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LAW OFFICES INDIA

## LIFESCIENCES AND HEALTHCARE

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## Pharmaceuticals

### LEGAL AND REGULATORY

#### **The Central Drugs Standard Control Organization Strengthens Enforcement against Unauthorized Promotion and Distribution of GLP-1 Based Drugs**

The Central Drugs Standard Control Organization (“CDSCO”) has released a public notice bearing reference no. F. No. Enforc-11021(11)/34/2026-eoffice-Part(1) on May 18, 2026, (“Notice”) regarding CDSCO strengthening enforcement against the unauthorized promotion and distribution of GLP-1 based drugs.

The Notice states that CDSCO has conducted a nationwide enforcement drive to curb illegal distribution channels, noncompliant dispensing practices, and misuse of GLP-1-based weight loss drugs by performing audits and inspections across online pharmacy warehouses, drug wholesalers, retail outlets, and wellness and slimming clinics. The Notice further requests State and Union Territory Drug Controllers to strengthen monitoring of the end-to-end supply chain of the GLP-1-based weight loss drugs to ensure strict adherence to the conditions of approval and the warnings on the label by ensuring that manufacture/import, distribution, retail/wholesale sales, and dispensing occur only through authorized channels and strictly in line with approved indications and labelling. Moreover, the Notice notes that any diversion, leakage into unauthorized channels, promotions influencing supply practices, or non-adherence to approval conditions should be viewed seriously with appropriate regulatory action.

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTQxNzE=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQxNzE=)

#### **CDSCO Issues Public Notice on Regulation of Cosmetics**

On May 18, 2026, CDSCO issued a public notice bearing reference no. COS-12/1/2026-eoffice (“Notice”) reiterating key provisions of the Drugs and Cosmetics Act, 1940 and the Cosmetics Rules, 2020.

As per Section 3(aaa) of the Drugs and Cosmetics Act, 1940, a “cosmetic” means any article intended to be **rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body** or any part thereof for **cleansing, beautifying, promoting attractiveness, or altering the appearance,** and includes any article intended for use as a component of cosmetic.

The Notice states that products supplied **in form of injectable preparation** do not fall under the definition of cosmetics. Moreover, no cosmetic is permitted to be used as injection by consumers/ professionals/ aesthetic clinics. Cosmetics are only intended to be **rubbed, poured, sprinkled or sprayed** to the human body. Thus, cosmetics are permitted to be supplied for its intended use as defined in the definition under the Drugs and Cosmetics Act, 1940 and no cosmetic is permitted to be used in treatment by professionals/individuals.

The Notice noted that as per the provisions of labelling of cosmetics, no cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user of cosmetics. Moreover, no person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetic.



Thus, the Notice reiterates that use of prohibited ingredients in cosmetic product, misleading claims on label, use of cosmetics for treatment and application of cosmetic through injection violates the Drugs and Cosmetic Act, 1940 and the Cosmetic Rules, 2020.

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTQxNzU=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQxNzU=)

### **GOVERNMENT INITIATIVES**

#### **Department of Pharmaceuticals Announces Modifications to Production Linked Incentive Scheme for Bulk Drugs**

On May 4, 2026, the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers issued a corrigendum bearing reference No. 31026/16/2020-Policy to the Production Linked Incentive (“PLI”) scheme for Bulk Drugs, modifying two clauses in the existing guidelines. The PLI Scheme for Bulk Drugs was originally notified on July 18, 2020, and has since been revised multiple times. The latest amendments were based on decisions taken at an Empowered Committee meeting held on March 12, 2026. The first amendment pertains to introducing an additional provision under Clause 15.4 for incentive disbursement and filing for claims. Under the revised Clause 15.4, incentive claims filed based on management certified/

unaudited financial statements or without filing of annual return will receive 80% of the eligible incentive upfront. The remaining 20% will be disbursed after submission of audited financial statements with an auditor's certificate and reconciliation with annual regulatory return filings. Claims for the remaining 20% must be filed within 10 months from the end of the relevant financial year.

<https://pharma-dept.gov.in/sites/default/files/Corrigendum%20dated%204.5.2026%20PLI%20BD.pdf>

#### **The Indian Council of Medical Research Transfers Three Indigenous Medical Technologies at National Technology Day 2026**

The Indian Council of Medical Research (“ICMR”) participated in the national programme 'विज्ञान-Tech' on National Technology Day 2026 at BRIC–National Institute of Immunology, New Delhi, transferring three indigenously developed medical technologies to industry partners under its Medical Innovations Patent Mitra initiative. The first, a cost-effective PSP94 ELISA for guiding prostate biopsy decisions, was licensed to Krishgen Labs Private Limited. The second, a Factor VIII Inhibitor and Coagulation Disorder Point-of-Care Diagnostic, was licensed to Meril Life Sciences Private Limited. The third, a Single-Tube Multiplex Real-Time RT-PCR test for simultaneous detection of Dengue, Chikungunya, and Zika viruses, was licensed to Vanguard Life Sciences. The transfers align with the Make in Bharat vision of promoting indigenous manufacturing and a self-reliant healthcare ecosystem.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2259926&reg=3&lang=2>

#### **The National Institute of Pharmaceutical Education and Research, Raebareli Signs MoU, Confidential Disclosure Agreement, and Technology Transfer Agreement with Lofty Laboratories**

The National Institute of Pharmaceutical Education and Research (“NIPER”), Raebareli, has signed an MoU, Confidential Disclosure Agreement, and Technology Transfer Agreement with Lofty Laboratories Private Limited (“Lofty Laboratories”), Hyderabad, to advance pharmaceutical and biotechnology research



through academia-industry collaboration. Under the agreement, Lofty Laboratories will commercialise an industry-ready technology developed at NIPER-Raebareli's Centre of Excellence on Novel Drug Delivery Systems. The transferred technology will significantly reduce the cost of gel-staining agents widely used in biology research, particularly in studies involving genes, cancer, and nucleic acid-related diseases, contributing to indigenous production and strengthening India's pharmaceutical and biotechnology sectors. Director Prof. Shubhini A. Saraf noted that several more technologies from the Institute are expected to be ready for transfer by the end of the year.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2259032&reg=3&lang=1>

### **Indian Pharmacopoeia Commission Organizes Scientific Conclave on Indian Pharmacopoeia 2026 at NIPER Hyderabad**

The Indian Pharmacopoeia Commission (“IPC”) in collaboration with NIPER Hyderabad, CDSCO, and the Indian Drug Manufacturers' Association Telangana Chapter, organised a Scientific Conclave and Interactive Session on Indian Pharmacopoeia 2026 at NIPER Hyderabad. The session was themed on *Significance of Indian Pharmacopoeia Reference Standards and Impurity Standards in Ensuring Pharmaceutical Quality*. A key highlight was that for the first time, IPC brought together experts from regulatory, analytical, industrial, and clinical backgrounds to deliberate on the clinical implications of pharmacopoeial impurities, including their potential association with adverse drug reactions and patient safety concerns. Dr. V. Kalaiselvan, Secretary-cum-Scientific Director, IPC, emphasised that impurity profiling and pharmacopoeial standards are essential in reducing adverse effects linked to pharmaceutical impurities. Technical sessions covered pharmacopoeial standards, impurity control, regulatory compliance, advancements in Indian Pharmacopoeia 2026, risk assessment approaches, and emerging global concerns in pharmaceutical impurity management.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2261510&reg=3&lang=1>

### **INVESTMENTS**

#### **Zydus Lifesciences Limited Agrees to Acquire US-Based Assertio Holdings, Inc for USD 166.4 Million**

On May 13, 2026, Ahmedabad-based Zydus Lifesciences Limited (“Zydus”) announced that Zydus Worldwide DMCC, a subsidiary of Zydus has signed a definitive agreement, through its wholly owned acquisition subsidiary, Zara Merger Sub Inc. to acquire Assertio Holdings, Inc (“Assertio”) through an all-cash tender offer at USD 23.50 per share, totalling approximately USD 166.4 million. Assertio is a specialty pharmaceutical company focused on oncology supportive care, with its key asset being ROLVEDON (eflapragrastim-xnst), a USFDA-approved long-acting G-CSF biologic used to prevent febrile neutropenia in adult cancer patients undergoing myelosuppressive chemotherapy. The acquisition strengthens Zydus's specialty and oncology presence in the US market and aligns with its long-term strategy of building differentiated global specialty businesses. The transaction is expected to close in the financial year 2026-27.

<https://zyduslife.com/investor/admin/uploads/21/83/Zydus-and-Assertio-Holdings-enter-into-an-agreement-for-Zydus-to-acquire-Assertio.pdf>

### **Medical Devices and Med-Tech**

### **LEGAL AND REGULATORY**



## CDSCO Issues Revised Regulatory Guidelines for Sampling of Drugs, Cosmetics and Medical Devices

On May 26, 2026, the CDSCO issued the revised version of the Regulatory Guidelines for Sampling of Drugs, Cosmetics & Medical Devices by Drugs Inspectors of Central & State Drug Authorities (“**Revised Guidelines**”). The original version of these guidelines was released on February 09, 2024 (“**Original Guidelines**”).

The Original Guidelines were introduced to streamline and rationalize the sampling procedures for drugs, cosmetics, and medical devices, while establishing a centralized monthly database of Not of Standard Quality (“**NSQ**”) and spurious drugs for publication on the CDSCO website. They provided detailed instructions covering the entire sampling process across the distribution chain and specified sample quantities for tablets, capsules, medical devices and etc. The Revised Guidelines build upon this framework and are primarily focused on strengthening the reporting and dissemination of information relating to NSQ and spurious product. The key changes introduced are as follows:

- Two new annexures have been introduced. Annexure 6 prescribes a structured NSQ alert format, while Annexure 7 prescribes a structured spurious alert format. Both annexures replace the simpler inline reporting tables contained in the Original Guidelines.
- The newly introduced Annexure 6 in relation to NSQ products now includes information regarding the product category, brand name, dosage form, route of administration, manufacturing state and etc.
- Spurious reporting alert under Annexure 7 incorporates the full statutory definition of a “spurious drug” under Section 17-B of the Drugs and Cosmetics Act, 1940. The revised format additionally requires authorities to report details such as the reason for classification of the product as spurious, who has drawn the sample and any regulatory comments.

[https://www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTQyMTM=](https://www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQyMTM=)

### GOVERNMENT INITIATIVES

#### **ICMR organizes the Medical Innovations Patent Mitra: Innovators-to-Industry Connect**

ICMR organised the Medical Innovations Patent Mitra: Innovators-to-Industry Connect at the Manekshaw Centre, New Delhi, on May 25, 2026. A major highlight was the transfer of 41 public health technologies from ICMR institutes to industry partners, covering diagnostics, vaccines, and medical devices, including vaccines for Typhoid and Paratyphoid and diagnostics for TB and Mpox. Moreover, inactivated Kyasanur Forest Disease and Chandipura virus biomaterials were also transferred to industry, strengthening India's vaccine manufacturing ecosystem. The Indian Biomedical Patent Landscape Report and Technology Compendium were released at the event, reinforcing ICMR's commitment to translating indigenous research into real-world healthcare solutions under the vision of Viksit Bharat 2047.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2264989&reg=3&lang=1>

### **Healthcare and Hospitals**

### LEGAL AND REGULATORY

#### **ICMR Introduces Single Ethics Review Framework for Multicentric Research**



ICMR has released the *Operational Guidelines for Single Ethics Review of Multicentre Research in India, 2026*, enabling a designated Single Ethics Committee to conduct ethics review for multicentric biomedical and health research studies. The framework is intended to eliminate duplicative ethics approvals across participating institutions, streamline review processes, reduce procedural delays, and support the efficient conduct of collaborative research while maintaining participant protection and ethical oversight. This development is expected to promote a more efficient and coordinated approach to ethics review and study approvals within India's clinical research landscape.

[https://ethics.ncdirindia.org//asset/pdf/Addendum\\_ICMR\\_National\\_Ethical\\_Guidelines\\_1.pdf](https://ethics.ncdirindia.org//asset/pdf/Addendum_ICMR_National_Ethical_Guidelines_1.pdf)

## **GOVERNMENT INITIATIVES**

### **MoHFW Releases Guidance Document on Diabetes Mellitus in Children**

On May 3, 2026, MoHFW released a Guidance Document on Diabetes Mellitus in Children at the National Summit on Best Practices in Public Healthcare Service Delivery. The document establishes for the first time a structured national framework for screening, diagnosis, treatment, and long-term management of childhood diabetes, placing India among a select group of countries to integrate childhood diabetes care into the public health system. It mandates universal screening of children from birth to 18 years through community and school-based platforms, with free-of-cost care at public health facilities, including lifelong insulin therapy, glucometers, test strips, and regular follow-up. The document introduces the "4Ts" awareness framework covering Toilet, Thirsty, Tired, and Thinner, to help parents and caregivers identify early warning signs of Type 1 Diabetes. Care is structured as a continuum linking community screening to district hospitals and medical colleges to ensure no child is lost in the system.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2257618&reg=3&lang=1>

### **MoHFW Launches Journey of Antenatal, Natal and Neonatal Integrated Care Platform for Maternal and Child Healthcare**

MoHFW launched Journey of Antenatal, Natal and Neonatal Integrated Care ("JANANI") platform at the 10th National Health Summit, a service-oriented digital platform designed to comprehensively monitor and maintain digital health records of women during their reproductive age. An upgraded version of the existing RCH portal, JANANI, creates a longitudinal health record covering antenatal care, delivery, postnatal care, newborn care, and family planning. Key features include QR-enabled digital Mother and Child Health ("MCH") Cards, automated alerts for high-risk pregnancies, real-time dashboards, and due-list generation. The platform integrates with national platforms, including U-WIN and POSHAN, and supports registration via the Ayushman Bharat Health Account, Aadhaar, and mobile number, ensuring continuity of care for migratory populations.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2258625&reg=3&lang=2>

### **Union Health Minister Addresses Side Event on Artificial Intelligence in Health at 79th World Health Assembly, Geneva**

Union Health Minister Shri J.P. Nadda addressed the side event on "Artificial Intelligence in Health: Laws, Ethical Oversight, Research and Equity" at the 79th World Health Assembly in Geneva, emphasising that while AI presents immense opportunities for healthcare delivery, it must be shaped by sound regulation,



rigorous research, ethical oversight, and a commitment to equity. He highlighted India's digital health journey from the Digital India initiative in 2015 through the Ayushman Bharat Digital Mission in 2021, and the launch of Strategy for AI in Healthcare for India in February 2026, describing it as the first comprehensive strategy emerging from the Global South guiding healthcare in an ethical, transparent, and people-centric manner. He also spoke about Benchmarking Open Data Platform for Health AI, which ensures AI solutions are benchmarked against real-world datasets to perform safely and equitably for every Indian. Calling for global collaboration, Mr. Nadda stressed that innovation must be guided by regulation, scale must be earned through trust, and that India believes not merely in "Artificial Intelligence" but in "All-Inclusive Intelligence."

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2263531&reg=3&lang=1>

## Other Updates

### LEGAL AND REGULATORY

#### **Food Safety and Standards Authority of India Mandates Digital Shift through New Single Window System for Product Approvals**

Effective June 1, 2026, the Food Safety and Standards Authority of India is transitioning all prior approval processes to a Single Window System via the Electronic Product and Claim Approval Application System ("ePAAS portal"). This digital interface is designed to ensure transparency and parity in risk assessments for products and claims. The system will serve as a unified digital interface for submitting, monitoring, and reviewing applications. It covers a wide range of categories, including approvals of Non-Specified Foods, Ayurveda Aahara, vegan endorsements, claims, and authorizations for Recycled Polyethylene Terephthalate. Food Business Operators are informed that manual, offline, or email-based applications will no longer be accepted after the deadline. All necessary forms and guidelines are now available on the ePAAS portal.

<https://fssai.gov.in/upload/advisories/2026/05/69fb29a607ad7Order%20dt%2006.05.2026.pdf>



*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.*

## The Team



**PRADNESH WARKE**  
Partner  
Email – [p.warke@luthra.com](mailto:p.warke@luthra.com)



**TANAY JHA**  
Associate  
Email – [t.jha@luthra.com](mailto:t.jha@luthra.com)



**PRAGNA YENDURI**  
Associate  
Email – [syenduri@luthra.com](mailto:syenduri@luthra.com)

## OFFICES



### NEW DELHI

1st and 9th Floors, Ashoka Estate, 24  
Barakhamba Road, New Delhi - 110 001  
T: +91 11 4121 5100  
F: +91 11 2372 3909  
E: [delhi@luthra.com](mailto:delhi@luthra.com)



### MUMBAI

20th Floor, Indiabulls Finance Center,  
Tower 2 Unit A2, Elphinstone Road,  
Senapati Bapat Marg, Mumbai - 400 013  
T: +91 22 4354 7000  
F: +91 22 6630 3700  
E: [mumbai@luthra.com](mailto:mumbai@luthra.com)



### BENGALURU

3rd Floor, Onyx Centre, No. 5, Museum Road,  
Bengaluru - 560 001  
T: +91 80 4112 2800 / +91 80 4165 9245  
F: +91 80 4112 2332  
E: [bengaluru@luthra.com](mailto:bengaluru@luthra.com)



### HYDERABAD

Serene Towers,  
House No. 8-2-623/A,  
Road No. 10, Banjara Hills,  
Hyderabad, Telangana - 500034  
T: +91 40 7969 6162  
E: [hyderabad@luthra.com](mailto:hyderabad@luthra.com)



### CHENNAI

Prestige Palladium Bayan,  
8th Floor, Greams Road, Nungambakkam Division,  
Egmore, Chennai, Tamil Nadu - 600 006

T: +91 95604 88155  
E: [chennai@luthra.com](mailto:chennai@luthra.com)