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LIFESCIENCES AND HEALTHCARE

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Pharmaceuticals

LEGAL AND REGULATORY

Central Drugs Standard Control Organisation Directs Pharmaceutical Companies to Maintain Pharmacovigilance Systems

The Central Drugs Standard Control Organisation ("**CDSCO**"), through a circular bearing File No. PSUR-11/13/2024-eoffice (Comp. No. 17367) dated June 03, 2026 ("**Circular**"), directed all pharmaceutical manufacturers and other stakeholders to establish and maintain an effective pharmacovigilance system in accordance with Paragraph 6.11 of Schedule M of the Drugs Rules, 1945. The Circular reiterates that every licensee is required to have a pharmacovigilance system for collecting, processing and forwarding reports of adverse drug reactions arising from drugs manufactured or marketed by it to the licensing authorities. CDSCO further clarified that compliance with these requirements will be verified during inspections conducted by CDSCO, State Licensing Authorities and Union Territory administrations, reinforcing pharmacovigilance as an integral component of Good Manufacturing Practices and post-market drug safety monitoring.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQyNzg=

Ministry of Health and Family Welfare Notifies Drugs (Fifth Amendment) Rules, 2026

On June 09, 2026, the Ministry of Health and Family Welfare ("**MoHFW**") notified the Drugs (Fifth Amendment) Rules, 2026 ("**Amendment Rules**") vide Notification No. G.S.R. 477(E), thereby amending the Drugs Rules, 1945 ("**Drugs Rules**").

Rule 123 of the Drugs Rules provides that the drugs specified in Schedule K are exempt from the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 ("**Act**") and the rules made thereunder, to the extent and subject to the conditions specified in Schedule K. Chapter IV of the Act regulates the manufacture, sale and distribution of drugs and cosmetics.

Serial no. 13 of Schedule K specifies certain "household remedies" and grants them a limited exemption from the licensing requirements applicable under Chapter IV of the Act and the Drugs Rules. The products listed in serial no. 13 of Schedule K are exempt from the requirement of being sold under a retail sale licence in Form 20-A, subject to the following conditions:

- The drugs are sold only in a village having population of not more than one thousand persons and where there is no licenced dealer under the Act.
- The drugs do not contain any substance specified in Schedules G, H or X of the Drugs Rules.
- The drugs are sold in the original unopened containers of the licenced manufacturers.
- When the drugs are sold under clause (a) condition 3 under 'Conditions of licence' of Form 20-B shall not apply.

Before the Amendment Rules, as per item no. 7 under serial no.13 of Schedule K, syrups, lozenges, pills and tablets for cough were exempt from the requirement of being sold under a retail sale licence in Form

20-A, subject to the aforementioned conditions. However, as per the Amendment Rules, in Schedule K of the Drugs Rules, under serial no. 13, item no. 7, the word "Syrups" has been omitted. Consequently, cough syrups no longer fall within the category of "household remedies" eligible for the regulatory exemption available under Schedule K.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQzNjA=

MoHFW Prohibits Use of Sixteen Fixed-Dose Combination Drugs

On June 11, 2026, the MoHFW issued a series of notifications bearing reference no. S.O. 3068(E) to S.O. 3083(E) prohibiting the manufacture, sale, or distribution of 16 Fixed Dose Combinations ("**FDCs**") for human use with immediate effect. These measures were taken on the basis of the determination that these FDCs are irrational and pose risks to humans while safer alternatives are available. Following the examination, the Sub Committee of Drugs Technical Advisory Board, in its report, concluded that, in the larger public interest, it is necessary to prohibit the manufacture, sale, or distribution of these fixed dose combinations as there is no therapeutic justification for the fixed dose combination of these ingredients. Ultimately, the MoHFW determined that prohibiting the manufacture, sale, or distribution of these 16 FDCs was necessary and expedient in the larger public interest due to the absence of clinical justification for combining their specific ingredients. The 16 FDCs that are prohibited are:

1. Acetyl Salicylic Acid + Ethoheptazine
2. Aloe vera + Jojoba oil + Wheat germ oil + Tea tree oil
3. Amoxicillin + Serratiopeptidase + Lactobacillus Sporogenes
4. Dicyclomine + Paracetamol + Clidinium Bromide + Chlordiazepoxide
5. Amoxicillin + Serratiopeptidase
6. Aloe Extract + Allantoin + Alphatocopherol Acetate + D-Penthenol + Vitamin A
7. Aloe Extract + Vitamin E + Dimethicone + Glycerine
8. Aloe Vera + Jojoba Oil + Vitamin E
9. Aloe vera + Orange oil
10. Aloe vera + Vitamin E + Herbal
11. Dicyclomine + Paracetamol + Clidinium Bromide
12. Paracetamol + Lignocaine
13. Gliclazide + Chromium Picolinate
14. Amoxicillin + Cloxacillin + Lactic acid bacillus + Serratiopeptidase
15. Cefadroxyl + Probenecid
16. Cefuroxime + Serratiopeptidase

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQzOTc=

MoHFW Proposes Revised Residual Shelf-Life Requirements for Imported Drugs

MoHFW vide Draft Notification no. G.S.R. 505(E) dated June 22, 2026, has proposed amendments to the Drugs Rules, 1945 to revise the residual shelf-life requirements for imported drugs under Rule 31, which prescribes the standards applicable to imported drugs. The second proviso to Rule 31 requires that the licensing authority shall not permit the import of any drug having a residual shelf-life of less than 60% as on the date of import. The draft amendment proposes to substitute this second proviso, so that the licensing authority shall instead not permit the import of any drug with a residual shelf-life of less than one year as on the date of import. However, recognising the limited shelf-life of certain specialised products, it introduces an exception for biological drugs and radiopharmaceuticals, for which the existing threshold of 60% residual shelf-life at the time of import will continue to apply.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MTY=

MoHFW Notifies Drugs (Seventh Amendment) Rules, 2026 Expanding Scope of Schedule H2

MoHFW vide Notification G.S.R. 506(E) dated June 22, 2026, notified the Drugs (Seventh Amendment) Rules, 2026, amending the Drugs Rules, 1945 to expand the scope of Schedule H2. Schedule H2 was inserted under the Drugs Rules, 1945 to identify specified drug formulations that are required to have Bar Code or Quick Response Code, with a view to curbing counterfeiting and strengthening supply chain oversight for high-risk categories of drugs. The amendment expanding the scope of Schedule H2 inserts a new Table 2 under Schedule H2, bringing all vaccines, all antimicrobials, all narcotic drugs and psychotropic substances listed under the Narcotic Drugs and Psychotropic Substances Act, 1985, and all anticancer drugs within its ambit. The revised framework is intended to strengthen traceability and regulatory oversight over the sale and distribution of these critical categories of drugs.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MDU=

Government Proposes Simplified Procedure for Import of Drugs for Examination, Test or Analysis

On June 23, 2026, MoHFW issued Draft Notification No. G.S.R. 509(E) ("**Draft Notification**"), proposing amendments to the Drugs Rules, 1945 aimed at easing the process for securing permission to import small quantities of drugs for examination, test, or analysis. Under the existing framework, Rule 33 of the Drugs Rules, 1945 permits the import of small quantities of drugs, otherwise prohibited under Section 10 of the Drugs and Cosmetics Act, 1940, for the purpose of examination, test or analysis, subject to the licensee obtaining a licence in Form 11, while Rule 34 of the Drugs Rules, 1945 sets out how to apply for that licence, in Form 12. The Draft Notification seeks to introduce an intimation-cum-acknowledgement mechanism, whereby an applicant would be required to submit a prior intimation in the prescribed form and may import the drug upon receipt of an acknowledgement generated by the licensing authority.
https://egazette.gov.in/WriteReadData/2026/273857.pdf

Department of Pharmaceuticals Amends the Drugs (Prices Control) Order, 2013

The Drugs (Prices Control) Order, 2013 ("**DPCO 2013**") is the principal legal framework governing the regulation of drug prices in India. It empowers the Central Government, acting through the National

Pharmaceutical Pricing Authority (NPPA), to fix and revise the ceiling prices of scheduled formulations specified in the First Schedule to the DPCO 2013, determine the retail prices of new drugs, and monitor the prices of non-scheduled formulations. DPCO 2013 also imposes compliance obligations on manufacturers, including requirements relating to applications for price fixation, the display and dissemination of price lists, and the maintenance of records and furnishing of information. In addition, it provides for the recovery of amounts overcharged, together with applicable interest, where manufacturers sell scheduled formulations at prices exceeding the notified ceiling price. On June 30, 2026, the Ministry of Chemicals and Fertilizers, issued Notification No. S.O. 3516(E), notifying the Drugs (Prices Control) Amendment Order, 2026 ("**Amendment Order**"), further amending the DPCO 2013.

The key changes introduced by the Amendment Order are as follows:

- Paragraph 15(2) of DPCO 2013 requires every existing manufacturer launching a "new drug" under DPCO 2013 — that is, a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines — to apply for prior price approval from the Government in Form-I of the DPCO 2013. The Amendment Order inserts two provisos to Paragraph 15(2), under which an existing manufacturer launching the same new drug within twelve months of the retail price fixation of such new drug is no longer required to apply for price fixation afresh, and is instead only required to intimate the details of such launch in the newly inserted Form-IA under Schedule-II, within one month of the launch.

- Paragraph 24(1) of the DPCO 2013 contains a proviso permitting manufacturers a forty-five-day window to bring down the maximum retail price of pre-existing stock to the ceiling price following a price notification. The Amendment Order inserts another proviso, noting that if the manufacturer furnishes the prescribed documentary evidence, upon demand, demonstrating sufficient efforts to disseminate a notified price revision to all stakeholders, then the overcharged amount for such manufacturer shall be calculated solely on the stock handled by each retailer, distributor, or stockist found selling the formulation above the ceiling price (plus local taxes as applicable) pertaining to that batch.

- Paragraph 29 of the DPCO 2013 earlier required manufacturers to maintain sales records relating to active pharmaceutical ingredients, bulk drugs and formulations, without specifying any minimum retention period. The Amendment Order now requires every manufacturer to maintain such records, along with any other records directed by the Government, for a period of not less than seven financial years immediately preceding the current financial year and further provides that where any proceeding has been initiated or is pending against the manufacturer under the DPCO 2013, such records must continue to be maintained until the final disposal of that proceeding.

https://egazette.gov.in/WriteReadData/2026/273983.pdf

GOVERNMENT INITIATIVES

Second Pharma Summit & Awards 2026 Highlights Biopharma SHAKTI Initiative

Smt. Anupriya Patel, Union Minister of State for Chemicals and Fertilizers, spoke at the 2nd Pharma Summit and Awards 2026, hosted by the Associated Chambers of Commerce and Industry of India in New Delhi, where she noted that the Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation) initiative aims to bring 100 biologics to market by 2047. She observed that biologics are projected to make up close to 40% of prescription drugs by 2031, and emphasized that India must build stronger capabilities in next-generation biologics even as it continues to build on its existing strength in affordable generic medicines. Her address also touched upon complementary initiatives across the pharmaceutical value chain, including the Promotion of Research and Innovation in Pharma MedTech Sector Scheme and the National Biopharma Mission.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2271807&reg=48&lang=1

National Pharmaceutical Pricing Authority Integrates the Pharma Jan Samadhan Portal with the Pharma Sahi Daam Portal

The National Pharmaceutical Pricing Authority merged the Pharma Jan Samadhan Portal ("**PJSP**") with the Pharma Sahi Daam Portal ("**PSDP**"), consolidating medicine price information and grievance redressal services into a single digital platform, accessible through both the application and the web portal. The PSDP allows consumers to check the prices of scheduled and non-scheduled medicines, helping them confirm that medicines are being sold within government-approved price limits, while the PJSP enables consumers to report and pursue resolution of complaints relating to medicine pricing. Although the two services had already been integrated at the mobile application level, they had until now continued to function through separate web portals. With this development, the integrated platform is operational with immediate effect through the unified Pharma Sahi Daam interface.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2277731&reg=48&lang=1

INVESTMENTS

Immuneel Therapeutics Private Limited Raises Over INR100 Crore in Series B Funding

On **June 08, 2026, Immuneel Therapeutics Private Limited** ("**Immuneel**"), a Bengaluru-based cell and gene therapy company founded by Kiran Mazumdar-Shaw, announced the successful closure of a **Series B funding round of over INR 100 crore.** The funding round saw participation from new investors, including Singularity AMC, and Rainmatter by Zerodha, together with high-net-worth individuals, as well as existing investors Kiran Mazumdar-Shaw, Eight Roads Ventures, and F-Prime Capital. Immuneel stated that the proceeds will be utilised to expand its Good Manufacturing Practice – manufacturing capacity, advance its cell and gene therapy pipeline, support the commercialisation of its Qartemi, India's first-approved CAR-T cell therapy, and accelerate its expansion into international markets across the Asia-Pacific region and the Middle East.
https://immuneel.com/wp-content/uploads/2026/06/Series-B-Funding.pdf

Shilpa Biocare Private Limited Acquires a 30.4% Stake in Gate2Brain S.L. for EUR 7 Million

On June 16, 2026, Shilpa Biocare Private Limited ("**Shilpa Biocare**"), a wholly owned subsidiary of Shilpa Medicare Limited, entered into a strategic equity partnership with Gate2Brain S.L. ("**Gate2Brain**"), a Barcelona-based biotechnology company, acquiring a 30.4% equity stake for a total consideration of EUR 7 million.

Gate2Brain develops peptide-based delivery systems designed to transport therapeutics across the blood-brain barrier for the treatment of central nervous system diseases. The partnership focuses on the development of G2B-002, Gate2Brain's first-in-class lead candidate for aggressive paediatric and adult brain tumours, and it has received Orphan Drug Designation from the U.S. Food and Drug Administration and the European Medicines Agency. By combining Gate2Brain's technology with Shilpa Biocare's expertise in manufacturing and regulatory strategy, the partnership aims to accelerate the development of G2B-002 while supporting the expansion of Gate2Brain.
https://gate2brain.com/wp-content/uploads/2026/06/Gate2Brain_Press_Release_Final_ENG.pdf

Medical Devices and Med-Tech

LEGAL AND REGULATORY

MoHFW Proposes Amendments to the Medical Devices Rules, 2017 to Streamline the Manufacture Licensing Process of Medical Devices

MoHFW published a draft notification vide Notification no. G.S.R. 515(E), dated June 23, 2026, proposing amendments to the Medical Devices Rules, 2017 ("**Draft Amendment**") with the objective of simplifying and expediting the licensing process for medical devices, while maintaining compliance with quality, safety and performance requirements. Under the Medical Devices Rules, 2017, medical devices are classified into four risk-based categories, being Class A, Class B, Class C and Class D, with Class D comprising the highest-risk devices. The Draft Amendment proposes to tighten the timelines at each stage of the licensing process across the Class B, Class C and Class D device categories. For Class B devices, the State Licensing Authority is required to complete scrutiny and assign the application to a Notified Body within 30 days, the Notified Body must complete its audit within 30 days of assignment, verify compliance of any non-conformance within 20 days, and submit its final report within 15 days of completing the audit. A new requirement is also introduced for the manufacturing site to demonstrate conformity with Quality Management System standards under the Fifth Schedule prior to grant of a Class B licence. For Class C and Class D devices, the timeline for inspection of the manufacturing site is reduced from 60 to 55 days, compliance verification of non-conformances found during inspection is required within 15 days, and the timeline for grant of the licence following receipt of the inspection report is reduced from 45 to 20 days. The appeal period against rejection of a Class B licence application is also reduced from 45 to 30 days.
https://egazette.gov.in/WriteReadData/2026/273896.pdf

GOVERNMENT INITIATIVES

Government Invites Proposals under the Scheme for Strengthening of Medical Device Industry

The DoP invited proposals from eligible entities under the Scheme for Strengthening of Medical Device Industry, which seeks to promote domestic manufacturing, reduce import dependence, and foster innovation in the medical devices sector.

Applications have been invited under two sub-schemes, being the Marginal Investment Scheme for Reducing Import Dependence ("**MISRID**") and the Medical Device Clinical Studies Support Scheme ("**MDCSSS**"). Under the MISRID, selected applicants may be incentivized through a one-time capital subsidy of up to INR 10 crore on a reimbursement basis, while under the MDCSSS, financial support of up to INR 5 crore is available for conducting clinical investigation, clinical performance evaluation, post-market follow-up studies and animal studies. Proposals are to be submitted through the designated online portal on or before July 23, 2026.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2278917&reg=48&lang=1

Healthcare and Hospitals

GOVERNMENT INITIATIVES

Union Health Minister Launches the Unified Health Interface under the Ayushman Bharat Digital Mission

Union Health Minister Shri Jagat Prakash Nadda launched the Unified Health Interface ("**UHI**"), the service layer of the Ayushman Bharat Digital Mission ("**ABDM**"), an open network built on common technical standards that enables patients and healthcare providers to connect across different digital platforms without being tied to any single application. UHI operates through open protocols on a core Gateway of the ABDM, developed and maintained by the National Health Authority, and relies on ABDM building blocks, including the Ayushman Bharat Health Account as the patient identifier, the Healthcare Professionals Registry and the Health Facility Registry for provider verification, and the Health Information Exchange for consent-based data sharing. The network is built on the principles of interoperability, fair discoverability of verified providers, verification of participants, and open protocols, such that only doctors and facilities credentialed through the ABDM registries are permitted to participate.

At launch, the services live on the network include blood bank discovery integrated with e-RaktKosh, search of hospitals empanelled under the Pradhan Mantri Jan Arogya Yojana, discovery of Pradhan Mantri Jan Aushadhi Kendras, ambulance discovery and booking, and booking of in-person doctor consultations. The next phase is envisaged to bring lab diagnostics discovery, vaccination-centre discovery and slot booking, pharmacy discovery covering both licensed private pharmacies and government-run outlets, and discovery of services across major government health platforms.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2278987&reg=48&lang=1

INVESTMENTS

Krishna Institute of Medical Sciences Limited Receives Stock Exchange Approvals for Listing of Equity Shares Allotted under Qualified Institutional Placement

On June 23, 2026, Krishna Institute of Medical Sciences Limited ("**KIMS**") received approvals from the National Stock Exchange of India Limited and BSE Limited for the listing of 1,98,67,549 equity shares of face value INR 2 each, allotted pursuant to its Qualified Institutional Placement ("**QIP**"). The listing approvals follow KIMS' intimation dated June 19, 2026, regarding the allotment of the said equity shares to qualified institutional buyers. The successful fundraise is expected to strengthen KIMS' capital structure, enhance financial flexibility, and support its long-term growth and expansion strategy in the healthcare sector.
https://nsearchives.nseindia.com/corporate/KIMS_23062026140112_finalintimation.pdf

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This newsletter is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke.

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