Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

Newsletter - January 2026 Edition

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LAW OFFICES INDIA

INSIDE

Pharmaceuticals

LEGAL AND REGULATORY

I. The Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2025

On 10 December 2025, the Department of Revenue under the Ministry of Finance issued the Narcotic Drugs and Psychotropic Substances **(Amendment)** Rules, 2025. The amendment substituted Form no. 4A, relating to approval for the import of substances under the proviso to rule 54 of the Narcotic Drugs and Psychotropic Substances Rules, 1985. The Form no. 4A prescribes strict conditions on use, record maintenance, monthly reporting, and the prohibition of domestic sale or diversion for cases where the import of morphine, codeine, thebaine is for analytical purposes or for use in manufacturing of products for export purposes. Additionally, any quantity of morphine, codeine, thebaine and their salts or finished formulations for export which remain unutilised must be surrendered to the Government Opium and Alkaloids Works, the accounting for this purpose must be submitted to the Narcotics Commissioner. Moreover, Form no. 5 was amended to streamline details required for export authorization of narcotic drugs and psychotropic substances.

https://egazette.gov.in/WriteReadData/2025/268398.pdf

II. NPPA Fixes Retail Prices of 37 Drug Formulations under DPCO

On 24 December 2025, the National Pharmaceutical Pricing Authority ("**NPPA**"), under the Ministry of Chemicals and Fertilizers, issued an order bearing reference number S.O. 5975(E) ("**Order**") and fixed the retail prices of 37 formulations under the Drugs (Prices Control) Order, 2013 ("**DPCO**"). Some of the formulations include commonly used medicines such as Aceclofenac & Paracetamol Tablets, Bilastine & Montelukast Tablets, Levocetirizine Dihydrochloride & Montelukast Sodium Syrup, and etc. The retail price for a pack of the respective formulations shall be arrived at by the concerned manufacturer in accordance with the retail price specified in the aforementioned Order. The concerned manufacturers must issue updated price lists in Form-V of the DPCO and upload them on the Integrated Pharmaceutical Database Management System portal, with copies submitted to State Drug Controllers and dealers. Retailers and dealers are mandated to display the price lists prominently at their business premises. Any non-compliance or overcharging will result in the recovery of the excess amount, along with interest, under the DPCO, read with the Essential Commodities Act, 1955.

https://nppa.gov.in/uploads/tender/398b2a9c74d8c30dd82e425bda8c611c.pdf

III. Ministry of Health and Family Welfare Bans Manufacturing, Sale and Distribution of Oral Formulations Containing Nimesulide Above 100 mg

On 29 December 2025, the Ministry of Health and Family Welfare ("**MOHFW**") issued a notification bearing reference number S.O. 6091(E), prohibiting all oral formulations containing Nimesulide above 100 mg in immediate release dosage form, as these are considered likely to pose a risk to human health. It was further observed that safer alternative medicines to Nimesulide are available for therapeutic use. In view of these concerns, the MOHFW concluded that continued manufacture and availability of such formulations is not in the interest of the public. Exercising its statutory powers under Section 26A of the Drugs and Cosmetics

Act, 1940, the MOHFW took regulatory action to prohibit the manufacture, sale, and distribution of such formulations. The decision was taken after consultation with the Drugs Technical Advisory Board. The prohibition has been brought into force with immediate effect, thereby prohibiting their use for human consumption in the country.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM3NTA=

GOVERNMENT INITIATIVES

I. Union Health Minister Reviewed Healthcare Reforms and Tuberculosis Elimination Efforts in Haryana

On 29 December 2025, the MOHFW, Government of India, held a high-level review meeting chaired by Union Health Minister Shri J.P. Nadda with the Health Minister and senior officials of Haryana to assess healthcare delivery and the implementation of national health programmes. The discussions focused on strengthening the public health system, improving patient-centric care, ensuring strict regulatory oversight, and advancing the goal of Tuberculosis Mukt Bharat. It emphasised continuous monitoring across the pharmaceutical supply chain to ensure the quality and safety of medicines and called for sustained improvements in regulatory compliance. Emphasis was placed on professional hospital management, oversight of blood banks, and uninterrupted availability of laboratory reagents. The role of technology, particularly telemedicine, was highlighted as a means to improve access to healthcare in remote areas. Reiterating the commitment to eliminate tuberculosis, the Union Health Minister emphasised the importance of district-level interventions, enhanced screening, early diagnosis, treatment adherence, and community participation. The meeting concluded with an assurance of continued Centre–State collaboration to strengthen healthcare reforms and accelerate progress towards tuberculosis elimination.

https://www.mohfw.gov.in/?q=en/press-info/9827

INVESTMENTS

I. Pfizer India and Cipla Limited Enter Exclusive Marketing and Distribution Partnership

On 19 December 2025, Pfizer India ("**Pfizer**") and Cipla Limited ("**Cipla**") announced an exclusive marketing and distribution partnership under which Cipla will solely market, distribute and sell certain Pfizer brands in India. The agreement covers four key brands, including the cough syrups Corex Dx and Corex LS; the non-steroidal anti-inflammatory drug, Dolonex; the proton pump inhibitor, Neksium; and the oral antibiotic Dalacin C. Under the arrangement, Pfizer will remain responsible for the manufacture, source and supply of these medicines to Cipla for the Indian market. The release stated that the partnership is aimed at significantly enhancing the availability of these established brands for patients across the country. It highlighted that the collaboration combines Pfizer's legacy portfolio, quality and innovation with Cipla's extensive distribution network and market reach. The announcement also noted that this is the first

partnership between Pfizer and Cipla in India and is intended to improve patient access to trusted therapies while strengthening both companies' presence across key therapy areas.

https://www.cipla.com/sites/default/files/Pfizer-%26-Cipla-Announce-Exclusive-Marketing-and-Distribution-Partnership-for-Select-Brands-in-India.pdf

Medical Devices and Med-Tech

LEGAL AND REGULATORY

I. MOHFW Proposes Amendments to Medical Devices Rules, 2017

On 04 December 2025, the MOHFW issued a notification bearing reference no. G.S.R. 883(E), proposing amendments to the Medical Devices Rules, 2017, ("**Draft Amendment Rules**") and invited objections and suggestions within 30 days from the date on which copies of the Draft Amendment Rules are made available to public. In rule 44, clause (m) of the Medical Device Rules, 2017, after the word "M. L"; the phrase "or "Registration number" or "Reg. No." in case of Class A (Non-Sterile and Non-Measuring) Medical Devices" is proposed to be inserted by the Draft Amendment Rules. Amongst the various amendments, the Draft Amendment Rules further provide that certificates and licences under various forms of the Medical Device Rules, 2017, shall remain valid in perpetuity, unless, it is suspended or cancelled or surrendered, provided that the registration certificate holder or license holder deposits a registration retention fee or license retention fee as per the provisions of Medical Devices Rules, 2017 ("**MDR**").

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2OTY=

II. Central Drugs Standards Control Organization Introduces Online Risk Classification Module for Non-IVD Medical Devices

On 04 December 2025, the Central Drugs Standards Control Organization ("**CDSCO**") issued a circular bearing reference no. MED-16035/14/2025, noting the addition of a Risk Classification Module for medical devices other than In-Vitro Diagnostic ("**IVD**") medical devices. The Risk Classification Module has been made functional on the CDSCO Online System for Medical Devices portal, effective from 27 November 2025, aiming to simplify the regulatory approval procedures and risk classification of medical devices, excluding IVD medical devices. The circular clarifies that applicants may apply online on the CDSCO Online System for Medical Devices portal, in accordance with the MDR, for risk classification of devices not included in the CDSCO classification list.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2Njc=

Healthcare and Hospitals

GOVERNMENT INITIATIVES

I. India Hosted 2nd WHO Global Summit on Traditional Medicine in New Delhi

On 19 December 2025, the Ministry of AYUSH concluded the 2nd World Health Organization ("**WHO**") Global Summit on Traditional Medicine in New Delhi. The Summit was held under the theme "*Restoring Balance for People and Planet: The Science and Practice of Well-Being*" and brought together global policymakers, researchers, practitioners and experts. The Prime Minister of India, Shri Narendra Modi, highlighted India's leadership in advancing traditional medicine as evidence-based, safe and globally trusted, emphasising integration with modern healthcare systems. A key outcome of this summit was the launch of the WHO Traditional Medicine Global Library, a digital repository providing equitable access to scientific research and policy resources. The event reaffirmed the global relevance of traditional medicine, which is practised across various WHO Member States. The role of the WHO Global Centre for Traditional Medicine in Jamnagar, Gujarat, was underscored as a global hub for research, regulation and collaboration. WHO Director-General, Dr. Tedros, praised India for elevating traditional medicine from a heritage to a mainstream healthcare approach. The summit concluded with the adoption of the Delhi Declaration, committing Member States of WHO to strengthen evidence, regulation and integration of traditional medicine. The announcement reinforced India's commitment to improving the quality, access, and global confidence in traditional medicine through the integration of scientific standards and public health.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2206859&reg=3&lang=1

II. Two-Day Influenza Chintan Shivir on Preparedness and Inter-Sectoral Convergence

On 22 and 23 December 2025, the MOHFW, through the National Centre for Disease Control and in collaboration with the World Health Organization India, organised a two-day Influenza Chintan Shivir in New Delhi to strengthen inter-ministerial and inter-sectoral convergence for influenza preparedness and response. On the first day, it focused on the inauguration of the Chintan Shivir and emphasised the need for preparedness, surveillance, surge capacity, and coordinated action ahead of the upcoming influenza season. The Union Health Minister highlighted that influenza preparedness needs to be strengthened and underscored the importance of a One Health approach, with coordinated efforts between the Centre and States through the Integrated Disease Surveillance Programme. The Chintan Shivir witnessed participation from multiple ministries, departments, research institutions, States, Union Territories, and international partners, enabling cross-learning and sharing of best practices. The discussions resulted in the development of a comprehensive and structured influenza preparedness checklist. The checklist is intended to guide the Centre, States and districts in preparedness planning across four key areas:

- surveillance, early warning, and risk assessment
- laboratory systems strengthening
- hospital preparedness and clinical response
- One Health Coordination and Risk Communication & Community Engagement

The Chintan Shivir concluded with a consensus among participating ministries and stakeholders to strengthen integrated surveillance, laboratory capacity and timely data sharing to effectively address seasonal and zoonotic influenza.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2207717&lang=1&reg=3

INVESTMENTS

I. Max Healthcare Announces Entry into Pune with 450-Bed Hospital

On 18 December 2025, Max Healthcare Institute Limited ("**Max Healthcare**") announced its entry into Pune with plans to establish a 450-bed super speciality hospital involving an investment of over Rs. 1,000 crores. The company stated that the advanced facility will be located in Yerawada, a centrally located area of Pune, and is aimed to be operational over the next three years. This expansion will mark Max Healthcare's fourth facility in Western India, further reinforcing its presence in Maharashtra. The announcement highlighted Pune's growing urban population and rising demand for high-end healthcare services as key factors behind the expansion. The project involves the staggered acquisition of a 100% equity stake in Yerawada Properties Private Limited, Pune, along with phased development of the hospital. The release noted that the proposed hospital will offer advanced medical care supported by modern technology. Max Healthcare stated that this entry aligns with its long-term strategy to expand across key healthcare markets in India and enhance access to quality healthcare services.

https://max-website20-images.s3.ap-south-1.amazonaws.com/SE_Intimation_Reg_30_LODR_Press_Release_18_12_2025_b52d2a16c8.pdf

II. International Hospital Limited to Acquire TMI Healthcare Private Limited

International Hospital Limited ("**IHL**"), a wholly-owned subsidiary of Fortis Healthcare Limited announced that it had entered into agreements to acquire TMI Healthcare Private Limited. TMI Healthcare Private Limited owns People Tree Hospital, a 125-bed healthcare facility located in Yeshwanthpur, Bengaluru. The acquisition will be carried out through a 100% purchase of TMI Healthcare Private Limited by IHL. In addition to the acquisition of TMI Healthcare Private Limited, IHL is also acquiring the underlying land and hospital building and an adjacent land parcel. The transaction is expected to be completed by the end of January 2026, subject to the fulfilment of customary conditions precedent. As a result of this deal, Fortis Healthcare Limited aims to expand its presence in Bengaluru.

https://www.bseindia.com/xml-data/corpfiling/AttachHis/990b96e4-d366-48ea-a8df-5d9796b1fc78.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.

The Team

PRADNESH WARKE
Partner
Email – p.warke@luthra.com

RAVI RAJ SHEKHAR
Senior Associate
Email – r.shekhar@luthra.com

DEVASHREE KULKARNI
Associate
Email – dkulkarni@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