TRILEGAL

PULSE IMPULSE

WHAT HAPPENED. WHAT CHANGED. WHAT MATTERS.

QUARTERLY REVIEW - INDIA'S HEALTHCARE & LIFE SCIENCES SECTOR

APR - JUL 2026

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REGULATORY

1. **Ministry of Health and Family Welfare notifies inclusion of Pregabalin in Schedule H1**

   The Ministry of Health and Family Welfare (**MoH&FW**), on 13 May 2026, notified the Drugs (Second Amendment) Rules, 2026, inserting Pregabalin (as Serial No. 51) into Schedule H1 of the Drugs Rules, 1945 (**Drugs Rules**). The amendment will come into force within 180 days from the date of its publication in the Official Gazette.[1]

   Industry Impact: Manufacturers, distributors and pharmacies dealing in pregabalin formulations will need to align their storage, sale and prescription practices with Schedule H1 requirements. Enhanced record-keeping and compliance controls may be necessary to avoid regulatory action.

2. **Drugs (Seventh Amendment) Rules, 2026 expand Schedule H2 to include therapeutic categories of drugs**

   The MoH&FW notified the Drugs (Seventh Amendment) Rules, 2026 on 22 June 2026, amending Schedule H2 to the Drugs Rules.[2] The amendment designates the existing table under Schedule H2 as Table 1 and inserts a new Table 2, classifying drug formulations under four therapeutic categories: vaccines; antimicrobials; narcotic drugs and psychotropic substances regulated under the Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS); and anticancer drugs. The rules will come into force on 1 July 2027, except for provisions relating to antimicrobials, which will come into force on 1 July 2028.

1 https://egazette.gov.in/WriteReadData/2026/272775.pdf
2 https://egazette.gov.in/WriteReadData/2026/273811.pdf

Industry Impact: The amendment changes the way drugs are classified under Schedule H2 by introducing therapeutic categories. The staggered implementation dates provide the pharmaceutical industry with sufficient time to prepare for the enhanced compliance under Schedule H2.

3. MoH&FW expands regulatory framework to cover cell and gene therapy products

The MoH&FW notified the Drugs (Eighth Amendment) Rules, 2026, on 29 June 2026, amending the Drugs Rules. The amendment extends specified provisions and prescribed licence application/licence forms that previously referred to recombinant DNA (r-DNA) derived drugs to also refer to cell or stem cell derived products, gene therapeutic products and xenografts. The rules came into force on the date of their publication in the Official Gazette.[3]

Industry Impact: The amendment formally brings advanced therapy products, including cell and gene therapies, within the existing licensing framework under the Drugs Rules. Manufacturers and developers of such products should review the revised licensing requirements and application forms to ensure regulatory compliance.

4. MoH&FW notifies Surrogacy (Regulation) Amendment Rules, 2026

The MoH&FW notified the Surrogacy (Regulation) Amendment Rules, 2026 on 17 June 2026, amending the Surrogacy (Regulation) Rules, 2022.[4] The amendment rules introduce provisions governing the mode of payment and utilisation of registration fees, renewal of registration certificates for surrogacy clinics, renewal fees, timelines and procedure for renewal applications, and mandates submission of renewal applications through the National Registry portal. They also prescribe that renewed certificates of registration shall remain valid for a further period of three years from the date of expiry of the existing certificate. The rules came into force on the date of their publication in the Official Gazette.

5. MoH&FW notifies Assisted Reproductive Technology (Regulation) Amendment Rules, 2026

On 17 June 2026, the MoH&FW also notified the Assisted Reproductive Technology (Regulation) Amendment Rules, 2026, amending the Assisted Reproductive Technology (Regulation) Rules, 2022.[5] The amendment introduces provisions relating to the payment and utilisation of registration fees, renewal of registration certificates for Assisted Reproductive Technology (**ART**) clinics and ART banks, renewal fees, timelines for submission of renewal applications, and the procedure for renewal through the National Registry portal and provides that renewed certificates of registration shall remain valid for a further period of five years from the date of expiry of the existing certificate. The rules came into force on the date of their publication in the Official Gazette.

3 https://egazette.gov.in/WriteReadData/2026/274000.pdf
4 https://egazette.gov.in/WriteReadData/2026/273573.pdf
5 https://egazette.gov.in/WriteReadData/2026/273565.pdf

6. MoH&FW proposes amendments to the Medical Devices Rules, 2017

The MoH&FW, on 10 April 2026, proposed amendments to the Medical Devices Rules, 2017 (**MD Rules**) to introduce a fee structure for testing and evaluation of medical devices by notified laboratories.[6] The draft also proposes additional labelling requirements for manufacturers that outsource sterilisation activities to a third-party facility holding a valid licence for sterilisation of medical devices, requiring the sterilisation site licence number to be prominently mentioned on the device label. The proposed changes are intended to improve traceability, post-market surveillance, and regulatory oversight.

Industry Impact: If implemented, the amendment will add a structured fee regime for device testing and evaluation, requiring manufacturers and laboratories to factor in the prescribed charges. Manufacturers outsourcing sterilisation will also need to revise labelling practices to ensure the sterilisation site licence number is duly disclosed in the prescribed manner.

7. MoH&FW revises testing and analysis fee framework under the Drugs Rules

On 22 May 2026, the MoH&FW notified the Drugs (Third Amendment) Rules, 2026, amending Schedule B and Schedule B(1) of the Drugs Rules to revise the fees prescribed for testing and analysis conducted by government drug testing laboratories.[7] Specifically, the fee structure applicable to the testing and analysis of drugs, biological products, medical devices, cosmetics, Ayurvedic, Siddha and Unani drugs, and homoeopathic medicines has been amended. The prescribed fees shall also be increased by 5 per cent annually. The rules came into force on the date of their publication in the Official Gazette.

8. MoH&FW proposes expansion of Rule 89 exemption to additional licence holders

On 21 April 2026, the MoH&FW published draft rules proposing to amend Rule 89 of the Drugs Rules. The draft proposes to substitute the words *"Form 25 or Form 28"* with the words *"Form 25 or Form 25A or Form 25F or Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA or Form 28F."* Objections and suggestions were invited within thirty days from the date on which copies of the draft rules were made available to the public. The draft also states that the final rules will come into force after three months from publication in the Official Gazette.[8]

Industry Impact: The draft amendment proposes to expand the list of licence forms referred to in Rule 89 of the Drugs Rules, subject to final notification.

6 https://egazette.gov.in/WriteReadData/2026/271705.pdf
7 https://egazette.gov.in/WriteReadData/2026/272962.pdf
8 https://egazette.gov.in/WriteReadData/2026/271969.pdf

9. MoH&FW excludes syrups from Schedule K exemption

The MoH&FW, on 9 June 2026, notified the Drugs (Fifth Amendment) Rules, 2026, amending Schedule K to the Drugs Rules. Schedule K sets out specified classes of drugs that are exempt, subject to stated conditions, from certain provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 (**D&C Act**) and the rules thereunder. The amendment omits the word *"Syrups"* from item (7) against serial number 13 in the column under the heading *"Class of Drugs."* The Rules came into force on the date of their publication in the Official Gazette.[9]

Industry Impact: The amendment modifies the scope of the exemption available under Schedule K by removing syrups from the specified category of drugs. Manufacturers, distributors and other stakeholders relying on the Schedule K exemption should review the revised requirements and assess the impact on their regulatory compliance.

10. Central Drugs Standard Control Organisation mandates the establishment and maintenance of a pharmacovigilance system

On 3 June 2026, the Central Drugs Standard Control Organisation (**CDSCO**) directed all stakeholders to ensure the establishment and maintenance of an effective pharmacovigilance system in compliance with Para 6.11 of Schedule M to the Drugs Rules, and the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). Para 6.11 requires that the licensee have a pharmacovigilance system in place for collecting, processing and forwarding reports to the licensing authorities on adverse drug reactions emerging from the use of drugs manufactured or marketed by the licensee. The circular further states that officers of the CDSCO, State Licensing Authorities and UT administrations may verify compliance during routine inspections and other regulatory activities.[10]

Industry Impact: Pharmaceutical companies must ensure robust pharmacovigilance frameworks, adverse event reporting systems and internal monitoring processes. Regulatory inspections may increasingly assess post-marketing safety compliance as part of routine oversight.

11. CDSCO operationalises prior intimation mechanism for export of bioavailability and bioequivalence studies

The CDSCO has operationalised the prior intimation system for online applications in Form CT-05 (for export purpose only) under the NDCT Rules with effect from 21 April 2026, pursuant to G.S.R. 50(E) dated 21 January 2026. The prior intimation system applies to single-dose, two-period, two-sequence, two-treatment bioavailability (**BA**) or bioequivalence (**BE**) studies in normal healthy adult human volunteers, for export purpose only, involving oral dosage forms of drugs already approved in India, the United States of America, the European Union, Japan, Australia, Canada, or the United Kingdom, subject to the prescribed conditions. These conditions include exclusion of cytotoxic drugs, hormone drugs, narcotic and psychotropic substances, drugs with narrow therapeutic index, and drugs having highly variable pharmacokinetics, submission through the SUGAM portal, Ethics Committee approval under Rule 8 of the NDCT Rules, sample size of at least 18, and separate record maintenance by the Ethics Committee.[11]

12. CDSCO eases import application process for Reference Listed Drugs and Investigational Medicinal Products

On 22 May 2026, the CDSCO clarified that Form CT-16 applications for import of Reference Listed Drugs or Investigational Medicinal Products for export-oriented BA/BE studies shall be submitted on a standalone basis through the National Single Window System portal. The clarification addresses operational issues due to lack of system linkage between

9 https://egazette.gov.in/WriteReadData/2026/273467.pdf
10 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular%20..pdf?
11 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular_20042026.pdf

CT-05 prior intimation applications and CT-16 applications on the SUGAM portal.[12]

Industry Impact: The clarification is expected to reduce procedural delays and facilitate smoother importation of comparator drugs and investigational products for BA/BE studies. Contract research organisations and generic drug developers may benefit from improved operational efficiency.

13. CDSCO prohibits import, manufacture, sale, distribution and use of drug formulations containing Chloramphenicol or Nitrofuran in food-producing animals

On 3 June 2026, CDSCO's veterinary division wrote to State and Union Territory Drugs Controllers regarding enforcement of the earlier ban under Notification S.O. 1158 dated 12 March 2025 on Chloramphenicol, Nitrofurans and their formulations in food-producing animal rearing systems. Referring to continued detection of residues in shrimp export consignments, the letter requests information on state-level implementation mechanisms, inspections of veterinary medical shops and related establishments, and punitive action taken against violators. It also requires that such drugs and formulations be sold only to licensed manufacturers through licensed premises for intended purposes, with proper reconciliation, and that appropriate regulatory action be taken in case of violations.[13]

Industry Impact: Stakeholders dealing with Chloramphenicol and Nitrofuran formulations for animal use may face closer scrutiny of distribution controls and enforcement records, particularly where such products may enter food-producing animal rearing systems.

14. CDSCO reiterates regulatory boundaries for cosmetics and bars injectable use

On 18 May 2026, CDSCO issued a public notice reiterating the regulatory position applicable to cosmetics under the D&C Act and the Cosmetics Rules, 2020 (**Cosmetics Rules**). The notice states that products supplied in injectable form do not fall within the definition of cosmetics and that no cosmetic is permitted to be used as an injection by consumers, professionals or aesthetic clinics. It also cautions against false or misleading claims and notes that the Bureau of Indian Standards (**BIS**) publishes lists of Generally Not Recognised as Safe (GNRAS) and restricted ingredients. The notice further states that the use of prohibited ingredients in cosmetic products, misleading claims on labels, use of cosmetics for treatment, and application of cosmetics through injection attract violations under the D&C Act and Cosmetics Rules.[14]

Industry Impact: The notification increases regulatory scrutiny on cosmetic manufacturers, importers, distributors, aesthetic clinics, and e-commerce platforms marketing cosmetic products for injectable applications. Companies must review product claims, labelling, promotional materials, and distribution practices to ensure cosmetics are not positioned or used as injectables or therapeutic products.

15. CDSCO issues advisory streamlining Periodic Safety Update Reports compliance

On 21 April 2026, CDSCO issued an advisory directing manufacturers and importers of new drugs to submit Periodic Safety Update Reports (**PSUR**) from the date of actual marketing of the new drug, even where approval had been granted earlier. The advisory also states that, ordinarily, all dosage forms, formulations and indications for a new drug should be covered in a single PSUR, with separate presentation of data for different dosage forms, indications or populations to avoid duplicate submission of PSUR applications.[15]

12 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/BE-NOC%20Prior%20Intimation%20procedure%20for%20obtaining%20CT-16%20application%20on%20NSWS%20Portal.pdf
13 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQyODI=
14 https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Public%20Notice%20dated%2018.05.2026.pdf
15 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQyMDQ=

Industry Impact: The advisory has reporting implications for manufacturers and importers of new drugs, particularly where market launch occurs after approval or where multiple dosage forms, formulations or indications are involved.

16. CDSCO directs compliance with BIS standards for hair colour cosmetic products

On 10 June 2026, CDSCO directed all importers and manufacturers of hair colour cosmetic products to ensure compliance with the Cosmetics Rules and the applicable BIS specifications, including IS 4707 (Part 1 and Part 2) and IS 8481.[16] The circular reiterates the requirements relating to permissible and restricted hair dye ingredients, product composition, labelling, mandatory cautionary statements and patch test instructions. It requires all changes to product labels, composition or quality specifications to be reported to the Central or State Licensing Authority, as applicable, in accordance with the Cosmetics Rules.

17. CDSCO advises parallel submission and processing of clinical trial applications

On 11 May 2026, CDSCO issued an advisory advising applicants and stakeholders to submit clinical trial protocols and related documents simultaneously to CDSCO and the concerned Ethics Committee registered under the NDCT Rules. The advisory further states that Ethics Committees registered under Rule 8 of NDCT Rules should independently review and process such clinical trial protocols in accordance with NDCT Rules, without awaiting prior approval from the Central Licensing Authority.[17]

Industry Impact: The advisory is intended to enable concurrent review by CDSCO and registered Ethics Committees, with the objective of reducing approval timelines and facilitating timely initiation of clinical trials.

18. Food Safety and Standards Authority of India streamlines the process for prior approval and risk assessment through a single window system

On 6 May 2026, the Food Safety and Standards Authority of India (**FSSAI**) issued an office order implementing a single-window system through the Electronic Product and Claim Approval Application System (**ePAAS**) to ensure parity and transparency in risk assessment and approval mechanisms. The

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

ePAAS portal will serve as a unified digital interface for submission, processing, monitoring, and appeal and review of applications relating to prior approval and risk assessment of products, ingredients, and claims, as applicable under the relevant regulations. Effective 1 June 2026, applications for approval or authorisation in respect of non-specified food and food ingredients, r-PET, claims, Ayurveda Aahara, Food for Special Medical Purpose (FSMP), vegan endorsement, specified nutrient notifications, and any other food, product, process or system requiring prior approval must be filed exclusively through the ePAAS portal. No manual, offline, or email-based applications will be entertained thereafter.

Industry Impact: Food businesses seeking prior approval, authorisation, endorsement or notification for the categories covered by the order will be required to submit such applications exclusively through the ePAAS portal from 1 June 2026, as manual, offline and email-based submissions will not be entertained thereafter.

19. FSSAI notifies amendments to Contaminant and Residue Regulations

On 14 May 2026, FSSAI notified the Food Safety and Standards (Contaminants, Toxins and Residues) Amendment Regulations, 2026, amending specified entries under the 2011 regulations for metal contaminants, aflatoxins, saffrole and veterinary drug residues. The changes cover, among other things, pulses and pulse flours, edible fats and oils, fish oils, oils and oilseeds, foods containing mace or nutmeg kernel, and seafood, and will come into force on 1 December 2026.[18]

Industry Impact: Food manufacturers, exporters and nutraceutical companies may need to strengthen supplier qualification, testing and quality control measures to meet the revised standards. Non-compliance could result in product recalls, import-export disruptions and enforcement actions.

20. FSSAI advises against the use of Ashwagandha (*Withania somnifera*) leaves in food products

On 15 April 2026, the Ministry of AYUSH issued an advisory directing all AYUSH drug/product manufacturers, exporters and sellers to use only Ashwagandha roots in crude, extract or any other form in single or compound AYUSH drugs/products, and strictly prohibiting the use of Ashwagandha leaves in crude, extract or any other form in Ayush drugs/products.

The advisory refers to the Ministry's earlier communication dated 6 October 2021 and notes that the 2024 updated Ashwagandha safety dossier recommended use of Ashwagandha roots for health benefits, while scientific studies reported possible safety concerns in relation to Ashwagandha leaves due to higher concentrations of reactive withanolides, particularly Withaferin-A. The Ministry also directed compliance with Rule 161 of the Drugs Rules, requiring labels to clearly mention the plant parts used in the drugs/products.[19]

Industry Impact: AYUSH drug/product manufacturers, exporters and sellers using Ashwagandha will need to ensure that only roots are used in crude, extract or any other form in AYUSH drugs/products, and that labels clearly mention the plant parts used in accordance with Rule 161 of the Drugs Rules.

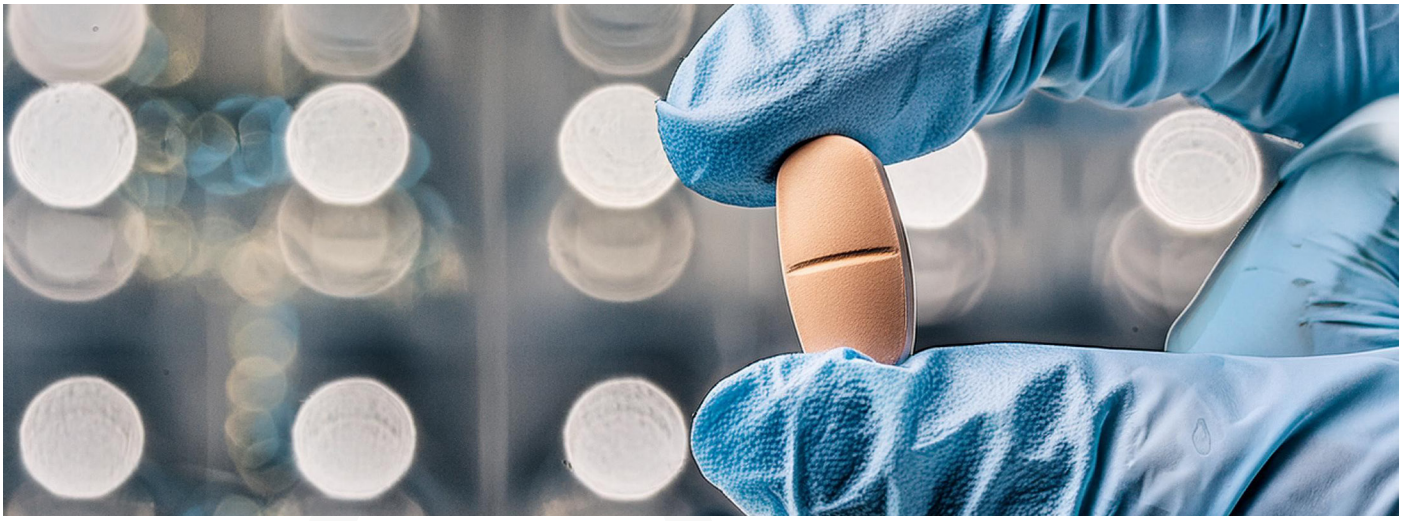
21. FSSAI revises official logo requirements for vegan food products

On 21 May 2026, FSSAI notified the Food Safety and Standards (Vegan Foods) Amendment Regulations, 2026, amending the Food Safety and Standards (Vegan Foods) Regulations, 2022 by substituting regulation 4(2). The amendment requires every package of vegan foods, after approval, to carry the logo as specified in the

18 https://egazette.gov.in/WriteReadData/2026/272840.pdf
19 https://fssai.gov.in/upload/advisories/2026/04/69e0d84fcac2fAdvisory%20on%20non%20use%20of%20ashwagandha%20leaves%20in%20crude%20or%20extract%20or%20any%20other%20form%20in%20food%20products-%20reg.pdf

notification, with prescribed dimensional specifications. The amendment will come into force on 1 July 2027.

Industry Impact: The amendment has operational implications for vegan food businesses, as approved products placed on the market from 1 July 2027 will need to carry the logo in the form specified under the amended regulation.



22. Department of Pharmaceuticals amends the Uniform Code for Marketing Practices in Medical Devices, 2024

On 30 April 2026, the Department of Pharmaceuticals (**DoP**) amended the Uniform Code for Marketing Practices in Medical Devices (**UCMPMD**), 2024, with immediate effect.[20] The amendments introduce a new compliance framework for overseas training programmes involving healthcare professionals (**HCP**). Medical device companies are now required to submit details of the proposed programme, its justification, participant information and estimated expenditure with their respective Industry Associations at least one month in advance, following which the information will be placed in public domain by the associations.

The amendments also clarify that violations of the overseas training framework will be dealt with under the penalty and reference provisions of the UCMPMD. In addition, the DoP has restated the restrictions on providing travel and hospitality to HCPs, clarifying that such benefits are permissible only where the HCP is participating as a speaker at a Continuing Medical Education (**CME**) or Continuing Professional Development (**CPD**) programme, or as a participant in an eligible training programme.

Industry Impact: Medical device companies should review their policies governing overseas training, sponsorship, travel and hospitality involving HCPs to ensure compliance with the revised disclosure and approval requirements. Internal governance and documentation processes may also require updating in light of the enhanced transparency obligations under the amended UCMPMD.

23. DoP amends Drugs (Prices Control) Order, 2013 to streamline pricing and compliance framework

On 30 June 2026, the Ministry of Chemicals and Fertilizers, DoP, notified the Drugs (Prices Control) Amendment Order, 2026, introducing targeted amendments to the Drugs (Prices Control) Order, 2013 (**DPCO**).[21] Effective from the date of their gazette publication, the amendments seek

20 https://pharma-dept.gov.in/sites/default/files/UCMDMD%20circular%201-2026%2BUCMDMP%20code%20as%20amended%20on%2030.4.2026%20%281%29.pdf
21 https://egazette.gov.in/WriteReadData/2026/273983.pdf

to refine the pricing and compliance framework applicable to pharmaceutical manufacturers, importers and marketers by addressing issues relating to differentiated pricing, overcharging liability, new drug launches, price dissemination and record retention.

Among the key changes, the amendments empower the government to prescribe separate ceiling or retail prices for different pack sizes or dosage forms of an existing scheduled drug, while also permitting manufacturers to seek differentiated pricing. The revised framework limits manufacturers' overcharging liability in specified circumstances where they have complied with prescribed price dissemination requirements, introduces a simplified reporting mechanism for follow-on manufacturers launching the same new drug within twelve months of a notified retail price, and mandates the retention of sales records for a minimum of seven financial years. A new Form IA has also been introduced for reporting follow-on launches.

Industry Impact: Pharmaceutical manufacturers will need to account for the amended provisions relating to separate price fixation in specified cases, launch intimation for the same new drug by other existing manufacturers, dissemination of revised price information, overcharging liability, and maintenance of records for at least seven financial years.

24. Ministry of Environment, Forest and Climate Change integrates AYUSH into bio-medical waste management framework

On 17 April 2026, the Ministry of Environment, Forest and Climate Change (**MOEFCC**) notified the Bio-Medical Waste Management (Amendment) Rules, 2026 vide G.S.R. 293(E), exercising powers under sections 6, 8 and 25 of the Environment (Protection) Act, 1986. The amendment makes two insertions into the Bio-Medical Waste Management Rules, 2016: first, the word *"Ayush"* is inserted after *"Departments of Health"* in rule 11(1), thereby including the Department of Ayush in the composition of the State/UT-level Advisory Committee chaired by the Health Secretary; and second, a representative nominated by the State or Union Territory Department of Ayush is inserted after *"District Health Officer"* in rule 12(6), thereby including an Ayush representative in the District Level Monitoring Committee.[22]

Industry Impact: AYUSH healthcare establishments may face increased regulatory oversight and closer monitoring of their bio-medical waste management practices following the inclusion of AYUSH representatives in the relevant state and district-level monitoring committees.

25. MoH&FW expands scope of Schedule H1, Drugs Rules, to include oral formulations containing more than 12% alcohol

On 8 July 2026, the MoH&FW notified the Drugs (Tenth Amendment) Rules, 2026, bringing "*All oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol)*" that are packed and sold in containers or bottles exceeding 30 ml within Schedule H1 of the Drugs Rules, as Serial No. 52.

The amendment also modifies Serial No. 10 of Schedule K, which provides exemptions from licensing requirements under Chapter IV of the D&C Act, for certain substances used both as articles of food and as drugs. The amendment expressly excludes oral formulations meeting the above criteria from this exemption. The amendment will come into force six months from the date of its publication in the Official Gazette.[23]

Industry Impact: The amendment subjects a new category of alcohol-containing oral formulations to the more stringent regulatory controls applicable to Schedule H1 drugs. Manufacturers, distributors and pharmacies dealing in such products will need to align storage, sale, and prescription practices with

22 https://egazette.gov.in/WriteReadData/2026/271923.pdf
23 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0NTc=

Schedule H1 requirements. Enhanced record-keeping and compliance controls may be necessary to avoid regulatory action. Further, if any substances specified in Serial No. 10 of Schedule K contain alcohol beyond the prescribed limits, the same will be required to be manufactured and sold in terms of licenses obtained under the Drugs Rules.

26. MoH&FW notifies framework for debarment under the Drugs Rules

On 30 July 2026, the MoH&FW notified the Drugs (Eleventh Amendment) Rules, 2026, introducing a statutory framework for debarment under the Drugs Rules. The amendment defines *"debarment"* as the prohibition, exclusion, or disqualification of any person, firm, or entity from importing, manufacturing for sale or for distribution, selling, stocking, exhibiting, or offering for sale, or distributing drugs, either for a specified period or permanently. The amendment also inserts Rules 29B, 66B, 84F, 93A, 122DBA, 122Q, and 150L, which empower the licensing authorities to debar a person, firm or entity if it is found to have submitted misleading, fake, or fabricated documents or information. Debarment may be imposed for such period as the licensing authority considers appropriate, after providing the concerned party an opportunity to show cause.[24]

Industry Impact: The amendments introduce a significant enforcement consequence for inaccurate or fraudulent submissions made under the Drugs Rules. Applicants for licences under the Drugs Rules should therefore ensure that all documents and information submitted to the licensing authorities are complete, accurate, and verifiable. Any lapse in this regard may result in the applicant being debarred.

27. CDSCO publishes guidance on medical device software

The CDSCO on 21 July 2026 published the final Guidance Document on Medical Device Software under the MD Rules. Software that meets the definition of a medical device has been regulated by the D&C Act since 1 April 2020. However, the MD Rules were not updated to clarify the regulatory framework for such software. Accordingly, a draft of the guidance document was published for stakeholders' comments in 2025. CDSCO has now issued the final guidance document to promote a consistent understanding and implementation of the regulatory framework, classification principles, safety and performance requirements, and post market obligations in relation to medical device software.[25]

Industry Impact: Entities engaged in the development and distribution of software that qualifies as a medical device must ensure that the software complies with the guidance document.

28. CDSCO initiates consultations on issue of brand name extension

On 6 July 2026, the CDSCO issued a notice seeking comments from stakeholders on the use of brand name extensions by certain firms. The notice follows deliberations at the 67th meeting of the Drugs Consultative Committee (**DCC**) held on 25 November 2025, in which the DCC was apprised of a company marketing multiple drug formulations under the same established brand name with different extensions. The DCC expressed concerns that using the same brand name for formulations containing different ingredients could mislead consumers and create confusion regarding their therapeutic use. It accordingly recommended stakeholder consultation on this issue. Stakeholders were given time till 17 July 2026 to submit their comments.[26]

29. FSSAI relaxes labelling requirements for coffee-chicory mixture

The FSSAI, on 21 July 2026, extended the timeline for implementation of the Food Safety Standards (Labelling and Display) First Amendment Regulations, 2025. The amendment had imposed requirements for certain declarations to be printed on labels of coffee-chicory mixtures with effect from 1 July 2026. The FSSAI has

24 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1NzU=
25 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1MTI=
26 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MzM=

now kept the amendments under abeyance until 1 July 2027 and has allowed food business operators to use simplified declarations on the labelling of coffee-chicory mixture packages until 1 July 2027.[27]

TRANSACTIONS

30. Sun Pharmaceutical Industries acquires Checkpoint Therapeutics

Sun Pharmaceutical Industries Limited (**Sun Pharma**), world's leading specialty generics company with a presence in specialty, generics and consumer healthcare products, announced the successful completion of its acquisition of Checkpoint Therapeutics, Inc. (**Checkpoint**), an immunotherapy and targeted oncology company.[28]

Under the transaction, Sun Pharma acquired all outstanding shares of Checkpoint at USD 4.10 per share in cash, with stockholders also receiving one non-tradable contingent value right per share of up to USD 0.70 in cash, upon achievement of specified milestones as set out in the contingent value rights agreement. As part of the acquisition, Sun Pharma acquired UNLOXCYT, the first and only FDA-approved anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma.

31. Infosys acquires Optimum Healthcare IT

Infosys completed the acquisition of Optimum Healthcare IT, a healthcare digital transformation and consulting firm known for assisting provider organisations in driving large-scale transformation. The acquisition strengthens Infosys' healthcare capabilities, particularly in the provider segment, and is expected to enhance its cloud, data and digital transformation offerings for healthcare organisations.

32. Everstone Capital Invests USD 270 Million in Apothecon and Navinta

Everstone Capital, a Singapore-based private equity firm, has invested about USD 270 million for a sizeable stake in a combined platform formed with the promoters of India's Apothecon Pharmaceuticals and US-based Navinta. The transaction creates Apothecon Group, a specialty formulations business focused on regulated markets, combining in-house formulation capabilities with captive API manufacturing and a commercial presence across the US, Europe and other global markets. Apothecon Group has a diversified portfolio spanning injectables, oral solids and other dosage forms.

27 https://fssai.gov.in/docs/food-law/advisory/6a604e4037173Direction_Coffee Chicory.pdf?csrt=12349299948206720976
28 https://sunpharma.com/wp-content/uploads/2025/05/Press-Release-Completion-of-Checkpoint-Acquisition.pdf

33. Rubicon Research acquires Arinna Lifesciences for INR 176 crore

Rubicon Research (**Rubicon**), in April 2026, completed the acquisition of an 85 per cent equity stake in Arinna Lifesciences (**Arinna**) for a consideration of approximately INR 175.92 crore.[29] The transaction expands Rubicon's presence in chronic care by adding Arinna's established portfolio of prescription brands and is expected to support the company's long-term growth strategy in the Indian pharmaceutical market.

34. Warburg Pincus acquires Integrace

Warburg Pincus acquired Integrace Pvt. Ltd. (**Integrace**) for INR 1200 crore. The deal involved the exit of existing investors True North and Temasek. Integrace operates in the pharmaceutical formulations sector with products in the orthopaedics and gynaecology segments.[30]

LITIGATION

35. Supreme Court directs integration of emergency helplines into 112 and implementation of PM Rahat and measures to protect good samaritans

The Supreme Court of India (**SC**), in its judgment dated 26 May 2026, considered a public interest litigation filed by SaveLIFE Foundation, a non-profit organisation focused on improving road safety and emergency care in India.[31]

The Court recognised that access to trauma care forms an integral part of the right to life under Article 21 of the Constitution of India. The Court observed that effective trauma response requires a coordinated framework covering emergency response, first aid, public awareness and protection for good samaritans. The Court accordingly directed the operationalisation of a common emergency helpline number, 112, across the country. It also called for systematic interventions to create a uniform trauma care framework, including public awareness measures, standardisation of first-aid skills, and effective implementation of good samaritan protections and related emergency care schemes.

36. High Court of Delhi clarifies that the scope of FSSAI's regulatory powers is limited to food intended for human consumption

29 https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/rubicon-research-acquires-arinna-lifesciences-for-175-cr/130282599

30 https://www.ndtvprofit.com/business/warburg-pincus-completes-1-200-crore-acquisition-of-integrace-health-temasek-true-north-exit-11775253

31 *Savelife Foundation & Anr v Union of India & Ors.* W.P. (Civil) No. 726/2025, judgment dated 26 May 2026

The High Court of Delhi (Delhi HC), in W.P.(C) 1079/2025 & CM APPL. 5331/2025, vide judgment dated 7 April 2026, held that FSSAI cannot regulate animal or cattle feed under the Food Safety and Standards Act, 2006, as the Act is confined to food intended for human consumption. The Court noted that the statutory provisions relating to unsafe food, sale of food and primary food are limited to products meant for human consumption.[32] Accordingly, any attempt by FSSAI to regulate animal or cattle feed would fall outside the scope of its enabling legislation.

The matter arose from a challenge by Godrej Agrovet Limited to certain FSSAI regulations that restricted the use of specified animal feed ingredients and required commercial manufacturers to comply with BIS standards. The petitioner contended that FSSAI had exceeded its statutory mandate by seeking to regulate animal feed through a framework intended for food meant for human consumption. The Court, in its judgment, while limiting FSSAI's jurisdiction, directed that milk- and meat-producing animals, other than poultry, pigs and fish, should not be fed feed containing meat or bone meal, blood meal, or tissues of bovine or porcine origin, except milk and milk products. The Court also directed that commercial animal feed must comply with applicable BIS standards.

37. Delhi HC directs the CDSCO to review safety concerns over semaglutide injections

The Delhi HC, in *Jyoti Shrivastava v Central Drugs Standard Control Organisation (CDSCO) & Anr.*, W.P.(C) 7559/2026 ,[33] vide order dated 2 June 2026, considered a petition challenging the manufacturing and marketing approvals granted by the CDSCO for semaglutide injections. The petitioner raised concerns regarding the safety profile of the product and the adequacy of the regulatory review undertaken prior to grant of approval.

In its order, the High Court directed CDSCO to formally examine the safety concerns raised in the petition and assess whether internationally established practices had been duly considered in relation to the manufacturing process. While the Court did not adjudicate upon the merits of the allegations, it required the regulator to independently evaluate the issues highlighted by the petitioner. The order signals increased judicial scrutiny of regulatory approvals for widely used pharmaceutical products and underscores the importance of robust regulatory review where concerns relating to product safety and manufacturing standards are raised.

38. Bombay High Court upholds NPPA's price control over Silver Sulphadiazine formulations

The Bombay High Court, in its judgment dated 4 May 2026 in *Cipla Limited v National Pharmaceutical Pricing Authority & Ors.*, considered a challenge to an NPPA Standing Order and Demand Notice directing Cipla Limited to deposit alleged overcharged amounts in respect of its product, Burnheal Cream. The challenge was premised on the contention that Silver Sulphadiazine is not a scheduled bulk drug under the Drugs (Prices Control) Order, 1995 (**DPCO 1995**) and therefore could not be subjected to price control measures. In its judgment, the Court rejected Cipla's challenge and upheld the NPPA's Standing Order and Demand Notice. Relying on the SC's decision in *Union of India v. Swiss Garnier Life Sciences*, the Court held that Silver Sulphadiazine is a derivative of Sulphadiazine and therefore falls within the definition of a *"bulk drug"* under Paragraph 2(a) of the DPCO 1995. Since Sulphadiazine is included in the First Schedule to the DPCO 1995, formulations containing its derivative were held to be subject to price control. The Court further rejected the argument that differences in therapeutic indication or route of administration were relevant to determining derivative status. While dismissing the writ petition, the Court granted Cipla protection from coercive recovery proceedings for a period of eight weeks from the date of uploading of the judgment.

32 *Godrej Agrovet Ltd. v Food Safety & Standards Authority of India,* W.P.(C) 1079/2025 & CM APPL. 5331/2025, Order dated 7 April 2026
33 *Jyoti Shrivastava v Central Drugs Standard Control Organisation (CDSCO) & Anr.*, W.P. (C) 7559/2026, Order dated 2 June 2026

The decision reaffirms the NPPA's authority to extend price control to formulations containing derivatives of scheduled bulk drugs, even where such derivatives are not independently listed in the relevant schedule. Manufacturers should therefore carefully assess pricing compliance for formulations containing derivatives of scheduled bulk drugs to mitigate regulatory and financial exposure.[34]

39. High Court of Jammu & Kashmir and Ladakh holds that criminal prosecution under the D&C Act cannot sustain merely on designation

The High Court of Jammu & Kashmir and Ladakh, in *Amit Kumar Bansal & Ors. v Sanjeev Kumar Gupta*, disposed of a batch of petitions challenging criminal complaints filed against M/s Theon Pharmaceuticals Ltd., its directors, and certain technical personnel after samples of Ceftriaxone Injection I.P. and Glimepiride and Metformin Hydrochloride (SR) Tablets were found to be not of standard quality. The Court held that, under Section 34 of the D&C Act, criminal liability cannot be fastened on directors and officers merely by virtue of their designation. Accordingly, it quashed the complaints against the Managing Director and Directors, while permitting proceedings to continue against the company, the nominated responsible person, and technical personnel against whom specific allegations of active involvement had been made.

The decision underscores the importance of a duly filed and endorsed Section 34 declaration and reinforces that directors and officers cannot be prosecuted in the absence of specific role-based allegations. Pharmaceutical companies should ensure that their Section 34 declarations are current, accurate, and duly endorsed by the competent licensing authority.[35]

40. Punjab and Haryana High Court reinforces record-keeping compliance under the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994

The Punjab & Haryana High Court, in CRR-2686-2010 (O&M), in judgment dated 10 April 2026, considered a criminal revision petition filed by the owner of a maternity care centre in Barnala, challenging the concurrent findings of conviction recorded by the trial court and the appellate court for violations of the record-keeping requirements prescribed under the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 (**PCPNDT Act**), including deficiencies in maintaining Form F (the prescribed record required under the PCPNDT Act to document the details, medical indication, referral particulars, declaration, and outcome of every prenatal diagnostic procedure or ultrasound conducted on a pregnant woman) and other mandatory statutory records. The Court held that non-maintenance of records under the PCPNDT framework is not a mere procedural lapse but a serious violation that facilitates the commission of offences such as female foeticide. It further observed that documents recovered during a procedurally irregular search remain admissible in evidence.

The High Court dismissed the criminal revision petition and affirmed the concurrent findings of conviction recorded by the trial court and the appellate court, along with the sentence of rigorous imprisonment for one year and a fine of INR 5,000. The Court declined to grant leniency notwithstanding the petitioner's advanced age. The decision reinforces the strict compliance standards imposed under the PCPNDT regime and underscores that deficiencies in mandatory records, including Form F, can attract penal consequences and sustain a conviction. Clinics and diagnostic centres must therefore ensure meticulous maintenance and completion of all prescribed records.[36]

34 *Cipla Limited v National Pharmaceutical Pricing Authority & Ors.*, W.P.(C) No. 2069 of 2022, vide judgment dated 4 May 2026
35 *Amit Kumar Bansal & Ors. v Sanjeev Kumar Gupta*, CRMC No. 450/2018, judgment dated 2 April 2026
36 *Pushap Lata v State of Punjab & Anr., CRR-2686-2010 (O&M)*, judgment dated 10 April 2026

POLICY

41. Jan Vishwas (Amendment of Provisions) Bill, 2026 proposes further decriminalisation of regulatory offences

The Jan Vishwas (Amendment of Provisions) Bill, 2026[37] proposes amendments to 784 provisions across 79 Central Acts administered by 23 Ministries, to reduce criminal liability for minor regulatory non-compliances. Key changes for the pharma, life sciences and healthcare sectors:

- The Bill proposes to amend the Clinical Establishments Act, 2010 by replacing criminal prosecution for certain minor and rectifiable deficiencies with a civil penalty of up to INR 10,000.
- Under the D&C Act, 1940, imprisonment for failure to disclose the place of manufacture or storage of specified Ayurvedic, Siddha and Unani drugs is proposed to be replaced with a higher monetary penalty.
- The Bill also proposes similar decriminalisation measures across other sectors, including under the Agricultural and Processed Food Products Export Development Authority Act, 1985, where certain procedural violations are proposed to move to a warning-and-penalty framework.

42. Drugs Consultative Committee approves real-time narcotic drugs and psychotropic substances tracking portal and recommends stricter scheduling changes for drugs prone to misuse

At its 68th meeting held on 20 March 2026, the DCC approved a proposal to develop a centralised, real-time, end-to-end digital portal for tracking the manufacture, import/export, sale/distribution, and stock of pharmaceutical products regulated under the NDPS. The DCC also discussed the portal's scope, key features, regulatory and legal considerations, implementation strategy, and the role of CDSCO and State Drug Regulatory Authorities. It further suggested that CDSCO hold a meeting with the Central Bureau of Narcotics, which currently maintains a portal for manufacturing units, and recommended that access to the portal be provided to all concerned agencies once developed for effective surveillance and monitoring.[38]

43. European Union includes India on list of authorised exporters of aquaculture products

The European Union (**EU**) has notified Commission Implementing Regulation (EU) 2026/1189 amending Regulation (EU) 2021/405, effective from September 2026, introducing additional requirements for countries exporting specified animal-origin products in light of concerns relating to antimicrobial resistance. India has been included in the revised list of authorised countries, ensuring continued market access to the EU beyond September 2026 for aquaculture products, eggs, honey, and animal casings. The

37 https://www.pib.gov.in/PressReleasePage.aspx?PRID=2248925
38 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=Mjk0Ng==

development is particularly significant for India's fisheries sector, with fish and fishery exports to the EU currently valued at approximately USD 1.59 billion, and follows sustained engagement by the Department of Commerce, the Export Inspection Council, and other stakeholders including MPEDA.[39]

44. Indian Council of Medical Research introduces single-window ethics review for multicentre research

The Indian Council of Medical Research (**ICMR**) has issued the *Operational Guidelines for Single Ethics Review of Multicentre Research in India, 2026* as an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. The guidelines introduce a Single Ethics Review model under which one designated Single Ethics Committee undertakes a comprehensive ethics review for a multicentre study, with its approval applying across all participating sites, replacing the earlier common and joint ethics review mechanisms. The framework also requires a Coordinating Principal Investigator to act as the single point of contact between the Single Ethics Committee and participating site investigators, with the objective of reducing duplication and streamlining multicentre research review in India.[40]

45. Drugs Technical Advisory Board recommends revision of microbial contamination limits under Schedule M of the Drugs Rules

At its 93rd meeting, the Drugs Technical Advisory Board agreed to a proposal to revise the microbial contamination limits applicable to Grade A areas under Schedule M of the Drugs Rules, in line with Annexure II of WHO Technical Report Series 1044. The proposal is intended to address the mismatch between the limits presently specified in Schedule M of the Drugs Rules and the WHO benchmark, and to support greater harmonisation of Indian manufacturing standards with global norms.[41]

46. Parliamentary panel recommends uniform framework to curb misleading AYUSH advertisements

A Parliamentary panel has recommended that the CDSCO develop a uniform regulatory framework to address misleading advertisements for AYUSH products, observing that the current system may lead to inconsistent enforcement across States.[42] The panel also noted that the absence of standardised timelines and a monitoring mechanism for resolving complaints could reduce the effectiveness of the grievance redressal process and discourage the reporting of violations.

47. Directorate General of Foreign Trade notifies new standard input output norms for chemical and allied products

The Directorate General of Foreign Trade (**DGFT**) has notified six new Standard Input Output Norms (**SION**) under the Chemical and Allied Product Group for specified pharmaceutical products through a public notice dated 29 May 2026.[43] The new SIONs enable Regional Authorities to issue Advance Authorisations without referring applications to the Norms Committee on a case-by-case basis. The notification is expected to reduce processing timelines, promote consistency in approvals, and facilitate ease of doing business for pharmaceutical exporters.

48. DGFT exempts Special Economic Zones from Quality Control Order and BIS requirements for authorised imports

India's DGFT has exempted Special Economic Zone (**SEZ**) units and developers from the applicability of conditions of Quality Control Orders and BIS rules.[44] This exemption will be applicable to permissible

39 https://www.pib.gov.in/PressReleasePage.aspx?PRID=2270317&reg=48&lang=1
40 https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1779363003_operationalguidelinesforsingleethicsreviewofmulticentrere-searchinindia-addendumtoicmrnationalethicalguidelines.pdf
41 https://www.pharmabiz.com/NewsDetails.aspx?aid=185185&sid=1
42 https://www.pharmabiz.com/NewsDetails.aspx?aid=185898&sid=1
43 https://content.dgft.gov.in/Website/dgftprod/c0438f8f-0edc-4e1c-8d4a-ddb6d777794e/english.pdf
44 https://content.dgft.gov.in/Website/dgftprod/54254473-1c85-4376-9781-79fda048fc4b/English_0003.pdf

imported goods like raw materials, components, consumables, spares and capital goods which are required for authorised operations within SEZs.

49. FSSAI issues notices to energy drinks manufacturers and marketers

The FSSAI, on 1 July 2026, issued notices to manufacturers and marketers of six energy drinks in India. The notices directed the manufacturers and marketers to remove the term *"energy drink"* from the labels of their products and to cease the usage of therapeutic claims such as *"vitalizes body and mind," "enhancing focus," "boost energy levels,"* etc., in their marketing materials. The manufacturers and marketers were given 90 days to comply with these directions.[45]

50. Parliamentary Standing Committee recommends early implementation of trade margin rationalisation for life saving drugs

The Parliamentary Standing Committee on Chemicals and Fertilisers raised concerns regarding the delay in implementation of trade margin rationalisation mechanism under the DPCO in relation to life saving drugs such as anti-cancer drugs. The committee recommended that the DoP implement the mechanism at the earliest.[46] It also recommended that the DoP review the existing mechanism for monitoring the prices of non-scheduled formulations to ensure affordability of chronic care and life saving drugs.[47]

51. Regulatory action against sale of nicotine pouches at international airports

The drugs licensing authorities inspected duty-free shops at Mumbai airport and ordered the operators to cease selling nicotine pouches and obtain necessary approvals before recommencing sales.[48] The duty-free shop operators challenged this regulatory action before the Bombay High Court. By an order dated 24 June 2026, the Bombay High Court granted interim relief to the petitioners and directed that no coercive action be taken in respect of the existing stock of nicotine pouches held at the duty-free shops until further orders.

45 https://economictimes.indiatimes.com/industry/cons-products/food/fssai-crackdown-on-energy-drink-brands-issues-notices-to-6-firms-including-red-bull-pepsico/articleshow/132118648.cms
46 https://www.pharmabiz.com/NewsDetails.aspx?aid=187593&sid=1
47 https://www.pharmabiz.com/NewsDetails.aspx?aid=187567&sid=1
48 https://www.reuters.com/legal/litigation/india-finds-adanis-mumbai-airport-shops-sold-nicotine-pouches-breach-law-2026-07-07/

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