into two distinct categories: household use and hospital/non-household use, each subject to differentiated regulatory requirements. It also exempted household liquid antiseptics from Chapter IV provisions, subject to conditions including manufacture by licensed manufacturers, absence of Schedule G, H, H1, or X substances, sale in original containers, and mandatory labelling "For household use". Form 20 or Form 20A sale licences are required for hospital and non-household liquid antiseptics, with additional conditions mandating purchase from licensed wholesalers or manufacturers and labelling "For hospital and other than household use".

h. *MoH&FW revises sample size threshold for BA/BE studies in draft NDCT Rules*[8]

The MoH&FW, *vide* notification G.S.R. 810(E) dated October 31, 2025, issued a corrigendum to its earlier draft notification G.S.R. 587(E) dated August 27, 2025, proposing amendments to the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). Through this corrigendum, the MoH&FW has revised the sample size requirement prescribed for bioavailability and bioequivalence (BA/BE) studies of new or investigational drugs. It has specifically substituted condition number 3 of the proviso to paragraph (Ctrl) of the draft rules to replace the requirement that the "sample size should not be more than 48", with the revised threshold stating that the "sample size should be more than or equal to 18."

i. *MoH&FW relaxes equipment requirements for corneal transplantation centres*[9]

The MoH&FW, *vide* notification G.S.R. 821(E) dated November 6, 2025, notified the Transplantation of Human Organs and Tissues (Amendment) Rules, 2025, substituting the equipment requirement "Specular" with "Specular (optional)" in Form 15 under the sub-heading for corneal transplantation centres. This rendered specular microscopy equipment optional rather than mandatory for such facilities. The modification applies to the entries in the second column against item C within the corneal transplantation centre specifications.

j. *MoH&FW proposes surrogacy clinic registration renewal framework*[10]

The MoH&FW, *vide* notification G.S.R. 872(E) dated November 27, 2025, published the draft Surrogacy (Regulation) Amendment Rules, 2025. The proposed amendments inserted Rule 10A prescribing the mode of payment and utilisation of registration fees through designated bank accounts maintained by appropriate authorities. Rule 11A established a comprehensive renewal framework, requiring surrogacy clinics to apply for certificate renewal 60 (sixty) days prior to expiry through the National Registry Portal, accompanied by a non-refundable fee of INR 1 lakh. It empowered the appropriate authority to renew certificates within 60 (sixty) days following inspection, with renewed certificates remaining valid for 3 (three) years from the expiry date of previously granted certificates.

k. *MoH&FW prohibits high-dose Nimesulide oral formulations*[11]

The MoH&FW, *vide* notification S.O. 6091(E) dated December 29, 2025, prohibited the manufacture, sale, and distribution of all oral formulations containing Nimesulide above 100 mg in immediate-release dosage form. The Central Government determined that such formulations posed risks to human beings and that safer alternatives were available. It imposed this prohibition in public interest following consultation with the Drugs Technical Advisory Board (**DTAB**) under Section 26A of the Drugs Act.

l. *MoH&FW proposes removal of syrups from Schedule 'K' exemptions*[12]

The MoH&FW, *vide* notification G.S.R. 927(E) dated December 29, 2025, published the Draft Drugs (Amendment) Rules, 2025, removing the word "Syrup" from entry number 7 under the "Class of Drugs" column in serial number 13 of Schedule K of the Drugs Rules. The rules will come into force on the date of their publication in the official gazette. The draft was published following consultation with the DTAB, with stakeholders invited to submit objections and suggestions within 30 (thirty) days.

7 https://egazette.gov.in/WriteReadData/2025/267024.pdf.
8 https://egazette.gov.in/WriteReadData/2025/267384.pdf.
9 https://egazette.gov.in/WriteReadData/2025/267487.pdf.
10 https://egazette.gov.in/WriteReadData/2025/268172.pdf.
11 https://egazette.gov.in/WriteReadData/2025/268922.pdf.
12 https://egazette.gov.in/WriteReadData/2025/268923.pdf.

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

a. *MoEFCC exempts common effluent treatment plants from prior environmental clearance requirements*[13]

The MoEFCC, *vide* notification S.O. 4506(E) dated October 1, 2025, notified draft amendments to the Environment Impact Assessment Notification, 2006 (**EIA Notification**), exempting Common Effluent Treatment Plants (**CETP**) from mandatory prior environmental clearance by omitting item 7(h) from the Schedule under *"Physical Infrastructure including Environmental Services"*. This exemption, recommended by Expert Appraisal and Advisory Committees, recognises technological advancements, robust compliance mechanisms, and sustainable water management practices, while ensuring environmental safeguards remain enforced through State Pollution Control Board consent mechanisms under the Water (Prevention and Control of Pollution) Act, 1974 (**Water Act**), and the Air (Prevention and Control of Pollution) Act, 1981 (**Air Act**).

b. *MoEFCC proposes exemption for common municipal solid waste management facilities from environmental clearance*[14]

The MoEFCC, *vide* S.O. 4531(E) dated October 3, 2025, notified draft amendments to the EIA Notification, exempting common municipal solid waste management facilities from mandatory prior environmental clearance by omitting item 7(i) from the Schedule under *"Physical Infrastructure including Environmental Services"*. This exemption, recommended by Expert Appraisal and Advisory Committees, recognises stringent regulatory oversight under the existing Water Act and Air Act, acknowledges Central Pollution Control Board (**CPCB**) new "blue category" classification for essential environmental services, and incentivises sustainable waste management practices. Environmental safeguards will remain enforced through State Pollution Control Board consent mechanisms.

3. Ministry of Chemicals and Fertilizers (MoCF) amends Pharma MedTech research scheme[15]

The MoCF, *vide* notification F. No. 50018/2/2022-NIPER dated October 1, 2025, notified amendments to the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector. The amendments introduced component B, providing financial assistance to Indian pharmaceutical and med-tech industry and start-ups for research and development, with early-stage projects eligible for up to INR 5 crore and later-stage projects up to INR 100 crore, while encouraging collaboration with reputed government academic institutions to develop institutional intellectual property and augment research capacities.

[13] https://egazette.gov.in/WriteReadData/2025/266719.pdf.
[14] https://egazette.gov.in/WriteReadData/2025/266725.pdf.
[15] https://pharma-dept.gov.in/sites/default/files/Gazette%20Notification%20-%20Dated%2001.10.2025_0.pdf.

4. Ministry of AYUSH designates nodal officer for digital content regulation[16]

The Ministry of AYUSH, *vide* notification S.O. 5323(E) dated November 19, 2025, designated the Coordinator, National Pharmacovigilance Coordination Centre, All India Institute of Ayurveda, New Delhi, as nodal officer under the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021. It empowered the designated officer, holding rank not below director level, to issue notices to intermediaries regarding unlawful content residing in or connected to computer resources controlled by such intermediaries. This designation specifically pertains to violations under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the National Commission for Indian System of Medicine Act, 2020, and the National Commission for Homeopathy Act, 2020.

5. The Central Drugs Standard Control Organisation (CDSCO) releases notifications/orders/circulars

a. *CDSCO releases Draft Guidance Document on Medical Device Software under Medical Devices Rules, 2017*[17]

The CDSCO, *vide* Notice No. F. No. MED-16028/2/2024-eoffice dated October 21, 2025, released the Draft Guidance Document on Medical Device Software under MD Rules. It clarified the regulatory scope by distinguishing between Software as a Medical Device (**SaMD**), i.e., standalone software performing medical functions, and Software in a Medical Device (**SiMD**), i.e., software embedded in or integral to hardware devices, with coverage also extended to software used in *vitro* diagnostics. The guidance proposed a risk-based classification system (for medical devices in Classes A–D), aligned with the MDR's general classification logic, to determine licensing pathways based on risk category and intended use. It also outlined regulatory requirements relating to technical documentation, quality management systems (**QMS**), safety and performance standards including compliance with relevant ISO/IEC norms, clinical or performance evaluation where applicable, and post-market vigilance obligations for software products. The document was open for stakeholder comments for 30 days from the date of its publication.

b. *CDSCO mandates online submission for post-approval changes in cell and gene therapy clinical trials*[18]

The CDSCO, *vide* notice dated October 27, 2025, operationalised the online submission mechanism for post approval changes pertaining to Clinical Trials (Form CT-06) for cell and gene therapeutics products through the SUGAM online portal system. It enabled applicants seeking permission, acknowledgement, or filing notifications to submit applications through the SUGAM portal following prescribed checklists in the developed modules. The notice mandated that offline submissions would not be accepted for processing after October 24, 2025.

c. *CDSCO reiterates mandatory resting of raw materials and formulations*[19]

The CDSCO, *vide* letter F. No. DC-DT-15011(11)/144/2025-eOffice dated October 7, 2025, reaffirmed the mandatory requirement under the Drugs Rules, for testing raw materials, including excipients, and finished pharmaceutical formulations. The move followed reports of quality lapses in drug manufacturing. In its communication to State and UT Drug Controllers, the CDSCO highlighted systemic non-compliance by certain manufacturers who failed to test each batch of raw and finished materials, as mandated by the Rules. The directive stressed that manufacturers must source raw materials only from approved vendors, ensure full traceability, and maintain records as per Schedule U. The Central Licensing Authority (**CLA**) has instructed State Licensing Authorities (**SLAs**) to report compliance actions taken in response.

d. *CDSCO mandates domestic licensing for medical device procurement*[20]

The CDSCO, *vide* Circular File No. MED-13/87/2025-eoffice dated November 17, 2025, notified mandatory licensing requirements for medical device procurement in India. The circular clarified that all medical devices regulated under the MD Rules require valid licences from the CDSCO or State/Union Territory (**UT**) licensing authorities for import, manufacture, sale, and distribution, superseding previous reliance on USFDA/CE certifications as primary technical bid requirements. The notification delineated licensing jurisdiction based on

[16] https://egazette.gov.in/WriteReadData/2025/267891.pdf.
[17] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Draft%20guidance %20document%20on%20Medical%20Device%20Software%2021%2010%202025.pdf.
[18] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/PAC%20Notice%20for%20Form%20CT-06.pdf.
[19] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM0NzI=.
[20] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular-17-11-2025.pdf.

risk classification, with SLAs issuing manufacturing licences for Class A and B devices and sale licences for all classes. The CDSCO also issued import licences for all classes and manufacturing licences for Class C and D devices.

e. *CDSCO mandates display of PvPI QR Code and toll-free number at pharmacy outlets*[21]

The CDSCO, *vide* Circular File No. PSUR-13011(14)/3/2025-eoffice dated November 20, 2025, has directed all State and UT Licensing Authorities, mandating prominent placement of the designated Pharmacovigilance Programme of India (**PvPI**) QR Code at retail and wholesale pharmacy premises across the country. The directive was issued pursuant to decisions taken during the 16th Working Group Meeting of PvPI held on June 18, 2025.

f. *CDSCO introduces online risk classification module for medical Devices*[22]

The CDSCO, *vide* Circular File No. MED-16035/14/2025-eoffice dated December 4, 2025, introduced a new Risk Classification Module on the CDSCO Online System for Medical Devices, operational from November 27, 2025, aiming to simplify regulatory approval procedures and streamline the risk classification process for medical devices excluding *in vitro* diagnostic devices.

6. National Pharmaceutical Pricing Authority (NPPA) updates pricing and other price-control/quality-control-related measures

a. *NPPA extends ceiling price regime for orthopaedic knee implants*[23]

The NPPA, *vide* notification S.O. 5190(E) dated November 14, 2025, extended the ceiling price regime for Orthopaedic Knee Implants for Knee Replacement System originally notified under S.O. 2668(E) dated August 16, 2017 (**2017 Notification**). The extension was granted for an addition one-year period until November 15, 2026, or until further orders, whichever occurs earlier. It followed the previous order S.O. 4171(E) dated September 15, 2025, which remained in force until November 15, 2025. The substantive Notes (b) to (t) of the 2017 Notification will remain operative during the currency of this order.

b. *NPPA fixes retail prices for 28 new drug formulations*[24]

The NPPA, *vide* notification S.O. 5017(E) dated November 4, 2025, notified retail price fixation orders under the Drugs (Prices Control) Order, 2013 (**DPCO 2013**). It fixed maximum retail price (**MRP**), excluding Goods and Services Tax (**GST**) for 28 (twenty-eight) new drug formulations was fixed across various therapeutic categories, including antihypertensive combinations, antidiabetic combinations, analgesics, and antimicrobials, manufactured by specified pharmaceutical companies.

c. *NPPA fixes ceiling prices for 6 essential pharmaceutical formulations*[25]

The NPPA, *vide* notification S.O. 5018(E) dated November 4, 2025, notified price fixation orders under the DPCO 2013. It fixed ceiling prices (excluding GST) for 6 (six) scheduled formulations: Riboflavin tablets, peritoneal dialysis solution, ethyl alcohol (denatured) solution, and human normal immunoglobulin solutions at varying concentrations (16.5%, 10%, and 5%). This order superseded the previous notification S.O. 1487(E) dated March 27, 2025, insofar as it related to the specified formulation packs.

d. *NPPA expands manufacturer list for non-glass intravenous (**IV**) fluid containers*[26]

The NPPA, *vide* notification S.O. 5021(E) dated November 4, 2025, notified amendments to previous orders dated March 27, 2025, and August 29, 2025, concerning ceiling price fixation for scheduled formulation packs of intravenous fluids (non-glass with special features). It added two manufacturers to Table B: IV Tech Healthcare (manufacturing Twin Port Euro Head Bottles) and Life Infusion Pharmaceuticals Private Limited (manufacturing Dual Port Plastic PP Bottles) along with specifying applicable formulation prices from Table A for each manufacturer.

[21] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2NDI=.
[22] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2Njc=.
[23] https://egazette.gov.in/WriteReadData/2025/267678.pdf.
[24] https://egazette.gov.in/WriteReadData/2025/267389.pdf.
[25] https://egazette.gov.in/WriteReadData/2025/267390.pdf.
[26] https://egazette.gov.in/WriteReadData/2025/267401.pdf.

e. *NPPA fixes retail prices for 11 pharmaceutical formulations*[27]

The NPPA, *vide* notification S.O. 5476(E) dated November 28, 2025, fixed retail prices for 11 (eleven) pharmaceutical formulations under the DPCO 2013. It prescribed MRP, exclusive of GST, for various formulations including Bisoprolol Fumarate and Telmisartan Tablets, Ceftriaxone and Sulbactam injections, Levocetirizine Dihydrochloride and Montelukast Sodium Syrup, Telmisartan combination tablets, Cefixime and Ofloxacin Oral Suspension, and Teneligliptin combination tablets for specific manufacturers and marketing companies.

f. *NPPA fixes retail prices for 37 pharmaceutical formulations*[28]

The NPPA, *vide* notification S.O. 5975(E) dated December 24, 2025, fixed retail prices for 37 (thirty-seven) pharmaceutical formulations under the DPCO 2013. It prescribed MRP, exclusive of GST, for various formulations including combination tablets of Aceclofenac and Paracetamol, Bisoprolol Fumarate and Telmisartan, Atorvastatin and Ezetimibe, suspensions containing Albendazole and Ivermectin, Mefenamic Acid and Paracetamol, injections of Meropenem and Sulbactam, and multiple electrolyte solutions with Dextrose for specific manufacturers and marketing companies.

7. The Food Safety and Standards Authority of India (FSSAI) issues notifications, orders, circulars on food safety standards

a. *FSSAI prohibits usage of "ORS" terminology in food product nomenclature*

The FSSAI, *vide* Order No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated October 14, 2025,[29] followed by clarification on October 15, 2025,[30] withdrew permissions for usage of the term "ORS", in any form-standalone, prefixed, suffixed, or embedded within a trademark, along with brand names. It superseded its earlier orders dated July 14, 2022, and February 2, 2024, which had conditionally permitted such usage, subject to disclaimer requirements. It determined employing "ORS" terminology in trademarked names or food product nomenclature, whether fruit-based, non-carbonated, or ready-to-drink beverages, even with prefix or suffix, constituted statutory violations. It deemed such practices misleading and misbranded and that these would attract penalties under Sections 52 and 53 of the Food Safety and Standards Act, 2006 (**FSS Act**). All food business operators (**FBOs**) were directed to remove "ORS" terminology forthwith.

[27] https://egazette.gov.in/WriteReadData/2025/268071.pdf.
[28] https://egazette.gov.in/WriteReadData/2025/268783.pdf.
[29] https://fssai.gov.in/upload/advisories/2025/10/68ee3ba06bb7eWithdrawal%20of%20Orders%20regarding%20Usage%20of%20the%20term%20ORS%20along%20with%20brand%20names%20dt%2014.10.2025.pdf.
[30] https://fssai.gov.in/upload/advisories/2025/10/68ef8cea74223clarification_151025.pdf.

b. *FSSAI prohibits PFAS and Bisphenol A in food contact materials*[31]

The FSSAI, *vide* notification F. No. SSDIVI-PF0SP20(16)/2/2025-Standard-FSSAI dated October 6, 2025, notified draft amendments to the Food Safety and Standards (Packaging) Regulations, 2018. It inserted two new sub-regulations under General Requirements. While Sub-Regulation (15) prohibits the use of poly- and perfluoroalkyl substances (**PFAs**) in manufacturing food contact materials, Sub-Regulation (16) mandates that food contact materials manufactured with polycarbonate and epoxy resins be free from Bisphenol A and its derivatives.

c. *FSSAI streamlines laboratory analysis procedures for imported food products*[32]

The FSSAI, *vide* notification F. No. QA/11023/31/2022-QA-FSSAI(1) dated October 27, 2025, notified the Food Safety and Standards (Import) First Amendment Regulations, 2025. The amendments expanded the scope of internationally recognised analytical methods permissible for food sample testing, including AOAC, ISO, Pearson's, Jacob, IUPAC, and other validated methodologies when authority-prescribed manuals lack specific parameter analysis methods. Additionally, the regulations mandated that notified and referral laboratories provide duly signed laboratory analysis reports in prescribed format in FORM-2 within 5 (five) days from the receipt of the sample. The regulations will become effective from May 1, 2026.

d. *FSSAI amends Alcoholic Beverages Regulations for enhanced labelling and product standards*[33]

The FSSAI, *vide* notification F. No. SS-TOSP21(NOTI)/1/2025-Standard-FSSAI dated October 30, 2025, notified draft amendments to the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018. The proposed amendments inserted a tolerance limit of 0.3 per cent for sugar content in Brut sparkling wine (below 1.2%), deleted references to *"special wine used"* from wine-based beverage provisions, and mandated (rather than permitted) labelling of standard drink information by substituting "shall" for "may".

e. *FSSAI clarifies classification of non-compliant honey samples*[34]

The FSSAI, *vide* advisory dated November 7, 2025, clarified standards for honey with elevated Hydroxymethylfurfural (**HMF**) levels. After deliberations at its 29th Scientific Panel meeting on December 18, 2024, the authority noted insufficient research to determine safety risks from exceeding prescribed HMF limits. Accordingly, honey samples above the 80 mg/kg limit will now be classified as "Substandard" rather than "Unsafe." This interim measure will remain until further scientific data is available, addressing earlier inconsistencies in how non-compliant samples were categorised.

f. *FSSAI revises ester content limits for alcoholic beverages*[35]

The FSSAI, *vide* notification F. No. Std/SP-21/A-1.2024/N-01 dated November 19, 2025, notified the Food Safety and Standards (Alcoholic Beverages) Second Amendment Regulations, 2025. The amendment substituted the maximum permissible limit for esters expressed as ethyl acetate (grammes per litre of absolute alcohol) from "0.2" to "3.0" in Table 2 against Serial Number 7 under column (7) of the principal regulations. The regulations will come into effect on June 1, 2026.

g. *FSSAI issues directive against use of industrial dye Auramine in food products such as roasted chana*[36]

The FSSAI, *vide* Order No. RCD-15001/16/2025-Regulatory-FSSAI dated November 28, 2025, has issued a directive calling for strict enforcement action following complaints regarding the illegal use of "Auramine", an industrial dye used in textiles and leather, in roasted *chana* and similar food items to enhance colour. Auramine is a non-permitted synthetic dye under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, and its presence in food renders the product unsafe under Section 3(1)(zz)(v) of the FSS Act. The FSSAI instructed authorities to conduct targeted inspections, sampling, testing, and necessary follow-up actions across organised and unorganised sectors, as well as e-commerce platforms. It directed Commissioners of Food Safety and Central Licensing Authorities to initiate appropriate action against defaulting FBOs.

[31] https://fssai.gov.in/upload/uploadfiles/files/Draft%20FSS_Packaging_Amendment%20regulations2025.pdf.
[32] https://egazette.gov.in/WriteReadData/2025/267381.pdf.
[33] https://fssai.gov.in/upload/uploadfiles/files/Notification%20dt%2030_10_2025.pdf.
[34] https://fssai.gov.in/upload/advisories/2025/11/690dd80e5809fHMF%20to%20be%20considered%20as%20quality%20parameter%20in%20honey.pdf.
[35] https://egazette.gov.in/WriteReadData/2025/267999.pdf.
[36] https://fssai.gov.in/upload/advisories/2025/12/692d256c22306Order%20to%20CFSCLAs%20%20Roasted%20Chana.pdf.

News Updates

1. Parliamentary Panel on Health and Family Welfare's 170th Report outlines comprehensive recommendations for healthcare and medical devices sector reform[37]

The Parliamentary Panel on Health and Family Welfare (**Panel**), chaired by Member of Parliament Prof. Ram Gopal Yadav, presented its 170th report to the Rajya Sabha and laid it before the Lok Sabha on December 11, 2025. The report outlined a series of recommendations aimed at strengthening healthcare and medical devices regulation, innovation, and financing.

a. *Panel recommends independent industry advisory board for medical devices regulation*

The Panel recommended that the Union Health Ministry establish an independent industry advisory board with balanced representation from across the medical devices sector. It also recommend that this advisory board provide structured feedback on regulatory practices, policy development, and dispute resolution. It called for the lateral induction of domain experts and the creation of a continuous professional development framework with periodic certification to ensure sustained competency in medical devices regulation.

b. *Panel advises introduction of measures to expedite approvals and innovation in medical devices sector*

To accelerate approvals and foster innovation, the Panel advised the Department of Health to fully digitise and automate the licensing process, introduce a single comprehensive query system, and implement a time-bound conditional approval mechanism within the CDSCO. While acknowledging initiatives such as the MD online portal, the Medical Devices Vertical, and the MedTech Mitra platform, the report highlighted persistent industry concerns regarding delays, inconsistent timelines, and the absence of end-to-end real-time tracking of applications.

c. *Panel urges higher health budget allocation and need-driven financial planning*

The Panel urged the MoH to seek enhanced budgetary allocations and adopt a need-driven approach in projecting financial requirements. It recommended preparing a "pipeline" document to plan infrastructure and capital creation projects over a three-to-five-year horizon, mapping major initiatives and articulating annual capital requirements. The report further advised the Ministry to engage with the Ministry of Finance to progressively increase health sector allocations, aligning

[37] https://sansad.in/getFile/rsnew/Committee_site/Committee_File/ReportFile/14/212/170_2025_12_14.pdf?source=rajyasabha.

with the National Health Policy, 2017, target of 2.5 per cent of GDP.

2. Parliamentary Panel on Chemicals and Fertilisers 14th report calls for price control and monitoring of stents to prevent overcharging[38]

The Parliamentary Panel on Chemicals and Fertilisers, chaired by Member of Parliament Kirti Azad Jha, presented its 14th report to the Lok Sabha on December 1, 2025. The report reviewed the price rise of medicines in the pharmaceutical sector and outlined recommendations to curb profiteering and ensure affordability for patients.

a. *Panel recommends price control and monitoring of stents*

The Panel recommended that the Department of Pharmaceuticals (**DoP**) and the NPPA examine the increase in stent prices and take steps to reduce them. It noted the rise in the prices of bare metal stents (**BMS**) and drug-eluting stents (**DES**) by approximately 44 per cent and 29 per cent, respectively, since NPPA fixed ceiling prices in February 2017. It urged strict monitoring to ensure stents are not sold above the ceiling price and that cases of overcharging are dealt with firmly.

b. *Panel urges regulation of trade margins in non-scheduled formulations*

The Panel expressed concern over unchecked trade margins in non-scheduled formulations, with markups ranging from 600 per cent to 1,100 per cent. It observed that while the DPCO 2013 empowers NPPA to fix ceiling prices for scheduled drugs under the National List of Essential Medicines (**NLEM**), it does not extend to non-scheduled medicines. The Committee termed the department's response unsatisfactory and recommended that NPPA consider appropriate controls on non-scheduled formulations to plug regulatory gaps and prevent profiteering.

3. The Drugs Consultative Committee's (DCC) 67th meeting updates[39]

The DCC, headed by Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (**DCGI**), in its 67th meeting held on November 17, 2025,[40] made the following recommendations:

a. *DCC recommends amendments in Drug Rules to include provisions for issuance of license for marketers*

The DCC considered the proposal for issuance of license to marketer under the definition of Rule 2(ea) of Drugs Rules, following information regarding the absence of any mechanism to oversee marketers' activities to guarantee the quality, safety, and efficacy of the marketed drugs. After comprehensive deliberation, DCC recommended amending the Drug Rules to incorporate provisions for issuance of license for marketers along with various conditions.

b. *DCC approves Schedule K listing and labelling requirements for Levonorgestrel Tablets*

After considering the various recommendations of the DCC sub-committee, the DCC agreed that Levonorgestrel Tablets 0.75mg/1.5mg are emergency contraceptives that required to be included/added as S.No.06 of entry No. 15 of Schedule K of Drugs Rules. It also agreed that the boxed warnings on the primary and carton label and package insert should include warnings such as: "The medicine does not provide protection against HIV or other sexually transmitted infections"; "It should not be taken more than twice in a month"; and "The use of alternative methods of contraception is recommended in consultation with a registered medical practitioner".

c. *DCC recommends conducting stakeholder consultation to examine pharmaceutical firm's use of multiple brand name extensions*

The DCC considered a representation claiming that a pharmaceutical company was marketing several drug formulations under one established brand name with different extensions. The claim highlighted that using the same brand name for drugs containing different active ingredients could mislead consumers and cause confusion about their therapeutic purposes. After detailed discussion, the DCC recommended conducting a stakeholder consultation to examine the issue from multiple perspectives.

d. *DCC recommends Drug Rule amendment to restrict unchecked advertisements of prescription-only and potent drugs*

The DCC was informed of concerns regarding the widespread and unregulated advertising of prescription-only and potent drugs, including critical injectables, antibiotics, hormonal preparations, psychotropic substances, anti-cancer drugs, and narcotic drugs. The DCC noted that the Drugs Rules already require

[38] https://sansad.in/ls/committee/departmentally-related-standing-committees/45-chemicals%20&%20fertilizers.
[39] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjgyNg==.
[40] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjgyNg==.

manufacturers, under their licensing conditions, to refrain from advertising drugs listed in Schedules H, H1, and X unless prior approval is obtained from the Central Government. After comprehensive discussion, the DCC recommended extending similar restrictions to licence holders engaged in the sale or distribution of such drugs.

4. Indian Council of Medical Research publishes lists of priority pathogens for Indian clinical settings[41]

The Division of Communicable Diseases at the Indian Council of Medical Research (**ICMR**) has identified key pathogens responsible for major infectious syndromes in India. These lists are intended to support clinicians, laboratory specialists, epidemiologists, and policymakers in improving diagnostic and surveillance strategies. Through this initiative, ICMR seeks to strengthen patient care, inform public health policy, and drive biomedical research and innovation.

5. ICMR and CDSCO launch the MedTech Mitra In Vitro Diagnostic (IVD) Innovators Handbook[42]

The ICMR, in collaboration with the CDSCO–IVD Division, has released the *MedTech Mitra In Vitro Diagnostic (IVD) Innovators Handbook*, which provides a structured framework for innovators to design and implement robust clinical validation strategies. Conceived as a practical workbook, it delineates critical milestones across the innovation lifecycle, enabling researchers to anticipate regulatory, ethical, and evidence-generation requirements. Comprising six comprehensive chapters, the handbook guides teams through the entire process, from identifying unmet clinical needs to developing, validating, and ultimately commercialising IVD technologies. It further consolidates regulatory expectations, best practices, and internationally harmonised standards, supporting manufacturers, developers, regulators, healthcare providers, and academic researchers in navigating the complexities of IVD development.

6. Government amends PRIP Scheme to strengthen Pharma-MedTech innovation ecosystem[43]

The Government has amended the Promotion of Research and Innovation in Pharma–MedTech Sector (**PRIP**) Scheme, with the revised framework notified on October 1, 2025, to enhance governance clarity, implementation efficiency, and benefit-sharing mechanisms. The scheme operates through two components: Component A focuses on strengthening research infrastructure by establishing Centres of Excellence at seven NIPERs, with an approved outlay exceeding INR 700 crore, and Component B supports industry- and start-up-led R&D and commercialisation in priority areas such as new medicines, complex generics, biosimilars, and novel medical devices. The amended scheme provides enhanced financial assistance for both early-stage and later-stage projects, with higher support directed toward strategic public health innovation areas. Overall, these changes are intended to accelerate industry–academia collaboration, improve the translation of research into market applications, and reinforce India's Pharma–MedTech innovation ecosystem.

7. Recognition of Indian Pharmacopoeia as book of standards in 17 countries to boost pharma exports[44]

The *Indian Pharmacopoeia* (**IP**) has achieved recognition as an authoritative book of standards in 17 countries since 2019, with 12 of these endorsements secured within the past two years. This expanding international acceptance reinforces the credibility of Indian medicines, facilitates broader global market access, and significantly strengthens India's pharmaceutical export potential. The Department of Health and Family Welfare continues to advance the global standing of the IP through bilateral technical engagements, Joint Working Group deliberations, and active participation in international conferences. It has also formalised Memorandums of Understanding on pharmacopoeial cooperation with Afghanistan, Ghana, Nepal, Mauritius, Suriname, Nicaragua, Bhutan, Mozambique, Solomon Islands, Sri Lanka, Nauru, Malawi, Guyana, Fiji, Cuba, Maldives, and Trinidad & Tobago.

[41] https://www.icmr.gov.in/icmrobject/uploads/Static/1762753179_syndromesurveillanceofinfectiousdiseases.pdf.
[42] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/MedTech%20Mitras%20Innovator%20Handbook%20Final.pdf.
[43] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2203001&reg=3&lang=2.
[44] https://www.pharmabiz.com/NewsDetails.aspx?aid=182343&sid=1.

8. Central Council for Research in Ayurvedic Sciences launches SIDDHI 2.0 for innovation in ayurveda sector[45]

The Central Council for Research in Ayurvedic Sciences (**CCRAS**) under the Ministry of AYUSH unveiled the second edition of its flagship industry–research collaboration platform, SIDDHI 2.0 (Scientific Innovation in Drug Development, Healthcare & Integration), in Vijayawada on November 25, 2025. This new phase represents a renewed emphasis on research-driven product development and the advancement of homegrown technologies within the Ayush sector. SIDDHI 2.0 is designed to bring researchers, industry players, policymakers, and innovators together on a unified platform to encourage meaningful engagement. Through this initiative, CCRAS aims to broaden the industry uptake of its research-based technologies, enhance collaboration between institutions, and strengthen quality standards and regulatory mechanisms.

9. WHO launches new framework to tackle drug resistance to HIV, hepatitis B and C, and STIs[46]

The World Health Organization (**WHO**) introduced the integrated drug resistance action framework for HIV, hepatitis B and C, and sexually transmitted infections (**STIs**), 2026 - 2030. This roadmap is designed to address to confront the escalating challenge of drug resistance and safeguard progress toward ending AIDS and the epidemics of hepatitis B and C, and STIs as public health concerns. The framework identifies five (5) strategic areas of work: prevention and response; monitoring and surveillance; research and innovation; laboratory capacity; and governance and enabling mechanisms. It emphasises antimicrobial stewardship, stronger surveillance systems, and equitable access to high-quality prevention, diagnosis, and treatment services for HIV, hepatitis B and C, and STIs.

10. WHO launches the Global Clinicals Trials Forum[47]

The WHO launched the Global Clinical Trials Forum (**GCTF**), a global, multi-stakeholder network designed to strengthen clinical trial systems and infrastructure at national, regional and global levels. This initiative stems from World Health

Assembly resolution–WHA75.8, which urged WHO to improve the quality and coordination of clinical trials to generate high-quality evidence for health decision-making. The GCTF is aligned with WHO's Guidance for Best Practices for Clinical Trials, which outlines key principles and actions to improve the design, conduct, oversight, and use of trials. It is further supported by the Global Action Plan for Clinical Trial Ecosystem Strengthening, which translates the guidance into nine priority action areas addressing barriers across current clinical trial ecosystems.

11. WHO issues guidelines on the use of Glucagon-Like Peptide-1 medicines in treating obesity[48]

The WHO issued its first guideline on the use of Glucagon-Like Peptide-1 (**GLP-1**) therapies to tackle obesity, a chronic and relapsing condition affecting over one billion people worldwide. In September 2025, WHO included GLP-1 therapies in its Essential Medicines List for managing type 2 diabetes among high-risk groups. Building on this, the new guideline provides conditional recommendations for their use in treating obesity, emphasising that they should form part of a broader strategy involving healthy diets, regular physical activity, and professional healthcare support. GLP-1 therapies mark the first effective medical option for adults with obesity, but WHO stresses that medication alone cannot resolve the crisis.

[45] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2194439.
[46] https://www.who.int/news/item/24-11-2025-who-launches-new-framework-to-tackle-drug-resistance-to-hivhepatitis-b-and-c-and-stis.
[47] https://www.who.int/news/item/07-10-2025-who-launches-the-global-clinical-trials-forum.
[48] https://www.who.int/news/item/01-12-2025-who-issues-global-guideline-on-the-use-of-glp-1-medicines-intreating-obesity.

12. DoP seeks Expression of Interest for manufacturing and supplying pharmaceutical products for Brazil[49]

The DoP, has invited expressions of interest for the manufacture and supply of pharmaceutical products to Brazil. The initiative aims to deepen strategic cooperation between India and Brazil in the pharmaceutical and healthcare sectors. Priority areas for cooperation include pharmaceutical production and technical support for domestic manufacturing of Active Pharmaceutical Ingredients (**APIs**), vaccines, and insulin. In addition, the plan emphasises technical partnerships and joint ventures to localise critical health technologies such as linear accelerators, tomography systems, X-ray detectors, and diagnostic ultrasound equipment. The collaboration also focuses on Brazil's major imported medical products, including laboratory diagnostic reagents, medical instruments and devices (such as probes and cannulas), and MRI machines.

13. NPPA monitors drug prices to prevent overpricing of loose medicines[50]

Minister of State for Chemicals and Fertilisers, Anupriya Patel clarified to the Parliament that the NPPA strictly monitors drug prices under the DPCO 2013 to prevent consumer exploitation through overpricing. The clarification came in response to questions raised during the December 2025 session on alleged consumer exploitation by pharmacies and medical stores in Maharashtra. Concerns were raised about medicines being sold in loose form at inflated prices exceeding the prescribed per-unit MRP. The minister stated that every manufacturer must print the MRP on each drug formulation label and that no dealer is permitted to sell any loose quantity at a price exceeding the pro-rata MRP calculated from the original strip or bottle. She stated that NPPA continuously monitors drug prices through price monitoring and resource units, state drugs controllers (**SDCs**), market reports, grievance redressal channels, and takes action against companies found overcharging consumers.

14. Over 3,000 drug samples fail quality standards in 2024–25[51]

Union Health Minister J.P. Nadda informed the Lok Sabha that 3,104 of the 1.16 lakh drug samples tested in 2024-25 were declared not of standard quality (**NSQ**) and 245 were found to be spurious or adulterated. This represents a slight increase from 2023–24, when 2,988 out of 1.06 lakh samples tested were declared NSQ and 282 were spurious or adulterated. In 2022–23, around 3,053 samples out of 96,173 samples tested were NSQ and 424 were spurious or adulterated. Since December 2022, the CDSCO and SDCs have conducted risk-based inspections of more than 960 premises, resulting in over 860 regulatory actions, including issuance of show-cause notices, warning letters, stop production orders, and cancellation of licences as per the provisions of the Drugs Rules.

15. DCGI to eliminate test licence requirement for pre-human clinical drug trials[52]

The DCGI, announced at the 10th edition of the Indian Pharmaceutical Alliance's (**IPA**) Advanced GMP Virtual Workshop that most of the test licences required before going to human testing would be removed from the regulatory system. The MoH&FW is amending the NDCT Rules, with proposed amendments published in the Gazette of India on August 28, 2025.

16. Cipla launches Yurpeak (tirzepatide) for obesity and Type 2 diabetes management in India[53]

Cipla, a leading pharmaceutical company, announced the introduction of Yurpeak (tirzepatide), a once-weekly injectable therapy for the management of obesity and type 2 diabetes mellitus (**T2DM**). The company has secured rights to distribute and promote Yurpeak, which represents the second brand of Lilly's tirzepatide in India, following regulatory approval from the DCGI. Tirzepatide is the first dual agonist targeting both glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1

[49] https://www.pharmabiz.com/NewsDetails.aspx?aid=181947&sid=1.
[50] https://medicaldialogues.in/news/industry/pharma/nppa-bars-pricing-of-loose-drugs-above-pro-rata-mrp-underdpco-parliamentinformed161070?utm_campaign=&utm_content=Calcutta%20High%20Court%20Quashes%20Blacklisting%20of%20Helax%20Healthcare&utm_medium=email&utm_source=Newsletter&utm_term=.
[51] https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/over-3000-drug-samples-declarednot-of-standard-quality-in-2024-25-nadda/125938795.
[52] https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/drug-regulator-to-drop-test-licensesrequirement-before-human-clinical-stage/125483187.
[53] https://www.expresspharma.in/cipla-launches-yurpeak-tirzepatide-for-obesity-and-type-2-diabetesmanagement-in-india/.

(GLP-1) receptors. It is indicated as an adjunct to diet and exercise for the treatment of type 2 diabetes, as well as for chronic weight management in adults with obesity (BMI ≥ 30) or overweight (BMI ≥ 27) accompanied by at least one weight-related comorbidity. The launch of Yurpeak is expected to broaden patient access to tirzepatide across India. Cipla has emphasised that the rollout will be supported by comprehensive patient education and assistance programs, including guidance on dosing, self-administration, and safe use of the therapy.

17. India seeks fast-track approval pathway for pharmaceuticals in Taiwan[54]

The Government of India has commenced formal discussions with Taiwanese authorities to establish a fast-track approval mechanism for Indian pharmaceutical products in Taiwan. This initiative seeks to facilitate market entry for medicines already approved by leading global regulators, including the United States Food and Drug Administration (**USFDA**) and the European Medicines Agency (**EMA**). To support this effort, the Pharmaceuticals Export Promotion Council of India (**Pharmexcil**) has initiated an industry-wide consultation with pharmaceutical exporters to gather comprehensive feedback on opportunities and challenges encountered during product registration in Taiwan. Pharmexcil Director General Raja Bhanu underscored that practical insights from exporters will be instrumental in shaping the Government's negotiating position.

The Taiwan Food and Drug Administration (**TFDA**) had, in June last year, proposed a fast-track approval process for 72 APIs, including drugs related to relief, antihypertensives, anticancer drugs, anti-inflammatory NSAIDs, antibiotics, and digestive tract medications amongst others.

18. Finance ministry permits 15 companies to import controlled alkaloids for export manufacturing[55]

The Union Ministry of Finance has permitted 15 pharmaceutical companies to import morphine, codeine, thebaine, and their salts. The approval, issued under Rule 54 of the NDPS Rules, 1985, is strictly for export formulations. Imported alkaloids must be utilised within 180 days, extendable by 30 days but capped at 270 days. Manufacturers must ensure exclusive use for export and maintain compliance with regulatory safeguards. Any unutilised substances or finished formulations must be surrendered to the Government Opium and Alkaloids Works. The directive balances industry needs with stringent oversight to prevent diversion and misuse.

19. Karnataka pharma retailers oppose "Instant Medicine Delivery" over safety and regulatory concerns[56]

A pharmaceutical retailers' body in Karnataka has called on state health authorities and regulators to intervene against a new quick-commerce campaign that promises medicine delivery within minutes. The association pointed out that online promotions suggest ultra-fast supply of prescription drugs, which they believe poses serious risks to patient safety and violates regulatory norms. They stressed that medicines cannot be treated like everyday consumer goods, as their distribution requires strict compliance with prescription rules, proper storage and handling, and meticulous record-keeping. Crucially, dispensing must be overseen by a licensed pharmacist to ensure prescriptions are valid and safe. According to the group, app-based rapid delivery models bypass these safeguards and contravene existing drug laws.

20. Kerala government launches Genome City[57]

The Government of Kerala plans to formally inaugurate Genome City in early 2026. The project will be located at the Bio360 Life Science Park in Thonnakkal, near the state capital, and will span approximately 60 acres with an estimated investment of INR 3,500 crore. Genome City is envisioned as an integrated life-sciences cluster, bringing together pharmaceutical companies, biotechnology firms, medical-device manufacturers, and advanced research centres under a single ecosystem. The initiative is expected to generate nearly 15,000 jobs while attracting substantial domestic and multinational investments over time. To promote early adoption, the government has announced a suite of incentives, including long-term subsidised land leases, capital-equipment subsidies, power tariff concessions, and expedited approvals through a single-window clearance system.

[54] https://www.pharmabiz.com/NewsDetails.aspx?aid=182950&sid=1.
[55] https://drugscontrol.org/news-detail.php?newsid=43836.
[56] https://www.pharmabiz.com/NewsDetails.aspx?aid=182644&sid=1.
[57] https://health.economictimes.indiatimes.com/news/policy/kerala-govt-likely-to-launch-genome-city-project-earlynext-year/125529140?utm_source=top_story&utm_medium=homepage.

21. Telangana government launches India's first single-use bioprocess design and scale-up facility at Genome Valley[58]

The Government of Telangana has inaugurated *Telangana 1 Bio*, a pioneering facility at Genome Valley that represents India's first single-use bioprocess design and scale-up centre. Conceived to advance the nation's biologics and next-generation therapeutics sector, the initiative has been developed in collaboration with Telangana Lifesciences, the Department of Biotechnology, and the Telangana Industrial Infrastructure Corporation. The Bioprocess Design Centre, established in partnership with Thermo Fisher Scientific, operates under a public–private partnership framework. The state has invested INR 150 crore in core infrastructure, while Thermo Fisher has contributed INR 90 crore towards the design and customer experience centre. *Telangana 1 Bio* is projected to attract an additional INR 500 crore in investments from tenant firms and to generate more than 500 new jobs, reinforcing Genome Valley's position as a leading hub for life sciences innovation.

22. FSSAI integrates its Food Import Clearance System (FICS) with CBIC's ICEGATE platform under SWIFT 2.0[59]

The FSSAI has integrated its Food Import Clearance System (FICS) with CBIC's ICEGATE platform under the advanced SWIFT 2.0 initiative. Building on the earlier SWIFT 1.0 integration, this marks a major milestone in trade facilitation and the Government's vision of "Ease of Doing Business". The system is live on a pilot basis at four entry points: ICD Dadri, ICD Star Track, ICD Albatross, and ICD Patparganj. Importers can now obtain FSSAI NOC directly through the SWIFT Portal for consignments at these locations. This collaboration streamlines clearance, reduces delays, and enhances transparency, aligning with flagship initiatives like "Digital India".

[58] https://www.expresspharma.in/telangana-launches-telangana-1-bio-to-support-biologics-scale-up-andinnovation/.
[59] https://fssai.gov.in/upload/uploadfiles/files/Press%20Release%20SWIFT%202_0%20First%20Draft.pdf.

Litigation Updates

1. Kerala private hospitals challenge Kerala Clinical Establishments Act before Supreme Court[60]

The Supreme Court of India (**SC**), in SLP (C) No. 36014 of 2025, *vide* order dated December 26, 2025, issued notice in a petition filed by the Kerala Private Hospitals Association challenging the constitutional validity of provisions of the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 (**Kerala Clinical Establishments Act**) and the Rules framed thereunder. A Bench comprising Justice Vikram Nath and Justice Sandeep Mehta directed that no coercive steps be taken against the petitioners until the next date of hearing on February 3, 2026, subject to the condition that members of the petitioner association continue the process of seeking permanent registration under Section 19 of the Kerala Clinical Establishments Act.

The plea assails, among other provisions, Section 39 of the Kerala Clinical Establishments Act, which requires every clinical establishment to display the fee rate and package rate of all services provided. The medical bodies contend that the Act does not define expressions such as *"fee rate"* and *"package rate,"* rendering compliance arbitrary and exposing hospitals and clinics to subjective enforcement by authorities. The petition argues that medical treatment is inherently dynamic and varies from patient to patient, making any obligation to pre-display exhaustive price structures commercially oppressive and practically unworkable.

The Petition arises from the Kerala High Court's judgment upholding the Kerala Clinical Establishments Act and issuing further directions, including that hospitals cannot deny life-saving treatment for non-payment of advance or lack of documents. The medical bodies have also challenged Section 47 of the Kerala Clinical Establishments Act, which obligates all clinical establishments to provide life-saving treatment and ensure safe transportation of patients in emergencies. They submitted before the Court that the provision applies uniformly to all establishments regardless of size, infrastructure, or capability. While clarifying that there is no objection to the mandate that life-saving care should not be denied for want of money, the Petitioners requested that interim protection be continued.

2. SC calls for national policy to address inconsistencies in organ transplantation[61]

TThe SC, in W.P. (Civil) No. 39 of 2025, *vide* judgment dated November 19, 2025, called for the formulation of a national policy to address inconsistencies in organ transplantation.

[60] Kerala Private Hospitals Association v. State of Kerala, Order dated December 26, 2025, in SLP(c) No. 36014 of 2025.
[61] Indian Society of Organ Transplantation v. Union of India & Ors., Judgement dated November 19, 2025, in W.P. (Civil) No. 39 of 2025.

The judgment arose from a writ petition filed by the Indian Society of Organ Transplantation, which sought to highlight concerns regarding uniformity, equality, and access in organ donation for both donors and recipients.

The Court observed significant deficiencies in the implementation of the Transplantation of Human Organs and Tissues Act, 1994 (**THOTA Act**), particularly its 2011 amendments. Although the THOTA Act was enacted after extensive consultations, placed under Entry 6 of the State List, and ratified by all States, several jurisdictions have yet to adopt the amendments and associated regulations intended to streamline transplant procedures. The Apex Court noted that Karnataka, Tamil Nadu, and Manipur have not adopted the revised rules, while Andhra Pradesh has yet to implement the 2011 amendments. It further expressed concern that regions such as Manipur, Nagaland, the Andaman and Nicobar Islands, and Lakshadweep continue to function without State Organ and Tissue Transplant Organisations, despite this being mandated under the national framework. In addition, the Court directed the Union Government to prepare guidelines to safeguard live donors and prevent exploitation, following consultations with the National Organ and Tissue Transplant Organisation and the Petitioner.

3. SC emphasises strong consumer protection mechanisms in pharmaceutical marketing Code[62]

The SC, in W.P. (C) No. 323 of 2021, *vide* order dated November 18, 2025, observed that the rules under the Uniform Code of Pharmaceutical Marketing Practices – 2024 (**UCPMP 2024**) must be sufficiently robust to safeguard consumers. The petition, filed by the Federation of Medical and Sales Representatives Associations of India along with other industry associations, sought a plea to strengthen the UCPMP 2024 to curb alleged unethical marketing practices by pharmaceutical companies.

The Bench emphasised that procedures enable any individual affected by unethical practices to easily lodge a complaint and obtain appropriate redress. It further remarked that clear and effective mechanisms are essential to provide consumers with a simple and convenient way to report misconduct and to guarantee strict action against violators. The Government submitted that several policies are already in place to regulate drug pricing and marketing activities, highlighting that the UCPMP 2024 prohibits pharmaceutical companies from offering gifts, travel benefits, or hospitality to doctors and their family members. However, the Bench questioned why the Code does not incorporate strong, user-friendly complaint mechanisms, noting that consumers should have a convenient system for lodging complaints and ensuring accountability of erring companies. The Petitioners argued that the UCPMP 2024 remains voluntary and therefore inadequate to prevent unethical practices. The Court directed the Centre to clarify whether it intends to introduce binding legislation to regulate such issues and to respond after reviewing the petitioners' suggestions. The petition further highlighted that while doctors are penalised for accepting inducements, pharmaceutical companies that instigate or facilitate such misconduct face no consequences, creating an imbalance in enforcement.

4. SC issues contempt notices to 28 States and UTs for non-compliance with ICU standards directive[63]

The SC, in Misc. App No. 30408 of 2024, *vide* order dated November 20, 2025, issued contempt notices and summoned the Additional Chief Secretary or senior-most health officials of 28 States and UTs for their "casual" failure to comply with directions on formulating nationwide standards for Intensive Care Units (**ICUs**) and Critical Care Units (**CCUs**). A Bench of Justices Ahsanuddin Amanullah and N. Kotiswar Singh directed all concerned officers to appear with affidavits explaining why action should not be taken against them, clarifying that no excuse of prior engagement would be entertained.

The matter originates from a 2016 medical negligence case that the SC converted into a Public Interest Litigation (**PIL**) to establish uniform, feasible standards for critical care. On August 19, 2025, the SC had mandated States and UTs to convene regional conferences with public and private healthcare experts and submit reports by early October. Most failed to comply within the deadlines.

Expressing displeasure, the SC observed it was "more pained than shocked by the casualness shown by various States" and warned that perfunctory compliance would invite strict action. It also co-opted Dr. Nitish Naik of AIIMS Delhi to lead a three-member expert committee to oversee the process.

[62] Federation of Medical and Sales Representatives Associations of India & Ors. v. Union of India & Ors., Order dated November 18, 2025, in W.P.(C) No. 323 of 2021.
[63] Asit Baran Mondal & Anr. v. Dr. Rita Sinha Mbbs Ms (Obst. Gynae) & Ors., Order dated November 20, 2025 in Misc. App No. 30408 of 20245.

5. SC issues notice on PIL seeking statutory rules for criminal prosecution in medical negligence cases[64]

The SC, in W.P.(C) No. 1080 of 2025, *vide* order dated December 1, 2025, issued notice on a public interest litigation filed by Sameeksha Foundation seeking statutory rules or executive instructions to govern criminal prosecution of medical practitioners in medical negligence cases. A Bench of Justices Vikram Nath and Sandeep Mehta passed the order after noting that despite the Court's observations in *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1, no such framework has been notified even after two decades.

The Petition highlights that in the absence of clear rules, medical negligence cases remain difficult to prosecute, as they rely heavily on inquiry reports prepared by committees largely composed of doctors. It alleges that such reports are often biased, citing the 73rd Parliamentary Standing Committee Report on Health and Family Welfare, which found medical professionals to be lenient towards colleagues accused of negligence. The Petitioner refers to the Standing Committee's recommendation that medical negligence inquiries should be conducted by panels including diverse experts such as social activists and patient representatives. It also cites research from the National Library of Medicine estimating up to 5.2 million cases of medical malpractice annually in India, contrasting this with NCRB data recording only 1,019 deaths by medical negligence between 2017 and 2022.

The PIL suggests that inquiry panels should include not only doctors but also representatives of patient NGOs, retired judges, NHRC-nominated members, senior advocates, and social and human rights activists to ensure fair and transparent proceedings.

6. High Court of Delhi directs GST Council to consider reducing tax on air purifiers to 5 per cent[65]

The High Court of Delhi (**Delhi HC**), in W.P.(C) 19644 of 2025, *vide* order dated December 24, 2025, directed the GST Council to convene at the earliest and consider lowering to 5 per cent or abolishing the GST on air purifiers and HEPA filters, currently charged at 18 per cent. The PIL filed by advocate Kapil Madan sought a declaration that air purifiers fall within the definition of "medical device" under Notification S.O. 648(E) dated February 11, 2020, issued under Section 3(b)(iv) of the Drugs Act, which defines medical devices as *"all devices including an instrument, apparatus, appliance, implant, material or other article" intended for "diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder"* and *"investigation, replacement or modification or support of the anatomy or of a physiological process"*, and directing the Union of India and CBIC to clarify GST applicable to air purifiers as 5 per cent as applicable on medical devices. The Petitioner contended that air purifiers qualify under this definition and that the continued imposition of 18 per cent GST is illegal, arbitrary, and

[64] Sameeksha Foundation -A Crusade against Medical Negligence v. Union of India and Anr., Order dated December 1, 2025 in W.P.(C) No. 1080 of 2025.
[65] Kapil Madan v. Union of India of Ors, Order dated December 24, 2025, in W.P. (C) 19644 of 2025.

violative of Articles 14 and 21 of the Constitution. The Bench, comprising the Chief Justice and Justice Tushar Rao Gedela, observed that *"considering that GST rate being charged on the devices enlisted in the Notification dated 11.02.2020 is @ 5% and also considering the function being performed by the air purifiers and HEPA filters, prima facie we do not find any reason why the GST @ 5%, based on the said notification, can also not be provided for air purifier and HEPA filters."*

The Court drew attention to the Parliamentary Standing Committee report submitted to both Houses of Parliament on December 12, 2025, which observed that *"the Committee finds it contradictory that whilst Government efforts to mitigate the country's severe air pollution crisis have consistently fallen short, a prohibitive tax is levied on a critical device that citizens are forced to rely on for personal protection. Imposing such a tax effectively monetises a public health failure"*. The Court directed that *"the issue of lowering or abolishing the GST on air purifiers and HEPA filters shall be considered by the GST Council at the earliest"*, stating that *"taking into consideration the air quality situation in the State of Delhi and nearby areas, we find it appropriate to require the Council to meet at the earliest"*. In a subsequent hearing on December 26, 2025, the ASG appearing on behalf of the Union submitted that the meeting of the GST Council is possible only physically and cannot be convened through video conferencing, citing Regulations 14 and 15 of the Procedure and Conduct of the Business Regulations of GST Council, following which the Court directed the respondents to file a counter affidavit within 10 (ten) days and listed the matter for hearing in January 2026 before the Roster Bench.

7. Delhi HC upheld FSSAI ban on the ORS branding[66]

The Delhi HC, in W.P.(C) 16303 of 2025 and CM APPL.66695/2025, *vide* order dated October 31, 2025, upheld FSSAI's prohibition on the use of the term "ORS" (Oral Rehydration Solution), whether standalone or in combination with any prefix/suffix, in the naming of food products including fruit-based, non-carbonated, or ready-to-drink beverages. The controversy arose from FSSAI's October 2025 circulars that withdrew earlier accommodations and categorically prohibited the use of "ORS" in labelling, branding, or marketing of food products, emphasising that the term is intrinsically associated with WHO-approved therapeutic formulations for treating acute diarrhoea and dehydration, and its use in commercial food products creates serious risk of consumer misidentification. Dr. Reddy's Laboratories, which marketed *"Rebalanz Vitors"*, and JNTL Consumer Health, which marketed "ORSL" for nearly two decades under valid composite trademarks, challenged the circulars contending they were issued without notice, hearing, or stakeholder consultation, violated principles of natural justice, and imposed retrospective restrictions without adequate transition periods.

The Delhi HC observed that FSSAI's measures were driven by serious public health considerations and aligned with its statutory mandate, noting documented instances where caregivers administered these high-sugar beverages during acute diarrhoea, mistaking them for WHO-approved therapeutic ORS, resulting in inadequate treatment or worsening dehydration with potentially life-threatening consequences, particularly for vulnerable populations such as infants and young children. Consequently, the Delhi HC upheld the ban following the deleterious effect and adverse health outcomes, affirming that the FSS Act retains primacy over trademark protections.

8. Delhi HC refuses Novo Nordisk's plea for stay on Dr Reddy's Semaglutide export order[67]

The Delhi HC, in FAO (OS) (COMM)-204/2025, *vide* Order dated December 12, 2025, refused Danish drug maker Novo Nordisk's plea for an immediate *ex parte* stay on a single judge's order that allowed Dr Reddy's Laboratories to manufacture and export Semaglutide-based formulations to countries where Novo Nordisk does not hold patent rights. While hearing Novo Nordisk's application for interim relief in its appeal, a Division Bench of Justice C Hari Shankar and Justice Om Prakash Shukla noted that the single judge had not rejected Novo Nordisk's injunction plea but had granted limited relief to Dr Reddy's by permitting exports only to non-patent territories.

In its appeal, Novo Nordisk argued that manufacturing the disputed drug substance itself amounts to infringement. The Court acknowledged this contention but emphasised that the single judge's order was confined to permitting exports to jurisdictions where no patent exists. It observed, *"We are aware that even manufacturing constitutes infringement; nonetheless it is only an interim relief by which Dr Reddy's can export to countries where Novo does not have patent. It has not been allowed to sell in India or export to countries*

[66] Dr Reddys Laboratories Limited & Ors v. Union of India, Order dated October 31, 2025, in W.P.(C) 16303/2025 and CM APPL.66695/2025.
[67] Novo Nordisk v. Dr. Reddy's Laboratories Limited & Anr., Order dated December 12, 2025, in FAO (OS) (COMM)204/2025.

where Novo has patent, so on irreparable loss and balance of convenience, it is a very weak case today to grant a stay." It noted that the single judge had compared the claim in Novo's patent with the claims in the prior art to assess whether the patented claim had already been disclosed, observing that there appeared to be only one point of difference which, for a person skilled in the art, is obvious. The Division Bench observed, *"whether it is obvious or not, is a matter which needs examination and cannot be decided on first day of hearing as it would require detailed analysis."* Instead of granting any interim relief, the Court listed the appeal for final hearing and issued notice, stating that the single judge had given only a limited window for Dr Reddy's which, at this stage, did not call for greater interference.

9. Delhi HC upholds sex determination of foetus as violation of law[68]

The Delhi HC, in Bail Appln. 3786 of 2025, *vide* order dated October 15, 2025, ruled on a petition filed by the accused seeking anticipatory bail in connection with an FIR alleging his involvement in an organised scheme facilitating illegal sex determination, in violation of the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994.

The Delhi HC observed that the practice of determining the sex of a foetus and taking subsequent actions based on that information constitutes a clear violation of law. Opining that each such instance undermines the value of female life and perpetuates the notion that certain lives are less worthy due to gender, the Court emphasised that such practices not only foster a culture of treating girls as burdens rather than equal members of society but also expose pregnant women to unsafe medical procedures. Accordingly, the Court dismissed the Petitioner's application for anticipatory bail.

10. High Court of Madras directs expert panel to review of diabetes drugs Pioglitazone and Sitagliptin[69]

The High Court of Madras, in W.P. No. 44138 of 2025, *vide* judgment dated November 17, 2025, directed the MoH&FW to constitute a panel of medical experts to conduct a comprehensive inquiry into the safety and efficacy of the diabetes drugs "Pioglitazone" and "Sitagliptin". The petition, filed by Dr. B. Mukesh, a practicing diabetologist, alleged that Pioglitazone was wrongly discredited as carrying a risk of bladder cancer, leading to its temporary ban, and that this was part of a conspiracy to promote the costlier drug Sitagliptin, priced nearly 10 (ten) times higher. The Petitioner further contended that the ICMR failed to comply with earlier court directions to conduct a fair hearing, as different authorities heard the petitioner and the respondent diabetologist separately. Acknowledging the technical nature of the dispute, the Court acknowledged its lack of expertise to determine which drug is more beneficial and mandated the Ministry to form an expert body. The panel must hold a joint inquiry, hearing both parties on the same day, and provide an evidence-based recommendation on the suitability of the drugs for diabetes patients in India.

The Court imposed strict compliance timelines, directing the completion of the entire process, including constitution of the expert team and submission of recommendations, within three months of receipt of the order. The judgment underscores the broader public health implications of the case, highlighting concerns over medical integrity, affordability, and access to treatment for millions of diabetes patients nationwide.

11. High Court of Kerala recognises denial of medical insurance as violation of Article 21[70]

The Hight Court of Kerala (**Kerala HC**), in WP(C) No. 13244 of 2017, *vide* judgment dated September 8, 2025, held that although insurance disputes are ordinarily contractual in nature and best suited for adjudication before civil courts, writ jurisdiction may be invoked in cases involving gross miscarriage of justice, violation of fundamental rights, or breach of natural justice.

The case arose from the denial of a health insurance claim filed by the petitioner on the ground of non-disclosure of a pre-existing condition. The Court noted that the insurer had failed to provide the insured an opportunity to be heard before rejecting the claim, which amounted to a violation of the principles of natural justice. It further observed that there was no specific allegation of fraud under the policy, and that a mere reference to a past ailment, without establishing its materiality or connection to the treatment in question, could not justify repudiation. Considering the broader public interest and the growing trend of arbitrary repudiation of claims by both public and private insurers, the Court deemed judicial intervention necessary and directed the insurer to honour the claim without further delay.

[68] Bhupender Singh v. State (NCT of Delhi), Order dated October 15, 2025, in Bail Appln. 3786 of 2025.
[69] Dr. B. Mukesh v. Ministry of Health and Others, Judgment dated November 17, 2025 in W.P. No. 44138 of 2025.
[70] Dr. AM Muraleedharan v. Senior Divisional Manager, Order dated September 8, 2025, in WP(c) No. 13244 of 2017.

Transaction Updates

1. Healthium Medtech strengthens surgical consumables portfolio with Paramount Surgimed stake[71]

Healthium Medtech announced the acquisition of a controlling stake in Paramount Surgimed Ltd., one of India's largest manufacturers and exporters of surgical blades, scalpels, and dermal biopsy products. Healthium, a KKR-backed med-tech company, has a growing portfolio across surgical, post-surgical, advanced wound care, arthroscopy, and infection prevention. Paramount, founded in 1993 and headquartered in New Delhi, is led by the Grover family and has built a strong export presence in precision surgical instruments. As part of the transaction, Paramount's non-surgical businesses, including lifestyle and hygiene segments, will be carved out and retained by the promoters. The acquisition enhances Healthium's specialised presence in surgical consumables, creating synergies that broaden product offerings and strengthen its global expansion strategy in high-precision technologies.

2. Natco Pharma to acquire 35.75 per cent stake in Adcock Ingram Holdings Ltd[72]

Natco Pharma Ltd. has announced the successful delisting of Adcock Ingram Holdings Ltd. from the Johannesburg Stock Exchange (JSE) as of November 11, 2025, following the acquisition of a 35.75 per cent stake valued at approximately USD 226 million (ZAR 4 billion). Adcock Ingram, incorporated in 1891, is one of South Africa's oldest pharmaceutical companies and reported a strong presence in the market with trusted brands such as Panado, Myprodol, Epi-Max, Citro-soda, and Allergex. The acquisition, approved in October 2025 after Natco's offer of ZAR 75 per share to minority shareholders, establishes Natco's market presence in South Africa. As per press statement issued by Natco, the deal is a strategic move to preserve Adcock Ingram's legacy while leveraging its established market position and consumer trust to expand product offerings and drive growth across Africa and beyond.

3. CIPLA to acquire Inzpera Healthsciences for INR 110 crore[73]

Cipla Ltd. has announced the acquisition of 100 per cent stake in Inzpera Healthsciences Limited for INR 110.65 crore in cash. Inzpera, incorporated in 2016, specialises in paediatric and wellness products and reported a turnover of INR 26.75 crore in the last fiscal year. The acquisition, based on an enterprise value of about INR 120 crore, will make Inzpera a wholly owned subsidiary of Cipla. As per press statement issued by Cipla, the deal is a strategic move to

[71] https://www.expresshealthcare.in/news/healthium-medtech-acquires-stake-in-paramount-surgimed-to-expand surgical-consumables-business/451947/.
[72] https://www.thehindubusinessline.com/companies/natco-pharma-completes-delisting-of-adcock-ingram holdings-from-jse/article70270596.ece.
[73] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/cipla-to-acquire-inzpera healthsciences-for-rs-110-crore/125080121?utm_source=top_news&utm_medium=sectionListing.

integrate Inzpera's differentiated paediatric and wellness portfolio with Cipla's extensive distribution network and operational capabilities.

4. Omega Hospital expands cancer care network with Cytecare acquisition[74]

Omega Hospitals announced the acquisition of Cytecare Hospitals, a Bengaluru-based oncology centre. Backed by Morgan Stanley Private Equity, Omega Hospitals operates a leading cancer care network under Hyderabad Institute of Oncology Pvt. Ltd. Cytecare, established in 2016, is a 150-bed NABH-accredited hospital located on Bengaluru's international airport road, known for its patient-centric oncology services and research initiatives. The acquisition marks Omega's entry into North Bengaluru and strengthens its pan-India expansion strategy. As per reports, the deal involves both primary capital infusion and secondary share purchase. This strategic move is expected to enhance Omega's footprint in South India and position it to deliver advanced cancer care, including immunotherapy, across a wider network.

5. Pluro raises INR 125 crore Series A led by Bessemer Venture Partners[75]

Pluro Fertility announced securing INR 125 crore in Series A funding led by Bessemer Venture Partners, valuing the company at INR 1,000 crore. Founded as a healthcare partnership platform, Pluro manages non-clinical operations for fertility and IVF clinics, including practice management, compliance, technology, and marketing. The capital raised will be used to expand its network of fertility specialists, carry out investment in advanced reproductive technology, and deepen clinical capabilities. The round also saw participation from prominent angel investors such as Vikram Chatwal (MediAssist), Dharmil Sheth and Hardik Dedhia (PharmEasy), and Salil Musale (Astarc Ventures).

6. Inviga Healthcare Fund acquires 21 per cent stake in Forus Health to advance AI ophthalmic diagnostics[76]

Inviga Healthcare Fund, a healthcare-focused investment platform, has acquired a 21 per cent stake in Forus Health, a Bengaluru-based medical technology company specialising in AI-led ophthalmic diagnostics. Founded in 2010, Forus Health develops innovative, affordable eye-care solutions such as its flagship "3nethra" devices, which enable early detection of conditions such as diabetic retinopathy, glaucoma, and cataracts. The investment will support Forus in scaling its AI-powered diagnostic tools, expanding reach across India and global markets, and strengthening its R&D capabilities. With this strategic partnership, Inviga aims to accelerate the adoption of technology-driven preventive eye care, addressing the growing burden of avoidable blindness in India.

7. Omron Healthcare makes second strategic investment in Tricog Health to boost AI cardiac care[77]

Omron Healthcare, a Japan-based global leader in medical equipment and home healthcare devices, has announced its second investment in Tricog Health, a Bengaluru-headquartered health-tech start-up specialising in AI-powered cardiac diagnostics and remote monitoring solutions. Tricog, founded in 2015, leverages advanced algorithms and cloud-based platforms to provide real-time ECG interpretation and predictive insights for early detection of heart disease. This renewed investment underscores Omron's commitment to strengthening digital health and AI-driven cardiac care in India, where cardiovascular diseases remain a leading cause of mortality. The partnership aims to accelerate deployment of Tricog's AI solutions across hospitals and clinics, expand access to affordable cardiac diagnostics, and integrate Omron's expertise in medical devices with Tricog's digital ecosystem.

8. MedGenome acquires majority stake in Green Cross Genetic Lab to expand genomics diagnostics[78]

MedGenome, a leading genomics-driven diagnostics and research company headquartered in Bengaluru, has acquired a majority stake in Green Cross Genetics Lab, a Chennai-based diagnostics provider. MedGenome, backed by investors such as Sequoia Capital and Novo Holdings, offers advanced genetic testing services across oncology, rare diseases, reproductive health, and wellness. Green Cross Genetics Lab, known for its molecular diagnostics and pathology services, strengthens MedGenome's presence in South India and enhances its ability to deliver affordable,

[74] https://www.expresshealthcare.in/news/omega-hospitals-acquires-cytecare-hospitals-in-bengaluru-to-expand cancer-care-network/451346/.
[75] https://www.business-standard.com/companies/news/pluro-secures-125-crore-series-a-funding-led-by bessemer-venture-partners-125103001496_1.html.
[76] https://www.expresshealthcare.in/news/inviga-healthcare-fund-acquires-21-stake-in-forus-health-to-support-ai led-ophthalmic-diagnostics/451329/.
[77] https://healthcare.omron.com/press-releases/omron-healthcare-announces-second-investment-in-tricog-health to-advance-ai-powered-cardiac-care-in-india.
[78] https://health.economictimes.indiatimes.com/news/diagnostics/medgenome-acquires-majority-stake-in-green cross-to-expand-genomics-footprint-across-india/125085544.

accessible genomics-led diagnostics. The acquisition is part of MedGenome's strategy to expand its nationwide footprint, integrate cutting-edge genomic technologies into routine diagnostics, and accelerate adoption of precision medicine in India.

9. Lords Mark India acquires 85 per cent stake in Renalyx Health Systems[79]

Lords Mark Industries, a diversified Indian conglomerate with interests in healthcare, diagnostics, renewable energy, and technology, has acquired an 85 per cent stake in Renalyx Health Systems, a Bengaluru-based med-tech company specialising in renal care solutions. Renalyx, founded in 2016, develops innovative dialysis and kidney health technologies, including its flagship portable dialysis machine aimed at improving accessibility and affordability of treatment for chronic kidney disease patients. The acquisition strengthens Lords Mark's healthcare portfolio, aligning with its vision to expand into affordable and technology-driven medical solutions. With this deal, Lords Mark plans to scale Renalyx's operations, enhance R&D capabilities, and extend its reach across India's growing dialysis market, which faces rising demand due to increasing kidney-related disorders.

10. Sai Parenterals acquires 74.6 per cent stake in Noumed Pharmaceuticals[80]

Sai Parenterals Limited, a Hyderabad-based diversified pharmaceutical formulations company, has acquired a 74.6 per cent controlling stake in Noumed Pharmaceuticals Pty. Ltd, an Adelaide-based pharma firm, for INR 125 crore. Noumed, with annual revenues of AUD 60 million, is a supplier of private-label over-the-counter (**OTC**) products to pharmacy chains across Australia and New Zealand. The company is also investing AUD 53 million in a new manufacturing facility in Adelaide, which is expected to commence operations by Q4 2026. With a portfolio of over 451 product dossiers across therapeutic categories, Noumed strengthens Sai Parenterals' global footprint and enhances its innovation-led formulations and CDMO platform. The acquisition aligns with Sai Parenterals' expansion strategy, coming shortly after the company filed its IPO draft papers with SEBI in September 2025, signaling its ambition to scale internationally.

11. Pandorum Technologies to raise USD 10 million Series B for tissue engineering expansion

Pandorum Technologies, a Bengaluru-based biotechnology start-up specialising in tissue engineering and regenerative medicine, is set to raise INR 85 crore (around USD 10 million) in a Series B round. Founded by Tuhin Bhowmick and Arun Chandru, the company develops lab-grown human tissues, such as liver and corneal models, for drug discovery, disease modeling, and therapeutic applications. The Series B funding is being led by Protons Corporate, contributing INR 27 crore, with additional participation from Noblevast Advisory (INR 16.1 crore) and several prominent angel investors. As per reports, this capital infusion will support scale-up of operations, subsidiary growth, and advancement of proprietary bioprinted tissue technologies, positioning Pandorum as a leader in India's deep-science biotech ecosystem.

12. Cadabams invests USD 7.3 million in MindTalk to build AI-powered mental health platform[82]

Cadabams Group, one of India's largest mental healthcare providers with over three decades of clinical expertise, has announced USD 7.3 million (INR 65 crore) investment in its newly launched digital mental health platform, MindTalk, on November 12, 2025. MindTalk is designed to become the world's first "Deep Agent" for mental health, combining advanced DeepTech, AI infrastructure, and clinical research integration to deliver structured, measurable therapeutic outcomes. The investment will be deployed over the next 12–18 months to strengthen deep learning capabilities, expand AI-driven tools, and scale services to reach at least one million users. As per reports, unlike conventional wellness chatbots, MindTalk aims to provide a clinically intelligent digital companion that retains the rigour and empathy of real-world therapy, marking a significant technology-led expansion in India's mental health sector.

13. ImmunitoAI raises USD 6.1 million Series A to advance AI-driven antibody discovery[83]

ImmunitoAI, a Bengaluru-based biotech and AI start-up founded in 2020, focuses on accelerating antibody discovery through its proprietary AI-powered platform that eliminates

[79] https://www.expresshealthcare.in/news/lords-mark-india-acquires-85-per-cent-stake-in-renalyx-health systems/451617/.
[80] https://www.thehindu.com/business/sai-parenteral-acquires-stake-in-australian-pharma-firm-for-125 crore/article70346166.ece.
[81] https://entrackr.com/exclusive/exclusive-biotech-firm-pandorum-to-raise-10-mn-in-series-b-10816807.
[82] https://www.entrepreneur.com/en-in/news-and-trends/cadabams-invests-73-mn-in-mindtalk-to-build-worlds first/499486.
[83] https://inc42.com/buzz/immunitoai-bags-6-1-mn-from-pi-ventures-others-to-build-antibodies/.

reliance on traditional biological sources. On November 26, 2025, the company announced raising USD 6.1 million (around INR 54 crore) in Series A funding, led by Ashish Kacholia, with participation from pi Ventures, Anicut Capital, 3one4 Capital, AC Ventures, and existing backers including JITO Incubation & Innovation Foundation, LVX, JJ Family Office, and several angel investors. The round saw Kacholia contribute about INR 25 crore (USD 3 million), while pi Ventures and Anicut Capital invested INR 10.4 crore (USD 1.25 million) and INR 8.3 crore (USD 1 million), respectively. The funds will be used to scale its AI-led antibody therapeutics pipeline, strengthen intellectual property, and expand global collaborations. This positions ImmunitoAI as a disruptive force in biotech, aiming to reduce costs and timelines in therapeutic antibody development.

14. HRS Navigation secures USD 5 million Pre-Series A to scale surgical navigation solutions[84]

HRS Navigation, a Bengaluru-based med-tech start-up specialising in advanced surgical navigation systems, has raised USD 5 million in a pre-Series A funding round in December 2025. Founded by healthcare technology innovators, HRS Navigation develops AI-powered intraoperative navigation platforms that enhance precision in complex surgeries, particularly in oncology and neurosurgery. The funding round was led by healthcare-focused investors and strategic partners, aimed at accelerating product development, clinical validation, and expansion into domestic and international markets. HRS Navigation's solutions are designed to improve surgical accuracy, reduce complications, and make advanced navigation technology more accessible to hospitals across India.

15. Helex secures USD 3.5 million to advance gene therapies for kidney diseases[85]

Helex announced raising USD 3.5 million in a seed funding round led by pi Ventures, with participation from Bluehill Capital, SOSV, and other global investors. Founded in Hyderabad and the US, Helex is a biotech start-up pioneering programmable non-viral lipid nanoparticle therapeutics to deliver genetic medicines directly to kidney cells. As per reports, the funds raised will accelerate preclinical development of its lead candidate for autosomal dominant polycystic kidney disease, a genetic disorder affecting nearly 12 million people worldwide and 5 per cent of chronic kidney disease patients in India. With this round, Helex has raised over USD 6 million to date, positioning itself as a key innovator in targeted therapies for chronic and rare kidney disorders.

16. Specialty Surgical Oncology raises USD 2.8 million from Everhope Oncology Platform[86]

Specialty Surgical Oncology (**SSO**), a Mumbai-based cancer care provider focused on advanced surgical oncology services, has secured USD 2.8 million in funding from the Everhope Oncology Platform in December 2025. Founded by leading oncologists, SSO operates a network of specialised cancer centres across India, delivering evidence-based treatment with emphasis on surgical precision and multidisciplinary care. The investment will be used to expand its footprint across tier-1 and tier-2 cities, strengthen infrastructure, and enhance access to affordable oncology services. Everhope Oncology, backed by healthcare-focused investors, aims to build a pan-India cancer care ecosystem by supporting innovative providers like SSO.

17. Lumov secures USD 1.2 million seed funding to transform orthopaedic recovery in India[87]

Lumov, a health-tech start-up focused on orthopaedic recovery solutions, has raised USD 1.2 million in a seed round led by Incubate Fund Asia, with participation from Beyond Next Ventures, Artesian, and angel investors. Founded in Bengaluru, Lumov develops AI-driven rehabilitation platforms and wearable technologies that enable personalised recovery programs for patients undergoing orthopedic treatments and surgeries. The fresh capital will be used to scale product development, strengthen clinical collaborations, and expand market reach across India's healthcare ecosystem. By integrating advanced data analytics and patient-centric design, Lumov aims to redefine post-surgical recovery, improve patient outcomes, and reduce the burden on hospitals. This funding marks a significant step in building India's first comprehensive orthopaedic recovery platform, bridging gaps in rehabilitation care and accessibility.

[84] https://www.expresshealthcare.in/news/hrs-navigation-raises-5-million-in-pre-series-a/451427/.
[85] https://economictimes.indiatimes.com/tech/funding/biotech-startup-helex-raises-3-5-million-in-round-led-by-pi ventures/articleshow/124912263.cms?from=mdr.
[86] https://www.expresshealthcare.in/news/specialty-surgical-oncology-secures-2-8-million-in-funding-from-the everhope-oncology-platform/451784/.
[87] https://www.bwdisrupt.com/article/lumov-raises-1-2-mn-to-build-india-first-orthopedic-recovery-solutions-582754.

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