Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

Newsletter - February 2026 Edition

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LAW OFFICES INDIA

INSIDE

Pharmaceuticals

LEGAL AND REGULATORY

CDSCO Issues Guidelines on Drugs and Cosmetics (Compounding of Offences) Rules, 2025

On 1 January 2026, the Central Drugs Standard Control Organization (**"CDSCO"**) released a guidance document to operationalise the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 (**"Rules"**) framed under Section 32B of the Drugs and Cosmetics Act, 1940. These Rules establish a statutory framework for the compounding of specified offences under the Drugs and Cosmetics Act, 1940, enabling individuals and companies to seek settlement of such offences in lieu of prosecution, subject to prescribed conditions and the discretion of the designated Compounding Authority. This guidance document has been issued to facilitate understanding and effective implementation of the Rules by all stakeholders, including manufacturers, importers, distributors, and regulatory authorities. It seeks to clarify the procedural requirements, eligibility criteria, roles and responsibilities of authorities, immunity provisions, and the applicable forms in relation to the Rules.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM3NjE=

Stop Use Notice Regarding Almont-Kid Syrup Found Adulterated with Ethylene Glycol

On 10 January 2026, the Government of Telangana, under the Drugs Control Administration (**"Administration"**), issued a Stop Use Notice since it received an alert from CDSCO to stop the use of a specific batch of Almont- Kid Syrup, which was found adulterated with Ethylene Glycol, a highly toxic substance. Therefore, the Administration has issued an urgent advisory directing the public to immediately stop using the specified syrup and report any possession to the nearest Drugs Control Authority or via the toll-free helpline 1800-599-6969. All Drug Inspectors and Assistant Directors have been instructed to alert retailers, wholesalers, distributors, and hospitals to freeze the affected batch and not dispense or sell it. Thus, the public has been instructed to exercise utmost caution and refrain from using the aforementioned product to avoid any potential health hazards associated with Ethylene Glycol toxicity.
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwj8o-f69s6SAxXIcWwGHXyXMCkQFnoECBkQAQ&url=https%3A%2F%2Fdca.telangana.gov.in%2Fopenfile.php%3Ff%3D407&usg=AOvVaw1cLX1_fGVnp1EuztfBZ0AP&opi=89978449

CDSCO to Reject Long-Pending Applications on SUGAM Portal Awaiting Query Responses

On 16 January 2026, the CDSCO issued a public notice announcing a structured reminder mechanism to dispose of pending applications on the SUGAM portal where applicants have failed to respond to regulatory queries. CDSCO observed significant backlogs across divisions such as New Drugs, Investigational New Drugs, Fixed Dose Combinations, Import, Cosmetics, Biologics, Medical Devices, and In Vitro Diagnostics, with some applications pending since 2016. To address this, CDSCO has implemented a three-stage reminder system, issuing reminders at fixed intervals to applicants to submit responses to pending queries within prescribed timelines. If applicants fail to respond even after these three reminders, a fourth and final communication will be issued, after which the application will be rejected and the application fee

forfeited, in accordance with applicable provisions. Thus, stakeholders are advised to ensure that all pending queries are addressed within the prescribed time period to avoid any rejections of their applications https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM4MTc=

CGHS implements the Drug Procurement Policy, 2026

On 15 January 2026, the Central Government Health Scheme **("CGHS")** implemented a comprehensive Drug Procurement Policy **("Policy")** in response to the fragmented and regionally driven procurement which has resulted in inconsistent availability of medications, delayed supply, a lack of real-time stock visibility, and a heavy dependence on private chemists, generating panic for patients. The Policy replaces this ad hoc approach with a structured, technology-driven, and centrally governed framework that ensures the continuous availability of essential medicines, encourages the use of quality-assured generic drugs, and allows for cost-effective bulk procurement through authorized channels such as Medical Stores Organisation, Pharmaceuticals & Medical Devices Bureau of India, and public sector undertakings. By connecting the entire supply chain with the Healthcare Management Information System **(HMIS)**, the Policy enables real-time stock tracking, precise demand forecasting, expiry management, and inter-centre redistribution, reducing shortages, waste, and overstocking. The policy strengthens governance and accountability through transparent procedures, strict quality controls, and layered electronic oversight, while also restoring beneficiary confidence by ensuring that prescribed medicines are available, safe, and affordable at CGHS Wellness Centres, ultimately improving the reliability and effectiveness of public healthcare delivery.
https://cghs.mohfw.gov.in/CGHSGrievance/FormFlowXACTION?hmode=ftpFileDownload&fileName=15012026205256_MoHFW%20OM%20dated%2015012026_New%20Drug%20Procurement%20Policy-1.pdf&folderName=Circular&isGlobal=1

New Drugs and Clinical Trials (Amendment) Rules, 2026

On 20 January 2026, the New Drugs and Clinical Trials (Amendment) Rules, 2026 **("Rules")** were published. These Rules aim to streamline regulatory procedures, shorten approval timelines, and accelerate clinical research and pharmaceutical development in India. Previously, pharmaceutical companies needed a test licence from the Central Drugs Standard Control Organization to manufacture small quantities of drugs for research, testing, or analysis. The Rules introduce a prior-intimation system for non-commercial manufacturing. Thus, companies can begin development after submitting a prior intimation to CDSCO, except in cases for certain high-risk categories such as cytotoxic drugs, narcotics, and psychotropic substances. This change is expected to reduce the drug development cycle by at least 90 days, significantly supporting research and innovation. For categories where a test licence is still required, the processing time has been reduced from 90 days to 45 days. Since CDSCO handles roughly 30,000 to 35,000 test licence applications annually, this reform will greatly lessen regulatory workload and assist a large number of industry stakeholders.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM4MjE=

GOVERNMENT INITIATIVES

Union Health Minister Releases 10th Edition of Indian Pharmacopoeia 2026

On 2 January 2026, the Union Minister for Health and Family Welfare, Shri J. P. Nadda, released the Indian Pharmacopoeia 2026 (**"IP 2026"**), the 10th edition of India's official book of drug standards, at Dr. Ambedkar International Centre, New Delhi. The IP 2026 introduces 121 new monographs, increasing the total to 3,340, with expanded coverage of anti-tubercular, anti-diabetic, anti-cancer medicines, iron supplements, and drugs used under National Health Programmes. For the first time, it includes 20 blood component monographs for transfusion medicine, in line with the Drugs and Cosmetics (Second Amendment) Rules, 2020.
https://www.mohfw.gov.in/?q=en%2Fpress-info%2F9840

India-EU FTA Unlocks Access to USD 572.3 Billion EU Pharmaceuticals Market

On 27 January 2026, India and the European Union (**"EU"**) declared the conclusion of negotiations for a Free Trade Agreement (**"FTA"**), which is described as the "Mother of All Trade Deals", marking a historic milestone in India–EU economic relations. The FTA facilitates enhanced access to the USD 572.3 billion EU pharmaceuticals and medical devices market, providing a significant boost to the Indian pharmaceuticals sector. This access will enable the pharmaceutical industry to scale operations, generate employment, and reinforce India's position as a reliable partner in the global pharmaceuticals sector, underscoring its growing stature as the pharmacy of the world. Highlights of the FTA include:

- Preferential market access aimed at accelerating growth in high-value segments
- Liberalised tariff structures for select "Made in India" medical devices
- Growth across inorganic and organic chemicals, fertilisers, pharmaceuticals, cosmetics, soaps, and detergents
- Sectoral growth driven through capacity expansion and the development of MSME clusters
- Potential expansion opportunities across industrial hubs in Gujarat, Maharashtra, Karnataka, and Andhra Pradesh

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2219406&reg=3&lang=1

INVESTMENTS

Biocon Limited Successfully Raises Rs 4,150 Crore through QIP

On 14 January 2026, Biocon Limited, an innovation-led global biopharmaceutical company, announced the successful completion of a Qualified Institutions Placement (**"QIP"**). Through the QIP, it raised Rs. 4,150 crore. The funds were raised by issuing 112,664,585 equity shares to eligible institutional investors. The QIP opened on January 12, 2026, and closed on January 14, 2026. The money raised through the QIP will mainly be used to pay the cash consideration payable to Mylan Inc. (Viatris) for buying its remaining stake in Biocon Biologics Limited. This move is an important step for Biocon Limited as it aims to strengthen its

position therapeutic areas of diabetes, oncology, and immunology through its range of biosimilars, insulins, generics, and peptide-based products.
https://www.bioconbiologics.com/biocon-limited-concludes-rs-4150-crore-usd-460-million-equity-fundraise-through-a-qualified-institutions-placement-qip/#:~:text=Biocon%20Limited%20,35%20per%20Equity%20Share

Syngene International extends research collaboration with Bristol Myers Squibb until 2035

On 19 January, 2026, Syngene International Limited **("Syngene")**, a global contract research, development, and manufacturing organisation, has announced the extension of its long-standing strategic partnership with Bristol Myers Squibb until 2035. Syngene provides integrated research, development, and manufacturing services to clients across the pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemicals sectors worldwide. Under the expanded agreement, the range of services covered by the collaboration broadens the scope of integrated services across the drug development lifecycle. This includes early-stage discovery work such as chemistry, biology, and drug metabolism studies, as well as translational sciences, pharmaceutical development and manufacturing, clinical trials, and data and information technology support. The objective is to ensure smooth movement from research to commercial production. This extension represents the next stage of the partnership and further strengthens Syngene's role as a key partner providing end-to-end scientific and manufacturing services.
https://cdn.syngeneintl.com/2026/01/19170635/Press-Release_Syngene-BMS-Extension_FINAL_SE.pdf

Medical Devices and Med-Tech

GOVERNMENT INITIATIVES

National Health Authority hosts 2-Day Chintan Shivir in Odisha

The National Health Authority **("NHA")** organised a 2-Day Chintan Shivir of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana and Ayushman Bharat Digital Mission from 19-20 January 2026 in Bhubaneswar, Odisha. The deliberations focused on innovation, digital integration, AI-driven healthcare solutions, and inclusive service delivery, with active participation from nearly 30 States and Union Territories. The key outcomes included the NHA exchanging Memoranda of Understanding with Bhashini, the Indian Institute of Science Bengaluru, and the National Accreditation Board for Hospitals & Healthcare Providers, of the Quality Council of India, to promote multilingual digital health, AI innovation, and quality standards, along with the launch of the Health Benefit Package **(HBP)** Manual – Part 2 and a Best Practices Compendium. The Chintan Shivir reaffirmed NHA's roadmap for building a transparent, efficient, and citizen-centric digital health ecosystem, aligned with the vision of Swasth Bharat, Sashakt Bharat.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2216576&reg=3&lang=1

Healthcare and Hospitals

GOVERNMENT INITIATIVES

National Review Meeting of Metropolitan Surveillance Units Held in Nagpur to Strengthen Disease Surveillance

The Ministry of Health and Family Welfare organised a two-day National Review Meeting of Metropolitan Surveillance Units **("MSUs")** in Nagpur on 6–7 January 2026, with participation from representatives of 20 cities, to review and strengthen urban disease surveillance mechanisms. The meeting focused on improving early warning systems, ensuring timely public health responses, and enhancing urban preparedness, with technical sessions showcasing best practices and outbreak investigation and response experiences. Experts from the National Centre for Disease Control, Indian Council of Medical Research, AIIMS, municipal authorities, and other stakeholders highlighted the role of MSUs in collaborative surveillance and multisectoral coordination. The discussions also emphasised on the development of City Emergency Response Plans, to strengthen preparedness and coordinated response mechanisms for public health emergencies. The meeting concluded with a shared commitment to building safer and more resilient cities against public health threats.
https://www.mohfw.gov.in/?q=en%2Fpress-info%2F9846

INVESTMENTS

Novo Holdings Invests in Surya Hospitals to Expand Access to Women's and Children's Healthcare in India

On 20 January 2026, Novo Holdings, a prominent global investor in healthcare and life sciences, announced that it has acquired a minority stake in Surya Hospitals, the largest private women's and children's specialty hospital network in Western India, underscoring its long-term commitment to advancing quality healthcare in the country. Surya Hospitals operates NABH-accredited super-specialty facilities in Mumbai, Pune, and Jaipur, with a strong emphasis on maternal, neonatal, and paediatric care. Surya Hospitals is recognised for its strong clinical expertise and consistently positive patient outcomes supported by advanced infrastructure and an integrated, multidisciplinary approach to care. This investment is intended to support Surya Hospitals' expansion across Western India by enhancing clinical infrastructure and strengthening specialist medical teams, while leveraging Surya Hospitals' clinical expertise alongside Novo Holdings' global healthcare experience. This collaboration seeks to improve access to care, clinical outcomes, and healthcare delivery for women and children, in alignment with India's broader healthcare system strengthening initiatives.
https://novoholdings.dk/news/novo-holdings-invests-in-surya-hospitals-to-strengthen-access-to-high-quality-women-s-and-children-s-healthcare-in-india

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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