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synapse

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

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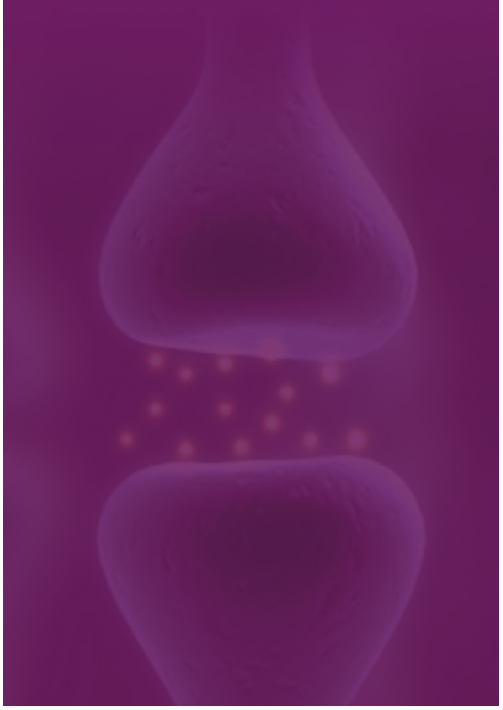

Dear Readers,

As we slip into the festive season, we look at the third quarter of 2025, a period marked by continued policy efforts aimed at streamlining India's healthcare ecosystem, focusing on fiscal stimulus and even more regulatory simplification. The government's decision to reduce GST rates across several drugs and medical devices categories and health insurance premiums was a significant step towards improving accessibility and affordability and driving domestic value addition. Globally, while the U.S. administration's executive order on tariffs remains pending, it continues to shape expectations around trade and supply chain resilience. Indian manufacturers are increasingly exploring ways to soften the blow from disruption, should it hit them. Together, these developments underscore a sector in transition, one that is steadily aligning economic incentives with 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 July and September 2025 reflect India's healthcare regulatory landscape transformation, with comprehensive reforms spanning pharmaceutical manufacturing, pricing controls, environmental compliance, and food safety standards. The Ministry of Health and Family Welfare amended the New Drugs and Clinical Trials Rules, 2019, mandating digital submissions for manufacturing approvals while reducing processing timelines from 90 to 45 working days. This digitalisation extends to bioavailability and bioequivalence studies, though exemptions remain for controlled substances including sex hormones, cytotoxic compounds, and narcotics. Further streamlining import processes, the online dual-use No Objection Certificate system through the Sugam Portal advanced facilitation for non-medicinal pharmaceutical applications. On the pricing front, responding to recent GST revisions, the NPPA issued clarifications on re-stickering and re-labelling requirements, permitting manufacturers to continue selling existing inventory without mandatory recall or re-labelling, provided price compliance is ensured at the retailer level. Additionally, the NPPA extended the validity period of ceiling prices for orthopaedic knee implants for a further two months beyond September 15, 2025, effective until November 15, 2025. Complementing these pharmaceutical reforms, amendments in UCPMP and UCMPMD introduced marketing practice standardisation through standardised valuation methodologies and streamlined disclosure procedures. Environmental measures included comprehensive audit frameworks and deferred quality control implementation timelines until September 2026, while food safety enhancements addressed edible oil specifications, meat sausage standards, and introduced six genetically modified microorganism-derived enzymes for food processing applications.

In the news and policy updates space, the Parliamentary Standing Committee on Chemicals and Fertilisers' 13th report on "Health hazards due to use of

compromised or substandard quality of food grade plastics and their exposure to extreme Indian climatic conditions" highlighted the substantive role of FSSAI in enforcing the Food Safety and Standards Packaging Regulations, 2018, raised concerns over migration of plastic and nano plastic in food contents, and underscored the absence of a framework for safety of biodegradable and compostable plastics packaging. The Committee also recommended that BIS develop standards for food grade bowls. In a landmark fiscal reform, the 56th GST Council meeting, chaired by Union Finance Minister Nirmala Sitharaman, implemented significant tax reforms effective September 22, 2025, reducing the GST rate on all drugs and medical devices to 5 per cent and granting full exemption to 36 lifesaving medicines, including treatments for cancer, rare diseases, and severe chronic conditions. The Council also lowered GST on a wide range of medical apparatus and supplies, such as diagnostic kits, reagents, bandages, and glucometers. On the innovation front, the government launched the Promotion of Research and Innovation in Pharma MedTech sector scheme and expanded the Production Linked Incentive Scheme for Pharmaceuticals to include rare disease therapies, with domestic manufacturing of Eliglustat for Gaucher's Disease reducing annual treatment costs from INR 1.8–3.6 crore to just INR 3–6 lakh. The Government of Goa introduced a pricing policy for innovative and lifesaving therapies, while CDSCO and ICMR jointly released a compendium of Standard In-Vitro Diagnostic Evaluation Protocols covering tuberculosis, malaria, dengue, and other critical infectious diseases. Internationally, the WHO updated its Model Lists of Essential Medicines, incorporating 20 new medicines for adults and 15 for children, including key cancer and diabetes treatments. This edition of *Synapse* covers many more such developments.

In the litigation space, the Supreme Court recognised stem cell banking services as healthcare services and exempted them from service tax. The Court also held that the limitation period for offences under the Drugs Act begins from the date of receipt of the Drug Analyst's Report. The Madras High Court stressed the need to amend existing rules, prescribe proper standards, and introduce appropriate forms for applications and import licences relating to ayurvedic drugs. The Delhi High Court issued three significant rulings: directing the Drug Controller General of India to consult medical experts on safety and licensing of weight loss drugs; holding that "conscious possession" under the NDPS Act requires both knowledge of the contraband and ability to exercise control over it; and ordering a three-member inspection of a preclinical contract research organisation for alleged animal abuse. The Allahabad and Rajasthan High Courts delivered key judgements on medical termination of pregnancy, while the Karnataka High Court quashed criminal proceedings, holding that under the Food Safety and Standards Act, 2006, it is mandatory to have the company as accused and officials in charge alone are not liable.

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 to 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 that 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. Ministry of Health and Family Welfare notifies Cosmetics (Amendment) Rules, 2025[1]

The Ministry of Health and Family Welfare (Department of Health and Family Welfare) (**MoH&FW**), *vide* notification G.S.R. 513(E) dated July 29, 2025, has notified the Cosmetics (Amendment) Rules, 2025 (**Cosmetics Amendment Rules**). The Cosmetics Amendment Rules define *"use before"* as the date preceding the first day of the mentioned month, while *"date of expiry"* refers to the last day of that month. Terminology changes include replacing *"Controlling Officer"* with *"Controlling Authority"* and updating the definition of *"Government Analyst"*. Licensees are required to maintain records of manufactured batches and raw materials for three years or six months after batch expiry, whichever is later, in hard copy or electronic format. The rules also outline procedures for licence cancellation or suspension by State Licensing Authorities, with a provision for appeal to the State Government within 90 (ninety) days.

2. Appointment of compounding authority under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025[2]

The MoH&FW, *vide* notification S.O. 3551(E) dated August 1, 2025, has appointed the compounding authority under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025. The Central Government appointed the Additional Director General of Health Services dealing with matters of the Central Drugs Standard Control Organisation (**CDSCO**) as the compounding authority for exercising powers and functions of the Central Government in respect of compounding of offences under the regulatory framework established by the Drugs and Cosmetics (Compounding of Offences) Rules, 2025.

3. MoH&FW issues Drugs (Second Amendment) Rules, 2025, to include details of excipient on every strip of medicines[3]

The MoH&FW, *vide* G.S.R. 554(E) dated August 18, 2025, has notified the Drugs (Second Amendment) Rules, 2025, effective March 1, 2026. Following public consultation, the key change to Rule 96(7) of the Drugs Rules, 1945 (**Drugs Rules**) includes revising Clause (vii) to "date of expiry" and inserting Clause (ix) mandating disclosure of qualitative details of excipients, enhancing transparency in drug labelling.

4. MoH&FW issues notification prohibiting usage of select antimicrobials on animals[4]

The MoH&FW, *vide* S.O. 4338(E) dated September 23, 2025, has officially prohibited the import, manufacture, sale, and distribution of specified antimicrobial medicinal products and their formulations for animal use. This decision follows the publication of a draft notification (S.O. 2298(E) dated May 22, 2025) under Sections 10A and 26A of the Drugs and Cosmetics Act, 1940 (**Drugs Act**), and subsequent consultation with the Drugs Technical Advisory Board (**DTAB**). As no objections or suggestions were received during the public consultation period, and considering the availability of safer alternatives, the Central Government has deemed it necessary in the public interest to enforce this prohibition. The banned categories include a wide range of antibiotics (carbapenems, glycopeptides, and oxazolidinones), antivirals (including oseltamivir, favipiravir, and molnupiravir), and the antiprotozoal agent, nitazoxanide. This measure aims to curb antimicrobial resistance and promote responsible use of critical medicines.

5. MoH&FW issues draft notifications to amend New Drugs and Clinical Trial Rules, 2019[5]

a. Draft Notification for application of unapproved drugs for conduct of BA BE studies for export purpose under NDCT Rules 2019[6]

The MoH&FW, *vide* draft notification G.S.R. 587(E) dated August 27, 2025, has proposed amendments to the New Drugs and Clinical Trial Rules, 2019 (**NDCT Rules**). The draft amendments, issued in exercise of powers under Sections 12 and 33 of the Drugs Act, follow consultation with the DTAB and aim to streamline regulatory

1 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5ODY=
2 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5ODg=
3 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3Nzg=
4 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM0MDk=
5 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMyNDY=
6 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMyNDY=

processes for bioavailability and bioequivalence studies. Specifically, they propose a simplified notification mechanism for single-dose, two-period, two-sequence, two-treatment studies in healthy adult volunteers for export purposes, involving oral dosage forms of drugs already approved in India or select geographies (the United States, the European Union, Japan, Australia, Canada, and the United Kingdom), excluding sensitive categories. Key conditions include ethics committee approval, separate record maintenance, and a sample size cap of 48. These studies may be initiated through online submission in Form CT-05, with fee exemptions for government-funded institutions.

b. *Draft Notification about changes to requirements of test license under NDCT Rules 2019*[7]

The MoH&FW, *vide* draft notification G.S.R. 588(E) dated August 27, 2025, has proposed amendments to the NDTC Rules. The amendments, issued in exercise of powers under Sections 12 and 33 of the Drugs Act, following consultation with the DTAB, propose a notification-based process for manufacturing new drugs or investigational new drugs intended for analytical and preclinical testing. This excludes sensitive categories such as sex hormones, cytotoxic agents, beta lactams, biologics with live microorganisms, and narcotic or psychotropic substances. Applicants may proceed with manufacturing upon submission of an online notification to the Central Licensing Authority. Additionally, the regulatory timelines under Rules 53[8] and 60[9] have been reduced from 90 (ninety) to 45 (forty-five0 working days, aiming to expedite approvals and streamline clinical trial processes.

6. Amendment in Uniform Code for Marketing Practices in Medical Devices[10]

The Ministry of Chemicals and Fertilisers (**MoC&F**), through Department of Pharmaceuticals (**DoP**) *vide* notification Circular No. 3 of 2025 dated September 1, 2025, has notified amendments to the Uniform Code for Marketing Practices in Medical Devices, 2024 (**UCMPMD**). These amendments aim to streamline valuation, disclosure, and data protection procedures applicable to medical device manufacturers and purchasers. The key changes introduced through the amendment include:

a. Manufacturers must value free evaluation samples on a per-unit basis using stockist prices.

b. Purchasers must use acquisition costs for sample valuation.

c. Annual averaging is mandatory for identical product variants.

d. Companies may now submit annual declarations to industry association websites instead of government portals.

e. Entities unaffiliated with any association shall continue using the UCMPMD portal for disclosures.

f. Industry associations must implement secure data storage systems with a five-year retention period.

g. Associations must facilitate information sharing with regulatory authorities upon request.

h. Clause 9.1 of UCMPMD has been amended to substitute the term "UCMPMD" with "UCPMP".

i. References to "UCPMP" have been omitted from Clauses 9.5 and 11.10 of UCMPMD.

j. The amendment eliminates duplicate reporting requirements to the UCPMP portal, thereby reducing administrative burden previously imposed by Clause 11.10.

7. Amendment to the Uniform Code for Pharmaceutical Marketing Practices[11]

The, MoC&F, through DoP, *vide* Circular No. 3 of 2025 dated September 1, 2025, has notified amendments to the Uniform Code for Pharmaceutical Marketing Practices, 2024 (**UCPMP**). These amendments introduce clarifications to valuation methodology and revise disclosure obligations applicable to pharmaceutical companies.

a. Manufacturer-supplied free samples distributed to healthcare professionals shall be valued on a per-unit basis using stockist prices.

b. Purchased samples shall be valued at actual purchase price.

[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMyNDc=
[8] Grant of permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study, or for examination, test and analysis
[9] Grant of permission to manufacture unapproved active pharmaceutical ingredient for development of pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study
[10] https://pharma-dept.gov.in/sites/default/files/ucmpmd%20circular%20with%20amended%20code_1.pdf
[11] https://pharma-dept.gov.in/sites/default/files/Circular%20No.%203%20of%202025%20and%20UCPMP%202024%20as%20amended_0.pdf

c. Annual averaging is mandatory for identical product variants.

d. Companies may now submit marketing expenditure returns to any member industry association.

e. Data security protocols must be upheld, including secure storage systems and a five-year retention period.

f. Technical corrections have substituted outdated references in relevant clauses.

g. Requirements for uploading disclosures to departmental portals have been removed where applicable.

h. Standardized format for disclosure of marketing expenditure has been introduced. Was previously part of the UCMPMD and is now incorporated into the UCPMP as well.

8. Jan Vishwas Bill, 2025, proposes decriminalisation of certain offences under Drugs Act[12]

The Ministry of Commerce and Industry, *vide* the Jan Vishwas (Amendment of Provisions) Bill, 2025 (**Jan Vishwas Amendment Bill**), introduced in the Lok Sabha on August 18, 2025, has proposed decriminalisation of certain offences related to Ayurveda, Siddha, and Unani drugs under the Drugs Act. The Jan Vishwas Amendment Bill seeks to amend sub-section (2) of Section 33-I of the Drugs Act by replacing imprisonment terms of up to six months with enhanced monetary penalties of not less than INR 30,000 (Rupees Thirty Thousand). The proposed amendments eliminate custodial sentences for contraventions involving misbranded, adulterated, or unlicensed AYUSH drugs, while retaining deterrence through increased financial penalties. The Jan Vishwas Amendment Bill builds upon the Jan Vishwas Act, 2023 framework, expanding decriminalisation across 16 (sixteen) Central Acts administered by 10 (ten) Ministries to promote ease of doing business and improve regulatory compliance in the traditional medicine sector.The Ministry of Commerce and Industry, *vide* the Jan Vishwas (Amendment of Provisions) Bill, 2025 (**Jan Vishwas Amendment Bill**), introduced in the Lok Sabha on August 18, 2025, has proposed decriminalisation of certain offences related to Ayurveda, Siddha, and Unani drugs under the Drugs Act. The Jan Vishwas Amendment Bill seeks to amend sub-section (2) of Section 33-I of the Drugs Act by replacing imprisonment terms of up to six months with enhanced monetary penalties of not less than INR 30,000 (Rupees Thirty Thousand). The proposed amendments eliminate custodial sentences for contraventions involving misbranded, adulterated, or unlicensed AYUSH drugs, while retaining deterrence through increased financial penalties. The Jan Vishwas Amendment Bill builds upon the Jan Vishwas Act, 2023 framework, expanding decriminalisation across 16 (sixteen) Central Acts administered by 10 (ten) Ministries to promote ease of doing business and improve regulatory compliance in the traditional medicine sector.

[12] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2157460.

9. Department of Consumer Affairs clarifies compliance requirements for revised MRP declarations for pre-packaged commodities following GST rate reduction[13]

The Ministry of Consumer Affairs, Food and Public Distribution, through Department of Consumer Affairs (**DoCA**), *vide* letter bearing reference I-10/14/2020-W&M, dated September 18, 2025, has issued a superseding circular applicable to pre-packaged commodities, replacing the earlier advisory dated September 9, 2025[14]. This clarification follows multiple representations from industry and trade associations regarding the implementation of revised pricing post-GST revision. The circular affirms that under the Legal Metrology (Packaged Commodities) Rules, 2011 (**LMPC Rules**), manufacturers, packers, and importers are not mandated to affix revised price stickers on unsold packages manufactured before September 22, 2025, making such price revisions entirely voluntary. Additionally, the circular permits the continued use of packaging material printed with pre-revision prices, provided it is not exhausted before the GST change. Such material may be used until March 31, 2026, or until stocks are exhausted, whichever is earlier.

This framework enables businesses dealing in pre-packaged commodities to sell existing inventory with original maximum retail price (**MRP**) declarations during an extended transitional period. However, the advisory provides requires that manufacturers and packers communicate the GST reduction clearly to wholesale dealers and retailers, with a copy of such communication endorsed to the relevant authorities as prescribed under law. The clarification offers operational flexibility while helping businesses manage inventory and compliance challenges during the GST implementation phase.

10. The Ministry of Environment, Forest and Climate Change releases pharma and environmental regulatory updates; marks key developments for healthcare and life sciences

a. *Environment Audit Rules, 2025*[15]

The Ministry of Environment, Forest and Climate Change (**MoEF&CC**), *vide* notification G.S.R. 3973(E) dated August 29, 2025, has notified the Environment Audit Rules, 2025, effective upon publication in the *Official Gazette*. These rules establish a structured framework for the certification and registration of environment auditors to assess compliance of projects, activities, and processes under applicable environmental regulations. Certification shall be granted through two pathways: Recognition of Prior Learning (**RPL**), based on relevant experience for a limited period, and the National Certification Examination (**NCE**), a formal assessment process. Registrations will be valid for five (5) years, with renewals subject to criteria outlined by the Central Government. The Central Government will notify Designated Environment Audit Agencies based on eligibility norms and performance-linked tenure renewal. A Steering Committee, chaired by the Additional Secretary of MoEFCC and comprising representatives from the Impact Assessment Division, Forest and Wildlife Division, CPCB, and Regional Offices, will oversee the implementation, monitoring, and supervision of these rules.

b. *Van (Sanrakshan Evam Samvardhan) Amendment Rules, 2025*[16]

The MoEF&CC, *vide* notification G.S.R. 593(E) dated August 31, 2025, has notified the Van (Sanrakshan Evam Samvardhan) Amendment Rules, 2025, effective upon publication in the *Official Gazette*. The amendments redefine forest clearance terminology as "Stage-I" and "Stage-II" approvals and clarify working permissions for linear projects to exclude black topping, railway track laying, and transmission line energisation. Non-official committee members may now resign *vide* written notice, with automatic vacancy creation. Approval validity has been extended from 2 (two) to 5 (five) years, with scope for discretionary renewal. Exemptions now cover critical and strategic minerals under the Mines and Minerals Act, 1957, while requiring threefold compensatory afforestation for non-critical minerals in states with forest cover below 33 per cent. Enforcement provisions mandate legal action by Divisional Forest Officers within 45 days of violations, with periodic reporting to Regional Offices.

[13] https://consumeraffairs.gov.in/public/upload/admin/cmsfiles/whatsnews/GST_revision_-_Permission_by_Central_Govtunder_Rules_33_of_the_Legal_Metrology_Packaged_Commodities_Rules2011to_relax_provisions_contained_in_Rule_183_whatsnews.pdf
[14] https://consumeraffairs.gov.in/public/upload/admin/cmsfiles/whatsnews/Permission_to_the_manufacturers_or_packers_or_importers_of_pre-packaged_commodities_to_declare_the_revised_retail_sale_price_MRP_on_the_unsold_stock_-Change_in_GST_rates_of_GoodsServices_-_reg_whatsnews.pdf
[15] https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/sep/doc202593627401.pdf
[16] https://parivesh.nic.in/publicdocument/UPLOAD_OM_NOTIFICATION/FC_DOCS/2007_11092025033553.pdf

c. *MoEFCC revises Pulp and Paper Industry Environmental Standards*[17]

The MoEF&CC, *vide* notification G.S.R. 612(E) dated September 4, 2025, has notified the Environment (Protection) Seventh Amendment Rules, 2025, effective after two (2) years from the date of publication in the *Official Gazette*. The amendment substitutes serial number 14 in Schedule-I of the Environment (Protection) Rules, 1986, introducing detailed standards for the pulp and paper industry, including effluent discharge norms, freshwater consumption limits, and emission thresholds. The revised norms distinguish between chemical pulp mills and recycled fibre-based mills, prescribing parameters for pH, suspended solids, biological and chemical oxygen demand, and freshwater usage ranging from 10 to 50 m^3 per tonne of product. Emission limits include odorous emissions of hydrogen sulphide (H_2S) capped at 10 mg/Nm^3 and particulate matter from chemical recovery plant boilers restricted to 100 mg/Nm^3. These standards shall not apply to the Rayon Grade Pulp industry.

11. Central Drugs Standards Control Organisation (CDSCO) Updates

a. *CDSCO issues guidance document outlining roles, responsibilities, and procedural frameworks of SECs in pharmaceutical evaluations*[18]

The CDSCO, *vide* the Subject Expert Committees (**SEC**) Guidance Document Version 1.0 dated July 17, 2025, has notified detailed guidelines outlining the roles, responsibilities, and procedural frameworks of SECs in pharmaceutical evaluations. The document standardises protocols for scientific assessment, risk-benefit analysis, and regulatory compliance across therapeutic areas, promoting fairness and consistency in review processes. Key provisions include timely preparation of meeting minutes within seven working days, justified recommendations for clinical trial waivers, and adherence to defined timelines for expedited approvals. The guidance emphasises consensus-based decision-making, robust conflict-of-interest management, and data integrity, thereby strengthening regulatory transparency and efficiency.

b. *CDSCO launches new online dual use system on SUGAM Portal*[19]

The CDSCO, *vide* circular issued by the Drugs Controller General of India (**DGCI**) dated August 1, 2025, has notified the introduction of a new online dual use No Objection Certificate (**NOC**) system through the SUGAM Portal, effective August 31, 2025. The system follows a two-step process: registration on the portal followed by NOC application at zonal offices, with approvals valid for one (1) year, subject to conditions for bulk imports of non-medicinal drugs. Applicants must complete fresh registration with supporting documents, including address proof, undertakings, and authorised personnel details. Clearance applications must be submitted at least two (2) months prior to import and will undergo technical review by Deputy Drugs Controllers. The framework excludes drugs intended for purification or sterilisation, aiming to strengthen regulatory compliance and facilitate ease of doing business.

c. *CDSCO excludes voglibose 0.2 mg+metformin Hcl 500mg from list of 35 new drugs*[20]

The CDSCO, *vide* File N. 4-01/2023 – DC (Misc.), dated September 10, 2025, has notified that the antidiabetic fixed dose combination (FDC) of voglibose 0.2 mg and metformin HCl 500 mg (sustained release form) has been approved and accordingly excluded from the list of 35 new drugs issued in April 2025. This position was recorded by the High Court of Delhi *vide* its order dated July 14, 2025, passed in W.P.(C) 8848/2025. The clarification removes regulatory ambiguity and provides certainty for manufacturers and distributors of this widely used antidiabetic formulation.

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

a. *Office Memorandum on monitoring of annual increase in MRP of non-scheduled formulations*[21]

The NPPA, *vide* Office Memorandum No. 21(01)/ 2025/ Div-III/ NPPA/ 1 dated July 22, 2025, has directed all stakeholders to align prices of non-scheduled formulations to ensure compliance with the annual price

[17] https://cpcb.nic.in/uploads/Industry-Specific-Standards/Effluent/PulpandPaper.pdf
[18] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/SEC%20guidance%20document.pdf
[19] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Dual%20Use%20NOC%20Circular.pdf
[20] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Corrigendum%20to%20the%20letter%20dated%2011.04.2025FDC.pdf
[21] https://nppa.gov.in/uploads/tender/df307ca74333039353fc3c275745127d.pdf

increase limitations under provisions of the Drugs (Price Control) Order, 2013 (**DPCO 2013**). The directive issued to address concerns over arbitrary pricing practices, mandates that the difference in MRP shall not exceed 10 per cent from the previous year, as stipulated under Paragraph 20 of the DPCO 2013. The NPPA has emphasised that any violation of these pricing parameters will attract penal action under the DPCO 2013 and Section 7 of the Essential Commodities Act, 1955 (**EC Act**). This directive aims to prevent excessive price increases while allowing reasonable market adjustments, thereby ensuring that pricing practices for non-scheduled formulations remain within regulatory bounds to safeguard consumer interests.

b. *NPPA on re-stickering and re-labelling pursuant to goods and services tax (GST) revisions*

The NPPA, *vide* Office Memorandums dated September 12, 2025,[22] and September 13, 2025,[23] clarified that all manufacturers and marketing companies: (i) selling drugs or formulations (including medical devices) should revise the MRP accordingly; (ii) must issue a revised or supplementary price list in Form V/VI to dealers and retailers for consumer display, and to State Drug Controllers and the Government, reflecting the revised GST rates and MRP; and (iii) if able to ensure price compliance at the retailer level, do not have to recall, re-label, or re-sticker containers or packs of stock released in the market prior to September 22, 2025.

c. *NPPA retail price fixation for 71 new drug formulations under DPCO 2013*[24]

The NPPA, *vide* notification S.O. 3001(E) dated July 4, 2025, has notified the retail price fixation for 71 (seventy-one) new drug formulations under the DPCO 2013. The notification establishes mandatory retail prices for pharmaceutical formulations, with prices ranging from INR 4.08 to INR 35.19 per unit excluding GST.

d. *NPPA separate price fixation for GlaxoSmithKline's paracetamol-phenylephrine sachet formulation*[25]

The NPPA, *vide* notification S.O. 2999(E) dated July 4, 2025, has notified the separate price fixation for Paracetamol I.P. 500 mg and Phenylephrine HCI I.P. 10 mg formulation under DPCO 2013. This notification follows recommendations from the Multi disciplinary Committee of Experts, which cited claimed advantages such as faster solubility, improved safety, and enhanced efficacy. Pursuant to paragraph 11(3) of DPCO 2013 and based on market data, the Authority fixed a retail price of INR 6.96 per sachet (exclusive of GST) for the specified formulation.

[22] https://nppa.gov.in/uploads/tender/01da3cf0cd3d17c68c9a63fe23878260.pdf
[23] https://nppa.gov.in/uploads/tender/12fbbb0cb337f1d2d70afb3fbcb57f39.pdf
[24] https://nppa.gov.in/uploads/tender/b84c87bfcc4e6d6788482ab161474c08.pdf
[25] https://nppa.gov.in/uploads/tender/75d29bebb2daf2afeba5135b6e42f8f5.pdf

e. *NPPA addendum to ringer lactate ceiling price orders*[26]

The NPPA, *vide* notification S.O. 2998(E) dated July 4, 2025, has notified the addendum to ceiling price fixation orders for scheduled formulation packs of Ringer Lactate (non-Glass with special features). The addendum amends NPPA Order No. 1474(E) dated March 27, 2025, by adding M/s Cartel Lifescience Pvt. Ltd. as SI. No. 22 in Table B with their product "Dual Port Cap". Specific pricing provisions establish that for M/s Cartel Lifescience Pvt. Ltd., the approved price for formulations specified at SI. No. 3 of Table A is INR 64.29 per pack excluding GST.

f. *NPPA addendum to IV fluids ceiling price orders*[27]

The NPPA, *vide* notification S.O. 3000(E) dated July 4, 2025, has notified the addendum to ceiling price fixation orders for scheduled formulation packs of I.V. fluids (non-Glass with special features). The addendum amends NPPA Order No. 1485(E) dated March 27, 2025, by adding M/s Cartel Lifescience Pvt. Ltd. as SI. No. 29 in Table B with their product "Dual Port Cap". Specific pricing provisions establish that for M/s Cartel Lifescience Pvt. Ltd., the approved prices for formulations specified at SI. No. 2, 4, 5, and 7 of Table A are INR 82.24, INR 85.49, INR 42.05, and INR 87.90 per pack excluding GST, respectively.

g. *NPPA price fixation notification for 37 pharmaceutical formulations*[28]

The NPPA, *vide* notification S.O. 3563(E) dated August 1, 2025, has notified the price fixation order for 37 (thirty-seven) pharmaceutical formulations under the DPCO 2013. The NPPA fixed retail prices exclusive of GST for various formulations including combination tablets, oral suspensions, capsules, and injections with specific strengths and designated manufacturer-marketing company partnerships. The notification mandates manufacturers to comply with pricing provisions, permits GST addition only upon actual payment to government, requires price list submission in Form-V through IPDMS to NPPA and State Drug Controllers, and establishes display requirements for retailers and dealers. Non-compliance with the prescribed retail prices renders manufacturers liable to deposit overcharged amounts with interest under DPCO 2013 provisions read with the EC Act.

h. *NPPA price fixation notification for 4 pharmaceutical formulations*[29]

The NPPA, *vide* notification S.O. 3562(E), dated August 1, 2025, has notified the price fixation order for 4 (four) pharmaceutical formulations under the DPCO 2013. The notification exercises powers fixing the ceiling prices exclusive of GST for Ipratropium respirator solution (INR 2.96 per ml), Sodium nitroprusside injection (INR 28.99 per ml), Povidone iodine ointment (INR 6.26 per gm), and Diltiazem modified release capsule (INR 26.72 per capsule).

i. *NPPA retail price fixation for 42 pharmaceutical formulations under DPCO 2013*[30]

The NPPA, *vide* notification F. No. 8(136)/2025/D.P./NPPA-Div-II, dated August 29, 2025, has notified the retail price fixation for "new drug" formulations under the DPCO 2013. The notification establishes fixed retail prices for 42 (forty-two) pharmaceutical formulations including combination tablets, capsules, injections, and oral suspensions covering cardiovascular, antidiabetic, antibiotic, and other therapeutic categories. Manufacturers of these formulations under Paragraph 2(1)(u) of DPCO 2013 are mandated to fix retail prices as specified in the notification tables.

j. *NPPA extends ceiling price validity for orthopaedic knee implants*[31]

The NPPA, *vide* notification S.O. 4171(E) dated September 15, 2025, has notified the extension of ceiling prices for orthopaedic knee implants for knee replacement system. The NPPA has extended the validity period of notification S.O. 3869(E) dated September 10, 2024, for a further period of 2 (two) months beyond September 15, 2025, effective until November 15, 2025.

k. *NPPA fixes MRP for nine pharmaceutical formulations*[32]

The NPPA, *vide* notification S.O. 4170(E) dated September 15, 2025, has notified the DPCO 2013 to fix maximum retail prices for nine specific pharmaceutical formulations. The notification establishes retail prices ranging from INR 0.55 to INR 34.50 for various combination tablets and suspensions including

[26] https://nppa.gov.in/uploads/tender/09451f3d7bcf01f848bfb05fb8bbb355.pdf
[27] https://nppa.gov.in/uploads/tender/85db47327f3fba9670dfe37b03b04420.pdf
[28] https://nppa.gov.in/uploads/tender/cbf3d0a2698376fb59bcd0d375b1fb99.pdf
[29] https://nppa.gov.in/uploads/tender/3a10f1fb8e6460318be708edddc9bcbe.pdf
[30] https://nppa.gov.in/uploads/tender/0433569a60c2e240d7cd9e5c8243e6ca.pdf
[31] https://nppa.gov.in/uploads/tender/5d22e8d2bfe64a17f91cd02520f1f66a.pdf
[32] https://nppa.gov.in/uploads/tender/b030fb3c3ca505b363f0ce02a1e51e16.pdf

Aceclofenac-Paracetamol-Thiocolchicoside, Ibuprofen-Paracetamol, and diabetes medications containing Dapagliflozin, Sitagliptin, Glimepiride, and Metformin.

13. Notifications/Orders/Circulars regarding food safety standards by Food Safety and Standards Authority of India (FSSAI)

a. *Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2025*[33]

The FSSAI, *vide* notification F. No. STD/43-FA-Notifications / 2024 dated July 10, 2025, has notified the Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2025. The amendments revise refractive index parameters for various edible oils, namely specifying measurement ranges between 40 degrees Celsius and 50 degrees Celsius. Comprehensive standards for meat sausages have been introduced, covering fresh, cooked, smoked, and fermented types, with detailed compositional and processing requirements. Technical revisions remove contamination-related notes from clauses on synthetic food colours, namely Sunset Yellow, Erythrosine, Indigo Carmine, Ponceau 4R, Carmoisine, Brilliant Blue FCF, and Fast Green FCF. The regulations also introduce six genetically modified microorganism-derived enzymes, namely Phospholipase A2, Lysophospholipase, Lipase triacylglycerol, Glucose Oxidase, Serine endopeptidase, and Chymosin, for food processing applications, subject to stringent quality criteria.

b. *Food Safety and Standards (Labelling and Display) Amendment Regulations, 2025*[34]

The FSSAI, *vide* notification F. No. SS-T017/1/2023-Standard-FSSAI dated August 8, 2025, has notified the Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2025. Effective from July 1, 2026, the regulations substitute subparagraph 2.2 in Schedule II, revising labelling requirements for coffee chicory mixtures. Packages must display either "coffee blended with chicory this mixture contains ___ per cent coffee and _____ per cent chicory" or an equivalent format indicating specific percentages on the front panel. Instant coffee chicory mixtures must declare "instant coffee chicory mixture made from blends of coffee and chicory" with corresponding percentages prominently shown. These amendments follow a 60-day public consultation period commencing February 20, 2025.

c. *FSSAI Order in relation to special festive drive to ensure food safety, quality and prevention of adulteration during the month of September–October, 2025*[35]

The FSSAI, *vide* letter reference RCD 02001/216/2025 Regulatory FSSAI dated September 23, 2025, addressed to Commissioners of all States and Union Territories and Regional Directors of FSSAI, launched a special festive drive to ensure food safety, quality, and prevention of adulteration during September and October 2025. Following increased demand for sweets, savouries, and milk-based products such as *ghee*, *khoa*, and *paneer*, all State and UT Commissioners and Regional Directors are requested to conduct targeted surveillance and enforcement activities, particularly in sensitive locations. Food Safety on Wheels units, wherever available, should be strategically deployed in key marketplaces or based on intelligence inputs to facilitate on-the-spot testing, enhance vigilance, and build consumer confidence. As per the contents of the letter, all inspection and sampling data must be mandatorily updated on FoSCoS or FoSCoRIS by November 15, 2025.

[33] https://fssai.gov.in/upload/notifications/2025/07/6879d8af12522Palm%20Oil_FPSFA_Notification.pdf
[34] https://fssai.gov.in/upload/notifications/2025/08/689d8d163d422coffee%20chicory_gazette.pdf
[35] https://fssai.gov.in/upload/advisories/2025/09/68d3851dc1cb2Letter%20dated%2023rd%20Septemeber%202025_Special%20Festive%20Drive.pdf

News Updates

1. U.S. Tariff Alert: President Trump announces 100 per cent duty on branded and patented pharma imports without Executive Order, raises industry concerns[36]

On September 25, 2025, U.S. President Donald Trump announced via Truth Social that a 100 per cent tariff would be imposed on all branded and patented pharmaceutical imports effective October 1, 2025, unless the manufacturer is building a production facility in the United States. The term "IS BUILDING" has been defined as "breaking ground" or "under construction". This sweeping measure aims to push pharmaceutical manufacturing onshore but has raised concerns over its scope and impact. Reports suggest that only a clear executive order can clarify which types of pharmaceutical imports may drive up U.S. prescription costs, as the announcement does not clearly define whether "branded" drugs are limited to patented products or include a broader category. The ambiguity has triggered uncertainty among industry stakeholders and policymakers.

2. Standing Committee issues report on health hazards due to use of compromised/substandard quality of food-grade plastics[37]

On August 20, 2025, the Parliamentary Standing Committee on Chemicals and Fertilisers issued its 13th report titled *"Health Hazards due to use of compromised/substandard quality of food-grade plastics and their exposure to extreme Indian climatic conditions"* addressing critical gaps in food safety enforcement and packaging regulations (**PSC Report**). The report underscores several areas requiring urgent regulatory intervention.

a. *Emphasis on the substantive role of FSSAI in the implementation of Food Safety and Standards Packaging Regulations, 2018*[38]

The Committee noted that FSSAI has been entrusted with implementing the Food Safety and Standards (Packaging) Regulations, 2018 (**FSS (Packaging) Regulations**) through issuing regulations, ensuring compliance through inspection, and creating awareness by training food handlers. The Committee recommended that FSSAI strengthen implementation and develop a roadmap to enforce the regulations strictly. This recommendation underscores persistent gaps in food safety enforcement infrastructure and highlights the need for FSSAI to move beyond regulatory formulation towards robust implementation mechanisms.

[36] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/trump-pharma-tariff-india-impact-white-house-executive-order-america-medical-bills-nifty-pharma-sun-pharma-cipla-zydus-share-price/articleshow/124143168.cms?from=mdr
[37] https://sansad.in/getFile/lsscommittee/Chemicals%20&%20Fertilizers/pr_files/Press%20Release%20of%20Twelfth%20and%20Thirteenth%20Report%20(Final).pdf?source=loksabhadocs
[38] https://sansad.in/getFile/lsscommittee/Chemicals%20&%20Fertilizers/18_Chemicals_And_Fertilizers_13.pdf?source=loksabhadocs

b. *Concern over migration of plastic and nano plastic in the food contents*[39]

The PSC Report raised concerns that, while food contents may meet FSSAI quality standards, contamination could occur during packaging, storage, or transportation, particularly when exposed to high temperatures. The Committee noted that no specific authority has been designated to monitor contamination resulting from plastic migration and recommended appointing a dedicated body to ensure such migration remains within permissible limits. This highlights a critical regulatory gap in India's food safety framework, where oversight ends at manufacturing and does not adequately extend to post-production conditions, posing significant public health risks given the country's extreme climatic variations.

c. *Concern over lack of framework for safety of biodegradable and compostable plastics used for packaging*[40]

The PSC Report noted that the Food Safety and Standards (Packaging) Regulations primarily focus on conventional packaging materials, while a comprehensive framework addressing the safety of biodegradable and compostable plastics, testing methods, and migration limits for emerging chemicals such as Bisphenol A (**BPA**), perfluorinated alkyl substances (**PFAS**), and phthalates remains under deliberation by FSSAI's Scientific Panel on Packaging. The Committee recommended that FSSAI issue a detailed framework enforcing zero tolerance for plastic contamination in food-packaging processes. As India advances toward sustainable packaging alternatives, the absence of safety standards for biodegradable materials creates regulatory uncertainty that could inadvertently compromise food safety while pursuing environmental goals.

d. *BIS to establish standards for food-grade bowls and utensils*[41]

The PSC Report noted serious concerns regarding the absence of Bureau of Indian Standards (**BIS**) for food-grade bowls and spoons. The Committee urged BIS to expedite the working panel's findings and complete the study within the stipulated two months. The absence of basic standards for commonly used food contact materials reflects systemic delays in India's standardisation processes and exposes millions to potential health risks.

3. Standing Committee Report raises concern over food safety and quality standards[42]

On August 20, 2025, the Department-related Parliamentary Standing Committee on Agriculture, Animal Husbandry, and Food Processing, chaired by Mr. Chanranjit Singh Channi, presented its report on initiatives taken in the food processing sector under the "Make in India" programme. The Committee noted that the proportion of non-conforming food samples remains persistently high each year and strongly urged the FSSAI to intensify nationwide compliance efforts, ensure adequate personnel deployment with regular training, and explore debarring or blacklisting individuals instead of units engaged in adulteration. The persistently high rate of non-conforming samples points to systemic enforcement challenges within India's food safety ecosystem, and the proposed shift towards individual accountability rather than institutional penalties could prove more effective in deterring violations and strengthening deterrence mechanisms across the supply chain.

4. Standing Committee of Finance Report recommends further decentralisation of Ayushman Bharat Scheme[43]

On August 18, 2025, the Standing Committee on Finance, chaired by Mr. Bhartruhari Mahtab, submitted its report titled *"Roadmap for Indian Economic Growth in Light of Global Economic and Geopolitical Circumstances"*. The Committee acknowledged notable progress in expanding affordable healthcare under the National Health Mission. It recommended that health services under the Ayushman Bharat scheme be further decentralised through mobile health units and telemedicine hubs, especially in tribal and hilly regions, to improve outreach and address gaps in accessibility. Although Ayushman Bharat has significantly expanded coverage since its inception, last-mile connectivity challenges persist in remote and difficult terrains. The Committee's emphasis on mobile and telemedicine-based solutions reflects an understanding

[39] Same as Footnote 38
[40] Same as Footnote 38
[41] Same as Footnote 38
[42] https://sansad.in/getFile/lsscommittee/Agriculture,%20Animal%20Husbandry%20and%20Food%20Processing/18_Agriculture_Animal_Husbandry_and_Food_Processing_21.pdf?source=loksabhadocs
[43] https://sansad.in/getFile/lsscommittee/Finance/18_Finance_26.pdf?source=loksabhadocs

that traditional infrastructure models face inherent limitations in overcoming geographical and topographical barriers to healthcare delivery.

5. AYUSH ministry and FSSAI jointly release official list of approved "Ayurveda Ahar" products[44]

On July 25, 2025, the Union Ministry of Ayush and the FSSAI jointly released an official list of approved "Ayurveda Ahar" products, marking a significant step toward popularising Ayurvedic dietary principles and promoting preventive health. The list features over 90 (ninety) dishes and preparations drawn from classical Ayurvedic texts such as *Bhojanakutuhalam*, *Bhavaprakasham*, and *Kshemakutuhalam*. It includes 21 (twenty-one) varieties of curd and buttermilk preparations, 4 (four) types of soups, 14 (fourteen) types of panakam, along with well-known items like *khichdi* and *gulkhand*. This initiative reflects a strategic convergence of traditional knowledge and modern food regulation, potentially unlocking new market opportunities for manufacturers while responding to growing consumer demand for wellness-oriented food products.

6. CDSCO and Indian Council of Medical Research jointly released a compendium of Standard In Vitro Diagnostic Evaluation Protocols[45]

The CDSCO, in collaboration with the ICMR, has issued a compendium of Standard In Vitro Diagnostic (**IVD**) Evaluation Protocols covering tuberculosis, malaria, dengue, chikungunya, Zika virus, typhoid fever, various respiratory viruses, Chandipura virus, and Nipah virus. These protocols establish comprehensive evaluation frameworks and define minimum standards and acceptance criteria for critical disease markers, aimed at accelerating the availability of high-quality diagnostic products while ensuring regulatory consistency. The standardisation of IVD evaluation protocols addresses a critical gap in India's diagnostic ecosystem, particularly for infectious diseases of public health significance, and is expected to enhance regulatory predictability, improve product quality, and expedite market access for manufacturers while safeguarding patient safety.

7. CDSCO issues clarification on licensing approvals for combi-pack of lyophilised injections and diluents[46]

The CDSCO has clarified that if the CDSCO has approved lyophilised dry powder for injection for more than four years with a specific diluent, then a combi-pack including the same approved diluent will not be considered a new drug. In such cases, the State Licensing Authority (**SLA**) may issue the licence without requiring additional CDSCO approval. However, if the lyophilised powder is paired with a different diluent, the product will be classified as a new drug and will require prior approval under the NDCT Rules. This clarification provides regulatory certainty for manufacturers by clearly distinguishing between established combinations and novel diluent formulations, thereby streamlining the approval process while maintaining oversight of genuinely new products.

8. Government to launch the Promotion of Research and Innovation in Pharma MedTech sector scheme[47]

The Government of India is preparing to formally launch the Promotion of Research and Innovation in Pharma MedTech Sector (**PRIP**) scheme, notified in August 2023 with a total financial outlay of INR 5,000 crore. News reports suggest that INR 4,250 crore of this outlay has been earmarked for accelerating research and development investments in the pharmaceutical and medical technology sectors. The scheme will cover pharma and medtech equally, with both early-stage and late-stage funding support ranging from 35 per cent to 50 per cent) of eligible project costs. The PRIP scheme represents a significant policy commitment to building India's innovation capacity in healthcare and could catalyse domestic R&D activity, reduce import dependence for critical therapies, and position India as a global innovation hub in pharmaceuticals and medical devices.

9. DCGI invites comments on consideration of problems faced by the blind / visually impaired people to read medicines[48]

The Directorate General of Health Services (**DGHS**) has invited stakeholder comments on proposals to address

[44] https://www.pharmabiz.com/NewsDetails.aspx?aid=180695&sid=1
[45] https://medicalbuyer.co.in/icmr-cdsco-roll-out-compendium-of-39-standard-ivd-evaluation-protocols/
[46] https://www.expresspharma.in/cdsco-clarifies-regulatory-pathway-for-combi-pack-approvals-of-lyophilized-injections-diluents/
[47] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/scheme-to-promote-innovation-in-pharma-medtech-sectors-to-be-launched-this-month-pharma-secretary/articleshow/123917828.cms
[48] cdsco.mohfw.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMyNzM=

problems faced by blind or visually impaired persons in reading medicine tablets and capsule strips. The proposals under consideration include additional labelling in Braille on a voluntary basis, increasing mandated font size and spacing on packaging, ensuring availability of information leaflets in accessible formats, and incorporating QR codes on medicines linked with voice assistance technology. This initiative reflects growing recognition of accessibility as a fundamental aspect of pharmaceutical regulation and patient safety, and could significantly improve medication safety, independence, and therapeutic adherence among visually impaired patients, who constitute a substantial yet often overlooked segment of the patient population.

10. DGFT notifies two new SIONs under chemical & allied products to expedite pharma export approvals[49]

The Directorate General of Foreign Trade (**DGFT**) has notified two new Standard Input Output Norms (**SIONs**), numbered A-3693 and A-3694, under the chemical and allied products category. These norms empower Regional Authorities to issue Advance Authorisation directly, without referring cases to the Norms Committee. SION A-3693 pertains to minoxidil topical aerosol 5 per cent (Foam), 60 g, while SION A-3694 relates to benfotiamine for export purposes. The introduction of these product-specific SIONs is expected to streamline export procedures, reduce processing time, and enhance India's competitiveness in global pharmaceutical markets, in line with the Government's broader export promotion objectives.

11. DGFT amends Import Policy condition of ATS -8 restricting its import till September 30, 2026[50]

The DGFT has issued a notification restricting the import of ATS-8 (4r-cis)-1,1-dimethylethyl-6-cyanomethyl-2,2-dimethyl-1,3-dioxane-4-acetate with a CIF value of less than USD 111 per kg, effective immediately and valid until September 30, 2026. However, imports by Advance Authorisation Holders, Export-Oriented Units (**EOUs**), and Special Economic Zones (**SEZs**) are exempt from this restriction. The measure is aimed at protecting domestic manufacturers from predatory pricing and dumping practices, while preserving supply chain flexibility for export-oriented units, striking a balance between safeguarding domestic industry and supporting export competitiveness.

12. Government adds Rare Diseases as a focus area under the Production-Linked Incentive (PLI) Scheme for Pharmaceuticals[51]

At the Rare Diseases Conference 2025, Amit Agrawal, Secretary of the DoP, announced that rare diseases have been formally included as a priority area under the Production-Linked Incentive (**PLI**) Scheme for Pharmaceuticals. This strategic inclusion has enabled support for eight drugs targeting rare conditions, notably including *"Eliglustat"* for Gaucher's Disease. As per the DoP's data, domestic manufacturing of Eliglustat has led to a dramatic reduction in annual treatment costs, from INR 1.8-3.6 crore to just INR 3-6 lakh. This over 90 (ninety) per cent cost decline highlights the transformative impact of targeted industrial policy in making high-cost therapies more affordable for patients with rare diseases, many of whom have long struggled with severe financial burdens due to reliance on imported treatments.

13. NABH launches MITRA Empanelment Programme to boost accreditation support in smaller cities[52]

The National Accreditation Board for Hospitals and Healthcare Providers (**NABH**) has launched the NABH MITRA Empanelment Programme (**MEP**) to empanel individuals and organisations known as MITRAs to assist healthcare institutions achieve NABH Accreditation, Certification and Digital Health Transformation. As per reports, the initiative

[49] https://www.pharmabiz.com/NewsDetails.aspx?aid=180884&sid=1
[50] https://www.thehindubusinessline.com/economy/policy/india-imposes-import-restrictions-on-key-pharma-chemical-till-sept-2026/article70072628.ece
[51] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2158801
[52] https://nabh-portal-live.s3.ap-south-1.amazonaws.com/wp-content/uploads/2025/09/10163615/Announceme-of-MITRA-EmpalenmetProgram.pdf

is designed to empower healthcare facilities in Tier 2, 3, and 4 cities by connecting them with verified, trained, and ethical consultants and advisors. This programme addresses a critical barrier to quality accreditation in smaller cities, the lack of accessible expertise and technical support, and is expected to accelerate accreditation uptake beyond metropolitan centres, thereby improving healthcare quality standards across India's diverse healthcare landscape.

14. NABL issued formal clarification on usage of accreditation symbol by laboratories[53]

The National Accreditation Board for Testing and Calibration Laboratories (**NABL**) has issued a formal clarification regarding the use of its logo and accreditation symbol. As per NABL 133 policy, the NABL logo is to be used exclusively by NABL itself, and accredited laboratories must strictly comply with the prescribed guidelines governing the use of the NABL symbol. The clarification states that any Conformity Assessment Body placed under suspension, withdrawal, or expiry of accreditation must immediately cease issuing certificates bearing the NABL symbol and discontinue any documentation referencing NABL accreditation status. This directive comes in response to rising concerns over misrepresentation of accreditation by certain laboratories, which poses a risk to public trust in laboratory testing and threatens the credibility of the national accreditation framework.

15. Delhi DCA issues notice to chemist associations on misuse of pregabalin & tapentadol formulations[54]

On August 14, 2025, the Drug Control Administration (**DCA**) of the National Capital Territory of Delhi issued a notice to all chemists and druggists associations in response to rising concerns over the misuse of *"pregabalin"* and *"tapentadol"* formulations. The advisory directed retail chemists to immediately halt over-the-counter (**OTC**) sales of these prescription medicines, maintain accurate stock records, and ensure strict adherence to the Drugs Rules. The DCA cautioned that firms found in violation of these directives would face stringent penal action under applicable legal provisions. This move reflects increasing awareness of pharmaceutical drug abuse in India, particularly involving prescription drugs with high abuse potential, and highlights the need for heightened vigilance in retail pharmacy operations to prevent diversion of controlled substances.

16. 56th GST council meeting recommends reduction of GST on all drugs, devices, and medical products[55]

The GST Council, in its 56th meeting held in New Delhi and chaired by Union Finance Minister Nirmala Sitharaman, implemented significant tax reforms effective 22 September 2025, reducing the GST rate on all drugs and medical devices to 5 per cent and granting full exemption to 36 (thirty-six) life-saving medicines. These include treatments for cancer, rare diseases, and severe chronic conditions, with three drugs, Agalsidase Beta, Imiglucerase, and Eptacog Alfa, moved from 5 per cent to exempt status, and 33 others reduced from 12 per cent to 5 per cent. The Council also lowered GST on a wide range of medical apparatus and supplies, such as diagnostic kits, reagents, bandages, and glucometers. The Ministry of Finance clarified that full exemption on all medicines would eliminate input tax credit for manufacturers, potentially increasing production costs and retail prices. While the rate cuts may deepen existing inverted duty structures, refund mechanisms remain available, and the reforms aim to make healthcare more affordable and accessible, particularly for economically vulnerable populations.

17. State Drugs Authorities of Delhi and Jharkhand issue instructions for necessary compliance with the revised GST rates[56,57]

The Drugs Control Departments of NCT of Delhi and Jharkhand have issued circulars, effective September 22, 2025, implementing the revised GST rates for pharmaceutical products and medical devices following the GST Council's decision at its 56th meeting. The circulars direct manufacturers and marketers to revise MRP in line with the new GST rates and permit label modifications by stamping, stickering, or printing after obtaining a NOC from the SLA under Rule 104A of the Drugs Rules and provide operational guidance to ensure GST reductions translate into consumer price benefits and to maintain regulatory oversight of labelling changes.

[53] https://www.pharmabiz.com/NewsDetails.aspx?aid=181427&sid=1
[54] https://thehealthmaster.com/2025/08/19/advisory-pregabalin-and-tapentadol-misuse/
[55] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2163555
[56] https://drugs.delhi.gov.in/sites/default/files/drugs/circulars-orders/circularrationalizationgst22-09-2025_0.pdf
[57] https://www.pharmabiz.com/NewsDetails.aspx?aid=181171&sid=1

18. World Health Organization updates list of essential medicines to include key cancer, diabetes treatments[58]

The World Health Organization (**WHO**) has published updated editions of its Model Lists of Essential Medicines (**EML**) and Essential Medicines for Children (**EMLC**), incorporating new treatments for conditions such as cancer, diabetes with comorbidities, cystic fibrosis, psoriasis, haemophilia, and other blood-related disorders. The revisions include 20 (twenty) new medicines added to the EML and 15 (fifteen) to the EMLC, along with expanded indications for 7 (seven) existing products. With these updates, the lists now comprise 523 essential medicines for adults and 374 for children, reflecting shifting global health priorities and advances in treatment options. For countries like India that rely on WHO's guidance for national formulary development, these changes may influence essential medicines selection, insurance coverage frameworks, and public procurement strategies.

19. WHO publishes national policy guidance to support equitable access to controlled medicines[59]

The WHO has released its comprehensive guidelines on balanced national policies for controlled medicines, aimed at ensuring access for legitimate medical and scientific use while minimising risks of misuse and diversion. The document outlines evidence-based recommendations across 7 (seven) key areas: policy development, pricing and financing, medicine selection, procurement and supply chain management, regulation, prescribing and dispensing practices, and education. Key measures include needs-based national planning to prevent shortages and oversupply, fair pricing mechanisms, restrictions on misleading marketing, and robust training for healthcare professionals alongside public awareness initiatives. These guidelines are intended to help countries strike an effective balance between enabling access to essential controlled substances and safeguarding public health.

20. Karnataka reduces withdrawal timeline for NSQ drugs from 30 days to just 3 days[60]

In a decisive move to strengthen drug quality enforcement, the Government of Karnataka has significantly reduced the withdrawal timeline for NSQ drugs from 30 days to just 3 days. Following the declaration by the State Food and Drug Administration that 59 samples were found non-compliant with prescribed quality standards, immediate enforcement measures have been initiated. Authorities have issued advisories to retail chemists, wholesalers, hospitals, and the general public to cease stocking the identified products, while medical practitioners have been urged to avoid

[58] https://www.who.int/news/item/05-09-2025-who-updates-list-of-essential-medicines-to-include-key-cancer--diabetes-treatments
[59] https://www.who.int/news/item/19-09-2025-who-publishes-full-guideline-report-to-help-countries-ensure-safe--equitable-access-to-controlled-medicines
[60] https://www.pharmabiz.com/NewsDetails.aspx?aid=180589&sid=1

prescribing these formulations. By shortening the withdrawal period by 90 per cent, Karnataka has set a new precedent in state-level pharmaceutical regulation, underscoring its zero-tolerance approach to substandard medicines and reinforcing its commitment to patient safety and public health.

21. Goa Government launches pricing policy for innovative and life-saving therapies[61]

The Government of Goa has introduced a dedicated pricing policy to enhance access to innovative cancer treatments and therapies for rare diseases. The policy enables the state to procure high-cost medicines from pharmaceutical companies at reduced prices through rebates, provided in the form of credit notes or goods, without modifying the listing price in public tenders. Reports suggest that this mechanism ensures pricing visible to countries referencing India for international benchmarking remains unaffected, while allowing the Government of Goa to obtain necessary concessions for public procurement. The initiative addresses a critical challenge in acquiring advanced therapies by balancing domestic affordability with global pricing sensitivities, which have historically constrained governments' ability to negotiate lower rates without influencing international pricing structures.

22. Bayer becomes first company to advance cell therapy as well as gene therapy against Parkinson's disease[62]

News reports suggest that Bayer has made notable progress on two experimental therapies for Parkinson's disease. The company has initiated patient enrolment in exPDite-2, a Phase III clinical trial evaluating bemdaneprocel, a cell-based therapy developed by its subsidiary BlueRock Therapeutics LP. Simultaneously, the first European participants have been randomised in REGENERATE-PD, a Phase II trial of AB-1005, a gene therapy candidate from AskBio Inc., another Bayer subsidiary. Both therapies target moderate-stage Parkinson's and are being developed independently. Industry observers note that this parallel advancement positions Bayer as the first pharmaceutical company to simultaneously pursue both cell and gene therapy approaches for Parkinson's, marking a significant moment in neurodegenerative disease research.

23. AIOCD seeks regulatory intervention on quick commerce dispensing of Scheduled Drugs[63]

All India Organisation of Chemists & Druggists ("AIOCD") has written to Union Home Minister Amit Shah urging immediate regulatory action to halt the online sale and rapid delivery of prescription medicines by certain e pharmacies and quick commerce platforms. The association alleges these platforms are dispensing Schedule H, H1, and X drugs within minutes without adequate prescription verification, contributing to a reported 55 per cent increase in drug abuse. The AIOCD has called for the closure of non compliant e pharmacies, stricter enforcement of existing regulations, and enhanced oversight of quick commerce operations to address this emerging public health concern. The legal status of these practices remains subject to judicial determination.

24. Gujarat FDCA-ONDCP discuss illegal production and export of narcotic & habit-forming drugs[64]

As part of the FDCA Gujarat–US FDA Regulatory Forum, the Office of National Drug Control Policy, Washington D.C., USA, and the Gujarat Food and Drug Control Administration held discussions on drug trafficking, precursor chemical manufacturing, and the illegal production and export of narcotic and habit-forming drugs derived from pharmaceuticals to the United States. During the visit, both delegations shared their respective national drug control strategies, efforts to curb the use of illicit narcotic and habit-forming substances, approaches to combat illegal manufacturing and trafficking, and concerns related to drug-related crime and violence. The dialogue emphasised strengthening public health outcomes and enhancing international cooperation. This bilateral engagement highlights the growing importance of global regulatory collaboration in addressing pharmaceutical diversion and illicit drug trafficking.

[61] Pricing Policy of Government of Goa For Innovative And Life Saving Therapies – NHM
[62] https://www.bayer.com/media/en-us/bayer-first-company-to-advance-cell-therapy-as-well-as-gene-therapy-against-parkinsons-disease/
[63] Chemists seek ban on quick commerce sale of prescription drugs - The Economic Times 64
[64] https://www.pharmabiz.com/NewsDetails.aspx?aid=180717&sid=1

Litigation Updates

1. Supreme Court of India recognises stem cell banking services as healthcare service and exempts them from service tax [65]

The Supreme Court of India (**SC**), in Civil Appeal Nos. 3816-3817 of 2025, *vide* judgment dated July 14, 2025, held that stem cell banking services, including enrolment, collection, processing, and storage of umbilical cord blood stem cells, fall within the definition of "healthcare services" and are, therefore, exempt from levy of service tax under the Finance Act, 1994. The SC relied on Entry 2 of Notification No. 25/2012-ST dated June 20, 2012, and Entry 2A of Notification No. 4/2014-ST dated February 17, 2014, and stated that healthcare services provided by clinical establishments, including cord blood banks, were exempt from the levy of service tax.

In an appeal preferred against the decision of the Customs, Excise and Service Tax Appellate Tribunal (**CESTAT**), the judgment held that the Appellant's services did not fall within the scope of "healthcare services." The Apex Court interpreted the term broadly, stating that the collection and preservation of stem cells, though preventive in nature, have potential curative applications for future illnesses. It held that processing, testing, cryopreservation, and eventual release for transplantation are integral components of healthcare aimed at future diagnosis, treatment, and care. The Court also referred to an Office Memorandum issued by the MoH&FW dated May 22, 2013, which, in consultation with the National AIDS Control Organisation, clarified that stem cell banking qualifies as a healthcare service and is eligible for exemption. This ruling provides significant clarity on the tax treatment of preventive healthcare services and affirms the therapeutic relevance of stem cell banking within the broader healthcare framework.

2. SC held that the limitation period for offence under Drugs Act starts from receipt of Drug Analyst's Report [66]

The SC, in SLP(CRL.) No(s). 3662-3663 of 2024, *vide* order dated July 29, 2025, held that the period of limitation for offences under the Drugs Act punishable with 3 (three) years' imprisonment must be calculated from the date of publishing of the government analyst's report. The matter pertains to a Drug Inspector's seizure of samples of Rabeprazole Tablets from a medical store in Kozhikode, Kerala, and Government Analyst reports dated March 30, 2010, and April 9, 2010, finding the drugs to be sub-standard. Complaints under Section 32 of the Drugs Act were filed in

[65] Stemcyte India Therapeutics (P) Ltd. v. CCE, Judgement dated July 14, 2025, in (2025) 144 GSTR 662.
[66] Miteshbhai J. Patel and Anr. V. The Drug Inspector and Anr., Order dated July 29, 2025, in SLP(CRL.) No(S). 3662-3663/2024.

June and July 2013, alleging violation of Section 18(a)(i) punishable under Section 27(d). The accused sought dismissal, contending that the complaints were barred by limitation under Section 468(2)(c) of the Code of Criminal Procedure, 1973 (**CrPC**), as samples were collected in January 2010, but the complaints were filed in 2013.

The SC observed that under Section 468(2)[67] of the CrPC, offences punishable with more than one year but up to three years have a three-year limitation period. The SC held that the date of the offence in drug quality cases is the date when the government analyst's report is published, not the date of sample collection. Accordingly, the appeal was allowed. This judgment clarified the critical question of when limitation begins to run in drug quality offences, providing certainty to both enforcement authorities and accused persons.

3. High Court of Delhi directs DCGI to review plea regarding safety and licensing of weight loss drugs[68]

The High Court of Delhi (**Delhi HC**), in W.P. (C) 8773 of 2025, *vide* final order dated July 2, 2025, directed the DCGI to examine regulatory concerns raised in a public interest litigation challenging the approval and sale of weight-loss drug combinations in India. The PIL was filed in response to CDSCO's recent decision to approve certain drugs for weight-loss purposes without requiring large-scale clinical trials specific to Indian demographics or mandating post-marketing surveillance. The PIL raised objections to the approval of Glucagon-like peptide-1 receptor agonist drugs *Semaglutide*, *Tirzepatide*, and *Liraglutide* for cosmetic weight loss purposes, claiming that these drugs have not undergone adequate India-specific trials or safety data.

The PIL further highlighted the international scrutiny that these drugs have attracted due to potential risks such as cancer, organ damage, and neurological complications. The Delhi HC instructed the DCGI to consult medical experts, stakeholders, and drug manufacturers before taking any regulatory decision. The Delhi HC directed the DCGI to pass a reasoned decision within 3 (three) months, after considering expert advice and inputs from industry stakeholders. With this direction, the matter was disposed of. This order reflects growing judicial scrutiny of accelerated drug approval processes and emphasises the need for India-specific clinical evidence, particularly for drugs intended for lifestyle indications rather than life-threatening conditions.

4. Delhi HC quashes FIR over alleged drug adulteration; clarifies Police jurisdiction under D&C Act[69]

The Delhi HC, in CRL.M.C. 2085/2021, *vide* judgment dated September 23, 2025, quashed an FIR registered under Sections 274 (*Adulteration of drugs*) and 275 (*Sale of adulterated drugs*) of the IPC and Section 13 of the Drugs Act, concerning alleged adulteration of Docetaxel injections. The complaint, filed by M/s Bhardwaj India Pvt. Ltd., claimed the Petitioners had supplied defective vials containing broken glass and foreign particles. The Court held that under Section 32 (*Cognizance of offences*) of the Drugs Act, only designated Drugs Inspectors could initiate proceedings for such violations, and the police lacked jurisdiction to register the FIR. It also noted that the drugs met quality standards at dispatch, contamination appeared to have occurred post-delivery, and with the FIR pending since 2019, the proceedings were barred by limitation under Section 468 of the CrPC.

The Petitioners argued that Revacure Lifesciences had only provided its facility under a loan licence and that product quality rested with Bhardwaj India. Inspection reports from CDSCO and FDA, Madhya Pradesh, supported GMP compliance and standard quality, while the complainant relied on later reports from Karnataka DCA declaring the drugs *"Not of Standard Quality"*. The Court found no *prima facie* offence under IPC, observing that the drugs were never sold, and adulteration was seen only at the complainant's premises. It therefore quashed the FIR under Section 482 of CrPC, clarifying that its findings were limited to the FIR and did not preclude other statutory action under applicable laws.

5. Delhi HC orders three-member inspection of preclinical contract research organisation[70]

The Delhi HC, in W.P.(C) 9350 of 2025, *vide* judgment dated September 16, 2025, appointed a three-member inspection team to conduct fresh inspection at the facility of Telangana-based preclinical contract research organisation

[67] Section 468 - Bar to taking cognizance after lapse of the period of limitation.
Sub-section 2(c) - three years, if the offence is punishable with imprisonment for a term exceeding one year but not exceeding three years.
[68] Jitendra Chouksey v. Union of India & Anr, Order dated July 2, 2025, in W.P. (C) 8773 of 2025.
[69] Revacure Lifesciences LLP & Ors. vs. State Govt. of NCT Delhi & Ors., Judgement dated September 23, 2025, in CRL.M.C. 2085/2021, CRL.M.A. 14031/2021 & CRL.M.A. 28366/2023
[70] People for the Ethical Treatment of Animals v. The Committee for Control and Supervision of Experiments on Animals, Ministry of Fisheries, Animal husbandry and Dairying, Government of India through its Chairman & Anr., Judgement dated September 16, 2025, in W.P.(C) 9350 of 2025.

Palamur Biosciences Pvt. Ltd. in connection with allegations raised by People for the Ethical Treatment of Animals India (PETA India) pertaining to the abuse and neglect of animals while conducting experiments and treatment of beagles used for breeding. PETA India approached the Court seeking direction to the Committee for Control and Supervision of Experiments on Animals (**CCSEA**) to revoke the licences and registrations of the company. An initial inspection conducted in June 2025 corroborated allegations of acts of cruelty and regulatory lapses; however, a subsequent inspection in July 2025 gave a clean chit to the facility. The decision to order fresh inspection was taken after considering the absence of the Court-appointed local commissioner during the previous inspection and conflicting findings between the inspection reports.

The Court directed the three-member inspection team to conduct inspection within 3 (three) weeks from the date of order, with the local commissioner entitled to the assistance of a veterinarian not affiliated with either party. The Court directed the CCSEA to take cognisance of any deficiencies revealed in the inspection report and to take appropriate steps in accordance with law. The Court also directed the Respondent to take immediate rectification steps as may be warranted in terms of the inspection report. The Court vacated the interim order dated July 8, 2025, which had restrained the company from procuring or housing any new animals at its facility, upon the inspection being conducted. This order reflects heightened judicial scrutiny of animal welfare in research facilities and demonstrates the court's willingness to intervene where inspection reports reveal inconsistencies.

6. Delhi HC held that merely receiving package and being unaware of its contents does not amount to "conscious possession" under the NDPS Act[71]

The Delhi HC, in Bail Appln. 591/2025, *vide* judgment dated July 21, 2025, held that mere act of receiving a parcel containing narcotics does not amount to "conscious possession" under the NDPS Act. The matter arose out of a case in which the Applicant was found with a parcel containing 100 (one hundred) LSD blots weighing approximately 3.5 g. Since the recovered quantity exceeded the prescribed threshold of 0.1 g, it qualified as a commercial quantity under the NDPS Act. The Court held that "conscious possession" requires both knowledge of the contraband and the ability to exercise control over it, and that the prosecution must establish personal knowledge and intent to maintain control.

The Court further observed that while the extent of the accused's knowledge and involvement would ultimately be determined at trial, the prosecution had produced no direct or circumstantial material to demonstrate that the Applicant knew or ought to have known about the parcel's contents. It clarified that the mere act of receiving a package, absent any material suggesting awareness of its illicit contents, cannot

[71] Saneesh Soman v. Narcotics Control Bureau, judgment dated July 21, 2025, in Bail Appln. 591 of 2025.

by itself satisfy the legal threshold of "*possession*" under the NDPS Act. This judgment underscores the centrality of *mens rea* in NDPS prosecutions and provides an important safeguard against liability based solely on physical custody without knowledge.

7. High Court of Madras flags the need for amended rules for import of Ayurvedic drugs[72]

The High Court of Madras (**Madras HC**), in W.P. Nos. 8920, 8924, & 8928 of 2025, *vide* judgment dated June 26, 2025, examined the classification of imported Axe medicated oil products as ayurvedic drugs. The Petitioner, an authorised importer, had challenged notices alleging violations under Section 33EEA of the Drugs Act, and Rule 154 of the Drugs Rules. While noting that the statute does not currently prohibit import of ayurvedic drugs, the Madras HC held that such products must conform to the same standards applicable to ayurvedic drugs manufactured in India and directed testing through CDSCO-accredited laboratories under SLA supervision.

The Court further observed that considering existing licensing forms and procedures are designed for allopathic medicines and are not suitable for ayurvedic imports that the rule-making authority may consider amending the framework to prescribe proper standards and create appropriate forms for ayurvedic products. As an alternative, Parliament could, as a policy choice, prohibit the import of such products. The decision highlights a regulatory gap in the current import framework for traditional medicines and the need for harmonised licensing procedures across systems of medicine.

8. High Court of Karnataka quashes proceedings against FMCG company CEO for offence liable under the FSSAI Act[73]

The High Court of Karnataka (**Karnataka HC**), in Criminal Petition No. 8536 of 2023, vide judgment dated July 3, 2025, quashed criminal proceedings initiated against the managing director & CEO of a leading FMCG organisation, regarding the discovery of pesticide "Chloropyrifos" beyond specified limits in a sample of Horlicks biscuits, which was deemed substandard and unsafe for human consumption. The Special Court for Economic Offences took cognisance for offences punishable under Sections 51 and 59 of the FSSAI Act, 2006 (**FSS Act**). The Petitioner contended that since the FMCG company was not arraigned as an accused and therefore, he, being the sole accused, could not be proceeded against.

The Karnataka HC observed that Section 66 of the FSS Act, which deals with offences by companies, is similar to Section 141 of the Negotiable Instruments Act, 1881. The Court held that when officials who are in charge and responsible for the conduct of business are prosecuted on the ground of vicarious liability for offences committed by the company, it is mandatory to arraign the company as accused. In the absence of such arraignment, the officials in charge are not liable. The Court stated that as per the FSS Act scheme, the company's presence is necessary to hold the person in charge liable. Accordingly, the Karnataka HC quashed the proceedings against the Petitioner. However, it granted liberty to the complainant to file a fresh complaint, this time arraigning the company as an additional accused. This judgment clarifies the mandatory requirement to prosecute companies alongside their officers under vicarious liability provisions of the FSS Act.

9. High Court of Uttarakhand upholds D pharma requirement for pharmacist posts[74]

The High Court of Uttarakhand (**Uttarakhand HC**), in W.P. No. 2511 of 2024, *vide* judgment dated August 25, 2025, determined whether the Petitioners holding bachelor's degrees in pharmacy are eligible for appointment to the post of pharmacist, which requires a diploma in pharmacy from a recognised institution and registration with the State Pharmacy Council. The Uttarakhand HC observed that the service rules mandate a diploma in pharmacy as the qualifying credential for the post.

Unless rules are changed, the Petitioners cannot claim eligibility for appointment. Reiterating the settled law that there cannot be any estoppel against the Legislature and that mere assurances of future changes do not change existing rules. Uttarakhand HC dismissed the writ petition. This judgment reinforces the principle that higher qualifications do not automatically substitute for specifically prescribed lower qualifications under service rules and that administrative assurances cannot override statutory requirements.

[72] Axeon Marketing India v. Commr. of Customs, Judgement dated June 26, 2025, in W.P. Nos. 8920, 8924 & 8928 of 2025.
[73] Rohit Jawa v. State of Karnataka, Judgement dated July 3, 2025, in Criminal Petition No. 8536 of 2023.
[74] Om Prakash and others vs. State of Uttarakhand and others, Judgement dated August 25, 2025, in W.P. No 2511 of 2024.

10. High Court of Allahabad permits termination of pregnancy at 31 weeks[75]

The High Court of Allahabad (**Allahabad HC**), in Writ (C) No. 20205 of 2025, *vide* judgment dated July 17, 2025, permitted the termination of pregnancy at 31 (thirty-one) weeks. The matter arose from a plea by a minor rape survivor seeking medical termination at an advanced stage of gestation. The Court referred to *A (Mother of X) v. State of Maharashtra*, (2024) 6 SCC 327, where the SC, while dealing with a similar case involving a 31-week pregnancy, had examined in detail the scheme and provisions of the Medical Termination of Pregnancy Act, 1971 (**MTP Act**). The Court reiterated that the right to abortion is a concomitant right flowing from the rights to dignity, autonomy, and reproductive choice, all of which are protected under Article 21 of the Constitution.

Building in this precedent, the Allahabad HC reiterated that Article 21 recognises and protects the right of a woman to undergo termination of pregnancy if her mental or physical health is at stake. It emphasised that the woman alone has the right over her body and is the ultimate decision-maker on whether to undergo an abortion. In the present case, despite a full session of counselling, the Petitioner and her parents did not agree to carry the pregnancy to term, possibly due to fear of social stigma and/or abject poverty, compounded by the profound trauma of the crime committed against her. The judgment thus reaffirms the constitutional protection of reproductive autonomy and recognises the psychological and physical impact of rape as a valid ground for late-term abortion.

11. High Court of Rajasthan denies abortion for 32-week pregnant minor rape survivor, outlines pre- and post-delivery care plans[76]

The High Court of Rajasthan (**Rajasthan HC**), in S.B. Civil Writ Petition No. 11932 of 2025, vide judgment dated August 8, 2025, refused termination of pregnancy at 32 (thirty-two) weeks. The matter arose from a petition filed by a minor deaf and mute rape survivor seeking termination of pregnancy at an advanced stage of gestation. The Court noted that Section 3 of the MTP Act governs the termination of pregnancy, with conditions depending on the length of gestation. Where pregnancy is alleged to have been caused by rape, the anguish suffered is presumed to constitute a grave injury to the mental health of the woman.

The Court noted that a Medical Board, comprising five doctors, had opined that termination at 32 (thirty-two) weeks was medically inadvisable and posed life-threatening risks to the minor. Taking into account the gestational age, the age of the Petitioner, and the delay in approaching the Court, the Bench held that termination was not feasible. Accordingly, the petition was disposed of with directions for comprehensive pre- and post-delivery care. This judgment underscores the delicate balance courts must maintain between reproductive rights and medical safety, especially in cases involving vulnerable minors, where late-stage termination presents serious health risks.

[75] Ab (2025) v. State of U.P., Judgement dated July 17, 2025, in Writ (C) No. 20205 of 2025.
[76] Victim v. State of Rajasthan, Judgement dated August 8, 2025, in S.B. Civil Writ Petition No. 11932 of 2025.

Transaction Updates

1. Manipal Hospitals completes acquisition of Sahyadri Hospitals network[77]

Manipal Health Enterprises Pvt. Ltd., a leading hospital chain and part of the Manipal Group, has completed its acquisition of Sahyadri Hospitals from the Ontario Teachers' Pension Plan, marking a significant expansion into Western India's healthcare market. The transaction includes 11 hospitals across Pune, Nashik, Ahilya Nagar, and Karad, increasing Manipal's nationwide footprint to 49 hospitals with a total bed capacity of 12,000. The deal, valued at approximately INR 6,400 crore, comes shortly after private equity firm KKR announced a USD 600 million structured financing package for the Manipal Group, one of India's most prominent conglomerates in healthcare, education, and health insurance.

2. Fortis Healthcare acquired Shrimann Superspecialty Hospital[78]

Fortis Healthcare Limited, through its wholly owned subsidiary Fortis Hospital Limited, has completed the acquisition of Shrimann Superspecialty Hospital. The transaction includes a 228-bed facility in Jalandhar, Punjab, along with the hospital building and an additional 2.4-acre land parcel earmarked for future expansion. Valued at INR 462 crore in an all-cash deal, the acquisition reinforces Fortis' cluster-focused growth strategy in Punjab, increasing its total bed capacity in the state to over 1,000 across five facilities.

3. Dr. Reddy's Acquires STUGERON Brand from Johnson & Johnson Across 18 Global Markets[79]

Dr. Reddy's Laboratories, a leading global pharmaceuticals company, has concluded an agreement with Johnson & Johnson for the acquisition of STUGERON and its associated brands, STUGERON FORTE and STUGERON PLUS, across 18 markets in the Asia-Pacific and Europe, Middle East, and Africa regions, including India and Vietnam. STUGERON is a Cinnarizine-based antihistamine indicated for the treatment of vestibular disturbances and vertigo. Reports suggest that the STUGERON brand ranks first in the Cinnarizine Represented Pharmaceutical Market (RPM) and second in the anti-vertigo Extended Represented Pharmaceutical Market (eRPM) in India. Reports also suggest that the transaction would grant Dr. Reddy's Laboratories the rights to the STUGERON brand and its associated product portfolio across the specified territories. A phased transition of operations is planned to ensure

[77] https://www.fortuneindia.com/business-news/manipal-hospitals-acquires-sahyadri-hospitals-expands-footprint-in-western-india/124756
[78] https://scanx.trade/stock-market-news/corporate-actions/fortis-healthcare-subsidiary-completes-acquisition-of-shrimann-superspecialty-hospital/14921355
[79] https://www.expresspharma.in/dr-reddys-acquires-stugeron-to-strengthen-its-cns-portfolio/

smooth business integration. The acquisition is expected to expand Dr. Reddy's presence in the anti-vertigo segment and strengthen its Central Nervous System ("CNS") portfolio.

4. Truemeds secures Series C funding[80]

Truemeds, a digital health platform, has secured USD 85 million in its Series C funding round, comprising approximately INR 740 crore, with participation from Accel, Peak XV Partners, WestBridge Capital, and Info Edge Ventures. The transaction was structured across two tranches, with the first tranche led by Accel, followed by a second tranche led by Peak XV Partners. Reports suggest that the latest round of capital infusion will facilitate Truemeds' nationwide expansion through new fulfilment centres in non-metro markets, enhanced engineering capabilities, and establishment of a technology hub in Bengaluru.

5. Kapiva secures Series D funding[81]

Kapiva, a Bengaluru-based ayurvedic startup, has raised USD 60 million in Series D funding led by investors 360 ONE Asset and Vertex Growth. As per reports, this round of funding will be used by the company for research, manufacturing, and brand-building efforts in the wellness industry. Kapiva's portfolio spans sports nutrition, daily energy, diabetes, blood pressure, cholesterol, liver care, hormonal balance, and overall wellness. Reports suggest that Kapiva has tied up with leading allopathic hospital chains, research institutions such as AIIMS, and government bodies like CSIR to clinically validate its products.

6. Rubicon Research raises INR 140 Cr from TIMF and 360 ONE ahead of IPO[82]

Rubicon Research Private Limited, a specialty pharmaceutical company operating R&D facility in Thane, Maharashtra and Ontario, Canada, has completed an INR 140 (one hundred forty) crore pre-IPO funding round. The funding was structured as an equity share transfer from General Atlantic Singapore RR to TIMF Holdings and 360 ONE funds. Following the transaction, General Atlantic retains majority shareholding with 52.15 per cent ownership. The company has filed its Draft Red Herring Prospectus with SEBI for a proposed initial public offering.

7. Asia Healthcare Holdings announces additional investment in Asian Institute of Nephrology and Urology[83]

Asia Healthcare Holdings, the healthcare investment platform backed by Singapore's GIC and TPG, has announced an additional INR 400 crore investment in Asian Institute of Nephrology and Urology (**AINU**) to accelerate nationwide expansion. The new round of capital infusion will double AINU's hospital network over the next four to five years, focusing on Tier 2 city penetration. Media reports suggest that the transaction brings AHH's total investment in AINU to INR 1,000 crore since FY24. AINU currently operates 7 (seven) centres, with expansion plans targeting 3 (three) to 4 (four) new hospitals by FY27.

8. IHH Healthcare announces strategic collaboration between Indian subsidiaries Fortis and Gleneagles[84]

IHH Healthcare Berhad, a leading international private healthcare group based in Malaysia, has announced a strategic collaboration between its Indian subsidiaries, Fortis Healthcare Limited and Gleneagles Healthcare India Private Limited, aimed at enhancing operational performance and driving sustainable growth. New reports suggest that under an operation and maintenance services agreement, Fortis will manage five hospitals within the six-hospital Gleneagles India network. This move is expected to strengthen IHH's pan-India healthcare platform by expanding operational scale, promoting clinical excellence, and broadening geographical reach, while preserving the autonomy of each entity's talent pool and financial management.

9. Zydus Wellness enters definitive agreement to acquire UK-based Comfort Click[85]

Zydus Wellness Limited, through its wholly owned subsidiary, Alidac UK, has entered into a definitive agreement to acquire UK-based Comfort Click Limited and its

[80] https://ehealth.eletsonline.com/2025/08/healthtech-startup-truemeds-secures-85-mn-to-strengthen-non-metro-fulfilment-and-digital-innovation/
[81] https://b2b.economictimes.indiatimes.com/news/entrepreneur/kapiva-secures-60-million-in-series-d-funding/124207806
[82] https://economictimes.indiatimes.com/markets/stocks/news/timf-holdings-360-one-funds-invest-rs-140-cr-in-rubicon-research-ahead-of-ipo/articleshow/124037808.cms?from=mdr
[83] https://ehealth.eletsonline.com/2025/08/asia-healthcare-holdings-to-invest-%e2%82%b9400-crore-in-asian-institute-of-nephrology-and-urology-to-double-hospital-network/
[84] https://www.thehindubusinessline.com/news/national/ihh-healthcares-india-subsidiaries-fortis-will-manage-five-gleneagles-hospitals/article69845628.ece#google_vignette
[85] https://timesofindia.indiatimes.com/business/india-business/zydus-wellness-acquires-uk-based-comfort-click-for-gbp-239-mn-enters-vms-market-strengthens-global-push/articleshow/123590416.cms

subsidiaries in Ireland, the United States, and India for GBP 239 million. Reports suggest this marks Zydus Wellness' first international acquisition and a strategic move into the vitamins, minerals, and supplements (VMS) segment. Comfort Click operates across the United Kingdom and major European markets, offering a diversified portfolio in adult, paediatric, and pet health through three brands: WeightWorld, Maxmedix, and Animigo.

10. ADIA to acquire minority stake in in Micro Life Sciences[86]

The Abu Dhabi Investment Authority (**ADIA**), UAE's largest sovereign wealth fund, through its wholly owned subsidiary, has entered into definitive agreements to invest USD 200 million for an approximately 3 per cent equity stake in Micro Life Sciences Private Limited (**Meril**), a leading Indian medical technology company. According to sources, the investment assigns Meril an enterprise valuation of USD 6.6 billion and is currently subject to clearance by the Competition Commission of India. Upon completion, Meril will be supported by two globally respected investors, ADIA and Warburg Pincus, further strengthening its position in the global MedTech sector. Founded by the Bilakhia Group, Meril is headquartered in Vapi, Gujarat, and operates a 100-acre integrated campus housing advanced manufacturing and research facilities. Its product portfolio spans cardiovascular devices, structural heart solutions, orthopaedics, endo-surgery, in vitro diagnostics, and surgical robotics.

11. Reveal HealthTech secures Series A funding to accelerate AI-driven healthcare transformation

Reveal HealthTech has completed a USD 7.2 million Series A funding round led by Leo Capital with participation from Sanos Capital. Founded in 2013, Reveal HealthTech specialises in AI transformation solutions for U.S. healthcare and life sciences enterprises. As per reports, the capital infusion will scale flagship products BioCanvas and Prism AI, which facilitate multimodal AI applications including clinical trial recruitment and intelligent workflow automation. The funding will support expansion of product capabilities, strengthening of sales channels, and deepening of strategic partnerships across healthcare sectors.

12. Shilpa Medicare subsidiary establishes Saudi Arabian Joint Venture for pharmaceutical manufacturing[87]

Shilpa Medicare Limited, a healthcare company with integrated capabilities in pharmaceutical APIs and formulations across research, development, and manufacturing, has announced that its wholly owned subsidiary, Koanna International FZ LLC, has entered into a definitive joint venture agreement with Pharma Pharmaceutical Industries & Biological Products (**PPIBP**), a Saudi Arabian enterprise, to establish a pharmaceutical manufacturing facility in the Kingdom of Saudi Arabia. As per publicly available sources, PPIBP will hold a 70 per cent stake, while Koanna International FZ LLC will retain the remaining 30 per cent pursuant to the terms of their agreement. The joint venture will follow a two-phase operational model: Phase One involves the bulk supply of finished pharmaceutical products by Shilpa Group for repackaging in Saudi Arabia, and Phase Two entails a full technology transfer to enable local manufacturing capabilities. The partnership aligns with Saudi Arabia's Vision 2030 strategy to diversify its economy and enhance domestic healthcare infrastructure.

[86] https://timesofindia.indiatimes.com/business/india-business/adia-invests-200-million-in-medical-devices-co-meril/articleshow/122824939.cms
[87] https://www.business-standard.com/markets/capital-market-news/shilpa-medicare-inks-pact-for-building-new-pharma-manufacturing-facility-in-saudi-arabia-125082800376_1.html

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