Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

Newsletter - March 2026 Edition

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LAW OFFICES INDIA

INSIDE

Pharmaceuticals

LEGAL AND REGULATORY

Ministry of Health and Family Welfare Issues Draft Amendments to the New Drugs and Clinical Trials Rules, 2019

On 2 February 2026, the Ministry of Health and Family Welfare ("**MoHFW**") issued draft amendments to the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**"). Rule 77 of the NDCT Rules governs the conditions for permission to import new drugs for sale or distribution, while Rule 82 prescribes the conditions for permission to manufacture new drugs for sale or distribution. The proposed amendment introduces an additional compliance condition under both rules, requiring manufacturers or their authorised agents to intimate the licensing authority in writing of any change in the manufacturing process, excipients, packaging, shelf life, specifications, testing methods, documentation, or related aspects. The proviso to this new condition classifies such changes into three risk-based categories, depending on their potential impact on product quality. As per the proviso, major quality changes (Level I) are those with a substantial potential to adversely affect the identity, strength, quality, purity, or potency of a drug and would require prior approval from the licensing authority before implementing such a change. Moderate quality changes (Level II), which carry a moderate risk of such adverse impact, would also require prior regulatory approval. In contrast, minor quality changes (Level III), are changes with minimal potential to affect product quality and may be implemented without prior approval, except in cases involving changes to shelf life of a drug substance and drug product. However, all such minor changes must be reported annually 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=MTM4NTI=

Drugs (Amendment) Rules, 2026

On 16 February 2026, the MoHFW notified the Drugs (Amendment) Rules, 2026 ("**Amendment Rules, 2026**"), introducing important changes to the licensing conditions governing wholesale sale of drugs. One of the key amendments relates to the conditions of licence prescribed under Form 20B (Licence to Sell, Stock or Exhibit or Offer for Sale, or Distribute by Wholesale, Drugs other than those specified in Schedules C, C(1) and X), Form 20G (Licence to Sell, Stock or Exhibit or Offer for Sale, or Distribute by Wholesale Drugs specified in Schedule X), and Form 21B (Licence to Sell, Stock or Exhibit or Offer for Sale, or Distribute by Wholesale Drugs specified in Schedules C and C(1) excluding those specified in Schedule X). Under the Amendment Rules, 2026 in the case of licences issued under Forms 20B and 20G, drug sales must now be conducted under the personal supervision of a designated competent person, whose name is required to be expressly recorded in the licence. In addition, licensees are mandated to notify the licensing authority within one month of any change in the competent person. For licences issued under Form 21B, licensees are required to intimate the licensing authority within one month of any change in the competent person.
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM4Nzc=

GOVERNMENT INITIATIVES

Union Budget 2026-27: Promoting Health, Biopharmaceuticals, and Medical Research

The Union Budget 2026–27 takes an important step towards strengthening India's healthcare system by increasing the allocation for the MoHFW to Rs. 1,06,530.42 crore. The allocation also includes Rs. 4,821.21 crore for the Department of Health Research. This steady increase in public spending shows the Government's continued focus on improving access to healthcare, strengthening healthcare infrastructure, supporting medical research, and ensuring affordable and quality healthcare services across the country. Under the MoHFW, spending on schemes has gone up by Rs. 6,175.96 crore, while non-scheme expenditure has increased by Rs. 2,500.96 crore compared to the revised estimates for FY 2025–26. The Union Budget 2026–27 also aims to support the biopharmaceutical sector through the launch of the 'Bio Pharma Shakti' initiative, with a total outlay of Rs. 10,000 crore over the next five years. The programme is intended to support domestic production of biologics and biosimilars, reduce dependence on imports, improve affordability, and strengthen India's role as a global manufacturing base for biopharmaceuticals, while also encouraging research, innovation, and advanced manufacturing.
https://www.pib.gov.in/PressReleseDetail.aspx?PRID=2221616&reg=3&lang=1

Issuance of Lung Cancer Treatment and Palliation: Evidence-Based Guidelines

On 3 February 2026, on the eve of World Cancer Day, Union Minister for Health & Family Welfare, Shri Jagat Prakash Nadda formally released India's first nationally developed "Lung Cancer Treatment and Palliation: Evidence-Based Guidelines" ("**Guidelines**") at Kartavya Bhavan, New Delhi. The Guidelines establish a uniform, evidence-based and patient-centric framework for lung cancer diagnosis, treatment and palliative care across the country. Comprising 15 evidence-based recommendations, they address early detection, standardised treatment protocols and strengthened palliative care, with the objective of reducing variations in clinical practice, improving decision-making and enhancing patient outcomes and quality of life across both public and private healthcare sectors. Developed using internationally accepted methodologies and expert inputs, the guidelines are available on the Department of Health Research website, along with a plain-language summary to aid understanding for patients, families and caregivers.
https://dhr.gov.in/whatsnew/eve-world-cancer-day-honorable-union-health-minister-releases-evidence-based-guidelines

Indian Pharmacopoeia Commission Signs MoUs with Goa State Pharmacy Council the Quality Council of India and HLL Infra Tech Services Limited

The Indian Pharmacopoeia Commission ("**IPC**"), an autonomous body under the Ministry of Health and Family Welfare, has signed Memoranda of Understanding ("**MoU**") with the Goa State Pharmacy Council ("**GSPC**"), the Quality Council of India ("**QCI**"), and HLL Infra Tech Services Limited ("**HITES**") to reinforce drug safety, quality assurance, and capacity-building efforts across the country. The MoU with GSPC establishes a mechanism for cooperation in pharmacovigilance, rational use of medicines, and professional development of pharmacists in Goa, with a focus on promoting the National Formulary of India, strengthening adverse drug reaction ("**ADR**") reporting under the Pharmacovigilance Programme of India, conducting training and continuing education programmes, and enhancing awareness on drug safety, pharmacopoeial standards, and sustainable pharmacopoeia. It also seeks to support the establishment and

strengthening of ADR Monitoring Centres and improve systematic reporting and documentation practices across healthcare facilities in the state. Under the MoU with QCI, IPC and QCI have agreed to collaborate on quality promotion, public health awareness, and capacity-building initiatives, including joint planning and execution of training and awareness programmes related to pharmacovigilance and allied areas. The MoUs play and essential role in training, capacity building, and continuing professional education of pharmacists, thereby promoting the improvement of public health outcomes.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2225435&reg=3&lang=1

INVESTMENTS

USV Acquires 79% Stake in Wellbeing Nutrition

USV Private Limited ("**USV**") has reportedly signed a definitive agreement to acquire a 79% stake in Nutritionalab Private Limited under the brand name, Wellbeing Nutrition & Values, for approximately Rs. 1,583 crore. Established in 1961 by Dr. Vithal Balkrishna Gandhi, USV aims to provide reliable healthcare solutions across multiple therapy areas globally, along with cosmeceutical and nutraceutical offerings in select markets. The transaction marks USV's strategic expansion into India's fast-growing direct-to-consumer nutraceutical and wellness segment, broadening its portfolio beyond prescription therapies to preventive health and lifestyle products.
https://pharma.economictimes.indiatimes.com/news/mergers-and-acquisitions/usv-acquires-79-stake-in-wellbeing-nutrition-for-rs-1583-cr/128244563

Medical Devices and Med-Tech

LEGAL AND REGULATORY

Issuance of Draft Guidance Document on Guidance for Import of In-Vitro Diagnostic Medical Device

On 2 February, the Central Drugs Standard Control Organisation ("**CDSCO**") released a draft guidance document on "Guidance for Import of In-Vitro Diagnostic Medical Device" to assist importers of in-vitro diagnostic ("**IVD**") medical devices in submitting import licence applications through the CDSCO Online System for Medical Devices portal and the National Single Window System ("**NSWS**"). The document serves as a consolidated reference outlining the regulatory framework, procedural steps, documentation requirements, and compliance obligations applicable to IVD imports in India in accordance with the Medical Devices Rules, 2017. The draft guidance document explains the application pathways for Form MD-14 (application for issue of import licence to import medical device) to be filed on the CDSCO Online System for Medical Devices, and Form MD-16 (application for licence to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training) to be submitted through the NSWS portal. The draft guidance document the end-to-end online workflow ultimately culminating in the grant of licences in Form MD-15 (for MD-14 applications) and Form MD-17 (for MD-16 applications).
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM4NDE=

GOVERNMENT INITIATIVES

Inauguration of Indo-French Centre for AI in Health

In a significant move to deepen Indo-French collaboration in healthcare and emerging technologies, Union Minister for Health & Family Welfare, Shri Jagat Prakash Nadda and Mr. Emmanuel Macron, President of the French Republic, jointly inaugurated the Indo-French Centre for AI in Health ("**IF-CAIH**") at All India Institute of Medical Sciences, New Delhi. IF-CAIH seeks to advance AI-enabled research, medical education and clinical innovation to address complex healthcare challenges, marking a major milestone in India–France cooperation in digital health and reinforcing India's ambition to emerge as a global leader in equitable, technology-driven healthcare solutions. The initiative builds on existing India–France institutional cooperation in priority areas such as digital health, antimicrobial resistance, human resources for health and responsible use of health data, aiming to strengthen scientific discovery, evidence-based policymaking, and capacity building through academic and researcher mobility. As part of RUSH 2026, a special session titled "RUSH – Conversation on Artificial Intelligence" featured President Macron in dialogue with young Indian innovators Ms. Priyanka Das Rajkakati and Mr. Manan Suri, moderated by Clara Chappaz, highlighting youth-led innovation and cross-border collaboration. President Macron emphasised the importance of building sovereign and ethical AI capabilities, safeguarding transparency, diversity and democratic values, particularly in healthcare. The Government of India reiterated its commitment to strengthening healthcare cooperation with France by leveraging innovation, shared democratic principles and collective expertise to build resilient health systems and improve global health outcomes.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2229745&reg=3&lang=1

Panel Discussion on "Scaling AI for Public Health Impact: Public-Private Partnership" at India AI Impact Summit 2026

The MoHFW hosted a high-level panel discussion on *"Scaling AI for Public Health Impact: Public-Private Partnership"* during the India AI Impact Summit 2026 ("**Summit**") at Bharat Mandapam. The Government of India organised the Summit from **16 to 20 February 2026** in New Delhi, marking the first global AI summit to be held in the Global South, and bringing together international leaders, policymakers, industry, academia and innovators to examine the transformative role of Artificial Intelligence with a focus on inclusive and sustainable development. In her keynote address, Union Health Secretary Punya Salila Srivastava noted that India's health system has, over the last decade, evolved from basic digitisation and improved data reporting to the creation of a nationally interoperable digital health ecosystem. Highlighting that while digital systems enable data capture and transmission, AI allows for intelligent analysis and action, she stressed that AI can ease the workload of healthcare professionals while reinforcing, rather than replacing, the physician–patient relationship. She cited initiatives such as MadhuNetrAI for AI-driven diabetic retinopathy screening, AI-enabled handheld X-ray and acoustic screening tools like Cough Against TB (CA-TB) for tuberculosis detection, AI-based surveillance systems for rapid epidemic alerts, and the establishment of Centres of Excellence for AI in healthcare at AIIMS Delhi, PGIMER Chandigarh, and AIIMS Rishikesh. Through its active participation in the Summit, the MoHFW reaffirms its commitment to using advanced technologies to reinforce public health systems and deliver accessible, affordable, and high-quality healthcare to everyone

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2228733&reg=3&lang=1

India and Brazil Sign MoU to Strengthen Collaboration in Pharmaceutical and Medical Product Regulation

On 21 February 2026, India and Brazil exchanged a Memorandum of Understanding to strengthen bilateral cooperation in the regulation of pharmaceutical and medical products. The MoU was exchanged at Hyderabad House by Brazilian Health Regulatory Agency's Director-President, Mr. Leandro Safatle and the Indian Ambassador to Brazil, Shri Dinesh Bhatia, in the presence of Shri Narendra Modi, Prime Minister of India and Mr. Luiz Inácio Lula da Silva, President of Brazil. The agreement establishes a structured framework for cooperation and information exchange on pharmaceuticals, biologicals, medical devices and active pharmaceutical ingredients, with the objective of strengthening oversight mechanisms, improving supply chains and ensuring access to safe, effective and quality-assured medical products.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2231289&reg=3&lang=1

INVESTMENTS

Medical Equipment Startup Pulse Raises $4 Million

Pulse, a medical equipment startup, raised $4 million in a funding round led by 3one4 Capital, with participation from Incubate Fund Asia and other strategic investors. Pulse is a full-stack, technology-driven OEM brand that develops, procures, and supplies affordable, globally compliant medical equipment at scale. It aims to streamline procurement of inventory and eliminate the inefficiencies caused by a fragmented supplier landscape. The capital infusion will be utilised by Pulse to expand its product portfolio, scale manufacturing capabilities, and strengthen distribution networks across India. https://www.3one4capital.com/blogs/pulse-raises-4-million-building-a-tech-enabled-full-stack-horizontal-medical-equipment-oem-brand

Healthcare and Hospitals

LEGAL AND REGULATORY

Legal Metrology (General) Second Amendment Rules, 2026

On 11 February 2026, the Department of Consumer Affairs amended the Legal Metrology (General) Rules, 2011 by issuing the Legal Metrology (General) Second Amendment Rules, 2026. The Legal Metrology (General) Second Amendment Rules, 2026 introduce specific metrological and technical requirements for clinical electrical thermometers for continuous measurement of human or animal body temperature and these instruments are normally used to monitor the temperature at appropriate body sites of a patient undergoing certain surgical procedures or during intensive care. The amendments prescribe labelling and marking requirements, maximum permissible errors, performance tests, and etc. Manufacturers of clinical electrical thermometers must ensure compliance with the Legal Metrology (General) Second Amendment Rules, 2026.
https://consumeraffairs.gov.in/public/upload/files/Continuous_Electrical_Thermometer_1771307283.pdf

GOVERNMENT INITIATIVES

India–Sri Lanka Health Technology Assessment Cooperation

On 9 February 2026 the five-day Knowledge Exchange Workshop on Health Technology Assessment ("**HTA**") for a delegation from the Ministry of Health, Government of Sri Lanka, formally commenced at Sushma Swaraj Bhawan, New Delhi. Hosted by the Department of Health Research ("**DHR**") under the MoHFW, in collaboration with the Ministry of External Affairs, the workshop aims to chart a pathway for advancing and institutionalising HTA in Sri Lanka. Addressing the inaugural session, Rajiv Bahl, Secretary, DHR and Director General of the Indian Council of Medical Research, described the initiative as a key milestone in bilateral health diplomacy and HTA knowledge exchange, reflecting India's commitment to regional health cooperation. Anu Nagar, Additional Secretary, DHR, highlighted the significant contribution of Health Technology Assessment India to evidence-based and cost-effective healthcare decision-making in India and expressed confidence that the exchange would support the institutionalisation of HTA in Sri Lanka. The five-day programme will cover HTA institutional frameworks, governance, methodologies, pricing and procurement decisions, and will also explore opportunities for future collaboration to strengthen HTA systems and capacities in both countries.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2225648&reg=3&lang=2

National Arogya Fair, 2026 held at Shegaon

From 25 to 28 February 2026, a four-day National Arogya Fair 2026, ("**Fair**") organised by the Ministry of Ayush in collaboration with the All India Ayurvedic Congress at Shegaon in Buldhana district, Maharashtra, was conducted, reaffirming India's commitment to holistic healthcare and rural empowerment through traditional systems of medicine. Inaugurated by the President of India, Smt. Droupadi Murmu, the Fair brought together practitioners, researchers, students, industry stakeholders and thousands of farmers, particularly from the Vidarbha region, while emphasising preventive and lifestyle-based healthcare rooted in Ayush systems. The Fair featured extensive free healthcare outreach through OPDs across Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy, along with Yoga demonstrations, therapy sessions, free medical consultations, health check-ups and authentic Ayush medicines. Overall, the Fair served as an integrated platform combining healthcare delivery, scientific dialogue, youth participation and farmer empowerment, underscoring the role of Ayush systems in public health and holistic wellness.
https://www.pib.gov.in/PressReleasePage.aspx?PRID=2234104&reg=3&lang=1

INVESTMENTS

Kotak Alts invests Rs. 400 Million in Zeroharm Sciences

Kotak Alternate Asset Managers Limited ("**Kotak Alts**"), through its Kotak Life Sciences Fund I, which focuses on early- to growth-stage investments in life sciences and healthcare, has invested Rs. 400 million in Zeroharm Sciences Private Limited ("**Zeroharm**"). This infusion enables Zeroharm, to scale its operations, strengthen brand presence, deepen customer engagement, and expand into new domestic and international markets. Established in 2020 by Sachin Darbarwar, Zeroharm is a plant-based nutraceutical direct-to-consumer brand with end-to-end in-house capabilities spanning extraction, formulation research and development, and manufacturing. Its products are distributed through its own website, leading e-

commerce platforms, and quick-commerce channels in India, while the company is also building an international footprint across the United States, the United Kingdom, and the Middle East. Kotak Alts, part of the Kotak Mahindra Group, specialises in alternative asset management and investment advisory services. Founded in early 2005, it has raised, managed, and advised on over USD 22 billion across multiple asset classes, including private equity, real estate, infrastructure, special situations, private credit, and investment advisory.
https://www.kotakalternateasset.com/wp-content/uploads/2026/02/Media-Release-Zeroharm.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

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