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

Volume IX | Issue III | April - June 2026

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Dear Readers,

The second quarter of 2026 brought with it a period of considerable activity across India's healthcare and life sciences landscape, with significant regulatory reform, landmark judicial pronouncements, and transformational transactions shaping the sector between April and June 2026. The quarter was characterised by a deepening regulatory focus on pharmaceutical and medical device compliance, accelerated adoption of digital processes across regulatory frameworks, and an unprecedented wave of cross-border consolidation activity underscoring the global ambitions of Indian and multinational life sciences companies alike. This edition of *Synapse* captures these evolving trends and their implications for India's healthcare ecosystem.

On the regulatory front, the Ministry of Health and Family Welfare (**MoH&FW**) proposed amendments to the Medical Devices Rules, 2017, introducing a revised framework for the testing and evaluation of medical devices, including rationalisation of fee structures for notified laboratories, strengthened labelling requirements, and the expansion of EU countries to the list of regulated jurisdictions, with meaningful implications for market entry. The MoH&FW also removed syrups from the Schedule K exemption under the Drugs Rules, 1945, thereby subjecting such formulations to full regulatory requirements under the Drugs and Cosmetics Act, 1940. At the Central Drugs Standard Control Organisation (**CDSCO**) level, the prior-intimation mechanism for Form CT-5 applications for export-purpose bioavailability and bioequivalence studies were operationalised, reflecting a move towards risk-based regulatory administration and reducing approval timelines for export-oriented studies. The CDSCO also strengthened enforcement against unauthorised promotion and distribution of GLP-1 receptor agonist-based drugs, signaling heightened regulatory scrutiny in high-demand therapeutic segments. On food safety, the FSSAI directed that *Ashwagandha* leaves are not to be used in food products in crude, extract, or any other form, requiring food business operators engaged in the manufacture of nutraceuticals and health supplements to undertake formulation reviews and labelling corrections. The FSSAI also mandated that specified prior approval and risk assessment applications are to be submitted exclusively through the electronic Prior Approval and Assessment System (**ePAAS**) portal from June 1, 2026, marking a significant operational shift in India's food safety regulatory framework.

In the news and policy space, the Parliament passed the Jan Vishwas (Amendment of Provisions) Bill, 2026, introducing amendments to the Drugs and Cosmetics Act, 1940, and the Pharmacy Act, 1948, replacing imprisonment for certain minor procedural violations with graded monetary penalties and introducing adjudication mechanisms, with the objective of reducing compliance burdens and improving ease of doing business. The Drugs Consultative Committee recommended that medicines be dispensed in quantities corresponding to exact

prescription requirements, including through the cutting of strip-packed medicines, a measure aimed at reducing medicine wastage and patient costs. AIIMS Delhi introduced India's first portable bedside MRI system for point-of-care brain imaging in critical care settings, enabling neurological scans to be performed inside ICUs without transporting hemodynamically unstable patients, thereby supporting faster clinical decision-making in emergency neurodiagnostics. The CDSCO initiated stakeholder consultations following the Coldrif cough syrup tragedy in Madhya Pradesh, reviewing the use of high-risk solvents including propylene glycol and its impurities in paediatric oral liquid formulations, signalling heightened regulatory focus on excipient safety and patient protection in paediatric medicines.

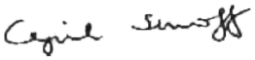
In the litigation space, the Delhi High Court upheld central oversight over fixed dose combinations classified as "new drugs", affirming that central approval under the New Drugs and Clinical Trials Rules, 2019, remains mandatory for such FDCs and that State Licensing Authorities cannot independently grant manufacturing or marketing licenses without prior central approval, reinforcing the regulatory hierarchy in the pharmaceutical sector.

This quarter also witnessed several landmark transactions, most notably Sun Pharmaceutical Industries' definitive agreement to acquire Organon & Co. in an all-cash transaction at an enterprise value of approximately USD 11.75 billion, representing one of the largest outbound transactions ever undertaken by an Indian pharmaceutical company, expected to close in early 2027 subject to regulatory and shareholder approvals. GSK announced its agreement to acquire Nuvalent in a transaction valued at approximately USD 10 billion, reflecting the company's strategic pivot towards precision oncology. Further, Gujarat-based Themis Biosyn announced the acquisition of MicroBiopharm Japan, a fermentation-based CDMO, for approximately INR 1,300 crore, underscoring the growing trend of Indian life sciences companies acquiring specialised overseas manufacturing assets to build global scale.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated pharmaceuticals, healthcare, and life sciences practice. This latest issue of *Synapse* is our effort to keep you abreast of the latest developments in this dynamic sector. We hope you find this issue of interest. As always, your feedback helps us improve our efforts. Please feel free to send your comments, feedback, and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blogs at https://corporate.cyrilamarchandblogs.com for more articles on matters of interest in the Indian pharmaceutical, life sciences, and healthcare spaces. We hope you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and healthy.

Regards,



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Regulatory Updates

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

a. *MoH&FW proposes amendments to the Medical Devices Rules, 2017*[1]

The MoH&FW, *vide* draft notification G.S.R. 270(E) dated April 10, 2026, proposed amendments to the Medical Devices Rules, 2017 (**MD Rules**) to introduce a fee structure for testing and evaluation of medical devices applicable to notified laboratories. The draft further proposes additional labelling requirements for manufacturers who outsource sterilisation activities to a third-party facility holding a valid licence for sterilisation of medical devices, mandating that the licence number of the sterilisation site be prominently mentioned on the label of the medical device, with a view to enhancing traceability, post-market surveillance, and regulatory oversight.

b. *MoH&FW proposes rationalisation of testing fee framework for medical devices*[2]

The MoH&FW, *vide* draft notification G.S.R. 269(E) dated April 10, 2026, proposed amendments to the MD Rules to expand the assessment criteria for manufacturers and importers of Class A (Non-Sterile and Non-Measuring) medical devices by requiring compliance not only with prescribed product standards but also with Quality Management System (**QMS**) standards as a condition for registration. The draft further proposes the inclusion of European Union member countries within the existing list of regulated jurisdictions under Rule 63(1), carrying significant implications for market entry, as manufacturers and/or importers of medical devices approved by the such regulatory authorities of EU member countries (along with other listed regulated authorities) may consequently not be required to submit clinical investigation data as part of their application for permission to import or manufacture a medical device that does not have a predicate device available in India.

c. *MoH&FW proposes expansion of Rule 89 licensing linkages for Form 29*[3]

The MoH&FW, *vide* notification G.S.R. 299(E) dated April 21, 2026, proposed amendments to Rule 89 of the Drugs Rules, 1945 (**Drugs Rules**). Rule 89 currently exempts holders of Forms 25 and 28 from the requirement of obtaining a separate test license in Form 29 licence to manufacture drugs for the purpose of examination, test, or analysis. The proposed amendment seeks to extend this exemption to holders of Forms 25A, 25F, 28A, 28B, 28D, 28DA, and 28F, thereby streamlining test and analysis-related manufacturing activities for a wider category of licence holders.

d. *MoH&FW includes Pregabalin in Schedule H1 of the Drugs Rules, 1945*[4]

The MoH&FW, *vide* notification G.S.R. 377(E), dated May 13, 2026, notified the Drugs (Second Amendment) Rules, 2026, adding Pregabalin to Schedule H1 of the Drugs Rules. As a Schedule H1 drug, Pregabalin will be subject to stricter prescription and record-keeping requirements to curb misuse and non-prescription use. The amendment will take effect 180 days from its publication in the *Official Gazette*.

e. *MoH&FW revises testing and analysis fee framework under the Drugs Rules*[5]

The MoH&FW, *vide* notification G.S.R. 407(E), dated May 22, 2026, notified the Drugs (Third Amendment) Rules, 2026, revising the testing and analysis fees prescribed under Schedule B and Schedule B(1) of the Drugs Rules. The revised fee structure applies to government drug laboratories conducting testing and analysis of pharmaceutical, biological, AYUSH, and related products, with fees set to increase by 5 per cent annually.

f. *MoH&FW introduces permanent registration framework for mental health establishments*[6]

The MoH&FW, *vide* notification G.S.R. 427(E), dated June 1, 2026, notified the Mental Healthcare (Central Mental

[1] https://egazette.gov.in/WriteReadData/2026/271705.pdf
[2] https://egazette.gov.in/WriteReadData/2026/271703.pdf
[3] https://egazette.gov.in/WriteReadData/2026/271969.pdf
[4] https://egazette.gov.in/(S(xfy3dklbziwi5tnyfxcfe4jv))/ViewPDF.aspx
[5] https://egazette.gov.in/(S(xfy3dklbziwi5tnyfxcfe4jv))/ViewPDF.aspx
[6] https://egazette.gov.in/(S(xfy3dklbziwi5tnyfxcfe4jv))/ViewPDF.aspx

Health Authority and Mental Health Review Boards) Amendment Rules, 2026 which introduce a formal procedure for grant of permanent registration to mental health establishments by the Central Mental Health Authority and prescribes a new registration certificate format. These rules also clarify that permanent registration certificates issued before the notification shall continue to remain valid.

g. *MoH&FW amends unit specification for folic acid under the Drugs Rules*[7]

The MoH&FW, *vide* notification G.S.R. 444(E), dated June 1, 2026, notified the Drugs (Fourth Amendment) Rules, 2026. The amendment revises Schedule V of the Drugs Rules, by substituting the unit of measurement specified for folic acid from "mg" (milligrams) with "mcg" (micrograms), aiming to align the prescribed unit with prevailing regulatory and scientific standards.

h. *MoH&FW removes exemption for syrups under Schedule K of the Drugs Rules*[8]

The MoH&FW, *vide* notification G.S.R. 477(E) dated June 9, 2026, notified the Drugs (Fifth Amendment) Rules, 2026, amending Schedule K of the Drugs Rules, 1945 by omitting the word *"Syrups"* from item (7) against Serial No. 13 under the specified class of drugs. Schedule K provides exemptions from certain provisions of the Drugs and Cosmetics Act, 1940 (**D&C Act**) for specified categories of drugs, subject to prescribed conditions.

2. The Central Drugs Standard Control Organisation (CDSCO)

a. *CDSCO operationalises prior-intimation pathway for export BA/BE studies in Form CT-05*[9]

The CDSCO, *vide* circular No. DC-DT-11013(11)/1/2025 dated April 20, 2026, operationalised the "prior intimation" mechanism for Form CT-05 applications (export purpose only) under the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**). The circular applies to single-dose bioavailability and bioequivalence (**BA/BE**) studies in healthy adult volunteers involving oral dosage forms of drugs already approved in India, United States, EU, Japan, Australia, Canada, or the United Kingdom, excluding cytotoxic, hormonal, narcotic, psychotropic, narrow therapeutic index, and highly variable pharmacokinetic drugs. Portal acknowledgement on SUGAM constitutes "prior intimation", with prior approval continuing for all other categories.

b. *CDSCO aligns PSUR filing timelines with actual date of market launch*[10]

The CDSCO, *vide* advisory No PSUR/4/2026 dated April 21, 2026, clarified that the periodic safety update report (**PSUR**) reporting timelines for new drugs will commence from the date the new drugs are marketed and not from the date of regulatory approval. The clarification is operationally significant for marketing authorisation holders (**MAHs**) whose commercial launch is delayed after approval and sets operational expectations for consolidated PSUR submissions via the SUGAM portal.

c. *CDSCO intensifies SUGAM pendency clean-up and signals rejection of long-pending applications*[11]

The CDSCO, *vide* public notice No.IT-11011(11)/16/2026 dated May 4, 2026, introduced a structured reminder mechanism for the disposal of applications pending at the applicant's end due to non-response to queries. The notice stipulates that, after multiple reminders followed by a final disposal notice, such applications may be rejected with fee forfeiture, if responses are not submitted within the prescribed timeline.

d. *CDSCO strengthens enforcement against unauthorised promotion of GLP-1 based drugs*[12]

The CDSCO, *vide* public notice No. Enforc-11021(11) / 34 / 2026 dated March 27, 2026, issued strengthened enforcement measures against unauthorised promotion and distribution of GLP-1 receptor agonist-based drugs. The notice signals increased regulatory scrutiny in high-demand therapeutic segments and reinforces compliance obligations relating to marketing practices, including restrictions on the promotion of prescription drugs to the general public and distribution through unauthorised channels.

7 https://egazette.gov.in/(S(xfy3dklbziwi5tnyfxcfe4jv))/ViewPDF.aspx
8 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQzNjA=
9 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular_20042026.pdf
10 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Advisory.pdf
11 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/disposal%20of%20long%20pending%20application.pdf
12 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQxNzE=

e. *CDSCO revises sampling and reporting framework for NSQ and spurious products*[13]

The CDSCO issued the Revised Regulatory Guidelines for Sampling of Drugs, Cosmetics & Medical Devices by Drugs Inspectors of Central & State Drug Authorities, published on May 26, 2026. The revised guidelines mandate broader market coverage and enhanced reporting of Not of Standard Quality and spurious products. These also introduce standardised alert formats to improve the speed and accuracy of regulatory communications, while further seeking to enhance traceability, transparency, and regulatory oversight across the supply chain.

f. *CDSCO mandates implementation of pharmacovigilance systems under Schedule M*[14]

The CDSCO, *vide* Circular No. PSUR-11/13/2024-eOffice (Comp. No. 17367), dated June 3, 2026, directed all licensees to implement an effective Pharmacovigilance system in compliance with Schedule M of the Drugs and Cosmetics Act, 1940, and Drugs Rules,. The circular reiterates the obligation of manufacturers and marketers to collect, process, and report adverse drug reactions to the licensing authorities regarding the drugs manufacture or market. Central and State Licensing Authorities have been empowered to verify compliance with these requirements during routine inspections and other regulatory activities.

g. *CDSCO directs compliance review for hair colour cosmetic products*[15]

The CDSCO, *vide* Circular No. COS-13011/4/2026-eOffice, dated June 10, 2026, directed all importers and manufacturers of hair colour cosmetic products to ensure compliance with the requirements prescribed under the Cosmetics Rules, 2020 and applicable Bureau of Indian Standards (**BIS**) specifications, including IS 4707 (Part 1 and Part 2) and IS 8481.

h. *CDSCO mandates parallel submission of Clinical Trial applications to CDSCO and Ethics Committees*[16]

The CDSCO, *vide* advisory No. ETHICS-11011/5/2026-e-office dated May 11, 2026, issued an advisory on the parallel submission and processing of clinical trial applications by the CDSCO and Ethics Committees, registered under the NDCT Rules. All applicants and stakeholders may submit Clinical Trial protocols and related documents simultaneously to the CDSCO and the concerned Ethics Committee registered under NDCT

[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQyMTM=
[14] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular%20..pdf?
[15] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQzMzM=
[16] cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQxMzY=

Rules. The registered Ethics Committees are required to independently review the Clinical Trial protocols submitted to them and process these in accordance with the provisions of the NDCT Rules, without awaiting prior approval from the CDSCO.

3. The Food Safety and Standards Authority of India (FSSAI)

a. *FSSAI notifies additional food import points and introduces fee-payment flexibility in import clearance workflow*[17]

The FSSAI, *vide* notification No. 1-1715 dated April 10, 2026, notified authorised officers and designated points of entry for food imports at ICD Naya Raipur, ICD Dahej, and ICD Varnama under the Food Safety and Standards Act, 2006 (**FSS Act**), and the Food Safety and Standards (Import) Regulations. Separately, *vide* public notice No. TIC/3/2023 dated April 10, 2026, the FSSAI introduced operational flexibility in the Food Import Clearance System (**FICS**)/ SWIFT framework, permitting importers to remit inspection and testing fees after visual inspection but prior to issuance of the Provisional No Objection Certificate (**PNOC**), No Objection Certificate (**NOC**), or Non-Conformance Certificate (**NCC**).

b. *FSSAI directs non-use of Ashwagandha leaves in food products*[18]

The FSSAI, *vide* advisory No. RCD-15001/11/2021 dated April 16, 2026, directed against the use of *Ashwagandha* leaves in food products in crude, extract, or any other form. The advisory reinforced the regulatory distinction between permitted and non-permitted plant parts under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, and is likely to require food business operators (**FBOs**) engaged in the manufacture of nutraceuticals, health supplements, and related products to undertake formulation reviews, specification amendments, and labelling corrections where *Ashwagandha*-derived ingredients are utilised.

c. *FSSAI extends compliance timeline for meat sausage standards and reiterates prohibition on calcium carbide in fruit ripening*[19]

The FSSAI, *vide* direction No. STD/43-FA under Section 16(5) of the FSS Act dated April 28, 2026, extended the compliance period for newly notified meat sausage standards, citing industry implementation challenges and the pendency of an ongoing scientific study. Separately, *vide* advisory No. RCD-15001/15/2025 dated April 29, 2026, the FSSAI reiterated the prohibition on the use of calcium carbide and other unauthorised ripening agents in fresh fruits, and directed the Commissioners of Food Safety and enforcement authorities to conduct intensified inspections and targeted surveillance at storage and ripening locations. Both measures underscore the FSSAI's continuing approach of calibrated transition support alongside targeted enforcement action.

d. *FSSAI mandates exclusive use of ePAAS portal for prior approvals and risk assessments*[20]

The FSSAI, *vide* office order No. SSDIV2-PA050(11)/2/2025 dated May 6, 2026, mandated that applications for specified prior approvals and risk assessments, including those pertaining to non-specified foods and ingredients, health claims, recycled PET (**r-PET**), food for special medical purposes (**FSMP**), vegan endorsements, and similar regulated categories, shall be submitted exclusively through the ePAAS portal with effect from June 1, 2026. The order discontinues manual, offline, and email-based submission routes for covered categories.

4. National Pharmaceutical Pricing Authority (NPPA)

a. *NPPA operationalises WPI-linked revision of ceiling prices for scheduled formulations*[21]

The NPPA, *vide* Order S.O. 1581(E) dated March 25, 2026 (along with allied orders including S.O. 1575(E) and S.O. 1589(E)), notified the revision of ceiling prices of scheduled formulations under the Drugs (Prices Control) Order, 2013 (**DPCO 2013**), based on the annual Wholesale

[17] https://fssai.gov.in/upload/advisories/2026/04/69d8c30f8e9d1Notification%20of%20total%20171%20PoEs_ICD%20Naya%20Raipur_ICD%20Dahej_ICD%20Varnama_09%20April%202026-1-17.pdf, https://fssai.gov.in/upload/advisories/2026/04/69d8c4dd019f6FICS_FeePayment_Flexibility_10-04-2026.pdf
[18] https:// fssai.gov.in/ upload/ advisories /2026/04/ 69e0d84fcac2f Advisory%20on%20non%20use%20of%20ashwagandha%20leaves%20in%20crude%20or%20 extract%20or%20any%20other %20form%20in%20 food%20products-%20reg.pdf
[19] https://fssai.gov.in/upload/advisories/2026/04/69f192d9de1dcDirection%20dt%2028.04.2026.pdf, https://fssai.gov.in/upload/advisories/2026/05/6a01c18490326Advisory_160426.pdf
[20] https://fssai.gov.in/upload/advisories/2026/05/69fb29a607ad7Order%20dt%2006.05.2026.pdf
[21] https://egazette.gov.in/WriteReadData/2026/271339.pdf

Price Index (**WPI**) adjustment for the year 2025 over 2024. The revised prices, reflecting a WPI increase of approximately 0.64956 per cent, were made effective from April 1, 2026.

b. *NPPA fixes retail prices for 42 new drug formulations and extends separate ceiling price for IV fluids with special features*[22]

The NPPA, at its 145th authority meeting held on April 30, 2026 (proceeding No.277/145/2026/F), notified retail price fixation orders for 42 new drug formulations under Paragraphs 5 and 15 of the DPCO 2013. The notification establishes mandatory retail prices, exclusive of Goods and Services Tax (**GST**), for pharmaceutical formulations across various therapeutic categories. Separately, the NPPA extended a separate ceiling price under Paragraph 11(3) of the DPCO 2013 for specified intravenous (**IV**) fluid packs with special features, following recommendations of the Multidisciplinary Committee of Experts.

c. *NPPA publishes draft price calculation sheets for stakeholder review*[23]

Through April and May 2026, the NPPA publishes draft price calculation sheets and worksheets for proposed retail and ceiling prices as part of its consultative pricing workflow under the DPCO 2013. The publication of draft calculation sheets enables manufacturers, marketers, and other stakeholders to review the methodology adopted, identify factual inconsistencies, and submit representations prior to finalisation of price fixation orders.

d. *NPPA fixes retail prices of 30 new drug formulations*

The NPPA, *vide* Order S.O. 1680(E), dated May 27, 2026, issued under Paragraphs 5, 11, and 15 of the DPCO 2013, fixed retail prices for 30 new drug formulations across therapeutic categories, including cardiovascular medicines, antibiotics, nutritional supplements, anti-allergic antibiotics, nutritional supplements, anti-allergic drugs, gastrointestinal formulations, analgesics and tropical preparations.

[22] 145th-Authority-Minutescompressedpdf-ae924df59c253a7438dc1b8c2618dddb.pdf
[23] https://nppa.gov.in/archive

News Updates

1. DTAB recommends revision of microbial contamination limits under Schedule M[24]

The Drugs Technical Advisory Board (**DTAB**) has recommended revising the microbial contamination limits applicable to Grade A cleanroom areas under Schedule M of the Drugs Rules, to align them with the standards prescribed under the WHO Technical Report Series 1044, Annexure II. The proposed revisions are intended to harmonise India's pharmaceutical manufacturing standards with international benchmarks and facilitate greater regulatory consistency in quality control and GMP compliance.

2. DTAB recommends expanding eligibility criteria for competent persons at wholesale drug premises[25]

The DTAB has recommended amending Rule 64 of the Drugs Rules to allow science graduates with relevant experience and a recognised certification course to serve as competent persons for wholesale drug licences under Forms 20B and 21B. The proposal, which expands the existing eligibility criteria beyond pharmacists and certain qualified personnel, is significant as it could broaden workforce eligibility in wholesale drug operations.

3. Parliament passes Jan Vishwas (Amendment of Provisions) Bill, 2026[26]

The Parliament has passed the Jan Vishwas (Amendment of Provisions) Bill, 2026, introducing amendments to several healthcare-related legislations, including the D&C Act and the Pharmacy Act, 1948. The amendments replace imprisonment for certain minor procedural violations with graded monetary penalties and introduce adjudication mechanisms for specified offences, with the objective of reducing compliance burdens, streamlining enforcement, and improving ease of doing business while maintaining public health safeguards.

4. WHO updates guidelines on opioid dependence treatment and overdose prevention[27]

The World Health Organization (**WHO**) has updated its guidelines on the treatment of opioid dependence and community management of opioid overdose. These guidelines reaffirm the use of methadone and oral buprenorphine as standard treatments and conditionally extend guidance to cover the long-acting injectable buprenorphine as a new treatment option. The full

[24] https://www.pharmabiz.com/NewsDetails.aspx?aid=185185&sid=1
[25] https://medicarepharmabusiness.com/dtab-recommends-amendment-of-rule-64-related-to-qualification-of-competent-person/
[26] https://ddnews.gov.in/en/parliament-passes-jan-vishwas-amendment-of-provisions-bill-2026/
[27] https://www.who.int/news/item/09-02-2025-who-updates-guidelines-on-opioid-dependence-treatment-and-overdose-prevention

guidelines, including detailed recommendations and the implementation guidance, are expected to be published later in 2026 or early 2027.

5. DCC recommends dispensing of exact prescription quantities of strip-packed medicines[28]

The Drugs Consultative Committee (**DCC**) has recommended dispensing medicines in quantities corresponding to the exact prescription requirement, including through the cutting of strip-packed medicines where necessary. While the recommendation aims to reduce medicine wastage and patient costs, it has raised concerns regarding traceability, inventory management, and losses from unsold partial strips.

6. AIIMS Delhi introduces India's first portable bedside MRI system for critical brain imaging[29]

AIIMS Delhi, in early May 2026, introduced India's first portable bedside MRI system for point-of-care brain imaging in critical care settings. The device enables neurological scans to be performed inside ICUs without transporting haemodynamically unstable patients to conventional MRI suites, thereby supporting faster clinical decision-making in emergency neurodiagnostics.

7. ICMR and ICAR launch "SEHAT" mission integrating agriculture, nutrition and public health[30]

The Indian Council of Medical Research (**ICMR**) and the Indian Council of Agricultural Research (**ICAR**), on May 12, 2026, jointly launched the national mission "SEHAT – Science Excellence for Health through Agricultural Transformation", aimed at addressing malnutrition and the rising burden of non-communicable diseases through convergence between agriculture, nutrition and public health policy. The initiative, seeking to drive evidence-backed interventions and institutional convergence, is relevant for food-health strategy, public health planning, and nutrition governance at the national level.

8. India and the Netherlands announce strategic partnership framework for pharma and medtech cooperation (2026–2030)[31]

India and the Netherlands, on May 17, 2026, entered into a strategic partnership framework (2026–2030) to enhance bilateral cooperation in pharmaceuticals and medical technology. The framework encompasses supply chain resilience, innovation collaborations, and investment facilitation across the pharma and medtech sectors. The partnership is relevant for Indian pharmaceutical and medtech companies seeking to deepen engagement with European markets and for stakeholders involved in cross-border supply chain planning, technology transfer, and regulatory harmonisation initiatives.

9. Innovations in rapid immunotherapy delivery introduced in India[32]

Innovations in oncology treatment, including significantly faster immunotherapy delivery models, were introduced in India in mid-May 2026. The developments reduce treatment administration time and improve patient access to advanced therapies, reflecting the broader trend of clinical workflow optimisation and adoption of next-generation treatment protocols in the domestic oncology care landscape.

10. Global collaboration announced to advance neurosurgical technologies in India[33]

The World Federation of Neurosurgical Societies (**WFNS**) and Time Medical India, on May 18, 2026, announced a global collaboration to advance neurosurgical technologies, supporting innovation, training, and adoption of advanced medical imaging and surgical solutions. The partnership is relevant for medtech companies and healthcare providers engaged in neurosurgical care delivery and reflects the growing emphasis on international collaborations to accelerate technology adoption and clinical capability building in specialised surgical disciplines in India.

[28] https://www.news18.com/lifestyle/health-and-fitness/govt-mulls-rule-to-force-pharmacies-to-dispense-exact-prescription-quantities-chemist-body-resists-10024929.html
[29] https://health.economictimes.indiatimes.com/news/hospitals/aiims-delhi-introduces-indias-first-portable-mri-system-for-bedside-brain-imaging/130730220
[30] http://icar.gov.in/index.php/en/union-ministers-shri-shivraj-singh-chouhan-and-shri-jp-nadda-launch-national-mission-sehat
[31] https://www.pmindia.gov.in/en/news_updates/roadmap-of-india-netherlands-strategic-partnership-2026-2030/
[32] https://health.economictimes.indiatimes.com
[33] https://indiamedtoday.com/wfns-innovation-technology-committee-announces-partnership-with-time-medical-international-ventures-india-pvt-ltd-for-first-in-class-medical-technology-innovation/

11. AIOCD raises concerns regarding regulation of e-pharmacies[34]

The All-India Organisation of Chemists and Druggists (**AIOCD**) organised a nationwide pharmacy bandh on May 20, 2026, to highlight concerns regarding the continued operation of e-pharmacies in the absence of a dedicated regulatory framework governing online sale of medicines. The development has renewed calls for the introduction of specific regulations for e-pharmacies and regulatory oversight of digital pharmaceutical distribution channels.

12. ICMR introduces single-window ethics approval framework for multicentre medical studies[35]

The ICMR, in May 2026, introduced operational guidelines providing for a single ethics review mechanism for multicentre biomedical and health research studies conducted across multiple institutions in India. The new framework allows a designated ethics committee to conduct a single review for multicentre studies, replacing the requirement for separate approvals at each site. The measure aims to reduce administrative burden, expedite study initiation, and improve participation in clinical research across diverse regions.

13. India–Oman CEPA to provide zero tariffs on Indian pharmaceutical exports[36]

The India–Oman Comprehensive Economic Partnership Agreement (**CEPA**), effective from June 1, 2026, provides for zero customs duties on Indian pharmaceutical exports, including active pharmaceutical ingredients (**APIs**) and formulations. The agreement is expected to enhance the competitiveness of Indian pharmaceutical products in Oman through tariff elimination, expedited marketing authorisation pathways for products approved by major international regulators, and acceptance of GMP inspection documents. The CEPA also includes provisions supporting cooperation in traditional medicine, nutraceuticals, and healthcare services, creating new export opportunities for India's pharmaceutical and wellness sectors.

14. Stakeholder Consultations initiated by the CDSCO following the Coldrif Cough Syrup Tragedy[37]

The CDSCO, on May 11, 2026, initiated stakeholder consultations to review the use of high-risk solvents, including propylene glycol and its related impurities, namely diethylene glycol (**DEG**) and ethylene glycol (**EG**), in paediatric oral liquid formulations. The consultations, undertaken pursuant to recommendations of the DCC, seek to assess the prevalence of such excipients in marketed products and explore the feasibility of safer alternative formulations. The initiative follows the September–October 2025 "Coldrif" cough syrup tragedy in Madhya Pradesh, where at least 24 children died after consuming a syrup found to contain excessive levels of DEG, prompting regulatory action against the manufacturer and broader scrutiny of excipient safety.

15. Studies link GLP-1 therapies to reduced cancer risk and improved survival outcomes[38]

New research presented at the 2026 American Society of Clinical Oncology (**ASCO**) Annual Meeting suggests that GLP-1 receptor agonists, widely used for diabetes and obesity management, may be associated with a reduced risk of certain cancers, including breast, colorectal, lung, and liver cancers, and improved survival outcomes among cancer patients. Researchers have attributed the potential benefits to anti-inflammatory and immune-modulating properties of GLP-1 therapies, extending beyond weight loss alone. Researchers have nonetheless emphasised that the current evidence remains observational, and that randomised clinical trials will be required to establish causality and determine clinical utility.

[34] https://www.pharmabiz.com/ArticleDetails.aspx?aid=186146&sid=3
[35] https://vohnetwork.com/news/policy/cmr-introduces-single-ethics-review-framework-to-streamline-multicentre-clinical-trials-in-india
[36] https://taxguru.in/custom-duty/india-secures-duty-free-access-for-99-38-percent-exports-through-india-oman-cepa.html#google_vignette
[37] https://www.news18.com/india/drug-regulator-to-meet-pharma-industry-to-review-high-risk-solvents-in-cough-syrups-ws-l-10088009.html
[38] https://www.reuters.com/business/healthcare-pharmaceuticals/glp-1-drugs-may-have-beneficial-effect-across-many-types-cancer-2026-06-03/

Litigation Updates

1. Delhi High Court upholds central oversight over fixed dose combinations treated as "new drugs"[39]

The Delhi High Court (**Delhi HC**), in *Maxford Healthcare v. Union of India* (2026 DHC 3690), *vide* judgment dated April 21, 2026, upheld the communication issued by the CDSCO that requires State and Union Territory Drug Controllers to review and, where warranted, revoke licences granted for fixed-dose combinations (**FDCs**) that fall within the definition of a "new drug" under D&C Act and NDCT Rules. The Court affirmed that central approval under the NDCT Rules remains mandatory for such FDCs. It also affirmed that State Licensing Authorities cannot independently grant manufacturing or marketing licences for such products without prior permission from the Central Licensing Authority. The judgment emphasises patient safety considerations and reinforces the regulatory hierarchy between central and state licensing functions in the pharmaceutical sector.

2. Delhi High Court permits Intas to market "Bevatas" in trademark dispute with Sun Pharma[40]

The Delhi HC, in *Intas Pharmaceuticals Limited v. Sun Pharma Laboratories Limited* (RFA(OS)(COMM) 10/2026), *vide* judgment dated May 29, 2026, set aside a Single Judge order restraining Intas Pharmaceuticals from using the trademark *Bevatas* for its bevacizumab-based oncology product. The dispute concerned Sun Pharma's allegation that *Bevatas* was deceptively similar to its registered trademark *Bevetex* and could lead to confusion in the pharmaceutical market. The Division Bench held that the competing marks were not sufficiently similar to warrant an injunction and permitted Intas to continue manufacturing and marketing the product under the *Bevatas* brand. The judgment is significant as it provides guidance on the assessment of trademark similarity in the pharmaceutical sector and highlights the courts' approach to balancing intellectual property rights with competition and market access considerations.

3. Delhi High Court directs CDSCO to examine patient safety concerns over Zydus' semaglutide approval[41]

The Delhi HC, in *Dr. Jyoti Shrivastava v. Central Drugs Standard Control Organization & Anr.* (W.P.(C) 7559/2026), *vide* order dated June 2, 2026, directed the CDSCO to consider and decide a representation challenging the approval granted to Zydus Lifesciences for manufacturing and

[39] Maxford Healthcare & Ors. v. Union of India & Anr., Judgment dated April 21, 2026, in W.P.(C) No. 6845 of 2025
[40] Intas Pharmaceuticals Limited v. Sun Pharma Laboratories Limited,, Judgment dated May 29, 2026, in RFA(OS)(COMM) 10 of 2026 CM APPL. 21698 of 2026
[41] Dr. Jyoti Shrivastava v. Central Drugs Standard Control Organization & Anr., (W.P.(C) 7559/2026)

marketing of semaglutide injections, which are being marketed under the brand names *Semaglyn*, *Alterme*, and *Mashema*. The petition raised concerns regarding the product's delivery mechanism, alleging that it departs from internationally adopted pre-filled and pre-calibrated pen-device systems, thereby posing potential patient safety risks. The Court directed the CDSCO to examine the issues raised and take an appropriate decision within the prescribed timeframe. The order is significant as it reflects increasing judicial scrutiny of drug approval processes in India and underscores the importance of patient safety considerations in the regulation of novel diabetes and obesity therapies.

Transaction Updates

1. Biocytogen and Sihuan Pharmaceutical enter strategic partnership[42]

Biocytogen and Sihuan Pharmaceutical, in April 2026, announced a strategic partnership to develop innovative therapies, including weight-loss treatments, by combining Biocytogen's antibody discovery platforms with Sihuan Pharmaceutical's development and commercialisation capabilities. The collaboration highlights continued investment in next-generation therapies for obesity and other disease areas.

2. OneCyte and Kemp Proteins enter strategic partnership for biologics development[43]

OneCyte and Kemp Proteins, in April 2026, announced a strategic partnership to provide integrated cell line development services for biopharmaceutical companies. The collaboration combines OneCyte's single-cell analysis platform with Kemp Proteins' protein engineering and AI-driven design capabilities to accelerate development of complex biologics, improve production yields, and reduce development timelines for next-generation therapeutic products.

3. Neurocrine to acquire Soleno Therapeutics in USD 2.9-billion transaction[44]

Neurocrine Biosciences (**Neurocrine**), in April 2026, announced a definitive agreement to acquire Soleno Therapeutics in an all-cash transaction valued at approximately USD 2.9 billion. The acquisition will add Soleno's FDA-approved therapy VYKAT XR (diazoxide choline) for the treatment of hyperphagia associated with Prader-Willi syndrome to Neurocrine's portfolio and strengthen its presence in endocrinology and rare diseases. The transaction is expected to close in 2026, subject to customary regulatory approvals and closing conditions.

4. Rubicon Research acquires Arinna Lifesciences for INR 176 crore[45]

Rubicon Research (**Rubicon**), in April 2026 acquired an 85 per cent stake in Arinna Lifesciences (**Arinna**) for approximately INR 175.92 crore. The acquisition strengthens Rubicon's presence in the domestic formulations and CNS therapeutics markets and reflects ongoing consolidation in India's pharmaceutical sector.

[42] Biocytogen and Sihuan Pharmaceutical enter strategic partnership in weight loss and beyond
[43] Strategic Alliance Targets Faster, High-Yield Biologics Manufacturing - Biotechnologyt
[44] https://www.reuters.com/business/healthcare-pharmaceuticals/neurocrine-buy-soleno-therapeutics-29-billion-2026-04-06/
[45] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/rubicon-research-acquires-arinna-lifesciences-for-175-cr/130282599?utm_source=category_listing&utm_medium=sectionListing

5. Sun Pharma signs definitive agreement to acquire Organon in India's largest outbound deal[46]

Sun Pharmaceutical Industries Ltd. (**Sun Pharma**), in April 2026, announced entry into a definitive agreement to acquire Organon & Co. (**Organon**) in an all-cash transaction at USD 14 per share, representing an enterprise value of approximately USD 11.75 billion. The transaction significantly expands Sun Pharma's women's health and biosimilars footprint and is expected to strengthen its position in established brands and innovative medicines globally. The acquisition constitutes one of the largest outbound transactions by an Indian pharmaceutical company and is expected to close in early 2027, subject to customary regulatory approvals, antitrust clearances, and Organon shareholder approval.

6. IMG Pharma to acquire Matsumoto Pharmaceutical[47]

IMG Pharmaceutical Co., Ltd. (**IMG Pharma**), in April 2026, entered into a definitive agreement to acquire Matsumoto Pharmaceutical Co., Ltd., a Japanese pharmaceutical manufacturer. The acquisition combines IMG Pharma's research and product development capabilities with Matsumoto Pharmaceutical's established OTC drug portfolio and manufacturing infrastructure, including two production facilities in Japan. The transaction is expected to strengthen IMG Pharma's pharmaceutical and healthcare products platform and support the development of scalable health management solutions across Asia.

7. Monitra Health raises growth capital for remote cardiac monitoring platform[48]

Monitra Health, in April 2026, raised fresh funding to scale its remote cardiac monitoring platform, "upBeat". The transaction reflects continuing investor interest in clinically integrated remote monitoring and diagnostics infrastructure, particularly where digital tools are being combined with hospital and physician workflows to enable continuous patient surveillance outside traditional clinical settings.

8. Merck and Google Cloud announce strategic partnership for "agentic AI" deployment[49]

Merck & Co. (**Merck**) and Google Cloud, in April 2026, announced a multi-year strategic partnership valued at up to USD 1 billion, aimed at enterprise-scale deployment of "agentic AI" capabilities across R&D, manufacturing, and commercial functions. The partnership is relevant for life sciences companies globally as it signals the growing movement towards large-scale AI adoption in regulated environments and is expected to influence governance, validation, and compliance conversations across the pharmaceutical and medtech sectors.

9. Manipal Health completes additional acquisition tranche for Andheri hospital property[50]

Manipal Health Enterprises, in May 2026, completed the second tranche of its multi-stage acquisition of an operational hospital campus in Andheri, Mumbai, purchasing the remaining land and building portion along with associated development potential for approximately INR 495 crore. The cumulative consideration across both tranches is reported at approximately INR 908 crore. The transaction consolidates Manipal's ownership of the campus and provides expansion and redevelopment optionality, highlighting continuing healthcare real-estate consolidation and the strategic importance of location-driven hospital expansion in major urban markets.

10. Listed hospital chain enters Gurugram through acquisition of under-construction facility[51]

Yatharth Hospital & Trauma Care Services Ltd. (**Yatharth**), in May 2026, announced the acquisition of an under-construction 250-bed hospital facility in Gurugram for approximately INR 100 crore, with additional capital expenditure planned to complete construction and equip the facility. The transaction marks Yatharth's fifth acquisition since its IPO debut and its entry into the Gurugram market, reflecting continuing capacity build-out and hospital-market consolidation in the NCR region.

[46] https://money.usnews.com/investing/news/articles/2026-04-26/sun-pharma-to-buy-us-drugmaker-organon-for-11-75-billion-in-indias-largest-pharma-deal, Sun Pharma explores funding mix for $12 billion Organon deal - The Economic Times
[47] https://demo.pharmafocusasia.com/pressreleases/img-pharma-enters-into-definitive-agreement
[48] https://news.webindia123.com/news/Articles/Business/20260430/4445336.html
[49] https://www.merck.com/news/merck-and-google-cloud-partner-to-accelerate-agentic-ai-enterprise-transformation/
[50] https://www.business-standard.com/industry/news/manipal-health-buys-andheri-hospital-property-for-rs-908-crore-126051200558_1.html
[51] https://www.fortuneindia.com/business-news/yatharth-hospitals-makes-fifth-acquisition-since-ipo-debut-enters-gurugram-with-250-bed-hospital/137448

11. Hospital-device strategic partnership announced for deployment of diode laser platform[52]

A Bengaluru multi-speciality hospital, in May 2026, entered into a strategic partnership with a surgical technology company for the deployment of a diode laser platform across multiple specialties, including vascular surgery, proctology, and ENT. The arrangement illustrates the growing use of hospital-industry partnerships to expand device-enabled minimally invasive procedures in private healthcare settings.

12. Zydus Lifesciences to acquire Assertio Holdings in outbound specialty pharma deal[53]

Zydus Lifesciences Ltd. (**Zydus**), in May 2026, announced an all-cash acquisition of US-based Assertio Holdings, Inc. (**Assertio**) for approximately USD 166.4 million. The transaction is aimed at strengthening Zydus' US specialty commercial platform and supportive oncology presence, including access to Rolvedon (a marketed oncology-support asset) and a deeper commercial footprint in the US market. The acquisition provides Zydus with an established US commercial infrastructure and is expected to accelerate its specialty pharma growth strategy.

13. Themis Biosyn acquires Japanese CDMO for INR 1,300 crore[54]

Gujarat-based Themis Biosyn, a subsidiary of Themis Medicare, in May 2026, announced the acquisition of MicroBiopharm Japan Co. Ltd. (**MicroBiopharma**), a Japanese contract development and manufacturing organisation (**CDMO**), for approximately INR 1,300 crore. MicroBiopharm specialises in fermentation-based manufacturing and microbial technologies, serving pharmaceutical and biotechnology companies globally. The acquisition is expected to enhance Themis Biosyn's manufacturing capabilities, strengthen its presence in regulated international markets, and expand its footprint in the global CDMO sector. The transaction is significant as it represents a sizeable outbound acquisition by an Indian pharmaceutical company and underscores the growing trend of Indian life sciences companies acquiring specialised overseas manufacturing assets to build global scale and technological capabilities.

14. Skymap Pharmaceuticals to acquire state-run IMPCL for INR 121 crore[55]

Skymap Pharmaceuticals (**Skyman**) in May 2026, received approval to acquire state-owned IMPCL for approximately INR 121 crore. The transaction forms part of the Government's disinvestment programme and marks a significant privatisation in the AYUSH sector.

15. Pfizer and Innovent Biologics enter strategic oncology research and development collaboration[56]

Pfizer and Innovent Biologics, recently, entered a global collaboration for 12 early-stage oncology programmes, including ADCs and multispecific antibodies. The collaboration underscores continued investment in innovative cancer therapies and strategic R&D partnerships.

16. Serum Institute to manufacture Ebola vaccine backed by CEPI funding[57]

Serum Institute of India (**SII**) and the University of Oxford, in June 2026, announced plans to manufacture clinical trial doses of an investigational Ebola vaccine, supported by up to USD 8.6 million in CEPI funding. The initiative highlights India's role in global epidemic preparedness and vaccine development.

17. Immuneel Therapeutics raises INR 100 crore in Series B funding round[58]

Immuneel Therapeutics raised over INR 100 crore in a Series B round led by investors including Singularity AMC and Rainmatter. The funds will support commercialisation of

[52] https://www.pharmabiz.com/NewsDetails.aspx?aid=185887&sid=2
[53] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/zydus-life-acquires-us-based-assertio-for-166-million-cash/131080115
[54] https://medicaldialogues.in/news/industry/pharma/gujarat-themis-biosyn-to-acquire-japanese-biotech-firm-microbiopharm-for-rs-1300-crore-171402
[55] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/skymap-pharma-to-buy-state-run-indian-medicines-pharma-for-121-cr/131339656?utm_source=top_news&utm_medium=sectionListing
[56] https://www.pharmabiz.com/NewsDetails.aspx?aid=186205&sid=2
[57] https://www.ibef.org/news/serum-institute-of-india-to-manufacture-oxford-ebola-vaccine-backed-by-us-8-6-million-cepi-funding
[58] https://www.digitalhealthnews.com/immuneel-therapeutics-secures-over-inr-100-cr-series-b-funding

Qartemi, India's first approved CAR-T therapy, expand manufacturing capacity, advance the company's cell and gene therapy pipeline, and support international expansion.

18. Johnson & Johnson to acquire Firefly Bio in USD 1 billion oncology technology deal[59]

Johnson & Johnson, in June 2026, agreed to acquire Firefly Bio for USD 1 billion. The acquisition provides access to Firefly Bio's degrader antibody conjugate platform for developing therapies targeting KRAS-driven and other difficult-to-treat cancers, strengthening J&J's oncology pipeline.

19. GSK agrees to acquire Nuvalent in USD 10 billion oncology-focused transaction[60]

GlaxoSmithKline (**GSK**), in June 2026, announced an agreement to acquire US-based biotechnology company Nuvalent, in a transaction valued at approximately USD 10 billion. Nuvalent develops precision oncology therapies targeting genetically defined cancers, including next-generation kinase inhibitors designed to overcome treatment resistance. The acquisition will strengthen GSK's oncology pipeline and expand its portfolio of targeted cancer therapies, reflecting the company's strategic shift towards oncology as a core growth area. The transaction is significant as it underscores continued pharmaceutical investment in precision medicine and highlights the premium being placed on innovative oncology assets with differentiated clinical potential.

20. Roche enters $2 billion cancer drug agreement with Nurix Therapeutics[61]

Roche, in June 2026, entered into a licensing and collaboration agreement with Nurix Therapeutics, valued at up to USD 2.3 billion, for the development of bexobrutideg, a

targeted protein degrader designed for the treatment of blood cancers. The agreement underscores growing industry interest in protein degradation technologies as a promising therapeutic modality in oncology.

21. Viyash Scientific to acquire Bioforlife for INR 188 crore to expand pet healthcare business[62]

Viyash Scientific, in June 2026, announced the acquisition of Bioforlife Meditech Pvt. Ltd. (**Bioforlife**) for approximately INR 188 crore, as part of its strategy to strengthen its presence in the companion animal and pet healthcare segment. Bioforlife is engaged in the marketing and distribution of veterinary and pet care products, and the transaction is expected to enhance Viyash Scientific's product portfolio and distribution capabilities in the rapidly growing animal health market. The acquisition is significant reflects increasing consolidation within the veterinary and pet healthcare sector and underscores growing investor interest in animal health as a high-growth adjunct to the broader pharmaceutical industry.

[59] https://www.biospace.com/press-releases/johnson-johnson-to-acquire-firefly-bio-inc-to-expand-oncology-pipeline-with-novel-degrader-antibody-conjugate-platform
[60] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/gsk-bets-10-bn-on-us-biotech-nuvalnet-in-oncology-pivot/131602605?utm_source=most_read&utm_medium=sectionListing
[61] https://ir.nurixtx.com/news-releases/news-release-details/nurix-therapeutics-announces-global-collaboration-roche-co
[62] https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/viyash-scientific-to-acquire-bioforlife-for-188-crore-to-expand-pet-care-biz/131602622?utm_source=top_news&utm_medium=sectionListing

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