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LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

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PHARMACEUTICALS

LEGAL AND REGULATORY

Ministry of Health and Family Welfare Proposes Prohibition of Certain Antimicrobials for Animal Use

On September 03, 2026, the Union Ministry of Health and Family Welfare ("**MoHFW**") published a draft notification bearing reference no. S.O.4996(E) which proposes to prohibit the import, manufacture, sale, and distribution of specific antimicrobial medicinal products for animal use. The proposed prohibition specifically covers Carboxypenicillins and Phosphonic acid derivatives. The MoHFW has stated that the use of formulations containing the specified antimicrobials in animals is likely to involve risks to humans and that safer alternatives are available.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzM=

MoHFW Proposes to Exempt Levonorgestrel Tablets 0.75mg/1.5mg Under Schedule K of the Drugs Rules, 1945

On September 03, 2026, the MoHFW issued Draft Notification G.S.R. 792(E) ("**Amendment Notification**"), proposing a key amendment to Schedule K of the Drugs Rules, 1945. The Amendment Notification seeks to incorporate Levonorgestrel Tablets 0.75 mg/1.5 mg, commonly used as emergency contraceptives, under Serial No. 06 of Entry No. 15 of Schedule K. The Amendment Notification proposes mandatory boxed warnings on the packaging and package insert, including that the tablets are intended only for emergency use and not as a regular contraceptive, and that frequent use of the emergency contraceptive pill may lead to side effects and to visit the nearest health facility/Registered Medical Practitioner for regular contraception as soon as possible. Further, the Amendment Notification provides that such warnings should note that the product is not an abortion pill, and it does not protect against HIV or other sexually transmitted infections.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzY=

Central Drugs Standard Control Organisation Directs Intensified Coordinated Action Against Illegal Manufacture and Distribution of Misbranded Drugs

On September 05, 2026, Central Drugs Standard Control Organisation ("**CDSCO**") issued a public notice titled "*Drug Regulatory and Law Enforcement Agencies Intensify Coordinated Action Against Illegal Manufacture and Distribution of Misbranded Drugs*" ("**Notice**"), highlighting intensified and continuous surveillance by drug regulatory and law enforcement agencies against the illegal manufacture, distribution and supply of misbranded and spurious drugs. The Notice follows a joint search conducted by the Crime Branch, Delhi Police and Drugs Inspectors from the Drugs Control

Department, Government of NCT of Delhi, at an unlicensed premises, where rabies vaccine (Abhayrab), Batch No. KE25012, was seized. The product was subsequently found by the Central Drugs Laboratory, Kasauli to be misbranded and not of standard quality. Following the findings, the Drugs Controller General (India) directed all State Drugs Controllers to maintain strict vigilance over the movement and distribution of the concerned batch and take appropriate regulatory action under the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2Njg=

MoHFW Proposes Mandatory Closed-Circuit Television Surveillance at Licensed Drug Premises for Prescription Drug Sales

On September 08, 2026, the MoHFW issued a notification bearing reference no. G.S.R. 791(E), proposing to amend the Drugs Rules, 1945 ("**Draft Rules**"). The Draft Rules propose to amend rule 65 of the Drugs Rules by mandating that the supply of any drug prescribed by a Registered Medical Practitioner, other than by way of wholesale dealing, shall be made under a Closed-Circuit Television ("**CCTV**") surveillance system installed and maintained at the licensed premises. Further, recordings of the CCTV system must be preserved for a minimum period of three (3) months.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzQ=

CDSCO Issues Public Health Alert Against Unauthorised Cosmetic Products

On September 08, 2026, CDSCO issued a public notice bearing reference no. COS-11012/07/2026-office, prohibiting the sale, distribution, and advertisement of certain unauthorized cosmetic products, specifically identifying 'Goree Beauty Cream' and 'Chandni Whitening Cream', both stated to be made in Pakistan. CDSCO, through testing and analysis, determined that these products had not been issued registration certificates for import into India by the competent authority and contained excessive heavy metals beyond the specified limits, which may pose health risks to consumers, including toxic effects. CDSCO advised consumers not to purchase or use the identified products or similar products if already purchased, and reiterated that the manufacture and import of cosmetics in India are regulated under the Drugs and Cosmetics Act, 1940 and the Cosmetics Rules, 2020.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NzA=

CDSCO Issues Advisory on the Indiscriminate Use of Painkillers and Antibiotics Linked to Chronic Kidney Disease

On September 21, 2026, the CDSCO issued a circular bearing F. No. Legal-11018(11)/177/2026-eoffice ("**Advisory**"), warning against the indiscriminate use of painkillers, specifically Non-Steroidal

Anti-Inflammatory Drugs ("**NSAIDs**"), and antibiotics and associated risk of chronic kidney disease. The Advisory reiterates that, depending on the specific drug, NSAIDs and antibiotics are regulated under Schedules G, H, H1 and X of the Drugs Rules, 1945, and are required to be used under appropriate medical supervision. Further, the Advisory notes that most NSAIDs fall under Schedule H and are not to be sold by retail without a prescription from a Registered Medical Practitioner. Additionally, the Advisory also notes that most antibiotics fall under Schedule H1 and carry prescribed warnings stating that they are dangerous to take except in accordance with medical advice and must not be sold by retail without a Registered Medical Practitioner's prescription. CDSCO has accordingly advised the general public against self-medication, repeated or prolonged use of these medicines without medical advice, and directed healthcare professionals, pharmacists, retailers, wholesalers, hospitals and other healthcare institutions to ensure that such drugs are used at the appropriate dosage and for the appropriate duration as per the advice of a Registered Medical Practitioner.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2ODQ=

GOVERNMENT INITIATIVES

Ministry of Science and Technology Highlights India's Position as the World's Largest Vaccine Producer

The Union Minister of State (Independent Charge) for Science & Technology and Earth Sciences and MoS PMO, Personnel, Public Grievances, Pensions, Atomic Energy and Space, Dr. Jitendra Singh, stated that India has become the world's largest producer and supplier of vaccines by volume. Dr. Jitendra Singh was speaking at a reception in New Delhi for members of the Board of Directors and Investment Committee of the Coalition for Epidemic Preparedness Innovations ("**CEPI**"), where he stated that India now supplies vaccines to over 100 countries, accounts for close to 60% of global vaccine production and meets more than 65% of the World Health Organization's routine immunization needs. It was observed that India, a vibrant bio economy, and its capabilities can no longer be viewed only through the prism of vaccine manufacturing as it has moved into advanced vaccine technologies and complex biological products, supported by domestic research, manufacturing and clinical capabilities. Referring to India's role as a founding member of CEPI, Dr. Jitendra Singh suggested that the next phase of the partnership focus on universal and pan-pathogen vaccines, advanced biomanufacturing and wider collaborative research networks.

https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2309719&reg=48&lang=1

Indian Pharmacopoeia Commission Inaugurates the 6th National Pharmacovigilance Week to Promote Rational Use of Medicines and Strengthen Drug Safety

From September 17, 2026 to September 23, 2026, the 6th National Pharmacovigilance Week was observed across India under the theme "*Promoting Rational Use of Medicines through Pharmacovigilance – A Step Towards Safer Healthcare*". The campaign was inaugurated by the Indian

Pharmacopoeia Commission, the National Coordination Centre for the Pharmacovigilance Programme of India, with the objective of sensitising healthcare professionals, researchers and the public on the importance of Adverse Drug Reaction ("**ADR**") reporting and encouraging greater participation in pharmacovigilance. The programme also emphasised strengthening the pharmacovigilance network at the grassroots level, including establishing ADR Monitoring Centres and Medical Device Monitoring Centres in aspirational districts, and promoting effective use of pharmacovigilance data to support rational medicine use and patient safety.

https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2311715&reg=48&lang=1

INVESTMENTS

Anupam Rasayan India Limited Acquires Controlling Stake in Bliss GVS Pharma Limited

On September 28, 2026, Anupam Rasayan India Limited ("**Anupam Rasayan**") concluded the acquisition of a 48.2% stake in Bliss GVS Pharma Limited ("**Bliss GVS Pharma**") at INR 299 per share, through its wholly owned subsidiary, Mates Visa Consultancy Private Limited. The transaction marks Anupam Rasayan's third strategic inorganic acquisition and strengthens its presence in finished dosage formulations, complementing its existing capabilities in custom synthesis, specialty chemicals and pharmaceutical intermediates. The acquisition brings Bliss GVS Pharma's portfolio of more than 150 branded formulations across multiple therapeutic segments and its 6 manufacturing facilities in Maharashtra into Anupam Rasayan's expanding pharmaceutical business.

https://anupamcms.tinglabs.in/uploads/Completion_of_Acquisition_of_Bliss_GVS_Pharma_Limited_de4e40648a.pdf

MEDICAL DEVICES AND MEDTECH

LEGAL AND REGULATORY

Central Board of Indirect Taxes and Customs Issues Circular on Mandatory Compliance Checks for Imported Products

The Central Board of Indirect Taxes and Customs ("**CBIC**") issued a circular dated September 03, 2026, bearing F. No. CBIC-510401/4/2023 ("**CBIC Circular**"), developed in coordination with the CDSCO enhancing the facilitation of the import of cosmetics, drugs and medical devices. The CBIC Circular prescribes mandatory checklists for compliance verification of imported medical devices including in vitro diagnostics kits/devices and import of raw materials/ components (substance, piece, parts, software, firmware, labelling or assembling which is intended to be included as part of the finished, packaged and labelled device) used for manufacture of medical devices before customs clearance. Further, the CBIC Circular also provides mandatory checklists for compliance verification of drugs, import of drugs, and cosmetics before customs clearance. This initiative aims to ensure

stringent regulatory adherence while facilitating the ease of doing business for compliant importers at ports of entry.

https://taxinformation.cbic.gov.in/view-pdf/1003342/ENG/Circulars

GOVERNMENT INITIATIVES

Department of Pharmaceuticals Approves INR 1,600 Crore for Pharma-MedTech Innovation Projects

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, approved around INR 1,600 crore in financial assistance for 41 projects under the first call of the Promotion of Research and Innovation in Pharma-MedTech Sector. Out of these 41 projects, 9 projects are focused on novel medical devices. The approved projects are expected to attract an additional INR 3,020 crore in private investment, taking the total R&D investment across the projects to around INR 4,620 crore. The initiative brings together startups, micro, small and medium enterprises (**MSMEs**), large companies and MedTech innovators to support innovation and advanced medical technologies. The medical-technology projects supported under the initiative include portable plasmonic-PCR technology for point-of-care infection diagnosis and a microfluidic platform for tuberculosis detection.

https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=2317296&lang=1&reg=3&

INVESTMENTS

Cyrix Healthcare Private Limited Acquires Blue Star Engineering & Electronics Limited's MedTech Solutions Business

On September 01, 2026, Cyrix Healthcare Private Limited ("**Cyrix Healthcare**"), completed the acquisition of the MedTech Solutions business of Blue Star Engineering & Electronics Limited ("**Blue Star**"). The acquisition expands Cyrix Healthcare's capabilities across medical imaging, equipment sales, installation, maintenance, repairs, refurbishment and lifecycle management, particularly for multi-brand computed tomography (**CT**) and magnetic resonance imaging (**MRI**) systems. Blue Star has experience spanning more than 250 CT and MRI installations in India, covering sales, clinical applications, installation, maintenance and repairs. Blue Star's refurbishment capabilities will also strengthen AURUM, Cyrix Healthcare's refurbished medical-equipment business. Following the acquisition, existing customers will continue to be supported by the same experienced teams, while gaining access to Cyrix Healthcare's broader service network, refurbished equipment, spare parts and accessories across India.

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

HEALTHCARE AND HOSPITALS

LEGAL AND REGULATORY

MoHFW Launches Guidance Document for Hospitals in India for Safety Monitoring and Reporting of Medical Device-Related Incidents/Adverse Events

The MoHFW launched the Guidance Document for Hospitals in India for Safety Monitoring and Reporting of Medical Device-Related Adverse Events, Version 1.3, 2026 ("**Guidance Document**") during the 6th National Pharmacovigilance Week programme organised by the Indian Pharmacopoeia Commission. The Guidance Document forms part of the Materiovigilance Programme of India (**MvPI**), which focuses on monitoring the safety of medical devices. This Guidance Document is intended for all stakeholders involved in the use, monitoring, reporting, regulation, and post market surveillance of medical devices in India. The Guidance Document provides guidance for hospitals on reporting medical-device adverse events and malfunctions, and other safety concerns associated with the device component which is to be identified, documented, assessed, and reported in accordance with the principles outlined in this Guidance Document.

https://ipc.gov.in/images/mvpi/BOOK-FINAL-FOR-PRINTING-15-SEP_compressed.pdf

NMC issues Advisory on the Regulation of Stem Cell Therapy for Treatment of ASD as a Clinical Practice

The National Medical Commission **("NMC")** issued an advisory bearing reference no. R-13014/28/2022-Ethics dated September 05, 2026 clarifying that stem cell therapy for Autism Spectrum Disorder **(ASD)** cannot be offered as routine or commercial clinical treatment outside the regulatory framework of clinical trials. Stem cell therapy may be used as standard clinical care only for specific approved indications as listed by the MoHFW, Indian Council of Medical Research, or Department of Health Research. The advisory also states that unauthorized administration, prescription, promotion, or advertisement of stem cell therapy beyond approved indications may amount to professional misconduct.

https://nmc.org.in/whats-new/download/1023

GOVERNMENT INITIATIVES

MoHFW Organises Arogya Manthan 2026

On September 25, 2026, the MoHFW inaugurated Arogya Manthan 2026 at Vigyan Bhawan, New Delhi, marking eight years of the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana ("**AB PM-JAY**") and five years of the Ayushman Bharat Digital Mission ("**ABDM**"). Organised by the National

Health Authority ("**NHA**"), the event brought together government officials, healthcare providers, insurers, technology and digital health experts, academia and other stakeholders to review the progress of India's health assurance and digital health ecosystem and discuss priorities for its next phase.

A key focus of Arogya Manthan 2026 was on strengthening the efficiency, quality and interoperability of health services. The event saw the launch of the National Healthcare Providers Registry (**NHPR**) Mobile App, National Health Claims Exchange (**NHCX**) Implementation Guide for Payers, Guidebook for a Model Digital Health Facility, Secure Data Environment ("**SDE**") application and Framework for Auto-Adjudication of Claims under AB PM-JAY. The SDE, developed by the NHA with support from the Indian Institute of Science, Bengaluru, is designed to provide approved entities with controlled access to de-identified AB PM-JAY and ABDM health data for health research, programme planning, outcome analysis and responsible artificial intelligence innovation, with safeguards for personal data. It was further stated that the next phase should prioritise continuity of care, quality, and patient-centred healthcare, including seamless referral pathways for patients who require specialised treatment.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2314839

INVESTMENTS

Competition Commission of India Approves Acquisition of Apollo Fertility Centre Private Limited and Apollo Specialty Hospitals Private Limited by Kids Clinic India Limited

The Competition Commission of India ("**CCI**") approved the acquisition of up to 100% equity shareholding in Apollo Fertility Centre Private Limited ("**AFCPL**") and Apollo Specialty Hospitals Private Limited ("**ASHPL**") by Kids Clinic India Limited ("**KCIL**"). KCIL operates a chain of super-specialty hospitals focused on maternity, gynaecology, paediatrics and fertility across multiple Indian cities. Further, AFCPL is a chain of fertility clinics under the Apollo Group and is entirely held by Apollo Health and Lifestyle Limited and ASHPL had three business segments: cradle, fertility and spectra until June 2024. The regulatory clearance, issued under the Competition Act, 2002, paves the way for KCIL to significantly expand its footprint in the reproductive, and paediatric healthcare segments.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2305742&reg=48&lang=2

Prodoc AI Secures Seed Funding to Build Artificial Intelligence Systems for Hospitals

On September 30, 2026, Prodoc AI ("**Company**"), an emerging MedTech and digital health startup, announced the successful closure of its seed funding round. The Company's seed funding will accelerate Agentic AI, deeper hospital integrations, and the next phase of their Patient Journey OS. The Company is building Patient Journey OS designed to work alongside existing hospital systems and connect intelligence across different stages of the patient journey, including patient acquisition, customer relationship management, partner and referral management, outpatient department

intelligence, care coordination, Voice AI, and etc. The Company currently works with more than 100 hospitals, manages over one million patient engagements each month, and supports more than 50 software integrations.

https://prodoc.ai/blog/prodoc-ai-raises-seed-funding-to-build-the-ai-layer-for-hospitals

OTHER UPDATES

Ministry of Consumer Affairs Mandates Vegetarian and Non-Vegetarian Declarations for Various Products

On September 21, 2026, the Ministry of Consumer Affairs, Food and Public Distribution notified the Legal Metrology (Packaged Commodities) Fourth Amendment Rules, 2026, via Notification No. G.S.R. 826(E) ("**Amendment Rules**"). The Amendment Rules insert clause (d) under Rule 6(4A) of the Legal Metrology (Packaged Commodities) Rules, 2011, requiring packages of soap, shampoo, toothpaste, other cosmetics and toiletries to display a green dot for products of vegetarian origin and a red or brown dot for products of non-vegetarian origin. The prescribed mark must be displayed at the top of the principal display panel of the package.

https://consumeraffairs.gov.in/public/upload/files/PCR_4th_Amendment_Red_Green_dot_1790049731.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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