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# synapse

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

Volume VIII | Issue III | April - June 2025

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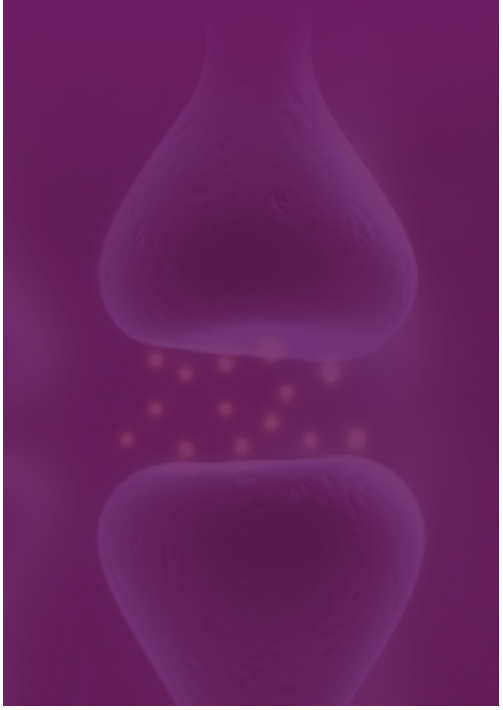

**Dear Readers,**

India's healthcare landscape continues to evolve with purpose and urgency, shaped by a strong convergence of regulatory innovation, judicial activism, and institutional reform. The second quarter of 2025 witnessed bold steps towards improving governance, ensuring patient-centric safeguards, and harmonising industry practices. From legislative advancements to enforcement clarity, and from litigation outcomes to pricing oversight, the momentum signals a maturing regulatory environment that seeks to balance public interest with stakeholder accountability. This edition of Synapse captures the highlights of these multidimensional shifts and reflects on their impact across the healthcare ecosystem.

Significant regulatory developments in India's healthcare sector between April and June 2025 reflect a concerted push towards clearer compliance pathways, stronger enforcement mechanisms, and enhanced patient safety safeguards. Building on this agenda, revised rules under the Drugs Act now permit the compounding of certain offences and streamlining the resolution of minor breaches without protracted litigation. Concurrently, the Pharmacy Council rolled out a unified framework for professional inquiries and penalties under the Pharmacy Act, ensuring consistent application of investigations and sanctions across practitioners. Meanwhile, the CDSCO issued comprehensive guidelines for transferring drugs from SEZs to the Domestic Tariff Area, simplifying cross-jurisdictional movement while maintaining regulatory oversight. The agency also mandated that expired and unused pharmaceuticals be segregated into defined categories, such as anti-infectives, antineoplastics, controlled substances, and radioactive compounds, to ensure safe disposal. In parallel, overprinting and stickering of imported drug labels became permissible under specific licensure conditions, subject to the preservation of original markings and a stated reason for alteration. Medical device manufacturers received relief when it was clarified that outsourcing sterilisation to licensed third parties no longer requires a separate loan licence under the Medical Devices Rules. At the sector level, drug pricing norms were updated to strike a balance between patient affordability and industry sustainability, while environmental requirements for pharmaceutical waste disposal were tightened to safeguard ecosystems and public health. Together, these interconnected reforms modernise India's healthcare regulatory framework by bolstering compliance, increasing transparency, and strengthening patient protections.

Recent news and policy updates in India's healthcare sector highlight a strong focus on accessibility, affordability, and regulatory oversight. The Parliamentary Standing Committee on Health and Family Welfare, in its 165$^{th}$ Report, recommended an integrated digital portal under the "Heal in India" initiative to

promote medical value travel, engaging private stakeholders. The DCC, during its 66th meeting, proposed incorporating Good Distribution Practices into the Drugs Rules and formed a sub-committee to address public grievances on medicine labelling and packaging. The DTAB, at its 92nd meeting, endorsed classifying all antimicrobials as "new drugs" and initiated a review of Nimesulide usage across age groups, backed by ICMR findings, while approving the authorised batch releaser's name on drug licenses.

The government is pushing forward with structural reforms to enhance transparency and safety. The NPPA launched a price review for cementless knee implants with expert consultation, while the CDSCO sought regulatory support for a national initiative to combat antimicrobial resistance in veterinary care. The West Bengal Assembly passed a bill mandating clear patient cost disclosures in clinical establishments, reinforcing accountability. These developments signal progress, with ongoing efforts to improve coordination and resource allocation.

In the litigation space, courts actively addressed regulatory gaps and reinforced patient safety standards. The Supreme Court directed the Central Government to finalise the regulatory framework for Front-of-Pack Nutrition Labelling within three months, responding to a PIL demanding mandatory warning labels on packaged foods to combat rising non-communicable diseases. The Bombay High Court upheld the right to timely organ transplants as a fundamental right, ordering a separate registration system for patients with urgent needs, following a legal challenge by a Stage-V chronic kidney disease patient. Meanwhile, the Delhi High Court issued two significant rulings: one requiring cough syrup manufacturers to warn against use in children under four and another ensuring swift medical termination of pregnancy for minor sexual assault victims, emphasising timely care and procedural urgency.

The judiciary's commitment to public health and systemic accountability was evident in other landmark cases. The Himachal Pradesh High Court quashed charges against individual partners in a substandard drug case but maintained action against the pharmaceutical company, reinforcing corporate accountability. The Kerala High Court dismissed petitions from private hospital associations and the Indian Medical Association, upholding the Kerala Clinical Establishments Act and affirming states' constitutional authority under Article 246 to regulate healthcare infrastructure. These rulings reflect a legal landscape increasingly attuned to patient dignity, ethical governance, and the evolving demands of public health.

We have also witnessed some significant transactions and investments-related updates in the sector and have endeavoured to cover the same in this edition of *Synapse*.

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,

**CYRIL SHROFF**
**Managing Partner**
**Cyril Amarchand Mangaldas**

India's leading law firm

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## Regulatory Updates

### 1. The Ministry of Health and Family Welfare restricts the use of Fixed Dose Combination of Chlorpheniramine Maleate + Phenylephrine Hydrochloride in children below 4 (four) years of age[1]

The Ministry of Health and Family Welfare (**MoH&FW**), *vide* notification S.O. 1717(E) dated April 15, 2025, has restricted the manufacture, sale, and distribution of all formulations of the fixed dose combination (**FDC**) of Chlorpheniramine Maleate IP + Phenylephrine Hydrochloride for use in children below 4 (four) years of age. This decision follows recommendations from the Subject Expert Committee and the Drugs Technical Advisory Board (**DTAB**), which concluded that this combination poses potential risks to children under four and that safer alternatives are available. The Central Government has mandated that all manufacturers include the warning: *"Fixed dose combination shall not be used in children below 4 (four) years of age"* on the label, package, and promotional literature of the drug.

### 2. MoH&FW notifies Drugs and Cosmetics (Compounding of Offences) Rules, 2025[2]

The MoH&FW, *vide* notification G.S.R. 259(E), dated April 24, 2025, has notified the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, providing a structured mechanism for the compounding of certain offences under the Drugs and Cosmetics Act, 1940 (**Drugs Act**). These rules empower both Central and State Governments to appoint compounding authorities and outline procedures for applying for compounding, determining compounding amounts, and granting or revoking immunity from prosecution. The framework aims to facilitate quicker resolution of minor violations while ensuring regulatory compliance and accountability.

### 3. MoH&FW proposes ban on certain antimicrobial drugs for animal use to combat AMR[3]

The MoH&FW, *vide* draft notification S.O. 2298(E), dated May 22, 2025, has proposed a ban on the import, manufacture, sale, and distribution of 34 (thirty-four) antimicrobial substances and their formulations intended for animal use. This regulatory action follows the recommendation of the DTAB and has been taken in the interest of public health and to combat antimicrobial resistance (**AMR**). The banned list includes 15 (fifteen) antibiotics, 18 (eighteen) antivirals, and 1 (one) antiprotozoal (i.e., nitazoxanide), known to contribute to resistance development when used non-therapeutically in animals. This step aims to reduce the misuse of critical antimicrobials in livestock and poultry sectors and safeguard the efficacy of these drugs for human use. Public objections and suggestions are invited within 30 (thirty) days from the date of publication of this draft notification.

### 4. MoH&FW constitutes Advisory Council under Allied and Healthcare Professions Act, 2021[4]

The MoH&FW, *vide* notification S.O. 2310(E), dated May 23, 2025, has constituted the *National Allied and Healthcare Advisory Council* under Section 12 of the National Commission for Allied and Healthcare Professions Act, 2021. The Council, which will advise the National Commission, comprises the chairperson and all the members of the commission, chairpersons of state councils, and principal secretaries dealing with medical education from each State and Union Territory.

### 5. MoH&FW issues Draft Drugs (Second Amendment) Rules, 2025 to strengthen oversight on parenterals and licensing[5]

The MoH&FW, *vide* notification G.S.R. 345(E), dated May 28, 2025, has released the draft Drugs (Second Amendment) Rules, 2025, proposing key changes to the Drugs Rules, 1945 (**Drug Rules**). The draft seeks to enhance quality assurance for parenteral drugs by replacing Rule 121A with a provision mandating bacterial endotoxin testing. It also introduces stricter supervision norms in retail and wholesale drug sales, requiring timely reporting of personnel changes mandated across various license forms (Forms 20B, 20BB, 20G, and 21B). It also limits previous exemptions for the sale of drugs, particularly antimicrobial, to non-medicinal manufacturers such as those producing beverages and confectionery. Furthermore, a new footnote under Schedule H excludes

1 https://egazette.gov.in/WriteReadData/2025/262456.pdf
2 https://egazette.gov.in/WriteReadData/2025/262711.pdf
3 https://egazette.gov.in/WriteReadData/2025/263340.pdf
4 https://egazette.gov.in/WriteReadData/2025/263357.pdf
5 https://egazette.gov.in/WriteReadData/2025/263437.pdf

drugs listed at Serial no. 15 of Schedule K from prescription-only requirements. The ministry invited public comments within 30 (thirty) days from the date on which the copies of the Gazette containing these draft rules are made available to the public.

## 6. Pharmacy Council of India notifies adjudication and penalty regulations under the Pharmacy Act, 1948[6]

The Pharmacy Council of India, *vide* notification F. 19-1/2025-PCI, dated June 10, 2025, has notified the Pharmacy Council of India (Manner of Holding Inquiry and Imposition of Penalty) Regulations, 2025 (**PCI Inquiry and Penalty Regulations**). The PCI Inquiry and Penalty Regulations prescribe a statutory framework for initiating inquiries and imposing penalties in cases of contravention of provisions under the Pharmacy Act, 1948, by designated adjudicating officers under Section 43A. Procedures for complaint submission, inquiry conduct, issuance of show cause notices, and appeals have been codified, with strict timelines governing each phase of adjudication. Furthermore, the sums realised through penalties shall be remitted to the account of the respective State Pharmacy Council, thereby institutionalising accountability in enforcement mechanisms.

## 7. Central Drugs Standards Control Organization (CDSCO) Updates

a. *CDSCO seeks feedback on revised risk-based classification of cardiovascular & neurological medical devices*[7]

The CDSCO, *vide* a public notice F. No. MED-16015(11)/ 1/ 2025-e office, dated April 1, 2025, has issued a draft notification revising the risk-based classification lists for cardiovascular and neurological medical devices under the Medical Devices Rules, 2017 (**MD Rules**). As per Rule 4(3) of MD Rules, devices must be classified based on potential risk to patients and users. The update, released on April 1, 2025, introduces new entries and reflects the latest regulatory approach aligned with the First Schedule (Part I) of MDR. To ensure transparency and regulatory accuracy, stakeholders and industry associations were invited to review the draft and submit comments by May 1, 2025.

b. *CDSCO issues guidelines for transfer of drugs from SEZ to DTA to ensure regulatory compliance*[8]

The CDSCO, *vide* circular IMP/141/2024-eoffice, dated April 8, 2025, has issued detailed procedures for the transfer of drugs manufactured in Special Economic Zones (**SEZs**) to the Domestic Tariff Area (**DTA**), with an aim to streamline the process and ensure that such drugs meet the prescribed standards of quality, safety, and efficacy. The CDSCO has categorically prohibited the transfer of banned drugs from SEZs to DTAs, and new or unapproved drugs must comply with the requirements under the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**), and the Drug Rules. Active Pharmaceutical Ingredients (**APIs**) require valid import licenses and registration to be sold domestically. While SEZs are exempt from certain provisions for export under clause 6 of Schedule D of the Drugs Rules, domestic diversion is allowed only if full import and registration requirements are met under Chapter III of the Drugs Act.

c. *CDSCO switches to auto-generated Neutral Code,*[9] *MSC, and NCC for medical device*[10]

The CDSCO, *vide* public notice File No.: MED/52/2024-eoffice, dated April 9, 2025, has implemented a system-generated process for issuing Neutral Code, Market Standing Certificate (**MSC**), and Non-Conviction Certificate (**NCC**) for medical device manufacturers, under MD Rules. This move aims to promote ease of doing business and streamline regulatory procedures. Manufacturers with valid licenses can now directly download auto-generated Neutral Codes from their dashboards on the Medical Devices Portal, replacing the previous manual issuance by the Central Licensing Authority (**CLA**). The Neutral Code enables manufacturers to export medical devices without disclosing their identity. The application workflow for MSC and NCC has been upgraded to an auto-generation mechanism, and all applications submitted under the old workflow will be automatically rejected. Stakeholders are requested to re-submit fresh applications through the updated system.

6 https://pci.gov.in/documents/1298/Gazette.pdf
7 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MjM=
8 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2Mzk=
9 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2NDc=
10 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2NDM=

d. *CDSCO notifies DTAB's review of Prof. Kokate Committee's Second Assessment Report on FDCs*[11]

The CDSCO, *vide* notice File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. III), dated April 11, 2025, has communicated the outcome of the DTAB's meeting held on September 26, 2022. The meeting examined the second assessment report submitted by Prof. Kokate Committee on FDCs. Key outcomes include the approval of one FDC as rational, with a direction to update the package insert to include usage instructions. Additionally, 6 (six) FDCs were categorised as "Generate Data", requiring the submission of safety and efficacy data (Phase IV or equivalent) within a year. The notice also states that the State Licensing Authorities (**SLAs**) may consider granting manufacturing licenses without prior approval of Drug Controller General of India (**DCGI**), subject to compliance with all regulatory requirements including submission of test specifications, stability data, and periodic safety update reports.

e. *DCGI flags 35 (thirty-five) unapproved FDCs, directs States to review and enforce compliance*[12]

The CDSCO, *vide* notice File No. 4-01/2023-DC (Misc.3), dated April 11, 2025, has directed all State and UT drug controllers to take urgent action against 35 (thirty-five) unapproved FDCs that were licensed by state regulators without safety and efficacy evaluation under the NDCT Rules. These FDCs were either cancelled by the licensing authorities or voluntarily surrendered by manufacturers after show cause notices. The CDSCO reiterated that any FDC classified as a *"new drug"* must undergo central evaluation before approval. States have been asked to ensure that these and any other unapproved FDCs are not allowed to be manufactured or sold, and to report compliance back to the DCGI as such approvals compromise patient safety and violate uniform enforcement under the Drugs Act.

f. *CDSCO seeks feedback on Draft Guidelines for Marketing Authorisation of Similar Biologics, 2025*[13]

The CDSCO, *vide* a public notice F. No. – Rdna-15011(11)/17/2024-eoffice, dated May 06, 2025, has issued draft guidelines titled *"Guidelines on Similar Biologics - Regulatory Requirements for Marketing Authorization in India, 2025"*, inviting stakeholder comments within 30 (thirty) days from the date of its publication. This update revises the earlier 2012 and 2016 rendition of the subject guidelines to align with evolving scientific advancements and global regulatory practices. The draft emphasises a stepwise approach to demonstrate similarity between the biosimilar and its reference biological product. It highlights enhanced and robust orthogonal analytical tools, reduced reliance on animal testing by incorporation of 3Rs principles -Replace, Reduce, and Refine, and updated statistical criteria for clinical studies. The new framework aims to streamline

[11] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2NDU=
[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2NDY=
[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3MDE=

approval processes while maintaining high standards of quality, safety, and efficacy, ultimately supporting the availability of affordable biologic therapies in India.

g. *CDSCO revises Export NOC Guidelines for unapproved and new drugs*[14]

The CDSCO, *vide* public notice dated May 7, 2025, has revised its procedure for issuing export No Objection Certificates (**NOCs**) for unapproved, approved new, and banned drugs, effective from May 15, 2024. Key changes include obtaining NOCs through the SUGAM Portal, discontinuing quantity-specific and purchase order-specific NOCs, and introducing stricter legal undertakings. NOCs will be valid for 1 (one) year or until the approved quantity is exhausted. Formulations with less than 60 (sixty) per cent and APIs with less than 3 (three) months residual shelf life must be destroyed under SLA supervision. The application process is now a two-step procedure involving registration with documentation and online submission at port offices. Companies must also follow labelling norms under Rule 94 of the Drugs Rules. These changes aim to centralise approvals, streamline processes, and improve regulatory oversight for drug exports.

h. *CDSCO issues detailed guidelines for safe disposal of expired and unused drugs*[15]

The CDSCO, *vide* a public notice F. No. E22967, dated May 26, 2025, has issued detailed guidelines on the comprehensive procedures for the disposal of expired and unused drugs, requiring the manufacturers to categorise pharmaceuticals as anti-infectives, antineoplastics, controlled substances, and radioactive drugs to prevent the mixing of hazardous drugs with other waste. The guidance outlines specific collection, storage, transport, and disposal methods, with strict prohibition on mixing hazardous drugs with general pharmaceutical waste. It also mandates adherence to the Bio-Medical Waste Rules, 2016, and AERB guidelines, aiming to minimise environmental impact and misuse of sensitive substances.

i. *CDSCO clarifies provision for overprinting or stickering will be allowed only for imported drugs*[16]

The CDSCO, *vide* a public notice F. No. r-DNA-15011(11)/ 26/ 2025-eoffice, dated May 26, 2025, has clarified that overprinting or stickering under Rule 104A of the Drugs Rules, is strictly permitted only for imported drugs and must be carried out by importers holding a valid manufacturing license. Such labelling must not conceal the original label and must mention the license number and purpose of alteration (e.g., "CGHS Supply"/"Overprinting done under Lic. No. MH/__A"). This clarification follows CDSCO's earlier Office Memorandum F. No. X-11026/247/2019-BD dated January 29, 2020,[17] which allowed importers to seek comprehensive permissions for overprinting across multiple products intended for hospital, government, or clinical use, strictly for *"Not for Sale"* drugs.

j. *CDSCO updates list of accredited labs for IVD performance evaluation*[18]

The CDSCO, *vide* an untitled public notice dated June 4, 2025, has released an updated list of accredited laboratories authorised to conduct performance evaluations of In-Vitro Diagnostic (**IVD**) medical devices in India. This list plays a crucial role under MD Rules, which require third-party performance testing prior to granting manufacturing or import licenses for IVDs. IVD manufacturers must use these accredited labs for regulatory compliance, ensuring standardised, evidence-based testing across diagnostics like HIV, hepatitis, TB, cancer, and genetic disorders. The initiative is expected to strengthen regulatory compliance, accelerate approvals, and reinforce India's diagnostic infrastructure.

k. *CDSCO directs States/UTs to submit veterinary drug manufacturing data*[19]

The CDSCO, *vide* public notice F. No. VET-13020(14) / 4 / 2025-22940, dated June 5, 2025, has directed all State and UT Drugs Controllers to furnish detailed data on manufacturing permissions granted for veterinary drug products, including antibiotics, FDCs, and their premixes. This move follows up on an earlier communication dated August 6, 2015, and aims to compile a national list to support domestic regulatory oversight and meet international obligations, particularly under EU norms and World Organization of Animal Health requirements. SLAs and Food and Drug Administrations (**FDAs**) have been asked to share the required information in the prescribed format at the earliest.

[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3MDI=
[15] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3NTI=
[16] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3NTE=
[17] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/office104a.pdf
[18] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3OTc=
[19] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3OTk=

l. *CDSCO mandates online submission of COPP applications via ONDLS portal from July 15, 2025*[20]

The CDSCO, *vide* circular notice F. No. IT / COPP / ONDLS / 2025 / 001, dated June 25, 2025, has made it mandatory for all applications seeking the WHO-GMP Certificate of Pharmaceutical Product (**COPP**) to be submitted exclusively through the Online Drugs Licensing System (**ONDLS**) portal. The COPP serves as a critical certificate for pharmaceutical exports, confirming that a product is authorised for sale in the country of origin. This directive effective from July 15, 2025, and applies to all zonal and sub-zonal offices of CDSCO. Manual or alternate submissions will no longer be accepted. The move is a part of the MoH&FW's broader push towards digitising regulatory processes to enhance transparency, efficiency, and traceability in pharmaceutical export documentation.

m. *CDSCO removes loan license requirement for outsourced sterilisation of medical devices; mandates stricter documentation and labelling*[21]

The CDSCO, *vide* public notice F. No. MED/48/2025-eoffice, dated June 24, 2025, has clarified that medical device manufacturers outsourcing sterilisation to licensed third-party facilities under the MD Rules will no longer need a separate loan license. This decision follows review by the Drugs Consultative Committee (**DCC**) and was approved at the 92nd DTAB meeting on April 24, 2025. However, manufacturers are required to submit documentary evidence, including mutual agreements and Quality Management System (**QMS**) documents like the Plant Master File and Device Master File. Additionally, product labels must display the license number of the outsourced sterilisation facility. These labelling changes are to be incorporated under Rule 44 of the MD Rules. This update addresses long-standing industry concerns about the duplicative burden of loan licensing and emphasises robust documentation and labelling to uphold product quality and patient safety.

n. *CDSCO declares Not of Standard Quality (**NSQ**) drugs list for April – June 2025*

i. *NSQ drugs list for April 2025*[22]

The CDSCO declared 60 (sixty) drugs tested either at central laboratories or by CDSCO in April 2025, as NSQ. The list of drugs that failed the quality test by the CDSCO and Central Laboratories includes samples of Calcium and Vitamin D3 Tablets IP by Quest Laboratories Limited, Nimesulide and Paracetamol Tablets (Somu Gold) by M/s. Pro -pharma Care Pvt. Ltd, etc. Moreover, 136 (one hundred and thirty-six) drugs declared as NSQ by the State Laboratories[23] include Ibuprofen Tablets IP 400 mg, Telmisartan and Amlodipine Tablets IP, etc.

ii. *NSQ drugs list for May 2025*[24]

The CDSCO declared 58 (fifty-eight) drugs tested either at central laboratories or by CDSCO in May 2025, as NSQ. The list of drugs that failed the quality test by the CDSCO and Central Laboratories includes samples of Paracetamol Tablet I.P 500 mg by M/s. Karnataka Antibiotics & Pharmaceuticals Limited, Sporlac Tablets by M/s. J.B. Chemicals & Pharmaceuticals Ltd, etc. Moreover, the State Laboratories[25] declared 128 (one hundred and twenty-eight) drugs as NSQ, including Paracetamol Tablets IP 650 mg, Dicyclomine HCL Powder, etc.

iii. *NSQ drugs list for June 2025*[26]

The CDSCO declared 55 (fifty-five) drugs tested either at central laboratories or by CDSCO in June 2025, as NSQ. The list of drugs that failed the quality test by the CDSCO and Central Laboratories includes samples of Dextrose Injection I.P. 5%w/v by M/s. Tam-Bran Pharmaceuticals Pvt. Ltd., Tranexamic Acid Injection IP 500 mg/5ml by M/s. Zee Laboratories Ltd., Glipizide & Metformin Tablets I.P. by M/s. Zee Laboratories Ltd., etc. Moreover, the State Laboratories declared 130 (one hundred and thirty) drugs as NSQ,[27] including Lorazepam Tablets I.P 1 mg by M/s. Reliance Formulation Pvt. Ltd., Pantoprazole Gastro Restant Tablets IP by M/s. Habitare Pharma Pvt. Ltd, etc.

o. *CDSCO announces spurious drugs list for April–June 2025*

i. *Spurious drugs list for April 2025*[28]

The CDSCO has declared Nandrolone Decanoate Injection IP 50 mg/ml (Decadurabolin 50 Inj.) as spurious following complaints from the original

[20] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NTA=
[21] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDk=
[22] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3Mzg=
[23] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3Mzk=
[24] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDc=
[25] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDY=
[26] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5Mjc=
[27] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5MjY=
[28] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3NDA=

manufacturers that they had not produced the batches concerned of these products.

ii. *Spurious drugs list for May 2025*[29]

The CDSCO has declared Telmisartan Tablets I.P. 40 mg (Telma 40) as spurious following complaints from the original manufacturers that they had not produced the relevant batches of these products.

iii. *Spurious drugs list for June 2025*[30]

The CDSCO has declared Cefixime Tablets I.P. (Taxim 200), Ointment of Heparin Sodium and Benzyl Nicotinate (Thrombophob), Rosuvastatin and Fenofibrate Tablets I.P. (Rosuvas F10), and Rosuvastatin and Fenofibrate Tablets I.P. (Rosuvas F 20) as spurious following complaints from the original manufacturers that they had not produced the batches concerned of these products.

## 8. NPPA notifications/orders/circulars on pricing and other price-control related measures

a. *Order on fixation of ceiling prices of 9 (nine) formulations under Drugs (Prices Control) Order, 2013 (**DPCO**)*[31]

The National Pharmaceutical Pricing Authority (**NPPA**), *vide* order S.O. 2027(E) dated May 6, 2025, fixed the ceiling price of 9 (nine) drug formulations, including Surfacant suspension for intratracheal instillation, Betamethasone valerate (lotion 0.05 per cent and gel 0.05 per cent), 5-amino salicylic acid (mesalazine/mesalamine) in the following forms: 500 mg suppository, retention enema (foam) and retention enema (liquid), Efavirenz Capsule 600 mg, Rifampicin Tablet 300 mg, and Ibuprofen Capsule 400 mg, exclusive of applicable goods and service tax (**GST**).

b. *Order on fixation of retail prices of 84 (eighty-four) formulations under DPCO*[32]

The NPPA, *vide* order S. O. 2023(E) dated May 6, 2025, has fixed the retail price of 84 (eighty-four) drug formulations, including Aspirin (gastro-resistant) and Atorvastatin Capsules from M/s Windlas Biotech Ltd, Clonazepam and Paroxetine (CR) Tablets from M/s Akums Drugs & Pharmaceuticals Ltd, Telmisartan, Cilnidipine

and Chlorthalidone Tablets from M/s Pure and Cure Healthcare Pvt. Ltd, etc., exclusive of applicable GST. The order clarifies that the fixed retail price applies only to the individual manufacturers/marketers mentioned in the order.

c. *Order on fixation of retail prices of 3 (three) formulations for M/s Otsuka Pharmaceuticals*[33]

The NPPA, *vide* order S.O. 2024(E) dated May 6, 2025, has fixed the retail price of 3 (three) intravenous infusion formulations manufactured by M/s Otsuka Pharmaceutical India Private Limited, including Potassium Chloride IP 150 mg + Dextrose Monohydrate IP 5000 mg + Sodium Chloride IP 900 mg at INR 92.82 per 500 ml pack, Potassium Chloride IP 150 mg + Dextrose Monohydrate IP 5000 mg + Sodium Chloride IP 450 mg at INR 75.67 per 500 ml pack, and a multiple electrolyte solution containing Sodium Chloride IP 526 mg, Sodium Gluconate USP 502 mg, Sodium Acetate Trihydrate IP 368 mg, Potassium Chloride IP 37 mg, Magnesium Chloride Hexahydrate IP 30 mg, and Dextrose Monohydrate IP 5000mg at INR 151.89 per 500 ml pack.

d. *Order on revision of ceiling price of "Iohexol Injection" as per the review order*[34]

The NPPA, *vide* order S.O. 2026(E) dated May 6, 2025, has revised the ceiling price of Iohexol Injection 300 mg iodine per ML to INR 19.74 per ml, including the Wholesale

[29] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDU=
[30] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5NTk=
[31] https://egazette.gov.in/WriteReadData/2025/262936.pdf
[32] https://egazette.gov.in/WriteReadData/2025/262935.pdf
[33] https://egazette.gov.in/WriteReadData/2025/262934.pdf
[34] https://egazette.gov.in/WriteReadData/2025/262933.pdf

Price Index (**WPI**) increase of 1.74 per cent , as against the ceiling price of INR 17.19 per ml fixed vide order S.O. 1489(E) dated March 27, 2025.

e. *Corrigendum in relation to revision of retail prices of 2 (two) applications*[35]

The NPPA, *vide* order S.O. 2025(E) dated May 6, 2025, has revised the retail price of Cholecalciferol (Vitamin D3) oral solutions. As per this notification, the retail price for the formulation listed at Serial Number 13 of order S.O. 5493(E) dated December 19, 2024, i.e., Cholecalciferol (Vitamin D3) oral solution in nano droplet form, where each 5 ml contains Cholecalciferol IP 60000 IU, has been reduced from INR 18.93 to INR 14.26 per 1 ml. This formulation is manufactured and marketed by M/s Ravenbhel Healthcare Pvt. Ltd. and M/s Aristo Laboratories Pvt. Ltd. Similarly, the revised retail price has been brought down from INR 20.23 to INR 14.26 per 1 ml for formulation listed at Serial Number 14 of order S.O. 5493(E) dated December 19, 2024, which contains the same strength and composition,. This formulation is manufactured and marketed by M/s Ravenbhel Healthcare Pvt. Ltd. and M/s Macleods Pharmaceuticals Ltd.

f. *Order on fixation of retail prices of 41 (forty-one) drug formulations under DPCO*[36]

The NPPA, *vide* order S.O. 2469(E) dated June 3, 2025, has fixed the retail price of 41 (forty-one) drug formulations, including Atorvastatin and Ezetimibe Tablets from M/s Windlas Biotech Ltd/ M/s Zydus Healthcare Ltd, Cholecalciferol Oral Drops from M/s Stedman Pharmaceuticals Pvt. Ltd, Sitagliptin, Glimepiride, and Metformin Hydrochloride Tablet from M/s Exemed Pharmaceuticals/ M/s Dr. Reddys Laboratories Ltd, etc., exclusive of applicable GST. The order clarifies that the fixed retail price applies only to the individual manufacturers/marketers mentioned in the order.

## 9. The Ministry of Environment, Forest, and Climate Change (MoEFCC) releases pharma and environmental regulatory updates; marks key developments for healthcare and life sciences

a. *MoEFCC notifies draft rules to operationalise carbon credit trading scheme.*[37]

The MoEFCC, *vide* notification G.S.R. 234(E), dated April 16, 2025, has released the Draft Greenhouse Gases Emission Intensity Target Rules, 2025 (**GEI Target Rules**) to implement the Carbon Credit Trading Scheme (**CCTS**), 2023, and support India's climate commitments under the Paris Agreement. The draft is open for public comments for 60 (sixty) days from the date of this notification. The draft set baseline emissions for FY 2023–24 and define reduction targets for FY 2025–26 and 2026–27, covering 282 industrial units across sectors like cement, aluminium, pulp and paper, and chlor-alkali. Industries are required to submit action plans to reduce GEI, with penalties for non-compliance enforced by the Central Pollution Control Board (**CPCB**). Entities that achieve reductions beyond targets can earn and trade carbon credits via the Indian Carbon Market, managed by the Bureau of Energy Efficiency under the Ministry of Power. The GEI Target Rules aim to drive low-carbon growth and contribute to India's target of a 45 (forty-five) per cent reduction in emissions intensity of GDP by 2030.

Subsequently, *vide* notification G.S.R. 234(E), dated June 23, 2025,[38] the MoEFCC has re-released the Draft GEI Target Rules for public comments for 60 (sixty) days from the date of this notification. The June 2025 notification perhaps serves as a reiteration or republication of the original draft for extended public consultation.

b. *MoEFCC notifies new Construction and Demolition Waste Management Rules with EPR mandate and digital oversight*[39]

The MoEFCC, *vide* notification G.S.R. 219(E), dated April 2, 2025, has issued the Environment (Construction and Demolition) Waste Management Rules, 2025, effective from April 1, 2026. The 2025 Rules replace the 2016 framework and introduce Extended Producer Responsibility (**EPR**) for construction waste, requiring producers to meet recycling targets or purchase EPR certificates from registered recyclers. While reusable materials like iron and wood are excluded from EPR assessments, key building materials such as concrete and bricks are included. An integrated online portal will regulate registration, monitoring, and reporting of all stakeholders, including waste generators, recyclers, and intermediate storage facilities. Non-compliance with disposal and EPR obligations will attract environmental compensation, with partial refunds possible on later

[35] https://egazette.gov.in/WriteReadData/2025/262932.pdf
[36] https://egazette.gov.in/WriteReadData/2025/263568.pdf
[37] https://egazette.gov.in/WriteReadData/2025/262568.pdf
[38] https://egazette.gov.in/WriteReadData/2025/264088.pdf
[39] https://egazette.gov.in/WriteReadData/2025/262313.pdf

compliance. The 2025 Rules also lay down protocols for accident reporting to the State Pollution Control Board.

c. *MoEFCC notifies Biodiversity (Amendment) Rules, 2025 to digitise medicinal plant certification*[40]

The MoEFCC, *vide* notification G.S.R. 295(E), dated May 6, 2025, has notified the Biological Diversity (Amendment) Rules, 2025, amending the Biological Diversity Rules, 2024, to streamline certification for farmers and cultivators of medicinal plants. Effective from November 1, 2025, the amendments introduce a dedicated web portal for submitting Forms - 11, 11A, and 12, allowing Biodiversity Management Committees to maintain digital records and issue Certificates of Origin through an automated and traceable system. While record maintenance (under Form 11) and certificate of origin issued to the applicant (under Form 12) remains free, a nominal fee of INR 200 applies for submitting the application for obtaining certificate of origin for cultivated medicinal plants (Form 11A). The move replaces manual declarations with a simplified, transparent process, enhancing compliance and traceability in the medicinal plant sector under the Biological Diversity Act, 2002.

d. *MoEFCC proposes new rules for use of recycled plastic in packaging*[41]

The MoEFCC, *vide* draft notification G.S.R. 365(E), dated June 3, 2025, has proposed the Plastic Waste Management (Second Amendment) Rules, 2025 to tighten plastic waste regulations. Effective from FY 2025–26, companies will be required to use a specific percentage of recycled plastic in their packaging. For example, Category I packaging are required to use at least 30 (thirty) per cent recycled plastic in FY 2025–26, rising to 60 (sixty) per cent by FY 2028–29. Similarly, brand owners must reuse large rigid plastic containers, starting at 70 per cent reuse in FY 2025–26 and reaching 85 (eighty-five) per cent by FY 2028–29. Some exemptions may be allowed by the CPCB in case of legal or technical difficulties. Companies are also required to report their compliance on a central CPCB portal.

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

a. *FSSAI proposes new standards for Cheese Powder, Drinking Water, and Additives*[42]

The FSSAI, *vide* notification F. No. SS-T0FA(NOTI)/2/2024-Standard-FSSAI(Part-I), dated June 04, 2025, has released the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations. Key highlights include the introduction of standards for cheese powder specifying minimum composition and labelling norms, updated quality parameters for purified drinking water, and a ban on food additives in certain flours such as atta, rice flour, and millet flours. The draft also revises the definition of "animal" by excluding fish and updates fatty acid limits in ghee. Additionally, sucrose esters of fatty acids (INS 473) are now permitted in sauce and gravy mixes up to 10,000 mg/kg. Interested stakeholders are invited to submit objections or suggestions by August 8, 2025, addressed to the FSSAI CEO.

b. *Notification regarding comprehensive guidelines for use of recycled Polyethylene terephthalate (PET) in food packaging*[43]

The FSSAI, *vide* notification F. No. SSDIVI-PF0SP20(16) / 1 / 2025-Standard-FSSAI, dated May 23, 2025, has released comprehensive guidelines for the use of recycled PET as Food Contact Material (**FCM-rPET**). The notification outlines the scope, definitions, approved recycling processes, acceptance criteria, labelling requirements, and the authorisation procedure for the use of FCM-rPET. It permits only FSSAI-approved recycling technologies, including super-clean, melt-in, paste-in, and chemical recycling processes. Conventional mechanical recycling without a validated decontamination step has been strictly prohibited for use in food-grade materials. Packaging made from FCM-rPET must carry labels indicating recycled content and compliance with national standards. Manufacturers must obtain FSSAI authorisation, maintain documentation, and undergo

[40] https://egazette.gov.in/WriteReadData/2025/262974.pdf
[41] https://egazette.gov.in/WriteReadData/2025/263615.pdf
[42] https://egazette.gov.in/WriteReadData/2025/263697.pdf
[43] https://egazette.gov.in/WriteReadData/2025/263372.pdf

annual audits. The FSSAI will publish a list of authorised manufacturers on its official website.

c. *FSSAI proposes fixed renewal dates and longer license validity in consultation paper*[44]

The FSSAI, *vide* notice RCD-01002/2021-Regulatory-FSSAI-Part(7) [E-12168], dated May 20, 2025, released a consultation paper proposing reforms to streamline the license renewal process for Food Business Operators (**FBOs**). The aim is to address industry concerns related to non-uniform expiry dates and administrative burdens. The key proposals include: (i) setting fixed renewal dates - January 15, April 15, July 15, and October 15, to help FBOs align and remember expiry timelines; (ii) longer license validity up to 10 (ten) years for selected business categories (e.g., storage, wholesale, retail, e-commerce, importer, etc.) under the Trade / Retail head; and (iii) a minimum 3 (three) year validity for registrations to reduce frequent renewals for small / petty FBOs. Stakeholders are invited to submit comments via the designated Google Form within 30 days of the notice.

d) *FSSAI mandates closure report submission for expired licenses from FY 2024–25 onwards*[45]

The FSSAI, *vide* order F. No. RCD-05007/1/2021-Regulatory-FSSAI-Part(5), dated May 16, 2025, mandated that all FBOs whose FSSAI License or Registration had expired during the financial year 2024–25 submit a closure report via the Food Safety Compliance System (**FoSCoS**) portal. The FBOs must declare whether the food business activities at the associated premises have ceased or whether a new license or registration has been obtained, along with reasons for non-renewal of the earlier license. To aid compliance, FSSAI has published a user manual outlining the step-by-step process for filing responses on the FoSCoS portal under the "Expired License/Registration" section. The move aims to enhance transparency, traceability, and regulatory compliance in the food business sector.

e) *FSSAI advises food businesses to discontinue use of "100 per cent" (hundred per cent) on labels and promotional materials*[46]

The FSSAI, *vide* advisory F. No. RCD-02001/133/2024-Regulatory-FSSAI [E-12084], dated May 28, 2025, has directed all FBOs to stop using the term "100 per cent" on food product labels, packaging, and related promotional material, citing its ambiguity and potential to mislead consumers. As the term is not defined under the Food Safety and Standards (Advertising and Claims) Regulations, 2018, its use may falsely imply absolute purity or superiority, and undermine trust in other products. The advisory emphasises that all claims must be truthful, unambiguous, and not misleading, in accordance with Sub-regulation 10(7) of the said Regulations.

f) *FSSAI seeks public comments on labelling and regulation of dairy analogues like fake paneer*[47]

The FSSAI, *vide* notice F. No. RCD-02001/2/2021-Regulatory-FSSAI-Part(1) [E-9768], dated April 16, 2025, has invited public comments on the enforcement and labelling of dairy analogues such as fake paneer made from non-milk ingredients. FSSAI defines dairy analogues as items made wholly or partly from non-dairy constituents but resembling milk products. Key proposals include mandatory use of terms like *"Non-dairy"* or *"Analogue"* on labels and menus, clear declaration of analogue ingredients in pre-packaged foods, restrictions on loose sales, and requiring State or Central licenses for their manufacture in place of basic registration. The notice further stipulates that Restaurants and food outlets using analogues like fake paneer or cheese clearly mention it on their menus, ensuring consumers can make informed choices. FSSAI also urged citizens to report misleading food labels through its mobile app or the FoSCoS portal. Interested stakeholders were invited to submit objections or suggestions by June 15, 2025.

g) *FSSAI reclassifies food-grade packaging as "critical" in inspections; certification now mandatory*[48]

The FSSAI, *vide* order F. No. 15(31)2020 / FOSCOS / RCD / FSSAIPt. 17 (Comp. No. 2394), dated April 03, 2025, has reclassified the food grade packaging material from *"non-critical"* to *"critical"* for key food sectors, including general manufacturing, milk and milk product processing, meat processing, fish and fish products processing, and catering. This update aligns with Schedule 4 of the Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011, and aims to strengthen food safety by tightening regulatory

[44] https://fssai.gov.in/upload/advisories/2025/05/682d5c005651cNotice%20for%20inviting%20stakeholder%20comments%20on%20Introduction%20of%20Fixed%20Renewal% 20Cycles%20and%20Prolonged%20Validity%20for%20FSSAI%20Licenses.pdf
[45] https://fssai.gov.in/upload/advisories/2025/05/682c7702a6406FSSAIs%20Order%20Dated%2016th%20May%202025.pdf
[46] https://fssai.gov.in/upload/advisories/2025/05/683854948c294Advisory%20-%20100_%20claim.pdf
[47] https://fssai.gov.in/upload/advisories/2025/04/67ffa639c8c29Consultation%20Paper%20for%20inviting%20comments.pdf
[48] https://fssai.gov.in/upload/advisories/2025/04/67ee5c2f2be74Order_Revised%20Inspection%20Checklist_packaging%20material_03rdApril2025.pdf

oversight on packaging. This reclassification increases the checklist score impact from two to four points and mandates inspectors to verify the presence of Certificate of Conformity during site inspections. Packaging materials must now be certified by a NABL-accredited laboratory as compliant with the FSS (Packaging) Regulations, 2018. FBOs are required to maintain records of such certification and ensure food packaging materials in direct food contact meet the required safety standards.

h) *FSSAI revises NOC validity for imported alcoholic beverages to 365 days*[49]

The FSSAI, *vide* public order File No. TIC-B05/1/2021-IMPORTS-FSSAI, dated June 13, 2025, has revised the validity period of the NOC for imported alcoholic beverages bottled in origin or in bulk (with alcohol content above 10 per cent) to 365 (three hundred sixty-five) days. For consignments held at Customs beyond this period, re-validation will be permitted through visual inspection upon payment of the applicable fee. This update aims to streamline import processes and enhance ease of doing business, while maintaining safety standards. The order overrides any earlier directives issued on this matter.

i) *FSSAI notifies major amendments to Alcoholic Beverages Regulations, 2025*[50]

The FSSAI, *vide* notification F. No. STD/SP-21/T(Alcohol-6), dated June 20, 2025, has notified the Food Safety and Standards (Alcoholic Beverages) First Amendment Regulations, 2025, set to take effect from January 1, 2026. Key changes include the introduction of a formal definition for *"alcoholic ready-to-drink beverages"* with alcohol by volume (ABV) between 0.5 (zero point five) per cent and 15 (fifteen) per cent, and a revised definition for *"Country/Indian Liquors"*, now sub-categorised into plain and blended types. The scope of wines has been expanded to include "honey wine" (mead), and a new category of *"Nitro Craft Beer"* has been introduced. Additionally, a new Annexure provides illustrative lists of Indian liquors classified into distilled, undistilled, and ready-to-drink segments, covering traditional beverages like *mahua*, *chhang*, and *zutho*. The amendment aligns various regulatory tables and maintains exemptions for products under other specific legislation. These changes follow a public consultation initiated in May 2023.

[49] https://fssai.gov.in/upload/advisories/2025/06/685cd16c4c091Order%20dated%2013.06.2025.pdf
[50] https://egazette.gov.in/WriteReadData/2025/264085.pdf

## News Updates

### 1. Parliamentary Panel urges Ministry of Ayush to develop one-stop portal and partner with private sector to boost medical tourism[51]

The Department-related Parliamentary Standing Committee on Health and Family Welfare, in its 165th Report on Demands for Grants (2025–26) for the Ministry of Ayush (**AYUSH Ministry**), has recommended the creation of a unified digital portal under the "Heal in India" initiative to streamline medical value travel (**MVT**) services. The portal is envisioned as a one-stop interface for foreign nationals seeking Ayush-based therapeutic care, wellness services, and accredited treatment facilities in India. To bolster India's standing as a global medical tourism hub, the Committee urged the AYUSH Ministry to collaborate with private healthcare providers and the tourism sector. It also emphasised the need to expedite the establishment of Ayush hospitals in underserved regions and to develop wellness centres at strategic tourist destinations. Addressing regulatory gaps, the panel flagged concerns over unregistered practitioners and misuse of Ayush credentials, calling for stricter enforcement under the National Commission for Indian System of Medicine Act, the National Commission for Homeopathy Act, and the Drugs Act. Notably, the Committee recorded the issuance of 1,646 (one thousand six hundred forty-six) Ayush Visas between January 2024 and February 2025 and recommended systematic monitoring of patient feedback to enhance service quality.

### 2. DCC endorses inclusion of Good Distribution Practices in Drugs Rules during 66th meeting[52]

The DCC, in its 66th meeting held on June 17, 2025, deliberated the proposal to include guidelines on Good Distribution Practices (**GDP**) for pharmaceutical products in the Drugs Rules. This follows an earlier discussion during the 64th DCC meeting, where the Committee observed that a draft guideline had been formulated in line with revised WHO TRS recommendations and applicable national regulations. The Committee had recommended broader stakeholder engagement before finalising the guidelines. Accordingly, a detailed stakeholder consultation was conducted, and the comments and concerns received were thoroughly reviewed. After comprehensive deliberation on the feedback, the DCC agreed to appropriately amend the Drugs Rules to include the GDP guidelines as a dedicated schedule, aiming to reinforce the safety, traceability, and integrity of pharmaceutical distribution across the country.

[51] https://www.bwhealthcareworld.com/article/government-plans-unified-digital-portal-to-boost-medical-value-travel-555026
[52] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjYyNg==

### 3. DCC reviews consumer concerns on Medicinal Packaging in 66th meeting[53]

The DCC, in its 66th meeting, considered various public grievances concerning the labelling and packaging of medicinal products, including torn expiry labels, overly shiny strip surfaces hindering legibility, excessively small font sizes, inconsistent placement of medicine names, and the need for a distinct symbol to differentiate generic medicines from branded ones. After thorough deliberation, the Committee recommended that the DCGI set up a sub-committee to examine the issue in detail, including the feasibility of regulatory provisions for packaging material and printed foil suppliers under the Drugs Rules. The DCC further advised that a packaging expert be included in the sub-committee to support its evaluation.

### 4. DTAB recommends reclassification of Antimicrobials as New Drugs to combat AMR[54]

The DTAB, in its 92nd meeting on April 24, 2025, recommended that all antimicrobials be classified as "new drugs" under the NDCT Rules. This recommendation aligns with the DCC's earlier proposals aimed at strengthening oversight by the CDSCO. The move seeks to tackle the growing threat of AMR, a global health priority highlighted in forums such as the UNGA, G7, and G20. DTAB also backed amendments to the Drugs Rules to restrict the sale of antimicrobials to non-pharma industries lacking proper licenses. The Board reiterated support for adding a distinct blue label for antimicrobial products to improve awareness and enforcement. Collectively, these steps mark a proactive regulatory shift to address AMR through tighter definitions, clearer labelling, and restricted distribution.

### 5. DTAB recommends age-specific review for Nimesulide post ICMR Report[55]

The DTAB, in its 92nd meeting, reviewed a proposal concerning the effects of "Nimesulide" on adult human beings, supported by a report submitted by Indian Council for Medical Research (**ICMR**). The discussion was prompted by the existing restriction on Nimesulide use in children under 12 (twelve) years of age. Recognising its role in short-term fever treatment, the DTAB recommended a systemic review of its usage in three groups: under 12 years, 12–18 years, and above 60 years. Based on the ICMR report, the Board advised limiting Nimesulide to second-line use only and against prescribing it to pregnant/lactating women, those planning pregnancy, and patients with renal or hepatic impairment. It also recommended prohibiting oral formulations above 100 mg in immediate release form, citing safety concerns.

### 6. DTAB backs licensing reform to enhance pharmaceutical oversight[56]

In a major regulatory update, the DTAB, at its 92nd meeting, has endorsed the inclusion of the name of the authorised person responsible for batch release on drug manufacturing licenses, aligning with recommendations made by the DCC in December 2024. The Board also supported standardising the format of batch release certificates and proposed amendments to Rule 89 (*Licenses*) of the Drugs Rules, to better accommodate licensing requirements for biologics, vaccines, and antibiotics. These measures, reinforced by a directive passed by the Hon'ble High Court of Himachal Pradesh, aim to elevate clarity, accountability, and regulatory coherence within India's pharmaceutical sector.

### 7. NPPA to involve expert panel in review of pricing for cementless knee implants[57]

The NPPA is initiating a review process to determine appropriate pricing for cementless knee implants. To assess industry appeals for differentiated pricing, NPPA will engage a panel of medical and orthopaedic experts from premier institutions including AIIMS, MAMC, Sports Injury Centre, Safdarjung Hospital, and NIPER. Currently, all knee implants, including cemented and cementless, are subject to ceiling prices under the DPCO. Manufacturers argue that newer cementless variants offer innovative features and clinical advantages, meriting a separate pricing category. The panel will advise NPPA on whether these products meet criteria under the provisions of the DPCO for superior or novel medical devices.

### 8. ICMR issues call for EoI to establish Cancer Guidelines Technical Resource Hub[58]

The ICMR, in collaboration with the MoH&FW, Directorate General of Health Services (**DGHS**), National Health Systems

[53] Same as above.
[54] https://www.pharmabiz.com/NewsDetails.aspx?aid=177698&sid=1
[55] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjU3Mw==
[56] Same as above.
[57] https://medicalbuyer.co.in/nppa-to-copt-subject-experts-on-separate-prices-for-cementless-knee-implants/
[58] https://www.icmr.gov.in/post/eoi-for-establishing-cancer-technical-resource-hub-trh-under-the-center-for-evidence-based-guidelines-dhr-last-date-july-10-2025

Resource Centre (**NHSRC**), and Department of Health Research (**DHR**), has invited Expressions of Interest (EoIs) for establishing a Cancer Guidelines Technical Resource Hub (**CGT Hub**). This initiative aims to support the development of national cancer care guidelines through rigorous evidence synthesis, including systematic reviews and meta-analyses assessed via the GRADE and Evidence to Decision frameworks. The CGT Hub will mentor technical resource centres, ensure methodological rigor in oncologic data review, and train Guideline Development Group members in evidence appraisal and interpretation. DGHS, NHSRC, and DHR will jointly facilitate scientific integrity, health systems integration, and biomedical research throughout the guideline development process. Selected hubs will receive up to INR 70 lakh annually, with deliverables including workshops, training modules, and validated evidence profiles for cancer care recommendations.

### 9. FSSAI's National Consultation on Sustainable Food Packaging unveiled by MoS Health and Family Welfare[59]

Union Minister of State for Health and Family Welfare, Prataprao Ganpatrao Jadhav, inaugurated the National Stakeholder Consultation on Sustainable Packaging for Food Business in Mumbai, organised by FSSAI. He emphasised that eco-friendly packaging is "the need of the hour", citing its critical role in protecting both public health and the environment. The event marked the formal release of FSSAI's guidelines for the use of recycled PET (rPET) in food packaging, developed through extensive stakeholder engagement and aligned with global standards. A dedicated logo for sustainable packaging was also unveiled to aid consumer awareness. Jadhav called for a nationwide shift towards biodegradable and recyclable materials, blending modern technology with India's traditional ecological wisdom.

### 10. CDSCO initiates Joint Working Group to tackle AMR in veterinary sector[60]

The CDSCO, under the MoH&FW, has issued a directive to all State and Union Territory Drug Controllers requesting support for a national initiative to mitigate AMR in the veterinary sector. In response to a communication from the Department of Animal Husbandry and Dairying (**DAHD**), the CDSCO is working to develop a structured Antimicrobial Use (**AMU**) reporting framework. This framework aims to systematically capture data on the production, sale, import, and registration of veterinary antibiotics.

### 11. India Launches competency-based curriculum for Allied Healthcare Professions[61]

The MoH&FW, in collaboration with National Commission for Allied and Healthcare Professions, unveiled structured curricula for 10 (ten) allied and healthcare disciplines. Union Health Secretary Smt. Punya Salila Srivastava inaugurated the initiative, calling it a benchmark for global healthcare training. Professions covered include Physiotherapy, Applied Psychology, Nutrition, Optometry, Dialysis, Radiology, and Operation Theatre Technology. Srivastava emphasised their vital role in preventive, promotive, curative, and rehabilitative care across the country. She noted that *"India is skilling its healthcare professionals not just for India, but for the globe."* This move aims to improve quality, foster professional recognition, and better align education with health sector needs.

### 12. India launches Ayush Nivesh Saarthi portal to boost investment in traditional medicine[62]

The Government of India launched the *Ayush Nivesh Saarthi portal* on May 29, 2025, aiming to streamline and promote investment in the AYUSH sector, that includes Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homeopathy. Developed in collaboration with Invest India and hosted at Vanijya Bhawan, New Delhi, the portal was unveiled by Commerce & Industry Minister Piyush Goyal and AYUSH Minister Prataprao Jadhav. This digital gateway consolidates policy frameworks, incentive schemes, investment-ready projects, and real-time facilitation tools. It supports both domestic and international investors, highlighting India's openness to 100 per cent FDI in AYUSH under the automatic route. With the AYUSH industry growing at an average annual rate of 17 (seventeen) per cent between 2014 and 2020 and contributing to a USD 13 billion MVT sector, the portal positions India as a global hub for traditional medicine and holistic wellness.

[59] https://economictimes.indiatimes.com/tech/funding/health-tech-startup-curebay-raises-21-million-in-round-led-by-bertelsmann-india/articleshow/121273974.cms?from=mdr
[60] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4MDA=
[61] https://www.pib.gov.in/newsite/pmreleases.aspx?mincode=31
[62] https://government.economictimes.indiatimes.com/news/healthcare/india-launches-ayush-nivesh-saarthi-portal-to-attract-global-investment-in-traditional-medicine/121663928

### 13. India introduces mandatory registration fees for pharmaceutical imports and exports under revised Import Monitoring System (IMS) [63]

The Directorate General of Foreign Trade (**DGFT**) has revised Appendix 2K of the Foreign Trade Policy (**FTP**) 2023, introducing mandatory registration fees for pharmaceutical imports and exports under the IMS. This move aims to enhance traceability, ensure compliance, and reduce dependency on non-compliant foreign APIs. The new system mandates online fee payments via the e-Miscellaneous Payments System (eMPS), streamlining processes and minimising manual errors. Refunds are permitted under specific conditions, such as overpayment or exemption eligibility, with applications to be submitted within one year of payment. Enhanced import monitoring is expected to strengthen supply chains, stabilise pricing, and ensure product quality amid growing international scrutiny.

### 14. India includes HPV vaccine and 116 drugs in Jan Aushadhi Scheme[64]

The Government has added 116 (one hundred and sixteen) essential drugs, including the HPV vaccine, to the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (Jan Aushadhi) initiative, enabling them to be sold through Jan Aushadhi Kendras at 50 (fifty) to 90 (ninety) per cent lower prices than branded alternatives. This move also supports a nationwide push to administer HPV vaccines at these centres, providing affordable cervical cancer prevention to women, an effort long delayed due to limited stock. Jan Aushadhi Kendras, now numbering over 10,000 (ten thousand), reinforce India's commitment to equitable access to both preventive vaccines and essential drugs.

### 15. Department of Pharmaceuticals amends Guidelines for Medical Devices Capacity Building Sub-Scheme[65]

On April 9, 2025, the Department of Pharmaceuticals (**DoP**) approved amendments to Chapter IV of the "Capacity Building and Skill Development for Medical Devices" sub-scheme under the *"Strengthening of Medical Device Industry"* initiative. Key changes include clarifications to the funding and reimbursement processes, assistance of up to 75 (seventy-five) per cent of course costs or INR 21 crore will now be provided on a reimbursement basis, as expenses are

incurred. Financial support to institutes will be reimbursed quarterly based on the number of enrolled students INR 25,000 ( per month for diploma and INR 10,000 per month for certificate/skill training). Additionally, grants must be refunded if the programme is discontinued or if admission numbers fall significantly below targets - less than 30 (thirty) per cent intake in the first year or less than 50 (fifty) per cent in the second and third years. Notably, non-recurring expenses already claimed will not require a refund. All other clauses of the original November 2024 guidelines remain unchanged.

### 16. Government to increase scrutiny on quick commerce firms after safety violations[66]

The Government, led by the FSSAI, is preparing to tighten oversight of quick commerce platforms, following multiple hygiene and food safety breaches in their fulfilment centres. Regulatory inspections, particularly by the Maharashtra FDA, uncovered serious violations: expired products, fungal growth, poor storage conditions, and operations without valid licenses. In response, the government plans surprise FSSAI led checks across the estimated 5,000 (five thousand) quick commerce dark stores nationwide. Franchise operators found non-compliant may face license suspensions, although compliant outlets can continue operations. The move aims to safeguard consumer health while allowing the fast-growing quick commerce sector to maintain its convenience-driven model responsibly.

63 https://www.indiapharmaoutlook.com/news/india-revises-pharma-import-monitoring-fees-to-boost-compliance-nwid-3362.html
64 https://www.news18.com/india/india-bets-on-jan-aushadhi-kendras-for-hpv-vaccine-to-prevent-cervical-cancer-adds-116-new-drugs-ws-kl-9375423.html
65 https://www.pharmabiz.com/PrintArticle.aspx?aid=178409&sid=1
66 https://economictimes.indiatimes.com/tech/startups/govt-may-increase-scrutiny-on-quick-commerce-firms-following-hygiene-food-safety-issues/articleshow/121760312.cms

### 17. Pharma body opposes DGHS ban on medical representatives in government hospitals[67]

The Indian Pharmaceutical Alliance (**IPA**), representing 65 (sixty-five) per cent of the domestic pharma market, has urged the MoH&FW to reconsider the recent DGHS directive that bars medical representatives (**MRs**) from entering central government hospitals. The IPA argues that MRs are vital for disseminating updated clinical data, treatment protocols, and global research to doctors, and that the ban could negatively impact patient care, slow the introduction of new therapies, and result in job losses. They recommend replacing the blanket restriction with a structured, time-bound engagement model within hospitals to ensure both ethical conduct and knowledge exchange.

### 18. Delhi Government reassigns doctors' registration to DGHS[68]

The Delhi State Government has officially dissolved the Delhi Medical Council (**DMC**) following allegations of corruption and procedural irregularities. Pursuant to Section 29 of the DMC Act, 1997, the State Government has invoked its authority to take control of the statutory body, designating the DGHS as the interim registrar for medical practitioners in the national capital.

### 19. West Bengal passes Clinical Establishments Healthcare Transparency Bill[69]

On June 17, 2025, the West Bengal Assembly passed the Clinical Establishments (Registration, Regulation, and Transparency) Amendment Bill, 2025. Under the Bill, hospitals must provide cost estimates for treatments not covered under fixed or package rates, and update patients or their representatives every 24 (twenty-four) hours. As per its provisions, *"final bills shall not exceed that estimate by a certain percentage, as may be specified by the Department of Health and Family Welfare of the State Government"*. The Bill also mandates electronic medical records, including e-prescriptions and detailed discharge summaries, to improve accountability. While the Opposition flagged concerns about patient confidentiality and women's safety, the State Government defended the Bill as necessary to regulate private establishments and protect consumer interests.

### 20. Odisha Govt. appoints 46 new Drug Inspectors following High Court directive[70]

In compliance with a March 13, 2025, judgment from the High Court of Orissa in W.A. Nos. 2260, 2305, 2371, and 2386 of 2024, the State Government of Odisha has appointed 46 (forty-six) new drug inspectors to reinforce its drug control infrastructure. Appointment orders were issued by Chief Minister Mohan Charan Majhi on June 6 in Bhubaneswar, addressing long-standing vacancies and increasing the total inspector strength to 66 (sixty-six). Recruited through the Odisha Public Service Commission, these Group B officers will undergo one month of in-house training before deployment across zones. According to sources, the officers were scheduled to report on June 9 and will serve a two-year probationary period aimed at enhancing regulatory oversight and enforcement across the state.

### 21. CCI approves merger between Aster DM Healthcare and Quality Care India[71]

The Competition Commission of India (**CCI**), in its meeting held on April 15, 2025, approved the merger of Aster DM Healthcare and Quality Care India Ltd under Section 31(1) of the Competition Act, 2002. The transaction is expected to be completed within the year, resulting in the formation of a new entity named Aster DM Quality Care, jointly controlled by Aster Promoters and Blackstone. The merged entity will consolidate four leading hospital brands - Aster DM, CARE Hospitals, KIMSHEALTH, and Evercare, with a combined footprint of 38 hospitals across 27 cities, totalling over 10,150 beds. It is expected to be among the top three hospital networks in India. The group aims to expand to 13,300 beds by FY27, unlocking synergies through improved operational efficiency, harmonised clinical protocols, and enhanced investment in healthcare technology and digital platforms.

### 22. Karnataka Chemists demand crackdown on counterfeit drug networks[72]

The Bangalore District Chemists and Druggists Association (**BDCDA**) has urged the Karnataka government to establish a high-level enforcement task force to curb the growing spread of counterfeit medicines. In a letter to Chief Minister Siddaramaiah, BDCDA proposed a team led by senior IPS

[67] https://www.business-standard.com/industry/news/ipa-urges-dghs-to-reconsider-ban-on-mrs-in-govt-hospitals-125061100918_1.html
[68] https://health.economictimes.indiatimes.com/news/policy/delhi-government-entrusts-doctors-registration-to-dghs/121950786
[69] West Bengal Assembly passes Bill on 'transparency' in medical costs in private facilities - The Hindu
[70] https://www.pharmabiz.com/NewsDetails.aspx?aid=178359&sid=1
[71] https://www.asterdmhealthcare.in/newsroom/detail/competition-commission-of-india-cci-approved-merger-between-aster-dm-healthcare-and-quality-care-india-ltd
[72] https://www.thehindu.com/news/national/karnataka/chemists-association-demands-high-level-enforcement-task-force-to-act-against-counterfeit-drug-networks/article69652590.ece

officers and drug administration officials. They cited a 50 (fifty) per cent spike in fake medicines post-pandemic, warning of compromised QR codes and unchecked distribution channels. The group identified 26 (twenty-six) spurious drugs used for acidity, pain, and cholesterol, raising serious safety concerns. BDCDA also called for temporary suspension of online medicine sales until tighter controls are enforced. Their demand highlights an urgent need to restore trust and safety in Karnataka's pharma supply chain.

### 23. Tamil Nadu Pharmaceutical Traders Association opposes DTAB proposal to allow OTC drug sales in non-pharmaceutical outlets[73]

During its 92nd meeting, the DTAB deliberated a proposal to permit the sale of over-the-counter (**OTC**) medicines in non-pharmaceutical retail outlets such as supermarkets and general stores. In response, the Tamil Nadu Pharmaceutical Traders Association submitted a formal objection, signed by President Chola Mahendran and Secretary M.S. Saravanan, stressing that both scheduled and non-scheduled OTC drugs should be dispensed exclusively by licensed pharmacies to ensure proper guidance and prevent misuse. The association warned that allowing untrained retail staff to handle medications like painkillers and cough syrups could lead to self-medication, dependency, and increase the risk of counterfeit drugs infiltrating the market. It also highlighted potential health risks associated with common medicines such as paracetamol and ibuprofen when taken incorrectly. These concerns echo earlier warnings issued by the All-India Organisation of Chemists and Druggists, urging DTAB to maintain strict control over OTC drug distribution.

### 24. India may implement minimum import price for select pharmaceutical raw materials[74]

India is reportedly planning to introduce minimum import prices (**MIPs**) on key pharmaceutical raw materials, particularly essential APIs, to curb inflated Chinese imports and protect domestic manufacturers. The move aligns with the government's upgraded PLI schemes that support API self-sufficiency and is designed to defend domestic producers from cheap dumping that undermines local capacity built under these programmes. The MIP floor would ensure imported inputs match or exceed local price thresholds, giving Indian firms a much-needed buffer to scale up and secure strategic API supply chains.

[73] https://www.thehindu.com/sci-tech/health/druggist-association-opposes-centres-move-to-sell-over-the-counter-medicines-without-licence/article68113378.ece
[74] https://www.livemint.com/news/india/govt-minimum-import-price-mip-pharmaceutical-raw-material-chinese-imports-11749358747840.html

## Litigation Updates

### 1. Supreme Court sets 3-month deadline for finalisation of front-of-pack nutrition labelling norms[75]

The Supreme Court (SC), in W.P.(C) No. 437 of 2024, *vide* order dated April 9, 2025, directed the Central Government to finalise the regulatory framework for Front-of-Pack Nutrition Labelling (FOPNL) within 3 (three) months. The directive was issued in response to a PIL filed by the NGO "3S and Our Health Society", seeking mandatory warning labels on packaged foods to address rising public health concerns linked to non-communicable diseases.

The regulatory basis for FOPNL stems from Sections 16 (*Duties and functions of Food Authority*) and 23 (*Packaging and labelling of Foods*) of the Food Safety and Standards Act, 2006 (**FSS Act**), and the Food Safety and Standards (Labelling and Display) Regulations, 2020. The SC noted that the FSSAI had released a draft notification on September 13, 2022, introducing the Indian Nutrition Rating (INR) system, a star-based format designed to reflect the health profile of food products based on nutrients such as sugar, salt, and saturated fats. However, given the delay in finalisation, the SC mandated the FSSAI Expert Committee to submit its final recommendations within 3 (three) months, followed by review and approval by the Food Authority.

In its concluding remarks, the SC directed that the matter be listed again after 3 (three) months to report compliance with its directions, ensuring timely implementation of the FOPNL norms.

### 2. Bombay High Court upholds right to timely organ transplant as fundamental right; seeks separate registration facility for patients with imminent need[76]

The High Court of Bombay (**Bombay HC**), in W.P. (C) No. 3048 of 2024, *vide* order dated April 30, 2025, emphasised that the right to life under Article 21 of the Constitution includes the right to timely access to organ transplants. The Petitioner, a Stage-V Chronic Kidney Disease patient not yet on dialysis, was denied registration for a cadaveric kidney transplant on the ground that he did not meet the dialysis requirement under the *"Deceased Donor Kidney Transplant Guidelines."* The Division Bench observed that while the need for a transplant might not be immediate, it was medically certain in the near future. In such cases, refusal to register based solely on guideline criteria would unjustly delay life-saving treatment.

[75] 3S and Our Health Society v. Union of India, Order dated April 9, 2025 in W.P. (C) No. 437 of 2024.
[76] Harshad Rohidas Bhoite v. State of Maharashtra, Order dated April 30, 2025 in W.P. (C) No. 3048 of 2024.

The Bombay HC highlighted that the Transplantation of Human Organs and Tissues Act, 1994 (**THOTA Act**) was enacted to regulate the removal, storage, and transplantation of human organs for therapeutic purposes and to prevent commercial exploitation. It held that the THOTA Act must be interpreted in a manner that furthers its objective and aligns with constitutional protections, especially where medical urgency is medically certifiable. Accordingly, the Court directed the State Government to consider creating a separate registration category for patients who would imminently require organ transplants, ensuring timely access without forcing patients to wait until their condition becomes critical.

### 3. Delhi High Court orders cough syrup makers to warn against use in children below 4 (four) years of age; directs issuance of public notices[77]

The High Court of Delhi (**Delhi HC**), in W.P. (C) No. 5037 of 2025 & CM APPL. 23137 of 2025, *vide* judgment dated April 24, 2025, held that the Government's ban on the fixed dose combination (**FDC**) of "chlorpheniramine maleate" and "phenylephrine hydrochloride" for children below 4 (four) years of age will apply prospectively. The ruling came in response to appeals filed by Glenmark and Zuventus challenging a notification dated April 15, 2025, issued by the Department of Health and Family Welfare under Section 26A (*Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest*) of the Drugs Act, which imposed the ban based on safety concerns flagged by the DTAB.

While granting interim relief, the Delhi HC directed the companies to comply with the notification by affixing warning labels stating *"fixed dose combination shall not be used in children below four years of age"* on all stocks manufactured or circulated after April 15, 2025. The companies were further directed to issue public advisories to doctors, chemists, and retailers within one week, clearly communicating that the FDC must not be prescribed or administered to children under four years of age under any circumstances. The advisory must be prominently published in two national newspapers (in both English and Hindi). Manufacturers were also instructed to file affidavits detailing all stocks manufactured or sold prior to April 15, 2025. The Court clarified that publication of such notices shall not be treated as promotional material nor considered a breach of the manufacturers' drug license conditions. Subject to full compliance with these directions, no coercive action shall be initiated against the companies.

### 4. Delhi HC issues directions to ensure timely medical termination of pregnancy for minor sexual assault victims[78]

The Delhi HC, in W.P. (Crl) No. 1231 of 2025 & Crl. M.A. 11665 of 2025, *vide* judgment dated April 17, 2025, underscored the importance of timely medical and legal assistance for minor rape survivors seeking medical termination of pregnancy beyond the statutory limit of 24 (twenty-four) weeks under the Medical Termination of Pregnancy Act, 1971 (**MTP Act**). The Court granted permission for the termination of a 27-week pregnancy of a 15-year-old rape victim, emphasising that procedural delays and institutional inertia must not obstruct a victim's right to safe and timely abortion, which is a direct facet of the right to life under Article 21 of the Constitution.

To ensure that such delays do not recur, the Court issued a set of binding directions: whenever a minor rape victim is referred to a hospital for MTP after being produced before the Child Welfare Committee (**CWC**) and the gestation period exceeds 24 (twenty-four) weeks, the CWC must immediately inform the Delhi High Court Legal Services Committee (**DHCLSC**). The DHCLSC must then assess the need for urgent judicial intervention and, if necessary, approach the competent court without delay. Importantly, the Delhi HC also clarified that hospitals must not insist on a court order to initiate the Medical Board's opinion on MTP, instead, the medical examination must be conducted immediately, and the report be kept ready to avoid any procedural lag. These directions are to be circulated and strictly followed by all CWCs across Delhi.

### 5. Himachal Pradesh High Court quashes complaint against partners in substandard drug case, retains charges against the pharma company[79]

The High Court of Himachal Pradesh (**HP HC**), in Cr. MMO No. 92 of 2022, *vide* judgment dated May 15, 2025, quashed a complaint under the Drugs Act against 2 (two) partners of a drug manufacturing company. The HP HC held that to invoke

[77] Glenmark Pharmaceuticals Limited & Anr v. Union of India & Anr., Judgment dated April 24, 2025 in W.P. (C) No. 5037 of 2025 & CM APPL. 23137 of 2025.
[78] Minor S (Thr. Father B) v. State & Anr, Judgment dated April 17, 2025 in W.P. (Crl) No. 1231 of 2025 & Crl. M.A. 11665 of 2025.
[79] M/s VADSP Pharmaceuticals & Ors v. Union of India, Judgment dated May 15, 2025 in Cr. MMO No. 92 of 2022.

vicarious liability under Section 34 of the Drugs Act (*Offences by Companies*), the complainant must specifically aver that such persons were both in charge of and responsible for the conduct of the company's affairs.

However, the HP HC refused to quash the complaint against the manufacturing company, which had allegedly produced substandard drugs, citing sufficient grounds to proceed against it. The HP HC further clarified that alleged non-compliance with procedural requirements under Rules 46 (*Procedure on receipt of sample*) and 57 (*Procedure for despatch of sample to Government Analyst*) of the Drugs Rules, such as failure to detail testing protocols, was a matter of evidence and could not be a ground for quashing. Accordingly, the complaint was quashed only against the individual partners, while proceedings against the firm were directed to continue.

### 6. Uttarakhand High Court quashes proceedings against Patanjali over ads promoting medicines for serious diseases under DMR Act[80]

The High Court of Uttarakhand, in Cr. M. A. No. 118 of 2025, *vide* order dated June 03, 2025, quashed criminal proceedings initiated against Patanjali Ayurved Ltd. under Sections 3, 4, and 7 of the Drugs and Magical Remedies (Objectionable Advertisements) Act, 1954 (**DMR Act**), over allegedly misleading advertisements promoting certain Patanjali products as cures for serious diseases like cancer, obesity, and diabetes. The case stemmed from a complaint filed by a Senior Food Security Officer, based on communications from the AYUSH Ministry that flagged misleading claims made about a list of medicines including Madhugrit, Divya Lipidom Tablet, Livogrit, Livamrit, Drishti Eye Drops, Mukta Vati Extra Power, and Swasari Gold. These products were advertised as effective cures for diseases falling within the prohibited list under the DMR Act.

However, the Court held that the complaint lacked specific allegations showing how the advertisements violated Section 3 (*Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders*) of the DMR Act, and no expert report or concrete evidence was furnished to establish the falsity or misleading nature of the claims. The complaint also failed to state what part of the advertisement was false and how it created a false impression about the character or efficacy of the drugs. Referring to legal standards set by the Supreme Court in *Sunil Bharti Mittal v. CBI and Aneeta Hada v. Godfather Travels*, it noted that no individual liability could be imposed without attributing specific acts. It also found that the Magistrate took cognizance without proper judicial application of mind and that the complaint was time-barred under Section 468 (*Bar to taking cognizance after lapse of the period of limitation*) of the Code of Criminal Procedure, 1973 (**CrPC**). Since the alleged ads were distinct and unrelated, combining them under one proceeding also violated Section 219(1) of the CrPC. Ultimately, the Court

[80] Patanjali Ayurved Ltd. v. State of Uttarakhand, Order dated June 3, 2025 in Cr. M. A. No. 118 of 2025.

emphasised that while the DMR Act seeks to protect public health by preventing misleading drug advertisements, its use must be legally sound and procedurally fair. In the absence of clear allegations linking Patanjali's ads to violations under the DMR Act, the proceedings were held to be an abuse of process and accordingly quashed.

### 7. Karnataka High Court stays trial in misleading ads case against Divya Pharmacy and its co-founder[81]

The High Court of Karnataka (**Karnataka HC**), in Crl. P. No. 8519 of 2025, *vide* order dated June 24, 2025, granted an interim stay on criminal proceedings initiated against Divya Pharmacy (an affiliate of Patanjali Ayurved) and its co-founder Acharya Balkrishna in a case involving alleged misleading advertisements. The Karnataka HC passed the stay order on a petition filed by the company and the co-founder, seeking to quash a private complaint and the subsequent trial proceedings before the Mysuru Trial Court.

The complaint, lodged by a Drugs Inspector, alleged that Divya Pharmacy had violated Sections 4 and 7 of the DMR Act, by publishing advertisements for ayurvedic products claiming to treat diabetes and high blood pressure in a misleading manner. The petitioners argued that such cognizance could not be taken on the basis of a private complaint alone and that a police report was necessary in matters under the DMR Act, relying on precedents from the Apex Court. The Trial Court had earlier issued a non-bailable warrant (**NBW**) on June 3, 2025, after the accused failed to appear despite being summoned. However, the NBW was later cancelled upon the appearance of their counsel, who clarified that the absence was not deliberate and due to logistical delays. The Petitioners also pointed to the Uttarakhand State Licensing Authority's order cancelling 14 (fourteen) Patanjali products and argued that the complaint was beyond the statutory limitation period. They further submitted that the complaint lacked specific evidence to sustain prosecution as the products were licensed ayurvedic medicines, and that the advertisements were not misleading but compliant with applicable legal and regulatory standards. Considering these submissions, the High Court stayed the trial proceedings and listed the matter for further hearing on July 28, 2025.

### 8. Andhra Pradesh High Court clarifies "ganja" definition under NDPS Act; grants bail for improper seizure[82]

The High Court of Andhra Pradesh (**AP HC**), in Criminal Petition No. 5306 of 2025, *vide* judgment dated June 23, 2025, granted bail to a tribal cultivator couple accused of illegal possession and transport of 32 kg of *"ganja"*. The Petitioners, Subbarao and his wife Jyothi, were arrested under Sections 20(b)(ii)(C), 25 read with Section 8(c) of the Narcotic Drugs and Psychotropic Substances Act, 1985 (**NDPS Act**). The Petitioners moved for bail under Sections 480 and 483 of the Bharatiya Nagarik Suraksha Sanhita, 2023. The Petitioners argued that the seized substance did not qualify as *"ganja"* under Section 2(iii)(b) of the NDPS Act, which includes only the flowering or fruiting tops of the cannabis plant, excluding leaves and seeds unless accompanied by those tops. The AP HC affirmed that the definition of *"ganja"* under the NDPS Act is restrictive and excludes seeds and leaves unless found with flowering/fruity tops. It held that failure to segregate these parts before weighing renders the process procedurally defective.

The AP HC reprimanded the State police for not following due process and for failing to comply with the evidentiary standards required for invoking Section 20(b)(ii)(c) of the NDPS enactment. Given the lack of procedural compliance and the narrow statutory definition of *"ganja"*, the AP HC allowed the bail application. It directed the release of the petitioners upon furnishing personal bonds of INR 20,000 each with two sureties of like amount, along with conditions including weekly police reporting and non-interference with the investigation.

### 9. Kerala HC upholds mandatory display of hospital fee/package rates; dismisses IMA & private hospital pleas[83]

The High Court of Kerala (**Kerala HC**), in W.P. (C) Nos. 1365 of 2019, 2870 of 2024, 2637 of 2019, 27168 of 2023, 29353 of 2019, and 41738 of 2023, *vide* common judgment dated June 23, 2025, dismissed writ petitions filed by private hospital associations and the Indian Medical Association (**IMA**) challenging provisions of the Kerala Clinical Establishments

[81] M/s Divya Pharmacy and Anr. v. State of Karnataka and Anr., Order dated June 24, 2025 in Crl. P. No. 8519 of 2025
[82] Killo Subbarao & Killo Jyothi v. State of Andhra Pradesh, Judgment dated June 23, 2025 in Criminal Petition No. 5306 of 2025.
[83] Kerala Private Hospitals Association & Anr. v. State of Kerala & Ors., Judgment dated June 23, 2025 in W.P. (C) Nos.1365 of 2019, 2870 of 2024, 2637 of 2019, 27168 of 2023, 29353 of 2019 and 41738 of 2023.

(Registration and Regulation) Act, 2018 (**Kerala CE Act**). The Petitioners opposed Sections 16(2), 39(2), and 39(3), which mandate the display of *"fee rates"* and *"package rates,"* alleging that the provisions were vague, arbitrary, and unconstitutional. The Kerala HC upheld the Kerala CE Act, ruling that states have legislative competence under Article 246 of the Constitution, even where a central law exists, namely, the Clinical Establishments (Registration and Regulation) Act, 2010.

The Kerala HC found no violation of fundamental rights or legislative incompetence, reiterating that *"arbitrariness"* alone is not a valid ground to strike down legislation. On procedural grounds, the Kerala HC held that the Kerala CE Act provides adequate safeguards, including provisions for appeal and revision in cancellation matters. It also upheld the inclusion of "dentistry" under the term "modern medicine," affirming the State's authority to do so. The Kerala HC also noted that prior directions of the Division Bench mandating fee displays were binding and already applicable to the Petitioners. While rejecting all constitutional and procedural challenges, it permitted the Petitioners to approach the Government to raise practical concerns, which may be considered for appropriate remedial action.

## 10. Kerala HC flags microplastic risks in food delivery packaging; orders probe into health impact[84]

The Kerala HC, in W.P. (C) No. 19941 of 2023, *vide* order dated June 12, 2025, raised urgent concerns over the use of plastic containers in food delivery. It warned about microplastics leaching into food, especially hot items, which pose serious health risks including cancer and organ damage. It questioned the safety of such packaging, particularly given the increasing reliance on food delivery by children and youth. The Kerala HC directed the Additional Director General of Prosecution to investigate the use of such packaging materials and examine their impact on public health. It also noted the lack of sufficient regulatory oversight and called for urgent measures to reform current practices in food packaging and delivery.

This matter arose in 2023, following the tragic death of a 16 (sixteen)-year-old girl, allegedly after consuming an expired shawarma. A writ petition was filed seeking compensation, alleging that the eatery was unlicensed and had not been inspected for over two years. Taking note of systemic lapses, the Court had earlier directed that all eateries must prominently display the date and time of food preparation on packaging and that the "Shawarma Guidelines" of 2022 and the "Order of Ban" dated January 12, 2023, be incorporated into all statutory food licenses. The Court has instructed the Director General of Prosecution to update on such actions on the next date of hearing.

[84] Prasanna E.V. v. State of Kerala & Ors, Order dated June 12, 2025 in W.P. (C) No. 19941 of 2023.


## Transaction Updates

### 1. TPG acquires 35 (thirty-five) per cent stake in SCHOTT Poonawalla, with Novo Holdings co-investing[85]

TPG Growth has agreed to acquire a 35 (thirty-five) per cent stake in SCHOTT Poonawalla, the drug containment joint venture between the Serum Institute of India (**SII**) and SCHOTT Pharma. Novo Holdings will join the transaction as a co-investor. Post-transaction, SCHOTT Pharma will retain a 50 per cent stake, while SII will continue to hold a minority position. The deal, valued at approximately USD 300 million, is aimed at enhancing SCHOTT Poonawalla's manufacturing infrastructure, particularly for injectable containers and auto-injector solutions, while allowing TPG to bring in healthcare expertise and Novo's global reach. This strategic investment is expected to support the JV's plans to scale operations both in India and internationally, with the transaction slated for completion in the first half of 2025.

### 2. Ujala Cygnus acquires majority stake in Amandeep Hospitals[86]

Ujala Cygnus, a regional hospital chain backed by private equity firm General Atlantic, announced that it has agreed to acquire a majority stake in Punjab-based Amandeep Hospitals. Ujala Cygnus has acquired a 60 (sixty) per cent stake with the deal valued between INR 400 crore and INR 500 crore. This acquisition marks Ujala Cygnus's entry into Punjab's healthcare market, adding five multi-specialty hospitals across Amritsar, Pathankot, Firozpur, and Srinagar to its network. The combined entity plans further growth in Ludhiana, Jalandhar, Patiala, and the Chandigarh Tricity region.

### 3. PB Fintech launches PB Health[87]

PB Fintech, the parent company of Policybazaar, has announced the launch of its new healthcare venture, PB Health, raising USD 218 million in seed funding. The round includes a USD 50 million investment from Silicon Valley-based venture capital firm General Catalyst. As per company sources, PB Health plans to establish four to five hospitals in and around New Delhi by 2027, aiming to eventually build a network of 25–30 hospitals across ten Indian cities. The initiative seeks to deliver quality, affordable healthcare while leveraging insurance solutions to address systemic challenges such as over-treatment and fraud.

[85] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/tpg-to-acquire-35-stake-in-schott-poonawalla-from-serum-institute-of-india/articleshow/120922468.cms?from=mdr
[86] https://www.business-standard.com/companies/news/ujala-cygnus-to-acquire-around-60-stake-in-punjab-hospital-chain-125041400773_1.html
[87] https://www.livemint.com/companies/start-ups/pb-healthcare-secures-218-million-in-seed-funding-from-pb-fintech-general-catalyst-healthcare-insurance-yashish-dahiya-11746680195278.html

### 4. ICICI Venture invests in prosthetics manufacturer to strengthen healthcare portfolio[88]

ICICI Venture, the alternative investment arm of ICICI Bank, has acquired a minority stake in Dentcare Dental Labs, a prosthetics manufacturing company. The investment is part of ICICI Venture's fifth private equity fund, which previously raised over USD 350 million and aligns with its strategy to diversify its healthcare portfolio and back innovative medical device players. By entering the prosthetics segment, ICICI Venture aims to capitalise on the rising demand for advanced medical devices and rehabilitation solutions across India.

### 5. Piramal Alternatives invests in Saimirra Innopharm[89]

Piramal Alternatives, the fund management arm of Piramal Group, has invested approximately INR 160 crore in Chennai-based pharmaceutical company Saimirra Innopharm Pvt Ltd through its performing credit fund. The investment, sourced from Piramal Alternatives' India Credit Opportunities Fund II, will support Saimirra's brand acquisitions and the expansion of its product portfolio across multiple therapies and markets. Saimirra manufactures and supplies over 275 products across 70 countries through its international business. In India, its domestic formulations are managed under its subsidiary Delvin Formulations, which houses more than 20 brands across various therapeutic segments.

### 6. Perfios acquires IHX to bolster healthcare data analytics capabilities[90]

Perfios Software Solutions, backed by private equity firms Warburg Pincus and Kedaara Capital, has acquired IHX, a leading healthcare information exchange platform in India. IHX processes over 40 (forty) per cent of all cashless health insurance claims nationwide, handling more than 10 (ten) million transactions annually valued at approximately USD 1 billion. The platform collaborates with over 30,000 hospitals, operating across more than 1,200 locations throughout the country.

### 7. Vetic to raise USD 26 million in Series C Round Led by Bessemer Ventures[91]

Vetic, a tech-enabled pet healthcare startup, is raising USD 26 million in its Series C funding round led by Bessemer Ventures, with participation from LGF3 (founded by Lachy Groom), Acorn Heavy Industries, JSW Venture Capital, and Reed India. According to publicly available web sources, Vetic's board has reportedly approved a resolution to issue 34,746 Series C preference shares at INR 64,517.50 each, aggregating INR 224 crore. Of this, Bessemer Ventures is expected to contribute INR 152 crore, with the remainder to be infused by other participating investors.

### 8. CureBay raises USD 21million to expand rural healthcare network[92]

CureBay, a tech-first hybrid healthcare startup, has raised USD 21 million in a funding round led by Bertelsmann India Investments, with participation from British International Investment and Elevar Equity. Founded in 2021, the Odisha-based startup operates over 150 e-clinics across Odisha and Chhattisgarh. With the fresh capital, CureBay plans to expand into underserved regions including Jharkhand, Bihar, Uttar Pradesh, and Madhya Pradesh. According to publicly available sources, the funds will be deployed to scale CureBay's e-clinic network, enhance its proprietary technology stack, and build high-impact teams to support its next phase of growth. By integrating digital infrastructure with on-ground care delivery, CureBay aims to make affordable healthcare more accessible across rural India.

### 9. HexaHealth raises USD 12 million to boost tech-driven surgical care[93]

Gurugram-based healthtech startup HexaHealth has raised USD 12 million in a Series A funding round led by 3one4 Capital, with participation from Orios Venture Partners, Enzia Ventures, ITI Growth Opportunities Fund, and existing investors. The capital will be used to drive national expansion, enter new surgical specialties, and enhance the

[88] https://www.vccircle.com/iciciventure-seals-a-healthcare-deal-with-prosthetics-maker
[89] https://www.piramalenterprises.com/Assets/download/Press-Releases/PR_Piramal_Alternatives_invests_INR_160_Cr_in_Saimirra_Innopharm_Pvt_Ltd.pdf
[90] https://perfios.ai/blogs/perfios-announces-strategic-acquisition-of-ihx/
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[92] https://economictimes.indiatimes.com/tech/funding/health-tech-startup-curebay-raises-21-million-in-round-led-by-bertelsmann-india/articleshow/121273974.cms?from=mdr
[93] https://www.outlookbusiness.com/start-up/investors/healthtech-start-up-hexahealth-raises-12-mn-from-3one4-capital-other-investors

company's technology platform. HexaHealth has partnered with over 350 hospitals, including Apollo, Fortis, Max, and Manipal, and has facilitated more than 30,000 surgeries to date. According to sources, the company boasts a category-leading Net Promoter Score (NPS) of over 70 and aims to further strengthen its leadership team to scale operations and improve patient outcomes.

### 10. Mosaic Wellness raises funding from Think Investment[94]

Health and wellness startup Mosaic Wellness, known for its digital-first brands Manmatters, Be Bodywise, and Little Joys, has raised approximately INR 175 crore from early-stage investor Think Investment. According to data from business intelligence platform Tofler, the company's board approved the issuance of 16,279 compulsory convertible preference shares at INR 1,07,498 each to complete the transaction. Founded in 2020, Mosaic operates a trio of full-stack digital clinics focused on wellness solutions for men, women, and children. Backed by Elevation Capital, the company plans to use the funds to strengthen its platform and improve accessibility across its verticals.

### 11. SRV Hospitals raises INR 140 crore from InvAscent to strengthen critical care model[95]

SRV Hospitals, a multispecialty hospital chain, has raised INR 140 crore in funding from private equity firm InvAscent to expand and enhance its critical care-focused healthcare model. Founded in 2015, SRV operates five tertiary care hospitals across Mumbai, Nashik, and Bengaluru, with a combined capacity of over 500 beds. The fresh capital will support the group's growth strategy, including scaling operations, investing in advanced medical technology, and upgrading its patient care infrastructure. According to sources, InvAscent's investment aligns with its strong portfolio of healthcare brands such as HCG Hospitals and Dr Agarwal's Eye Hospital. Alongside financial support, the firm brings valuable sectoral expertise and strategic vision to help fuel SRV's next phase of expansion.

### 12. Female Wellness brand Plush secures INR 40 crore funding to expand retail and wellness offerings[96]

Chennai-based feminine care startup Plush has raised INR 40 crore in a growth funding round led by investor Rahul Garg, with participation from Blume Founders Fund, OTP Ventures, Careernet, the Patni Family Office, Sumit Jalan, Ajay Kumar Aggarwal, and other strategic backers. Founded in 2019 by Prince Kapoor and Ketan Munoth, Plush plans to utilise the capital to expand its offline retail presence, enhance market positioning, and invest in brand-building initiatives. The company offers a curated portfolio of clean, modern products across period care, intimate wellness, hair removal, and skincare, and aims to establish itself as a leading name in the wellness sector.

[94] https://economictimes.indiatimes.com/tech/funding/health-and-wellness-startup-mosaic-wellness-raises-rs-175-crore-from-think-investment/articleshow/120163333.cms?from=mdr
[95] https://www.expresshealthcare.in/news/srv-hospitals-secures-rs-140-cr-from-invascent/448821/
[96] https://www.msn.com/en-us/money/smallbusiness/plush-raises-inr-40-cr-funding-from-rahul-garg-blume-founders-fund-otp-ventures/ar-AA1G9cCW

### 13. ASG Eye Hospitals acquires Mumbai-based eye care facility[97]

ASG Eye Hospitals, backed by private equity firms General Atlantic and Kedaara Capital, has acquired Vedanta Centre for Ophthalmic Sciences, a super-specialty eye hospital based in Mumbai. This marks the third acquisition by ASG in the past two months and strengthens its presence in western India, in line with its strategic goal of establishing a pan-India network of eye care facilities. Previously, ASG Eye Hospitals acquired Vasan Eye Care, adding 97 (ninety-seven) centres to its footprint. With this addition, ASG's network has grown to over 150 (one hundred and fifty) hospitals across 21 (twenty-one) states, positioning it among the largest eye care chains in the country.

### 14. Metropolis Healthcare acquires Dr. Ahuja's Pathology and Imaging Centre[98]

Metropolis Healthcare Ltd, India's second-largest pathology chain, has acquired Dehradun-based Dr. Ahuja's Pathology and Imaging Centre (DAPIC) for INR 35.01 crore in an all-cash deal. This marks Metropolis' third acquisition in four months, following Core Diagnostics and Agra-based Scientific Pathology, as part of its "String of Pearls" strategy to expand its footprint in North India. The latest acquisition is expected to boost Metropolis' revenue contribution from the region, increasing it from 8 per cent to approximately 14 to 15 per cent.

### 15. Farmako receives additional funding from Genesia Ventures in Pre-Series A Round[99]

Pharma quick-commerce startup Farmako has secured a follow-on investment from Genesia Ventures via its Genesia Venture Fund 3, reinforcing the firm's earlier backing during the August 2024 seed round. Although the investment amount remains undisclosed, the continued support underscores investor confidence in Farmako's growth trajectory and business model. Having presence in Gurgaon, New Delhi, and Moradabad, Farmako ensures 24/7 medicine delivery within 30 (thirty) minutes through its mobile/web app and WhatsApp.

### 16. Bain Capital backed Emcure acquires stake in Zuventus Healthcare [100]

Emcure Pharmaceuticals, backed by private equity firm Bain Capital, has announced the purchase of the remaining 20.42 per cent stake in its subsidiary, Zuventus Healthcare Ltd for INR 724.9 crore. This move will make Zuventus a wholly owned subsidiary, enabling full financial consolidation and unlocking operational synergies across Emcure's domestic portfolio. Zuventus operates multiple manufacturing facilities in Jammu, Sikkim, and Bengaluru. The acquisition underscores Emcure's strategy to streamline its business structure and enhance long-term value creation.

[97] https://www.scconline.com/blog/post/2025/03/03/jsa-advises-asg-hospitals-acquisition-of-a-majority-stake-in-vedanta-centre-for-ophthalmic-sciences/
[98] https://www.business-standard.com/companies/news/metropolis-acquire-dr-ahujas-pathology-imaging-centre-for-rs-35-cr-125040700863_1.html
[99] https://thebridge.jp/en/2025/06/pharmaceuticals-delivered-in-30-minutes-indias-farmako-secures-additional-pre-series-a-funding
[100] https://www.vccircle.com/baincapital-backed-emcure-takes-full-control-of-zuventus-healthcare

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