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WHAT HAPPENED. WHAT CHANGED. WHAT MATTERS.

QUARTERLY REVIEW - INDIA'S HEALTHCARE & LIFE SCIENCES SECTOR

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REGULATORY UPDATES

1. **Ministry of Health and Family Welfare expands exemption from separate Form 29 license under Rule 89 of the Drugs Rules, 1945**

   The Ministry of Health and Family Welfare **(MoH&FW)**, on 6 August 2026, notified the Drugs (Twelfth Amendment) Rules, 2026, expanding the categories of manufacturing license holders that are exempt from obtaining a separate license in Form 29 for the manufacture of drugs for examination, test, or analysis.

   Under the amended Rule 89 of the Drugs Rules, 1945 (**Drugs Rules**), this exemption, which previously applied to holders of license in Forms 25 and 28, has been extended to license holders under Forms 25A, 25F, 28A, 28B, 28D, 28DA, 28E and 28F as well.[1]

   Industry Impact: Manufacturers holding these licenses will no longer need to obtain a separate Form 29 license for the specified manufacture of drugs for examination, test or analysis. The amendment therefore reduces additional licensing and documentation requirements for the affected categories of manufacturers.

2. **MoH&FW introduces quality management system self-certification requirement for certain classes of devices and expands recognised jurisdictions under the Medical Devices Rules, 2017**

   The MoH&FW, on 14 August 2026, notified the Medical Devices (Third Amendment) Rules, 2026, amending the Medical Devices Rules, 2017 (**MD Rules**). The amendment introduces a new quality management system (**QMS**) self-certification requirement for Class A non-sterile and non-measuring devices. Under

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1OTQ=

amended Rules 19H and 19J, manufacturers and importers of such devices must now upload a self-certification of compliance with QMS requirements as part of the registration process. Separately, Rule 63 has been amended to include "*European Union countries*" among the jurisdictions whose regulatory approvals will be recognised when issuing manufacturing or import permissions for medical devices that do not have a predicate device.[2]

Industry Impact: Manufacturers and importers of Class A non-sterile and non-measuring devices will need to incorporate the QMS self-certification into their registration process and ensure that the underlying systems support the certification. Applicants seeking marketing authorisation for devices which do not have a predicate device, may also need to reassess their existing submissions and supporting regulatory approvals in light of the expanded recognition of European Union jurisdictions.



3. MoH&FW amends MD Rules to introduce sterilisation labelling requirements and prescribe central laboratory fees

The MoH&FW, on 14 August 2026, notified the Medical Devices (Second Amendment) Rules, 2026, amending the MD Rules. The amendment introduces a new labelling requirement for devices undergoing outsourced sterilisation and prescribes fees for testing and evaluation by specified central laboratories.

Under the amended MD Rules, medical devices undergoing outsourced sterilisation must carry the manufacturing license number of the licensed sterilisation facility on the device label. This requirement will come into effect from 14 February 2027. The amendment also introduces the Ninth Schedule to the MD Rules, prescribing fees for the testing and evaluation of medical devices by the Director or Medical Device Testing Officer of the relevant laboratory or institute, with the prescribed fees subject to an automatic 5% annual increase. It now also defines "*Certificate of Registration*" under Rule 3 to mean a registration certificate granted by the State Licensing Authority or the Central Licensing Authority in Forms MD-2, MD-40 and MD-42.[3]

Industry Impact: Manufacturers that outsource sterilisation should review their labelling processes and coordinate with licensed sterilisation facilities to ensure that the facility's license number is captured on product labels before 14 February 2027. Manufacturers should also factor the new testing and evaluation fees, including the annual 5% increase, into regulatory and compliance costs.

4. MoH&FW prohibits Chlorpheniramine Maleate-Phenylephrine Hydrochloride combinations for children below four

The MoH&FW, on 18 August 2026, notified a prohibition on the use of fixed-dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride in children below four years of age. The notification also requires the prescribed warnings to be included on the labels, package inserts and promotional literature of the affected formulations.[4]

[2] https://egazette.gov.in/WriteReadData/2026/275639.pdf
[3] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTQ=
[4] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTY=

Industry Impact: Manufacturers and marketers must identify the affected formulations and review their labels, package inserts, promotional literature and other product communications to ensure that the prescribed warning is incorporated.

5. **MoH&FW proposes inclusion of four additional drugs in Schedule H1 of the Drugs Rules**

The MoH&FW, on 19 August 2026, following consultation with the Drugs Technical Advisory Board (**DTAB**), published a draft amendment to the Drugs Rules proposing the inclusion of Flupentixol, Zopiclone, Gabapentin and Carisoprodol in Schedule H1 as Serial Nos. 53, 54, 55 and 56, respectively. Schedule H1 covers certain prescription drugs that are subject to additional controls on their sale and record-keeping, over and above the requirements generally applicable to non-prescription drugs.

The amendment will come into force 180 days after the publication of the final rules in the Official Gazette. The proposal is currently at consultation stage, with comments and suggestions invited from stakeholders.[5]

Industry Impact: Manufacturers, distributors and pharmacies dealing with the specified drugs may assess the implications of their proposed inclusion in Schedule H1, including the applicable requirements relating to their sale and record maintenance.

6. **MoH&FW proposes prohibition of certain antimicrobials for animal use**

The MoH&FW, on 3 September 2026, published a draft notification proposing to prohibit the import, manufacture, sale and distribution of specified antimicrobial medicinal products for animal use. The proposal covers Carboxypenicillins and Phosphonic Acid derivatives, on the basis that their use in animals may pose a risk to human health and that safer alternatives are available. Issued under Section 26A of the Drugs and Cosmetics Act, 1940 (**D&C Act**), following consultation with the DTAB, the draft notification has been released for comments and suggestions from stakeholders.[6]

Industry Impact: If finalised, the prohibition would directly affect manufacturers, importers, distributors and other entities dealing with the specified antimicrobial products for animal use. Such entities should review their existing products, supply arrangements and inventories against the proposed scope and monitor the proposal.

7. **MoH&FW proposes exemption of Levonorgestrel tablets from sale license requirements**

The MoH&FW, on 3 September 2026, published a draft amendment to the Drugs Rules proposing to include Levonorgestrel Tablets 0.75 mg/1.5 mg under Sr. No. 15 of Schedule K. The proposed amendment would exempt these tablets from the requirement of a sale license, subject to specified conditions.

The draft amendment also proposes mandatory boxed warnings on the packaging and package insert stating that the emergency contraceptive pill is intended only for emergency use, its frequent use may lead to side effects, it is not an abortion pill, and it does not protect against HIV or sexually transmitted infections. The proposal has been issued to invite comments and suggestions from stakeholders.[7]

Industry Impact: If implemented, the Schedule K exemption would reduce the licensing requirements application to the sale of Levonorgestrel tablets. Manufacturers and suppliers should, however, account for the proposed conditions, including the prescribed boxed warnings on packaging and package inserts.

[5] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTc=
[6] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzM=
[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzY=

8. **MoH&FW proposes to extend prior-intimation mechanism for bioavailability and bioequivalence studies**

The MoH&FW, on 3 September 2026, published a draft amendment to the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**) proposing to omit the words "*for export purpose only*" from the proviso to Rule 31(2). The amendment would extend the existing prior-intimation mechanism for specified bioavailability (**BA**) and bioequivalence (**BE**) studies conducted for the approval of new drugs in India beyond studies undertaken solely for export purposes. It also proposes corresponding amendments to recognise the acknowledgement of prior intimation and deemed approval under the NDCT Rules. The proposed amendment remains at the draft stage and has been issued for comments and suggestions from stakeholders.[8]

Industry Impact: If notified, the amendment would expand the circumstances in which eligible BA-BE studies for new-drug applications in India may proceed through the prior-intimation route, rather than being limited to studies conducted for export purposes. Sponsors and applicants conducting such studies should therefore assess whether the proposed changes could provide for a more streamlined regulatory pathway for their ongoing or planned BA-BE studies.



9. **MoH&FW proposes mandatory CCTV surveillance at premises supplying prescription drugs**

The MoH&FW, on 8 September 2026, published a draft amendment to the Drugs Rules proposing to amend Rule 65 to require the supply of any drug on the prescription of a Registered Medical Practitioner, other than by way of wholesale dealing, to be undertaken under a Closed-Circuit Television (**CCTV)** surveillance system installed and maintained at the licensed premises. The CCTV recordings would be required to be preserved for a minimum of three months. The proposed amendment remains at the draft stage and has been issued for comments and suggestions from concerned stakeholders until 8 October 2026.[9]

Industry Impact: If notified, licensed premises that supply prescription drugs will need to install and maintain CCTV surveillance systems and retain recordings for the prescribed period. Such premises should assess the potential infrastructure, storage and compliance requirements arising from the proposed amendment.

10. **MoH&FW issues advisory on oral nicotine pouches**

The MoH&FW, on 18 September 2026, issued an advisory on oral nicotine pouches (**ONP**), noting their increasing availability through online and offline channels in India. The advisory states that, having regard to their composition, intended use, claims, representation and manner of marketing, ONPs qualify as "*drugs*" under Section 3(b) of the D&C Act. Accordingly, their unauthorised manufacture, sale, distribution or storage would contravene Section 18(c) read with Section 27(b)(ii) or the D&C Act. The MoH&FW has advised

[8] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzU=
[9] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzQ=.

States/Union Territories to undertake coordinated surveillance and appropriate enforcement action against unauthorised, unapproved or unlicensed ONPs, including across retail, online, social media, e-commerce and delivery platforms. It has also directed Drug Control, Food Safety and AYUSH authorities to examine ONPs under their respective regulatory frameworks. The advisory notes that certain States, including Haryana, Andhra Pradesh, Tamil Nadu and Himachal Pradesh, have already initiated action against ONPs.[10]

Industry Impact: Issues relating to the regulatory status of these products are currently in a grey area. Companies considering India entry should therefore undertake a product-by-product assessment of composition, intended use, claims, labelling and marketing strategy before commercialisation. The heightened focus on online marketplaces, social media and delivery platforms also increases compliance and enforcement exposure across the distribution chain.

11. Central Drugs Standard Control Organisation clarifies authority for marketing authorisation applications for certain new drugs

The Central Drugs Standard Control Organisation (**CDSCO**), on 10 August 2026, issued a circular clarifying the processing of applications seeking permission to import and market new drugs that have not been approved anywhere in the world and for which Phase III Global Clinical Trials are ongoing or have been completed with participation of Indian subjects under the NDCT Rules. The circular explains that such applications will be examined and processed by the IND Division in accordance with the applicable regulatory requirements under the NDCT Rules, and directs applicants to submit such applications to the IND Division, CDSCO (HQ), New Delhi. The circular therefore only clarifies the competent division for processing applications and does not modify the substantive evaluation process.

Industry Impact: Sponsors developing new drugs supported by Global Phase III clinical trial data involving Indian participants should review their ongoing and proposed applications in India against the clarified processing requirements.

12. CDSCO directs regulatory action against unapproved Enclomiphene products

The CDSCO, on 10 August 2026, issued an Enforcement Letter to the Drugs Controllers of all State/ Union Territories, noting that certain manufacturers are manufacturing and/or marketing Enclomiphene and its combinations without permission from the CLA, despite such products being "*new drugs*". The letter directs the State/Union Territory licensing authorities to identify manufacturers, marketers, distributors, and retailers dealing with drug products containing Enclomiphene and its combinations without the requisite approvals and to initiate regulatory action against them.[11]

Industry Impact: Manufacturers, marketers, distributors and retailers dealing with Enclomiphene-containing products must review the regulatory status and permissions applicable to their products and supply chains, and assess any potential enforcement exposure arising from the CDSCO's directions.

13. The Food Safety and Standards Authority of India amends packaging requirements applicable to Pan Masala

The Food Safety and Standards Authority of India (**FSSAI**), on 7 August 2026, notified the Food Safety and Standards (Packaging) Amendment Regulations, 2026, to amend the Food Safety and Standards (Packaging) Regulations, 2018. The amendment inserts a new entry for Pan Masala in Schedule IV, specifying the packaging materials permitted for such products.

[10] https://ntcp.mohfw.gov.in/assets/document/CIRCULAR-ADVISORY/Advisory_on_Oral_Nicotine_Pouches_18-09-2026.pdf
[11] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2MDI=

Pan Masala may be packaged in paper, paperboard, cellulose or other naturally derived materials, provided these are free from plastic, including polyethylene, polypropylene, polyester, PVC and other synthetic polymers, copolymers or laminates, as well as aluminium foil or metallised layers. Tin and glass containers are also permitted. The amendment further incorporates, by reference, the relevant restrictions under the Plastic Waste Management Rules, 2016 on the use of plastic packaging for gutkha, tobacco and Pan Masala.[12]

Industry Impact: Pan Masala manufacturers and packers must review existing packaging materials and specifications and transition to packaging that complies with the revised requirements. This may require changes to packaging designs, procurement arrangements and contracts with third-party manufacturers and packing vendors, as well as an assessment of existing packing inventory, transition timelines and associated cost and supply-chain implications to mitigate regulatory and enforcement risks.

14. FSSAI proposes definitions for foods high in added fat, sugar or salt

The FSSAI, on 7 August 2026, published the draft Food Safety and Standards (Safe Food and Balanced Diets for Children in School) Amendment Regulations, 2026, proposing definitions for food products that are high in added fat, added sugar or salt. The draft sets separate thresholds for solid and liquid foods, based on the Dietary Guidelines for Indians, 2024, issued by the Indian Council of Medical Research (**ICMR**). The proposed amendment remains at the draft stage and has been issued for comments and suggestions from stakeholders.[13]

Industry Impact: Food businesses supplying or marketing products for consumption in schools should review the proposed definitions and thresholds against their existing product specifications and nutritional profiles. If finalised, the proposed definitions could require reassessment of product specifications, categorisation, nutritional information and representations relating to products supplied under school food programmes.

15. FSSAI prescribes timelines and methods for analysis of food samples

The FSSAI, on 14 September 2026, notified the Food Safety and Standards (Laboratory and Sample Analysis) Amendment Regulations, 2026. The amendment requires food analysts to issue reports for regulatory samples within 14 days of receipt and referral laboratories to issue reports in appeal cases within 14 days. For imported food samples, notified or referral laboratories must provide analysis reports within five days of receipt. The amendment also requires laboratories to use the methods of analysis specified in the FSSAI manuals and permits the use of validated methods prescribed by specified national or internationally recognised bodies where no method is available in the manuals. The amended regulations will come into force on 1 April 2027.[14]

Industry Impact: The amendment is expected to bring greater predictability and speed to regulatory testing and enforcement. The five-day timeline for imported food samples may reduce delays at ports and associated costs for importers. Laboratories will need to strengthen testing capacity and processes to meet the prescribed timelines. Recognition of validated national and international methods may provide greater flexibility, particularly for novel and technically complex products. Food businesses should review their laboratory arrangements and compliance protocols ahead of the 1 April 2027 implementation.

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[12] https://fssai.gov.in/docs/food-law/notice-comment/Final%20Food%20Safety%20and%20Standards%20(Packaging)%20Amendment%20Regulations,%202026.pdf?csrt=8851576380687509880.

[13] http://fssai.gov.in/docs/food-law/notice-comment/Draft%20Food%20Safety%20and%20Standards%20(Safe%20food%20and%20balanced%20diets%20for%20children%20in%20school)%20Regulations,%202026.pdf?csrt=16473719340775784972.

[14] https://fssai.gov.in/docs/food-law/notice-comment/Notification%20dated%2014.09.2026_amendment.pdf?csrt=10014054201402173931

16. FSSAI proposes restrictions on use of "*Paneer*" for non-milk products

The FSSAI, on 22 September 2026, proposed amendments to the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, to restrict the manufacture and sale of analogue products as "*Paneer*" where their constituents are not derived from milk. The proposed amendment seeks to introduce a new clause under Regulation 2.1.1 covering "*paneer made of constituents not derived from milk.*" Products already licensed or registered under the "*Analogue in Dairy Context*" category would also be required to discontinue the use of the term "*Paneer*" in their nomenclature, labelling and marketing. The proposed amendment remains at the draft stage and invites comments and suggestions from stakeholders until 21 November 2026.[15]

Industry Impact: The proposed amendment could have a significant impact on manufacturers of plant-based and other non-dairy products currently marketed as "*Paneer.*" Businesses may need to revise product names, labels, packaging and marketing materials. This could entail relabelling costs and changes to existing product registrations and distribution materials. The proposal may also increase regulatory scrutiny of products marketed under the "*Analogue in Dairy Context*" category. Industry stakeholders should assess the impact and consider making representations during the consultation period.

17. CDSCO's Subject Expert Committee recommends safety updates to semaglutide product information

The Subject Expert Committee on Endocrinology and Metabolism, at its meeting held on 8 September 2026, considered proposals to update the package inserts of semaglutide products. The Committee recommended approvals to certain changes to the safety information in package inserts of various Semaglutide formulations, including updates corresponding to safety information approved by the European Medicines Agency.[16]

Industry Impact: Marketing authorisation holders of semaglutide products should monitor the implementation of the recommended safety updates, obtain requisite approvals for making changes, and make corresponding changes to approved product information, where required.



18. CDSCO directs inclusion of DRESS Syndrome as an adverse drug reaction for Oxcarbazepine

The CDSCO, on 14 September 2026, directed the Drug Controllers of all States/Union Territories to require manufacturers of Oxcarbazepine based products to incorporate the Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome as an adverse drug reaction in the package inserts and promotional material for the affected products. The direction follows the assessment of adverse drug reaction reports by the National Coordination Centre of the Pharmacovigilance Programme of India and subsequent review by the Subject Expert Committee on Neurology and Psychiatry.[17]

[15] https://www.fssai.gov.in/docs/food-law/notice-comment/Notification%20dated%2023.09.2026.pdf?csrt=16694189601772281221.
[16] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/Recommendations%20Endocrinology%20and%20Metabolism%2008.09.2026.pdf
[17] https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadAdverseDrug/Recommendation%20of%20Oxcarbazepine%20%281%29.pdf

19. CDSCO raises concerns over unsupervised use of non-steroidal anti-inflammatory drugs and antibiotics

The CDSCO, on 21 September 2026, issued a circular highlighting the risk of chronic kidney disease associated with unsupervised use of non-steroidal anti-inflammatory drugs (**NSAID**) and antibiotics. The circular cautions against repeated or prolonged use of these medicines without medical advice, including self-medication, sharing of prescribed antibiotics and use of leftover medicines. Healthcare professionals have been advised to prescribe these drugs only where clinically indicated, in appropriate dosages and in line with antimicrobial stewardship practices. Pharmacists, retailers and distributors have been instructed to comply with the D&C Act while dispensing such drugs and not to encourage or facilitate self-medication with antibiotics or prescription-only NSAIDs.[18]

20. National Medical Commission reiterates restrictions on non-approved use of stem cell therapy

The National Medical Commission (**NMC**), on 5 September 2026, issued an advisory referring to the Supreme Court's order of 30 January 2026 in *Yash Charitable Trust & Ors. v Union of India & Ors.*[19] The advisory reiterates that stem cell therapy may be provided as routine clinical care only for certain approved conditions, and administering, prescribing, promoting or advertising such therapy for any other indication constitutes professional misconduct. State Medical Councils have been directed to examine suspected violations and, where misconduct is established after due process, take appropriate disciplinary action. The NMC has further clarified that such therapy for non-approved use may be offered only under an approved clinical trial.[20] In this regard, the MoH&FW, on 16 September 2026, also issued an advisory concerning the regulation of stem-cell therapy by States and Union Territories that have adopted the Clinical Establishments (Registration and Regulation) Act, 2010. The advisory provides that stem-cell therapy may be offered as standard care only for disease conditions or indications included in the approved list. It further states that stem-cell interventions for autism spectrum disorder should be undertaken only through clinical trials with all necessary regulatory approvals and directs State and district regulatory authorities to ensure compliance.[21]

Industry Impact: Clinics, practitioners and entities promoting stem cell therapies should ensure that their treatment offerings, prescriptions and advertisements remain within the scope of approved indications.

21. Directorate General of Foreign Trade introduces automated issuance of Free Sale and Commerce Certificates

The Directorate General of Foreign Trade (**DGFT**), through a notice dated 31 August 2026, introduced an automated process for issuance of Free Sale and Commerce Certificates (**FSC**) on its portal. Issued to exporters under the Foreign Trade Policy, these certificates cover products that fall outside the D&C Act. Eligible applications will be considered by the DGFT for automatic issuance based on specified processing parameters, while applications that do not meet these parameters will continue to be processed manually. The DGFT has also clarified that applications approved through the automated process may be subsequently flagged for review.[22]

Industry Impact: Exporters applying for FSCs should assess whether their applications meet the parameters for automated processing and ensure that supporting information remains accurate and complete, given that auto-approved applications may be subject to subsequent review.

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18 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2ODQ=
19 W.P.(C) No. 369 of 2022
20 https://nmc.org.in/whats-new/download/1023
21 https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=2311179&lang=1&reg=3.
22 https://content.dgft.gov.in/Website/dgftprod/48adc5b2-f0d4-4075-beb9-a2cd22993781/TN%20for%20FScc%20(1).pdf



TRANSACTIONS

1. **KKR to acquire Medicover India**
   KKR has entered into definitive agreements to acquire Medicover India, the Indian hospital operations of Swedish healthcare and diagnostics company Medicover AB, in a transaction valuing the business at approximately EUR 1.2 billion. The transaction involves the acquisition of the business from its existing shareholders, including the exit of minority shareholders, alongside a commitment from KKR to provide fresh capital to support its continued expansion. Medicover India operates 24 hospitals with approximately 4,800 beds across South and West India, with over 1,900 doctors and services spanning more than 80 clinical specialties. The acquisition will strengthen KKR's presence in India's organised hospital sector, with an established footprint across key healthcare markets including Maharashtra, Karnataka and Telangana.[23]

2. **Advent International to invest INR 3,150 crore in Yatharth Hospitals**
   Advent International has entered into a definitive agreement to invest INR 3,150 crore in Yatharth Hospital and Trauma Care Services Limited. Upon completion of the transaction, Advent is expected to acquire a 24.9% minority stake in the listed hospital company, subject to customary closing conditions. Founded in 2008, Yatharth operates nine multi-speciality hospitals with approximately 2,800 beds and an announced capacity of approximately 3,250 beds across NCR, Madhya Pradesh and Agra, making it one of North India's leading hospital networks.[24]

3. **Anupam Rasayan acquires controlling stake in Bliss GVS Pharma**
   Anupam Rasayan India has acquired 48.2% controlling stake in Bliss GVS Pharma Limited at INR 299 per share through its wholly owned subsidiary, Mates Visa Consultancy. The acquisition follows the definitive agreement signed in May 2026 and completion of the mandatory open offer process. Bliss GVS Pharma, a branded formulations company with over 150 brands across multiple therapeutic segments, operates six manufacturing facilities in Maharashtra with certifications including the U.S. Food and Drug Administration and European Union-Good Manufacturing Practice (**EU-GMP**). The transaction marks Anupam Rasayan's entry into finished dosage formulations and its third strategic inorganic transaction.[25]

[23] https://media.kkr.com/news-details?news_id=6a6c6df1-c849-4af4-a6a2-4fbef3d757a0.
[24] https://www.adventinternational.com/news/advent-international-to-invest-rs-3150-crore-in-yatharth-hospitals-for-24-9-stake/
[25] https://www.expresspharma.in/anupam-rasayan-concludes-acquisition-of-bliss-gvs-pharma/

4. **Kedaara Capital invests USD 200 million in Tynor Orthotics**

   Kedaara Capital has announced a USD 200 million investment in Tynor Orthotics Private Limited, acquiring a majority stake in the company. Founded in 1993, Tynor is a leading manufacturer of orthopaedic supports and rehabilitation products, with a distribution network covering more than 300,000 retail outlets and 8,000 hospitals across 60 countries. The company operates three manufacturing facilities and has built a broad portfolio of products for orthopaedic care and rehabilitation. Kedaara will work with Tynor's promoters, management team and existing strategic partner, Thuasne, to expand the business in India and international markets and increase manufacturing capacity.[26]

5. **Wipro Consumer Care acquires majority stake in Dermatouch**

   Wipro Consumer Care and Lighting has agreed to acquire a 60% stake in skincare company Dermatouch at an enterprise value of INR 387.5 crore, with the remaining 40% to be acquired over the next three years. Dermatouch offers skincare products including face washes, serums, creams, moisturisers and sunscreens, targeting concerns such as acne, pigmentation and sun protection. With a revenue of approximately INR 131 crore in FY 2026, the transaction marks Wipro Consumer Care's first investment in an Indian digital-first skincare brand and expands its presence in the growing beauty and personal care segment.[27]

6. **RPG Life Sciences acquires Raghava Life Sciences' active pharmaceutical ingredient and intermediates business**

   RPG Life Sciences, through its wholly owned subsidiary RPG Active Pharma Limited, has entered into a Business Transfer Agreement with Raghava Life Sciences Private Limited to acquire its active pharmaceutical ingredients (**API**) and intermediates business on a going-concern through a slump sale. The transaction involves a consideration of up to approximately INR 135 crore and includes an API manufacturing facility near Hyderabad with an installed capacity of around 300 KL. The EU-GMP-compliant facility manufactures 29 APIs, including 22 commercialised products and seven products under development.[28]

7. **Piramal Pharma acquires additional stake in Yapan Bio**

   Piramal Pharma completed the acquisition of an additional 40.67% stake in Yapan Bio Private Limited for an aggregate consideration of INR 76 crore. The acquisition increased Piramal Pharma's holding in Yapan Bio to 74%, making the Hyderabad-based company a subsidiary. Yapan Bio is a contract development and manufacturing organisation specialising in process development and characterisation, as well as good manufacturing practice (**GMP**) manufacturing services for Phase I and Phase II clinical trials involving vaccines and biologics. The company will continue to operate within Piramal Pharma Solutions.[29]



[26] https://kedaara.com/strategic-investment-in-tynor/

[27] https://www.business-standard.com/companies/news/wipro-consumer-care-to-acquire-60-stake-in-dermatouch-for-387-5-cr-126081800887_1.html

[28] https://www.rpggroup.com/assets/images/media/pg-active-pharma-acquires-api-business-of-raghava-life-sciences-to-strengthen-its-integrated-api-play-rpg-life-sciences..pdf

[29] https://www.prnewswire.com/news-releases/piramal-pharma-limited-completes-acquisition-of-controlling-stake-in-yapan-bio-private-limited-302854496.html

8. **Dr. Lal PathLabs acquires 70% stake in SN Genelab**

   Dr. Lal PathLabs Limited has approved the acquisition of a 70% stake in SN Genelab Private Limited from its existing shareholders. The acquisition is for cash consideration of up to INR 168 crore, together with a performance-linked earn-out capped at INR 31.5 crore. SN Genelab, incorporated in Gujarat in 2013, is engaged in diagnostic genomics services and reported a turnover of INR 57.96 crore for FY 2025–26. Following completion of the acquisition, which is expected by 30 November 2026, SN Genelab will become a subsidiary of Dr. Lal PathLabs. The transaction does not require any governmental or regulatory approvals. The acquisition is intended to strengthen Dr. Lal PathLabs' genomics capabilities and expand its portfolio of advanced diagnostic services.[30]

9. **LeapFrog Investments invests USD 40 million in Marengo Asia Hospitals**

   Marengo Asia Hospitals, an India focused hospital network, has raised USD 40 million in growth capital from LeapFrog Investments. Marengo operates five hospitals in India with approximately 2,000 beds and has expanded its network through a buy-and-build strategy involving regional hospitals and investments in clinical capabilities, technology and Centres of Excellence. The investment will support Marengo's continued expansion, including strengthening its presence in existing markets, enhancing specialised clinical capabilities and increasing its hospital bed capacity.[31]

10. **Rainbow Children's Medicare acquires 64% stake in Super Prime Medical Care**

    Rainbow Children's Medicare has acquired a 64% partnership interest in Super Prime Medical Care LLP, together with the corresponding capital contribution. The acquisition was completed pursuant to a Partnership Interest and Contribution Transfer Agreement with the existing partners of Super Prime Medical Care. Reports suggest that the transaction will strengthen Rainbow's existing healthcare network and expands its presence in the women and child healthcare segment. [32]

11. **Zenex Animal Health acquires SAVA Healthcare's companion animal business**

    Zenex Animal Health India, a leading animal healthcare company backed by Multiples Alternate Asset Management, has acquired SAVAVET, the companion animal business of SAVA Healthcare. The acquisition strengthens Zenex's presence in the growing pet healthcare segment and adds a portfolio of companion animal products across parasiticides, antibiotics, cardiac care, pain management, dermatology and wellness. The transaction marks Zenex's third acquisition following Ayurvet and VievePharma.[33]

12. **Cyrix Healthcare acquires Blue Star E&E's MedTech Solutions business**

    Cyrix Healthcare announced the completion of its acquisition of the MedTech Solutions business of Blue Star Engineering & Electronics Limited, a wholly owned subsidiary of Blue Star Limited. The acquired business provides medical imaging equipment sales, installation, clinical applications, maintenance, repairs, refurbishment and lifecycle management, with expertise in multi-brand computed tomography and magnetic resonance imaging systems. The transaction also brings the existing MedTech Solutions team and customer relationships into Cyrix Healthcare's platform. Financial terms were not disclosed.[34]

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30 https://nsearchives.nseindia.com/corporate/LALPATHLAB_24092026172628_Outcome.pdf

31 https://leapfroginvest.com/press-release/marengo-asia-hospitals-secures-40m-strategic-investment-to-expand-specialist-health-care-network/

32 https://nsearchives.nseindia.com/corporate/RAINBOWUSER_14082026134520_UpdateNellore.pdf

33 https://www.moneycontrol.com/news/business/companies/zenex-animal-health-acquires-sava-healthcare-s-pet-care-business-savavet-14041839.html#google_vignette

34 https://cyrixhealthcare.com/cyrix-healthcare-acquires-blue-star-medtech

13. Jagsonpal Pharmaceuticals to acquire Group Pharmaceuticals' wellness portfolio

Jagsonpal Pharmaceuticals has entered into a Business Transfer Agreement with Group Pharmaceuticals Limited for the acquisition of Group Pharma's Wellness Portfolio on a going-concern basis through a slump sale. The portfolio recorded turnover of approximately INR 24.6 crore in FY 2025-26 and comprises identified products, assets, contracts, employees and other arrangements relating to the business. The transaction provides for an initial consideration of INR 23.7 crore at closing, with additional consideration of up to INR 23 crore linked to FY 2027-28 sales, subject to an overall cap of INR 46.7 crore. The transaction is expected for completion on or before 1 November 2026, subject to the conditions contained in the agreement.[35]

14. Temple acquires London-based longevity medicine practice Longévous

Temple, a longevity and health-tech venture, has acquired Longévous, a London-based evidence-based longevity medicine practice, to strengthen its clinical and scientific capabilities ahead of its commercial launch. The financial terms of the acquisition were not disclosed. The acquisition comes as Temple prepares for the launch of its wearable device and expands its capabilities in longevity-focused healthcare. Longévous brings clinical and scientific expertise in longevity medicine to Temple as the company develops its healthcare and technology offerings.[36]

15. Sanofi Healthcare India acquires 15.20% stake in Sanofi India

Sanofi Healthcare India Private Limited, a part of the promoter group of Sanofi India Limited, acquired 35,00,000 equity shares of Sanofi India Limited from Hoechst GmbH on 24 September 2026. The shares, representing 15.20% of Sanofi India's equity share capital, were transferred through a block deal mechanism on the stock exchange as an inter-se transfer among members of the promoter and promoter group. The acquisition was undertaken pursuant to the exemption available under the SEBI (Substantial Acquisition of Shares and Takeovers) Regulations, 2011. Following the transaction, Sanofi Healthcare India held 15.20% of Sanofi India, while Hoechst GmbH's holding reduced from 60.38% to 45.18%.[37]



16. Linux Laboratories raises USD 70 million from ChrysCapital and Tata Capital Healthcare Fund

Linux Laboratories has raised USD 70 million in equity capital from ChrysCapital and Tata Capital Healthcare Fund III (TCHF III), with ChrysCapital acquiring a significant minority stake in the company. The transaction comprises a combination of primary capital and secondary purchase. Chennai based Linux is a specialty-focused domestic formulations company with over 125 brands spanning approximately 400 SKUs, with a strong presence in Central Nervous System therapies and a growing portfolio across dermatology, cardio-diabetics and nutraceuticals. The company also operates a WHO-GMP certified manufacturing facility supporting its formulations, contract drug manufacturing and export operations. [38]

[35] https://www.jagsonpal.com/wp-content/uploads/2026/09/SignedIntimationofAcquisition.pdf
[36] https://entrackr.com/news/temple-acquires-london-based-longevity-medicine-practice-longevous-12443989
[37] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/sanofi-healthcare-buys-15-2-stake-in-sanofi-india-for-rs-1068-crore/articleshow/134466492.cms
[38] https://www.expresspharma.in/linux-secures-usd-70mn-strategic-investment-from-chryscapital-and-tata-capital-healthcare-fund/

17. Ultrahuman raises USD 70 million

Ultrahuman has raised USD 70 million in funding led by Qualcomm Ventures, with participation from Labcorp, Alpha Wave, Blume, Nexus, Alteria and other investors. The Bengaluru-based healthtech company will use the capital to expand research and development across sensing technology, artificial intelligence, miniaturised electronics and health algorithms, while increasing investments in clinical science and large-scale research. The funding will also support the global expansion of its Blood Vision blood-testing platform and metabolic health platforms as Ultrahuman seeks to expand beyond its smart-ring business into a broader health intelligence platform built around continuous physiological data.[39]

18. Piramal Alternatives invests INR 215 crore in Kolors Healthcare

Piramal Alternatives, on 26 August 2026, invested INR 215 crore in Kolors Healthcare India Private Limited through its India Credit Opportunities Fund II. Kolors operates a chain of wellness and preventive healthcare centres in South India. The investment will support the expansion of its clinic network, improvements to existing infrastructure, diversification of its services and the development of its centres under the "*Kolors 2.0*" initiative.[40]

19. Butterfly Learnings raises INR 65 crore in Pre-Series B funding

Butterfly Learnings has raised INR 65 crore in a Pre-Series B funding round led by Inflexor Ventures, with participation from existing investors Enzia Ventures, Insitor Partners and IIM Ahmedabad Ventures. The company operates a paediatric behavioural healthcare platform focused on neurodevelopmental care.[41]

20. Disha raises INR 43.88 crore in Series A funding

Disha, formerly known as Curelink, raised INR 43.88 crore in a Series A funding round led by General Catalyst in September 2026, with participation from existing investor Elevation Capital and Flamel Performing Creatives. The company operates a health coaching platform enabled by AI and is focused on personalised chronic-care support.[42]

21. Medulance raises INR 24 crore in Series A-2 funding

Medulance raised approximately INR 24 crore in a Series A-2 funding round in September 2026 from Auxano Capital, existing investors Alkemi and Equentis, and a group of angel investors. The company operates a technology-enabled emergency response and ambulance network and provides services linking ambulances and medical teams and hospitals.[43]

22. Ayati Devices raises INR 15 crore in Pre-Series A funding

Ayati Devices has raised INR 15 crore in a Pre-Series A funding round led by Inflexor Ventures. The Bengaluru-based medical technology company develops portable diagnostic devices for diabetic foot complications and peripheral vascular disease, enabling screening outside tertiary hospitals. The funds will be used to expand manufacturing capacity, enter additional international markets, strengthen its team and continue research and development of its diagnostic technologies.[44]

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39 https://www.moneycontrol.com/news/business/startup/ultrahuman-raises-70-million-in-funding-led-by-qualcomm-ventures-14022588.html

40 https://www.ntvenglish.com/press-notes/piramal-alternatives-invests-%E2%82%B9215-crore-in-kolors-healthcare-to-accelerate-expansion-and-transform-preventive-wellness-delivery-across-india.html/amp

41 https://www.inflexor.vc/news/butterfly-learnings-raises-rs-65-cr-funding-led-by-inflexor-ventures

42 https://www.veilstrat.com/funding-news/93cdf031-16fb-4736-aa29-d3647ffc44f2

43 https://jantascope.com/news/medulance-raises-24-crore-as-it-builds-a-bigger-smarter-ambulance-network-across-india.

44 https://www.inflexor.vc/news/ayati-devices-raises-15-crore-pre-series-a-funding-led-by-inflexor-ventures-read-more-at-https-entrepreneur-economictimes-indiatimes-com-news-funding-ayati-devices-raises-15-crore-pre-series-a-funding-led-by-inflexor-ventures-133142047.

23. Hearzap acquires Amplifon's India business

Hearzap, an Indian hearing-care services provider, has completed the acquisition of Amplifon's hearing healthcare business in India. The acquired business includes approximately 115 directly operated clinics, 460 employees, and recorded revenues of around EUR 12 million in 2025. The acquisition brings Amplifon's Indian operations into Hearzap's existing hearing healthcare business. The consideration was not disclosed.[45]



LITIGATION

1. Supreme Court declines to interfere with High Court ruling on jurisdiction of Central Drugs Inspector

By an order dated 15 September 2026 in *Union of India v M/s Salus Pharmaceuticals & Ors.*,[46] the Supreme Court of India dismissed the Union Government's challenge to a judgment of the Himachal Pradesh High Court. The case concerned the prosecution of M/s Salus Pharmaceuticals and its partners under the D&C Act in relation to a drug formulation reported to be of non-standard quality.

The High Court found that the Central Government Drugs Inspector who initiated the prosecution did not have the authority to do so, as the relevant executive functions rested with the State authorities. It also noted that the complaints did not establish that the partners were responsible for the firm's business, particularly its manufacturing operations, which were handled by authorised technical personnel. The drug samples had also not been tested within the 60-day period prescribed under Rule 45 of the Drugs Rules, depriving the petitioners of their right to controvert the test reports. By a separate judgment dated the same day, the High Court also quashed the complaint and consequential proceedings in a connected matter involving a different drug sample manufactured by M/s Salus Pharmaceuticals.The Supreme Court found no sufficient ground to interfere with the High Court's decision under Article 136 of the Constitution and dismissed the Union Government's challenge.

[45] https://corporate.amplifon.com/en/investors/press-releases/f-pr-closing-india-12-08-2026
[46] SLP (Crl.) Diary No. 50645 of 2026

2. Supreme Court examines corporate criminal liability in pharmaceutical prosecution

In its judgment dated 7 September 2026 in *Sanofi India Ltd. v Central Bureau of Investigation*,[47] the Supreme Court considered whether criminal proceedings against a company could be quashed solely because no employee or official of the company had been separately arraigned. The case arose from the appellant company's supply of pharmaceutical products to the Rare Materials Project of the Bhabha Atomic Research Centre (**BARC**). The Central Bureau of Investigation alleged that a BARC official had conspired with the company in the procurement of medicines, causing wrongful loss to BARC. However, neither the appellant company nor any of its employees or officials was named as an accused in the chargesheet.

The Supreme Court rejected the appeal, holding that criminal proceedings against a corporate entity cannot be quashed merely because no natural person has been separately arraigned or named as an accused. A corporation's actions and state of mind can be assessed through the conduct of individuals acting on its behalf. Whether the conduct of and *mens rea* of a particular individual can be attributed to the corporation may need to be examined at trial. The Court therefore declined to quash the proceedings at the threshold stage. The judgment is particularly relevant to pharmaceutical companies, given the potential for criminal prosecution arising from the manufacture, supply, distribution, or procurement of pharmaceutical products, even where individual employees or officers have not been separately arraigned at the initial stage.

3. Supreme Court seeks clarification from FSSAI on proposed front-of-pack warning labels for packaged foods

In *3S and Our Health Society v Union of India*,[48] the Supreme Court considered the FSSAI's proposal to introduce Front-of-Pack Labelling (FoPL) for packaged foods containing specified levels of nutrients of concern. In its order dated 10 September 2026, the Court sought clarification from the Union Government and FSSAI on 13 aspects of the proposed framework, including the basis for the nutrient thresholds, the proposed red hexagonal warning label, its size and placement, the use of pictorial representations and the proposed period for voluntary compliance. The Court also directed the FSSAI to file an affidavit addressing these issues.

At the subsequent hearing on 28 September 2026, FSSAI placed its proposed implementation framework and timeline before the Court, which included approximately four months to finalise the draft regulations, a 60-day public consultation period and a 365-day voluntary compliance period after notification. FSSAI also proposed a single-phase warning system for products exceeding the prescribed threshold for any one specified nutrient. The Court questioned both the proposed timeline and the need for a voluntary compliance period and reserved the matter for orders. The framework therefore remains subject to the Court's further directions.

4. Bombay High Court rules that duty-free sales are not exempt from domestic laws; leaves classification of nicotine pouches open

In its judgment dated 22 September 2026 in *Mumbai Travel Retail Limited v Union of India & Ors*. and *Flemingo Dutyfree Shop Private Limited v Union of India*,[49] the Bombay High Court considered challenges by Mumbai Travel Retail Limited and Flemingo Dutyfree Shop Private Limited to communications dated 2 April 2026 and 8 April 2026, respectively, issued by the Assistant Drugs Controller (I), Mumbai Airport, directing them to stop the sale of nicotine pouches at duty-free shops at Mumbai International Airport on the ground that a valid Registration Certificate and import licence were required under the D&C Act. The petitioners argued that, since the products were sold exclusively through duty-free shops beyond the customs barrier, the domestic regulatory regime did not apply. The Court rejected this contention and held that duty-free transactions

[47] Criminal Appeal No. 4250 of 2026
[48] W.P. (C) No. 437 of 2024
[49] W.P. No. 3079 of 2026 and W.P. (L) No. 20740 of 2026

do not enjoy blanket immunity from domestic regulatory or public health laws, and that any exemption is confined to fiscal levies such as customs duty and taxes.

However, the Court did not decide whether nicotine pouches sold under the brands ZYN and FOX are "*drugs*" under Section 3(b) of the D&C Act. It noted that the communication dated 2 April 2026 did not specify which part of the Section 3(b) definition applied and that the available record lacked sufficient product specifications to determine their classification. The Court therefore left the classification and licensing questions open, while granting the petitioners liberty to file representations, supported by relevant material, before the appropriate authority, including CDSCO, within four weeks of the judgment being uploaded. Any such representations filed must be decided by a reasoned order within 30 days of receipt, after a hearing if necessary.

5. **Delhi High Court sets aside FSSAI order directing Red Bull to discontinue using the "*Energy Drink*" descriptor**

In its order dated 29 September 2026 in *Red Bull India Pvt. Ltd. v Union of India & Ors.*,[50] the Delhi High Court set aside an order issued by the FSSAI on 30 June 2026 directing Red Bull India to stop using the term "*Energy Drink*" on its products. The Court noted that Red Bull had not been given an opportunity to respond to the proposed action, show cause or explain its position before the order was issued by the FSSAI. Given the serious civil consequences of the order, including its potential impact on the company's business and employees, the Court held that the order violated the principles of natural justice. The Court also noted that the matter did not involve any extreme or emergent situation warranting such action without first hearing the company.

While setting aside the order and the consequential steps taken pursuant to it, the Court granted FSSAI liberty to pass an order afresh after issuing a show-cause notice to the petitioner, Red Bull, and providing it an opportunity to respond and be heard. The Court did not examine the merits of the dispute, including whether the products violate any provision of the Food Safety and Standards Act, 2006 (**FSS Act**), or whether FSSAI has the power to direct discontinuation of the "*Energy Drink*" descriptor. Thus, the substantive regulatory issues remain open for consideration by FSSAI following due process.

6. **Delhi High Court stays FSSAI prohibitory order against Dabur over "100%" claims**

In its interim order dated 7 August 2026 in *Dabur India Ltd. v Union of India & Ors.*,[51] the Delhi High Court considered the petitioner's challenge to a prohibitory order issued by the FSSAI on 3 August 2026. The order concerned the use of claims such as "*100% Pure*", "*100% Natural*", "*100% Purity Guaranteed*" and "*100% Organic*" by the petitioner on its food products. Dabur argued that the prohibitory order had been passed without issuance of a show-cause notice or affording an opportunity to be heard. The Court formed a *prima facie* view that a prohibitory order of this nature should not have been passed without first hearing the affected party. It therefore stayed the impugned prohibitory order and issued notice to the respondents.



[50] W.P. (C) No. 14413 of 2026
[51] W.P.(C) No. 11282 of 2026

At the subsequent hearing on 24 August 2026, the matter was re-notified for 16 December 2026, with the interim stay continuing until the next hearing. The Court has not yet determined whether Dabur's "*100%*" comply with the relevant FSSAI regulations. The matter remains pending.

7. Bombay High Court considers challenge to FSSAI prohibition order against Old Monk

In its order dated 3 September 2026 in *M/s Mohan Rocky Springwater Breweries Private Limited v Union of India & Ors.*,[52] the Bombay High Court considered a challenge by the manufacturer of Old Monk to an FSSAI prohibition order concerning its products. The dispute includes FSSAI's objections to the use of rum flavouring and the "*7 years old blended*" claim. FSSAI's position is that a product made using neutral spirit and added rum flavouring should not be marketed simply as "*rum*", but as "*rum-flavoured spirit*" or "*flavoured rum*". It also argued that where spirits of different ages are blended, the declared age should reflect the youngest spirit in the blend.

During the proceedings, the manufacturer submitted three revised product labels for FSSAI's consideration, without prejudicing its legal rights and contentions. The Court adjourned the matter to allow FSSAI to consider the proposed modifications. The Court has not yet ruled on the labelling issues, and the proceedings remain pending.

A similar challenge by United Spirits Limited (**USL**) concerned McDowell's No. 1 Celebration Matured Rum manufactured at its Baramati facility. USL had challenged FSSAI's prohibition order, including its findings on product labelling and the legal basis and procedure for the prohibition. Following discussions with USL, FSSAI revoked the order on 17 August 2026. USL then withdrew its petition, and the Bombay High Court recorded the withdrawal on 24 August 2026.[53]

8. Bombay HC examines Customs officers' power to test imported food before FSSAI sampling

In its order dated 6 August 2026 in *Indu Shekhar v Union of India & Ors.*,[54] the Bombay High Court considered whether Customs officers could independently draw samples of imported food articles and send them to the Central Revenues Control Laboratory (**CRCL**) for testing before an authorised FSSAI officer collected samples. The matter arose from the detention of imported consignments of roasted areca nuts and the petitioner's challenge to Customs' practice of conducting testing separately from FSSAI's prescribed import sampling process.

The Court observed that the issue was recurring and directed the Revenue authority to explain its position on compliance with the Food Safety and Standards (Import) Regulations, 2017 and the relevant Central Board of Indirect Taxes and Customs instructions. The Revenue was directed to file its affidavit by 3 September 2026, with liberty being granted to the petitioner to file a rejoinder by 10 September 2026. The matter is pending for final hearing and is now listed on 15 December 2026. The Court did not, at this stage, finally determine whether Customs could independently sample and test imported food through CRCL before FSSAI sampling takes place.

9. Bombay High Court holds that FSSAI license suspension cannot continue indefinitely after deficiencies are rectified

In its order dated 8 September 2026 in *Hotel Alankar v State of Maharashtra and Ors.*,[55] the Bombay High Court considered the continued suspension of an FSSAI license issued to a hotel. A surprise inspection of the petitioner's hotel establishment on 7 July 2026 found 69% compliance and identified deficiencies, including

[52] W.P. (C) No. 7422 of 2026
[53] W.P. (C) No. 10196 of 2026
[54] W.P. No. 8289 of 2026
[55] W.P. No. 3806 of 2026

the sale of alcohol and other beverages without the required license endorsement, common storage and frying facilities for vegetarian and non-vegetarian food, and improper disposal of used cooking oil. A subsequent re-inspection recorded 97% compliance.

The Court held that suspension of an FSSAI license under the FSS Act is a public-health measure and cannot continue indefinitely once the identified deficiencies have been rectified. It therefore revoked the suspension and restored the license, subject to continued monitoring and an undertaking from the hotel that it would not sell products not endorsed on its license. The Court also noted that any future violations could be addressed under Section 55 (failure to comply with the directions of a Food Safety Officer) and Section 63 (carrying out a food business without a license) of the FSS Act, rather than by continuing the suspension indefinitely.

10. Bombay High Court quashes prosecution against Britannia Dairy for failure to follow statutory procedure

In its order dated 11 September 2026 in *Britannia Dairy Pvt. Ltd. v State of Maharashtra & Anr.*,[56] the Bombay High Court quashed criminal proceedings against Britannia Dairy arising from an FSSAI prosecution concerning Britannia Cheese Cubes. The matter arose after a Food Analyst found that a sample of the product did not meet the applicable food safety standards. However, the Food Safety Officer issued the statutory notice to the marketer only after the product's shelf life had expired and did not provide the Food Analyst's report. This prevented the marketer from having the sample retested and challenging the Food Analyst's findings through the statutory appellate mechanism.

The Court held that the statutory safeguards governing sampling, communication of the Food Analyst's report and the opportunity for retesting were mandatory, and that their denial deprived the applicant of a substantive procedural right. It accordingly held that continuation of the prosecution would be untenable and quashed the proceedings.

11. Delhi High Court dismisses an FSSAI advertising dispute from Maharashtra for lack of territorial jurisdiction

In its judgment dated 14 September 2026 in *P.B. Agro LLP v Union of India & Ors.*,[57] the Delhi High Court considered a challenge by the petitioner to a show-cause notice issued by the Food and Drug Administration, Greater Mumbai Division, Mumbai (**FDA Mumbai**) to three brand ambassadors of one of its products, namely, VIMAL Elaichi. The notice alleged violations relating to the product's advertising and promotion, including restrictions on advertisements and unfair trade practices under Section 24, and the prohibition of pan masala under Section 30(2)(a) of the FSS Act. P.B. Agro contended that the Delhi High Court had jurisdiction because it was based in Delhi and central authorities, including the MoH&FW, FSSAI and Central Consumer Protection Authority (**CCPA**) were located there. The Court, however, noted that the show-cause notice had been issued by FDA Mumbai to three Mumbai-based brand ambassadors and that P.B. Agro itself had not been issued any notice.

The Court held that the notice was an independent action of FDA Mumbai to persons residing in Maharashtra concerning alleged activities in that State. The presence of central authorities in Delhi, without any decision or direction from them being challenged, did not create a sufficient territorial nexus under Article 226 of the Constitution. The Court emphasised that the petitioner was required to demonstrate that a material part of the cause of action had arisen within the territorial jurisdiction of the Delhi High Court. The Court accordingly dismissed the petition, without examining the merits of the allegations, for want of territorial jurisdiction and observed that the appropriate remedy lay before the competent courts in Maharashtra.

[56] Crim. Application No. 842 of 2017
[57] W.P.(C) No. 12664 of 2026

12. Delhi High Court clarifies that the warning requirement for Chlorpheniramine Maleate–Phenylephrine combinations applies prospectively

In its judgment dated 18 September 2026 in *Glenmark Pharmaceuticals Ltd. & Anr. v Union of India & Ors.*,[58] the Delhi High Court considered a challenge to a notification dated 18 August 2026 issued under Section 26A of the D&C Act, requiring manufacturers of fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride to carry a warning stating that the combination should not be used in children below four years of age. The Court held that since the notification came into force upon its publication in the Official Gazette and did not expressly provide for retrospective application, the warning requirement applied only from 18 August 2026 onwards.

The Court directed the petitioner to comply with the warning requirement for all stocks manufactured and circulated after that date. For stocks manufactured on or before 18 August 2026, Glenmark was directed to publish notices in two national newspapers, issue advisories to doctors, retailers and chemists, and file details of such stocks by affidavit. Subject to compliance with these conditions, the Court directed that no coercive measures be taken against the petitioner under Section 28B of the D&C Act.

13. Bombay HC holds that the National Pharmaceutical Pricing Authority cannot impose ceiling prices without following the prescribed pricing mechanism

In its judgment dated 22 September 2026 in *M/s. Pharmed Ltd. & Anr. v Union of India & Ors.*,[59] the Bombay High Court considered a challenge to National Pharmaceutical Pricing Authority (**NPPA**) notifications fixing ceiling prices for certain formulations and their application to Cartigen Forte, a formulation used to treat osteoarthritis. The dispute concerned a notification dated 27 September 2007 fixing ceiling prices for specified multivitamin and mineral formulations, a subsequent notification dated 30 January 2009 seeking to extend existing ceiling prices to formulations containing scheduled drugs, and consequential demands for alleged overcharging.

The Court held that the inclusion of scheduled bulk drugs in Cartigen Forte did not, by itself, make the formulation subject to an existing ceiling price. NPPA was required to determine and notify a ceiling price for the specific formulation in accordance with paragraphs 7 and 9 of the Drugs (Prices Control) Order, 1995 (**DPCO 1995**). The Court found that the 2007 notification did not cover Cartigen Forte and that the 2009 notification was *ultra vires* the DPCO 1995 because it bypassed the prescribed price-fixation mechanism. Accordingly, the Court quashed the 2009 notification in its entirety, the 2007 notification to the extent it was applied to Cartigen Forte, and the consequential demand and recovery proceedings.

14. Delhi HC stays NPPA demand notice against AstraZeneca Pharma India over alleged overcharging of Betaloc-50

In its order dated 24 August 2026 in *AstraZeneca Pharma India Limited v National Pharmaceutical Pricing Authority, Department of Pharmaceuticals & Anr.*,[60] the Delhi High Court considered AstraZeneca's challenge to a demand notice issued by the NPPA alleging overcharging for Betaloc-50 tablets under the Drugs (Prices Control) Order, 2013 (**DPCO 2013**). AstraZeneca challenged the notice on several grounds, including that it had been issued without giving the company an opportunity to be heard.

The Court stayed the operation of the demand notice until the next hearing, subject to AstraZeneca depositing 15% of the amount demanded with the Registrar General of the Court. The matter is next listed for hearing on 10 February 2027. The Court's order is interim and does not determine the merits of the alleged overcharging.

58 W.P.(C) No. 13762/2026
59 W.P. No. 595 of 2017
60 W.P. (C) No. 12314 of 2026

15. Delhi High Court grants FDC Limited eight months to exhaust existing Enerzal stock bearing "*electrolyte*" descriptor

In its order dated 25 August 2026 in FDC Ltd. v Union of India & Anr.,[61] the Delhi High Court considered FDC Ltd.'s challenge to an FSSAI notice directing it to discontinue the use of the descriptors "electrolyte" and "*electrolyte drink*" on its Enerzal products. FDC submitted that these descriptors had appeared on its product labels since 2018 and that its FSSAI license had been renewed as recently as January 2026. The Court noted that the respondents did not dispute that no improvement notice under Section 32 of the FSS Act had been issued to FDC before enforcement action was taken.

Without deciding the merits of the dispute, the Court granted FDC limited interim relief and stayed further coercive action for eight months. During this period, FDC was permitted to exhaust its existing stock bearing the disputed descriptors and was directed to make the necessary changes to its labels.

16. Delhi High Court quashes criminal proceedings arising from the 2015 Maggi prosecutions

In its judgment dated 6 August 2026 in *Dharmendra Hansraj Kotak & Ors. v State of Delhi & Anr.*,[62] the Delhi High Court considered petitions seeking quashing of criminal proceedings arising from samples of Maggi Noodles collected during the nationwide sampling exercise in May 2015. The prosecutions were based on Food Analyst reports alleging lead levels above the prescribed limit and, in one case, misbranding due to the declaration "*No Added MSG*".

The Court noted that the original Food Analyst reports had subsequently been subjected to judicial scrutiny and that fresh testing had been conducted by the Central Food Technological Research Institute, a Referral Food Laboratory, pursuant to directions of the Supreme Court. As the prosecutions rested entirely on the original reports, with no independent evidence of adulteration, the Court found that subsequent judicial scrutiny and fresh scientific evaluation had substantially eroded the evidentiary value of those reports. It also considered subsequent decisions of the Himachal Pradesh and Uttarakhand High Courts concerning prosecutions arising from the same controversy. The Court accordingly quashed the criminal complaints, the summoning orders, and all consequential proceedings, holding that their continuation would amount to an abuse of the Court's process.

17. Delhi High Court directs Pharmacy Council of India to issue permanent approval letters reflecting approved intake for pharmacy institutions

In its order dated 5 August 2026 in *R.S. College of Pharmacy & Anr. v Pharmacy Council of India* and connected matters,[63] the Delhi High Court considered petitions by pharmacy institutions seeking permanent approval under Section 12(1) of the Pharmacy Act, 1948 (**Pharmacy Act**). The petitions challenged communications issued by the Pharmacy Council of India (**PCI**) showing zero or reduced student intake for certain institutions despite their existing approvals.

The Court noted that, in its earlier judgment dated 1 July 2024, it had held that the requirement for annual continuation of approval was without authority of law. This decision was subsequently upheld by the Division Bench on 29 May 2026, and the Supreme Court had declined to grant an interim stay.

Accordingly, the Court directed the PCI to issue permanent approval letters, with QR codes, reflecting the intake already approved for the concerned institutions. It also set aside the PCI communications showing zero or reduced intake. The Court clarified that this direction did not curtail the PCI's statutory power under Section 13 of the Pharmacy Act to withdraw approval where the prescribed conditions are not met.

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61 W.P.(C) No. 8602 of 2026
62 CRL.M.C. Nos. 7013 of 2022 & 328 of 2023
63 W.P.(C) No. 11048 of 2026 & connected matters



POLICY

1. **Parliamentary Committee recommends tighter price regulation of medical devices**

   The Parliamentary Standing Committee on Health and Family Welfare, in its 176th Report on *Affordability and Accessibility of Healthcare Facilities in Public and Private Sector*, presented on 7 August 2026, recommended measures to address the high cost of medical devices and drugs and the significant margins between their landing price and maximum retail price. The Committee recommended that this difference should not exceed 20%, while emphasising that price rationalisation should not affect product quality or market availability.

   The Committee also proposed a framework for identifying medical devices requiring price intervention based on factors including disease burden, procedure volumes and the out-of-pocket expenditure associated with such devices. It recommended statutory price caps for medical devices in the highest-priority category, drawing on the existing regulation of coronary stents and knee implants, and trade-margin controls rather than an outright price cap for devices warranting a lower level of intervention.

   Further, the Committee recommended that high-volume diagnostic and therapeutic devices, including advanced pacemakers, ophthalmic lenses and implantable pumps, be evaluated for inclusion in the scheduled list under the DPCO 2013. The recommendations, if implemented, could significantly expand the scope of price regulation applicable to medical devices in India.[64]

2. **Parliamentary Committee recommends national strategy and digital registry for chronic kidney diseases**

   The Parliamentary Standing Committee on Health and Family Welfare, in its 177th Report on *"Prevalence of Chronic Kidney Disease in India – Prevention, Diagnosis, Treatment and Management"*, recommended that the MoH&FW formulate a comprehensive national strategy for chronic kidney disease (**CKD**), supported by dedicated CKD awareness programme, earlier diagnosis and improved disease surveillance.

   Key recommendations include requiring estimated glomerular filtration rate (**eGFR**) to be automatically reported alongside every serum creatinine test and establishing a National Renal Registry integrated with the Ayushman Bharat Digital Mission and Pradhan Mantri National Dialysis Program portal.[65]

[64] https://bucketapi.rajyasabha.digital/publicbucket/uploads/committee/2026_08_07_committee_3357_827_6a75ba41abac3.pdf
[65] https://bucketapi.rajyasabha.digital/public-bucket/uploads/committee/2026_08_07_committee_3360_3978_6a75bc6209cd2.pdf

3. **Parliamentary Committee recommends region-specific and technology-enabled vector-borne disease strategy for North-East India**

   The Parliamentary Standing Committee on Health and Family Welfare, in its 175th Report on "*A Study of Vector-Borne Diseases in North-East India*", recommended a region-specific, integrated and multi-sectoral strategy for control and elimination of vector-borne diseases in the North-East. The report emphasises strengthened surveillance, expanded diagnostic infrastructure, cross-border coordination, One Health implementation, climate-informed planning, AI-enabled early warning systems, and acceleration of vaccine development and immunisation measures for diseases such as dengue, chikungunya and Japanese Encephalitis.[66]

4. **94th Drugs Technical Advisory Board Meeting: Key recommendations on drugs, medical devices and clinical research**

   The DTAB, at its 94th meeting held on 27 August 2026, [67] considered various regulatory proposals concerning drugs, medical devices, blood centres and clinical research. Its recommendations covered restrictions on new nicotine formulations, eligibility requirements for wholesale drug license holders, a prior-intimation mechanism for specified imports and BA-BE studies, expansion of import infrastructure, relaxation of certain GMP requirements, enhanced blood donor traceability, wider exemptions for low-risk medical devices, and prohibition of the manufacture, sale and import of Lindane.

   The key recommendations are set out below.

   a. **Non-approval of new nicotine formulations:**
      DTAB recommended against approving new nicotine formulations in the public interest. The recommendation followed consideration of CDSCO applications for nicotine pouches containing 2 mg, 4 mg and 6 mg nicotine, proposed for smoking cessation and management of nicotine-withdrawal symptoms. DTAB considered the National Tobacco Control Programme's concerns regarding their addictive potential, health risks and lack of established efficacy as smoking-cessation aids, and observed that tobacco-control measures should support de-addiction rather than continued nicotine dependence through alternative products.

   b. **Competent persons under wholesale drug licenses restricted to registered pharmacists:**
      DTAB recommended amending Rule 64 of the Drugs Rules to restrict eligibility for competent persons supervising wholesale drug operations under Forms 20B and 21B to registered pharmacists. The recommendation follows reconsideration of the proposal, which had remained pending since a draft notification issued in 2016, and was based on the Board's assessment that a sufficient number of registered pharmacists are now available across the country.

   c. **Additional locations for drug, medical device and cosmetic imports:**
      DTAB recommended amendment of Rule 43A of the Drugs Rules to notify additional ports, inland container depots (and special economic zones for import of drugs, medical devices and cosmetics. The recommendation covers specified locations including Sanath Nagar, Thimmapur, Gandhidham/Mundra, Sonipat, Dadri, Noida International Airport, Garhi Harsaru, Piyala, Whitefield and Bommasandra, with the objective of facilitating import clearance and reducing logistical bottlenecks.

   d. **Prior-intimation mechanism for specified imports of new drugs:**
      DTAB recommended introducing a prior-intimation mechanism for imports of new drugs and investigational new drugs intended exclusively for examination, testing and analysis. The recommendation would exclude specified higher-risk categories, including sex hormones, cytotoxic drugs, beta-lactams,

[66] https://bucketapi.rajyasabha.digital/publicbucket/uploads/committee/2026_08_07_committee_3369_827_6a75ca152e61f.pdf
[67] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MzEwMg==

vaccines, cell and gene therapy products, live microorganism-containing biologics and narcotic or psychotropic substances. DTAB also recommended reducing the timeline for issuance of Form CT-17 from 90 to 45 working days.

e. **GMP requirements relaxation for products intended for analytical and non-clinical testing:**
DTAB recommended amending Rules 55 and 63 of the NDCT Rules to distinguish products manufactured solely for analytical and non-clinical testing from those intended for clinical trials and BA-BE studies. The recommendation would permit the former to be manufactured in accordance with GMP principles and appropriate traceability requirements, while retaining existing GMP requirements for clinical and BA-BE products.

f. **Mandatory e-RaktKosh registration and donor authentication:**
DTAB recommended amendments to the Drugs Rules to require all blood centres to register on the e-RaktKosh portal and upload relevant donor and blood collection data. The recommendation also contemplates donor authentication through Aadhaar-linked OTP or ABDM (Ayushman Bharat Digital Mission) ID / ABHA mechanisms to strengthen donor traceability, facilitate post-donation follow-up and prevent donations by deferred or high-risk donors at multiple centres.

g. **Expanded exemptions for low-risk and home-use medical devices:**
DTAB recommended amendments to the Eighth Schedule of the MD Rules to expand exemptions for specified low-risk and home-use devices, including absorbent cotton, bandages, gauze, adhesive plasters, pulse oximeters, blood pressure monitors, thermometers, pregnancy test kits and glucometers. DTAB also recommended exemptions for specified devices imported for exhibition or demonstration and for first-aid kits imported for captive use, subject to safeguards, including quality, residual shelf life, and restrictions on resale.

h. **Prohibition of manufacture, sale and import of Lindane:**
DTAB recommended prohibiting the manufacture, sale and import of Lindane in India, citing environmental and public health concerns, the availability of alternative therapeutic options and international regulatory developments.

i. **Prior-intimation for domestic BA-BE studies:**
DTAB recommended extending the prior-intimation mechanism to BA-BE studies conducted in India for obtaining approval of new drugs. The recommendation is intended to reduce procedural delays and provide a consistent regulatory framework for such studies, while retaining regulatory oversight under the NDCT framework.



5. **Drugs Consultative Committee's 70th Meeting: Key regulatory recommendations and proposed amendments**

The Drugs Consultative Committee (**DCC**), at its 70th meeting held on 18 September 2026, considered several regulatory proposals concerning drug regulation, licensing processes and oversight mechanisms. The minutes of the meeting, published on 30 September 2026,[68] set out the DCC's recommendations, including measures relating to labelling requirements, license retention, narcotic and psychotropic drug diversion, sterile drugs, and certain regulatory amendments, which have been summarised below.

a. **Red warning on cough syrup labels for children below four years:** DCC agreed in principle to require cough syrup labels to prominently display, in red, a warning against use in children below four years of age. It also recommended prohibiting images of infants, toddlers, toys or similar imagery suggesting suitability for young children and prescribing a sufficiently large font size for the warning. DCC recommended amending Rule 96 of the Drugs Rules to implement these requirements.

b. **Integration of license retention with Online National Drugs Licensing System:** DCC recommended integrating the license retention process under Rule 63 of the Drugs Rules with the Online National Drugs Licensing System, including electronic acknowledgements and a searchable database of retained licenses. The Committee also recommended that States and Union Territories expedite their integration with ONDLS.

c. **National framework to prevent diversion of narcotic and psychotropic pharmaceutical preparations:** DCC recommended a national action plan and harmonised information-sharing mechanism among States and Union Territories to address diversion of pharmaceutical preparations containing narcotic drugs and psychotropic substances. The proposal includes uniform monthly reporting, a common digital platform for regulatory and enforcement data, and exploration of the Central Bureau of Narcotics' online portal for end-to-end track-and-trace.

d. **Examination of all sterile drugs for inclusion under the Central License Approving Authority framework:** DCC recommended constitution of a sub-committee to examine the feasibility of bringing all sterile drug products within the Central License Approving Authority framework, including the legal implications of shared licensing responsibility between Central and State authorities.

e. **Agreement in principle on proposed regulatory amendments:**
DCC agreed in principle to several amendments, including:

i. *Definition of "change in constitution" under Drugs Rules:* Introduction of a definition aligned with the MD Rules, 2017 and Cosmetics Rules, 2020, including addition or deletion of partners in a partnership firm.

ii. *Powers of Licensing Authorities under MD Rules:* Amendment of Rule 30(1) to expressly empower licensing authorities to direct cessation of manufacture, sale or distribution and, where necessary, destruction of non-compliant medical devices and stocks.

iii. *Qualifications for Homoeopathy Inspectors:* Recognition of specified Homoeopathy qualifications and experience as eligibility criteria for Inspectors of manufacturing establishments.

iv. *Wholesale licensing of Homoeopathic medicines:* Amendment of Form 20D to address the requirement for competent-person details on ONDLS despite the absence of prescribed qualification requirements under the Drugs Rules.

[68] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MzEyMA==

6. **CDSCO intensifies enforcement against illegal manufacture and distribution of misbranded drugs**
   The CDSCO, on 5 September 2026, issued a public notice regarding coordinated action by drug regulatory and law-enforcement agencies against the illegal manufacture and distribution of misbranded drugs. The notice records enforcement activity involving multiple agencies and reiterates the regulatory consequences of operating outside the applicable drug-control framework.[69]

7. **CDSCO issues public health alert against unauthorised cosmetic products**
   The CDSCO, on 8 September 2026, issued a public health alert concerning certain unauthorised cosmetic products, including Goree Beauty Cream and Chandni Whitening Cream, identified in the notice as being manufactured in Pakistan. CDSCO stated that these products had not been issued registration certificates for import into India and that testing had found excessive levels of heavy metals beyond the specified limits. Consumers were advised not to purchase or use the identified products, and establishments and individuals were directed not to sell, distribute or advertise them.[70]

8. **NPPA proposes revision of internal guidelines for processing overcharging cases**
   The NPPA, at its 150th meeting under the DPCO 2013, held on 25 August 2026, considered a proposal to revise its internal guidelines dated 7 October 2016 for processing overcharging cases under the DPCO 2013. The proposed revision seeks to align the existing internal framework with the recent amendments to the DPCO 2013. The draft revised guidelines were circulated among the members for comments, with a period of ten working days provided for the submission of comments. The guidelines were proposed to be deemed adopted in the absence of any comments within the stipulated period.[71]

9. **National Accreditation Board for Testing and Calibration Laboratories launches accreditation scheme for mobile food-testing laboratories**
   The National Accreditation Board for Testing and Calibration Laboratories, on 10 August 2026, launched India's first accreditation scheme for mobile food-testing laboratories under the Integrated Assessment Programme. The scheme establishes a framework for extending accredited food-testing services beyond conventional laboratory settings and closer to communities. The launch formed part of the *"Gunvatta Samanvaya"* initiative, which also involved a multilateral memorandum of understanding aimed at coordinated assessments, regulatory convergence and strengthening the integrated quality infrastructure.[72]

10. **Ayush Grid expands to 24 e-governance platforms**
    The Ministry of Ayush, on 11 August 2026, reported that 24 e-governance platforms had been developed under the Ayush Grid initiative. These platforms span healthcare, research and development, education, drug administration, capacity building and medicinal plants. The Ayush Hospital Management Information System is compliant with the Ayushman Bharat Digital Mission, and other platforms include Ayush Nivesh Saarthi, e-CHARAK, the Ayush Research Portal and digital repositories for Ayurveda manuscripts and historical material.[73]

[69] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/DCGI_Notice12.pdf
[70] https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Public%20Notice%20-unauthorised%20cosmetics%20products%20on%2008.09.2026.pdf
[71] https://nppa.gov.in/storage/uploads/pdf/signed-minutes-150th-authority-meeting-fd2913dcca3c04e5e193f34157c7cfa0.pdf
[72] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2297325&lang=1&reg=48
[73] http://pib.gov.in/PressReleasePage.aspx?PRID=2297709&lang=1&reg=48

11. Ministry of Ayush advances AI applications across traditional medicine ecosystem

The Ministry of Ayush, on 19 September 2026, expanded artificial intelligence applications across its digital ecosystem, including the MAISP Chatbot, ARP Research Assistant, eLMS Chatbot and e-CHARAK Chatbot. These tools are intended to support citizen access to information, facilitate access to Ayush literature, assist student lifecycle management and provide information relating to medicinal plants.[74]

12. Government launches seventh National Formulary of India and hospital guidance on medical-device adverse events

The MoH&FW, on 21 September 2026, launched the seventh edition of the National Formulary of India (**NFI**), which has also been made available through NFI Online and is intended to support rational prescribing and appropriate medicine use. On the same occasion, the government launched the Guidance Document for Hospitals in India for Safety Monitoring and Reporting of Medical Device-Related Adverse Events and the ADR-PvPI 2.0 mobile application for iOS users. These initiatives were announced during the sixth National Pharmacovigilance Week, observed from 17 to 23 September 2026.[75]

13. Government approves Biovigilance Programme of India for organ and tissue transplantation

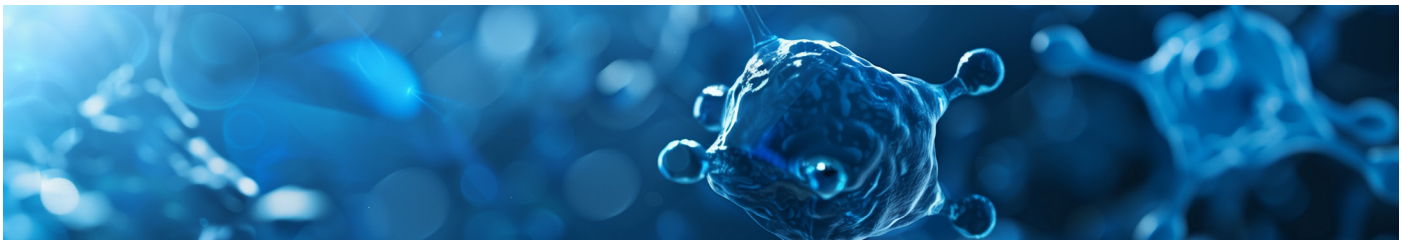
In September 2026, the government approved the Biovigilance Programme of India and designated the Indian Pharmacopoeia Commission to lead the monitoring of adverse events associated with organ and tissue transplantation. The programme extends the existing medicine-safety monitoring framework to transplantation-related adverse events and is intended to establish a structured mechanism for reporting, monitoring and analysing them.[76]

14. Drone-based Tuberculosis sample transport cuts diagnostic turnaround time

The ICMR, on 4 August 2026, reported the findings of a study conducted under the i-DRONE initiative, which found that transporting tuberculosis (**TB**) sputum samples by drone reduced the median diagnostic turnaround time from 15 days to five days. Conducted in Yadadri-Bhuvanagiri district of Telangana in collaboration with AIIMS Bibinagar and the National TB Elimination Programme, the study also recorded a reduction in mean patient out-of-pocket expenditure from approximately INR 9,451 to INR 91. The government stated that the model could help address delays in transporting samples from remote and hard-to-reach areas.[77]

15. Pharmacovigilance reporting network to be expanded to primary healthcare level

During the sixth National Pharmacovigilance Week, the government reported that approximately 1,150 Adverse Drug Reaction Reporting Centres were operational across the country. It further stated that the reporting network would be expanded to the primary healthcare level. The theme for the programme was *"Promoting Rational Use of Medicines through Pharmacovigilance: A Step Towards Safer Healthcare"*.[78]



[74] https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2312436&lang=2&reg=48
[75] https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2312930&lang=2&reg=48
[76] https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2312930&lang=2&reg=48
[77] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2294274&lang=1&reg=3
[78] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2312930&reg=6&lang=1

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