



Luthra and Luthra
LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

Newsletter - April 2026 Edition



**INSIDE****Pharmaceuticals**

- **Ministry of Health and Family Welfare Issues Draft Drugs Amendment Rules, 2026**
- **CDSCO Issues Advisory Regarding Promotion of Prescription Drugs**
- **Zepto Collaborates with Ministry of AYUSH to Launch an AYUSH Store**
- **Ministry of AYUSH partners with CISF to Institutionalise Preventive Healthcare for CISF Personnel**
- **Commemoration of World TB Day 2026 and Launch of Intensified TB Elimination Measures**
- **Lupin Limited and Zydus Lifesciences Limited Enter into a Co-Marketing Agreement for Marketing of Semaglutide Injection in India**

Medical Devices and Med-Tech

- **Department of Commerce Organizes Chintan Shivir on “Strengthening India’s Medical Devices Export Ecosystem”**

Healthcare and Hospitals

- **Enforcement of National Dental Commission Act, 2023**
- **NITI Aayog and UNICEF India Entered into a Statement of Intent to Strengthen Nutrition and Health Outcomes**
- **Government Expands New Clinical and Research Facilities at All India Institute of Ayurveda Goa**
- **National Workshop on One Health Organised in Nagpur on “Operational Frameworks for One Health: National Vision and State Action”**
- **MoHFW Identifies 219 Priority Districts for Intensified HIV/AIDS Intervention**

Other Updates

- **FSSAI Implements Food Recall Mechanism under the FoSCoS System**



Pharmaceuticals

LEGAL AND REGULATORY

Ministry of Health and Family Welfare Issues Draft Drugs Amendment Rules, 2026

On 9 March 2026, the Ministry of Health and Family Welfare (“**MoHFW**”) issued draft amendments to the Drugs Rules, 1945, seeking to regulate post-approval changes in drug manufacturing through a risk-based framework. The proposed amendments require manufacturers to classify quality-related changes in relation to drugs into three categories: major (Level I), moderate (Level II), and minor (Level III), with corresponding regulatory obligations. As per the proposed amendments, Level I changes have a substantial potential to adversely affect the identity, strength, quality, purity, or potency of a drug product and require prior approval from the licensing authority. Level II changes, having a moderate potential to have an adverse impact on these attributes, similarly require prior approval. In contrast, Level III changes, which carry only a minimal potential to have an adverse impact on the identity, strength, quality, purity, or potency of a drug product, may be implemented without prior approval (except in cases involving changes to the shelf life of the drug substance or product), subject to annual reporting to the licensing authority in the first quarter of each calendar year.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM5NjQ=

CDSCO Issues Advisory Regarding Promotion of Prescription Drugs

On March 10, 2026, the Central Drugs Standard Control Organization (“**CDSCO**”) issued an advisory bearing ref. no. SEC-11011(11)/45/2025-eoffice, reiterating that manufacturers and importers must ensure that the manufacture, sale, distribution, and promotion of drug products comply with the approved indications, conditions of permission, labelling requirements, and other statutory provisions under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945. The advisory flags concerns that certain pharmaceutical companies may be engaging in direct or indirect promotional practices, including surrogate marketing, digital outreach, and disease awareness initiatives in relation to GLP-1 receptor agonists and other prescription medicines used for obesity and metabolic disorders.

The advisory cautions that promotional practices directed at the general public, such as advertisements that overstate therapeutic effectiveness, promise guaranteed weight-loss outcomes, minimize the importance of lifestyle interventions like diet and exercise, or otherwise encourage demand for pharmacological treatment may constitute as misleading promotion and could invite regulatory action under the Drugs Rules, 1945. Through the advisory, CDSCO aims to safeguard public health by preventing misleading marketing practices and ensuring that vulnerable populations are not exploited through promotion of prescription drugs. In light of the CDSCO’s increasing focus on promotional practices in the pharmaceutical sector, companies may consider reviewing their marketing, therapy awareness, and digital outreach materials to assess compliance with the applicable regulatory framework and mitigate potential legal risks.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM5NjI=



GOVERNMENT INITIATIVES

Zepto Collaborates with Ministry of AYUSH to Launch an AYUSH Store

On 12 March 2026, the Ministry of AYUSH, in collaboration with the AYUSH Export Promotion Council and Zepto, launched a dedicated AYUSH storefront on the Zepto platform to enhance digital visibility of traditional wellness products. The initiative integrates AYUSH-certified products into a quick-commerce distribution model, signalling a policy shift towards platform-based aggregation and digital market access for traditional medicine manufacturers. It further reflects the government's broader strategy to formalise and scale indigenous healthcare systems through technology-enabled channels, to make such wellness products more accessible to consumers.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2239144®=3&lang=1>

Ministry of AYUSH partners with CISF to Institutionalise Preventive Healthcare for CISF Personnel

On 19 March 2026, the Ministry of AYUSH entered into a collaboration with the Central Industrial Security Force ("CISF") to promote preventive healthcare and wellness interventions among CISF personnel and their families through AYUSH-based systems. The collaboration focuses on initiatives such as awareness and sensitisation programmes, wellness interventions, yoga practices, lifestyle management, and the promotion of holistic healthcare through AYUSH systems. Pursuant to the MoU, the Ministry of AYUSH will provide technical assistance, design wellness modules, and offer expert support through its institutions and research councils. CISF will, in turn, enable and support the rollout of these initiatives across its units and establishments.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2242549®=3&lang=1>

Commemoration of World TB Day 2026 and Launch of Intensified TB Elimination Measures

On 24 March 2026, India celebrated World TB Day at a national event in Greater Noida to reaffirm the country's commitment to the elimination of tuberculosis ("TB") by India's Sustainable Development Goals deadline. The event emphasized that India continues to strengthen tuberculosis detection, treatment, and prevention through policies and people's participation. India has seen a 21% fall in the incidence of TB over the last decade, along with a 25% drop in TB deaths. According to evidence showing that a large share of TB cases are asymptomatic, the government has followed a symptom-agnostic screening under TB Mukh Bharat Abhiyaan. This includes the deployment of AI-enabled diagnostics, portable X-rays, molecular tests, etc. Since December 2024, over 20 crore individuals have been screened, leading to 32.65 lakh cases being detected.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2244703®=3&lang=1>

INVESTMENTS

Lupin Limited and Zydus Lifesciences Limited Enter into a Co-Marketing Agreement for Marketing of Semaglutide Injection in India

On 17 March 2026, Lupin Limited ("Lupin") and Zydus Lifesciences Limited ("Zydus") entered into a licensing and supply agreement to co-market Zydus' Semaglutide injection for the treatment of Type 2



diabetes in India. Lupin is a global pharmaceutical company with a presence in over 100 markets worldwide. Its portfolio spans a wide range of offerings, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Zydus is a research-driven global life sciences organisation with a strong footprint in pharmaceuticals and consumer wellness. It is further supported by a growing MedTech segment and maintains a significant presence across key markets such as the United States, India, and other global markets.

<https://www.lupin.com/media/press-releases/lupin-and-zydus-sign-licensing-agreement-for-co-marketing-innovative-semaglutide-injection-in-india>

Medical Devices and Med-Tech

GOVERNMENT INITIATIVES

Department of Commerce Organizes Chintan Shivir on “Strengthening India’s Medical Devices Export Ecosystem”

On 14 March 2026, the Department of Commerce, under the Ministry of Commerce & Industry, convened a “Chintan Shivir” in collaboration with the Department of Pharmaceuticals and the Export Promotion Council for Medical Devices (“EPCMD”) to deliberate on strengthening India’s medical devices export ecosystem. The deliberations highlighted that India’s medical device exports have surpassed USD 4 billion in FY25, with a strategic policy emphasis on enhancing global market share through regulatory harmonisation, R&D investment, and high-value manufacturing. The event brought together over 150 stakeholders, including policymakers, regulators, and industry leaders, to discuss strategies to boost India’s global competitiveness in the MedTech sector under the vision of achieving a USD 30 billion market size by 2030. The Chintan Shivir held discussions on pathways for consolidating India’s medical devices manufacturing ecosystem and enhancing export competitiveness.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2240258®=3&lang=1>

Healthcare and Hospitals

LEGAL AND REGULATORY

Enforcement of National Dental Commission Act, 2023

On 19th March 2026, the MoHFW issued 2 notifications to notify the enforcement of the National Dental Commission Act, 2023, repealing the Dentists Act, 1948. The primary functions of the National Dental Commission include framing regulations to implement the provisions of the National Dental Commission Act, 2023, conducting rating and assessment of dental institutions, evaluating human resources and promoting dental research, framing guidelines for fee regulations of private dental institutions, setting standards for community dental care, education, research and professional ethics. To facilitate the effective functioning of the National Dental Commission, three autonomous bodies have been established:

1. The Undergraduate and Postgraduate Dental Education Board, responsible for overseeing dental education.



2. The Dental Assessment and Rating Board, tasked with regulating accreditation and evaluating institutions.
3. The Ethics and Dental Registration Board, which supervises professional conduct and manages the registration of dental practitioners.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2242888®=3&lang=2>

GOVERNMENT INITIATIVES

NITI Aayog and UNICEF India Entered into a Statement of Intent to Strengthen Nutrition and Health Outcomes

On 5 March 2026, NITI Aayog and UNICEF India entered into a Statement of Intent (“**SoI**”) to advance nutrition and health outcomes with a focus on maternal and child health indicators in undeserved regions. The collaboration seeks to institutionalise a multi-stakeholder implementation framework, leveraging technical expertise, data-driven governance and private sector participation through Corporate Social Responsibility (“**CSR**”) mobilisation. Key interventions include strengthening Anganwadi infrastructure, improving uptake of Integrated Child Development Services, enhancing frontline workforce capacity, and promoting nutrition awareness initiatives.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2235681®=3&lang=1>

Government Expands New Clinical and Research Facilities at All India Institute of Ayurveda Goa

On 8 March 2026, the All India Institute of Ayurveda (“**AIIA**”), Goa, inaugurated multiple specialised healthcare units to strengthen patient care and expand access to integrative Ayurvedic treatment services. The newly operational facilities include a surgical facility, physiotherapy and rehabilitation services, pediatric Panchakarma units, and diagnostic infrastructure such as bone mineral density testing, aimed at enhancing clinical capacity and promoting evidence-based Ayurveda. Concurrently, plans were announced to expand the AIIA campus through the establishment of a cancer research centre, central research laboratories, a pharmacy, and other facilities. The expansion signals a move towards strengthening regulatory credibility and global positioning of traditional medicine systems.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2236596®=3&lang=1>

National Workshop on One Health Organised in Nagpur on “Operational Frameworks for One Health: National Vision and State Action”

On 18 March 2026, the MoHFW, through the Department of Health Research, convened a national workshop in Nagpur to develop operational frameworks for implementing the National One Health Mission (“**NOHM**”) across states. Key discussions emphasised integrated surveillance across human, animal, and environmental health systems, alongside the need for interoperable data-sharing mechanisms and decentralised outbreak response frameworks. The initiative signals a shift towards institutionalised inter-agency coordination for zoonotic disease management and pandemic preparedness. It also underscores the increasing importance of cross-sector regulatory alignment in planning the protection of public health.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2241910®=3&lang=1>



MoHFW Identifies 219 Priority Districts for Intensified HIV/AIDS Intervention

On 20 March 2026, MoHFW through the National AIDS Control Organisation convened the “Suraksha Sankalp Karyashala” to strengthen the district-level response to HIV/AIDS. It was noted during the workshop that, in the broader national context, 219 districts have been identified as priority areas for intensified HIV/AIDS interventions, including 11 in Haryana and 7 in Delhi. Discussions at the workshop focused on strengthening programme implementation through greater inter-sectoral convergence, capacity building, and improved monitoring mechanisms. Particular emphasis was placed on early diagnosis, timely initiation of treatment, sustained adherence to antiretroviral therapy, and addressing stigma and discrimination. The initiative aligns with India’s commitment to achieving the global target of ending AIDS as a public health threat by 2030.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2242838®=3&lang=1>

Other Updates

FSSAI Implements Food Recall Mechanism under the FoSCoS System

On 18 March 2026, the Food Safety and Standards Authority of India (“FSSAI”) issued an order notifying the implementation of a food recall mechanism under the Food Safety and Compliance System portal (“FoSCoS”) to facilitate dissemination of information regarding recalled food products and monitor the food recall process. In this regard, the FSSAI has directed Designated Officers / Central Licensing Authorities and Food Business Operators to fill-in the information with respect to food recalls undertaken in the FoSCoS system. Moreover, consumers can find details of recalled food products on the FoSCoS system.

https://www.fssai.gov.in/upload/advisories/2026/03/69bbb3b762053Order%20dt.%2018.03.2026_Implementation%20of%20Food%20Recall%20functionality%20in%20FoSCoS.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



RAVI RAJ SHEKHAR

Senior Associate

Email – r.shekhar@luthra.com



PRAGNA YENDURI

Associate

Email – syenduri@luthra.com



PRAGYA RANI

Associate

Email – prani@luthra.com



TANAY JHA

Associate

Email – t.jha@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



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



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



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



CHENNAI

Prestige Palladium Bayan,
 8th Floor, Greams Road, Nungambakkam Division,
 Egmore, Chennai - 600 006,
 Tamil Nadu
 T: +91 95604 88155
 E: chennai@luthra.com