Luthra *and* Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

August 2025 Edition

Pharmaceuticals and Hospitals

LEGAL AND REGULATORY

MoHFW Proposes Changes in Requirements of Test License under NDCT Rules

The Ministry of Health and Family Welfare (**MoHFW**) has released a draft amendment to the New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**), proposing prior permission from the Central Licensing Authority for manufacturing of new drugs or investigational new drugs for clinical trials, bioavailability/bioequivalence studies, or testing. However, for analytical and preclinical testing of certain drugs excluding sex hormones, cytotoxic drugs, betalactams, biologics with live microorganisms, and narcotics/psychotropic drugs, manufacturing can proceed upon submission of an online notification. The proposed amendment also reduces approval timelines from 90 working days to 45 working days for grant of permission to manufacture (i) new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study, or for examination, test and analysis; and (ii) unapproved active pharmaceutical ingredient for development of pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study.

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

MoHFW Proposes to Simplify Bioavailability and Bioequivalence Studies for Certain Drugs Intended for Export

The MoHFW has released a draft amendment to the NDCT Rules aimed at simplifying bioavailability (**BA**) and bioequivalence (**BE**) studies for certain drugs intended for export. Under the proposed amendment, single-dose, two-period, two-sequence, two-treatment BA/BE studies in healthy adult volunteers can be conducted for oral drugs already approved in India or select countries (USA, EU, Japan, Australia, Canada, and the UK) after submitting an online notification to the Central Licensing Authority, subject to ethical committee approval, a sample size limit of 48, and exclusion of cytotoxic, hormone, narcotic/psychotropic drugs, drugs with narrow therapeutic index, or drugs with highly variable pharmacokinetics.

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

CDSCO Introduces New Online Dual Use System on SUGAM Portal

The Central Drugs Standard Control Organization (**CDSCO**) has introduced a new online dual use no objection certification (**NOC**) system on the SUGAM portal to streamline the process for importing bulk drugs for non-medicinal use. The new system allows issuance of one-year NOCs subject to prescribed conditions and reduces the compliance burden. Applications must be submitted through the SUGAM portal via a fresh registration process along with the updated checklist and guidance documents. The new system became functional from 31 August 2025, with registration starting on 05 August 2025. From 01 September 2025, only registered and approved users can apply for Dual Use NOCs through the portal.

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

GOVERNMENT INITIATIVES

Government of India Initiates Steps Cyber Security under ABDM

The Union Minister of State for Health and Family Welfare, Shri Prataprao Jadha, stated in the Rajya Sabha that under the Ayushman Bharat Digital Mission (**ABDM**), exchange of health data between stakeholders is permitted only with patient consent, ensuring strong patient data protection. Before integration, digital health applications are tested in a sandbox environment and subjected to security audits, ensuring compliance with the Health Data Management Policy (**HDM Policy**), 2020. To enable seamless data flow, the Health Information Exchange and Consent Manager (**HIECM**) facilitates interoperability of health records using common data standards, while the Unified Health Interface (**UHI**) supports interoperability of health services through protocol-based frameworks. Further, the Ministry of Health has introduced electronic health record (**EHR**) standards since 2013, revised in 2016, and established the National Resource Centre for EHR standards (**NRCeS**) to drive adoption and uniformity across the healthcare ecosystem.

To ensure inclusivity, ABDM has developed the ABHA portal and the ABHA personal health record application in multiple languages, with user-friendly features designed to overcome digital literacy barriers. Recognizing challenges in connectivity, provisions for assisted and offline ABHA creation have also been introduced, thereby ensuring wider access across rural and underserved regions. These measures collectively reflect the government's efforts to standardize digital health infrastructure, safeguard sensitive patient information, and extend the mission's benefits to all citizens.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2152537

National Health Authority and C-DAC Sign MoU to roll out a Health Management Information System for Digitization of Small and Medium Healthcare Providers

The National Health Authority (**NHA**) and the Centre for Development of Advanced Computing (**C-DAC**) have signed a Memorandum of Understanding (**MoU**) to launch **e-Sushrut@Clinic**, a lightweight, cloud-based Health Management Information System (**HMIS**) tailored for outpatient clinics and small-to-medium healthcare providers. This initiative, part of the Ayushman Bharat Digital Mission (**ABDM**) ecosystem, aims to provide an affordable, government-backed digital solution to improve efficiency, data security, and patient care, addressing the demand identified during ABDM microsite rollouts. Leveraging C-DAC's proven e-Sushrut platform already in use across 17 AIIMS and over 4,000 facilities nationwide, e-Sushrut@Clinic enables easy onboarding via the Health Facility and Health Professional Registries, and supports outpatient management, pharmacy, nursing, prescriptions, billing, and telemedicine with minimal technical overhead. Integrated ABDM features, including AIIMS Clinical Decision Support Systems for hypertension and diabetes, further empower doctors to make informed clinical decisions, fostering a secure, interoperable, and accessible digital health ecosystem for both public and private clinics

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2156603

INVESTMENTS

Manipal Hospitals seeks CCI nod to acquire Sahyadri Hospitals for about Rs 6,400 cr

Healthcare major Manipal Hospitals has filed for approval with the Competition Commission of India (**CCI**) to acquire Pune-based Sahyadri Hospitals from the Ontario Teachers' Pension Plan Board in a deal valued at around Rs 6,400 crore. The transaction envisages the acquisition of up to 100% shareholding in Sahyadri Hospitals by Manipal Hospitals in multiple tranches. Both parties have stated that the deal is not expected to impact any relevant market in India or cause any appreciable adverse effect on competition, leaving the definition of the relevant product and geographic market open for CCI's assessment. The acquisition follows the signing of definitive agreements between Manipal Hospitals and Ontario Teachers' Pension Plan last month.

Read More:
https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/manipal-hospitals-seeks-cci-nod-to-acquire-sahyadri-hospitals-for-about-rs-6400-cr/articleshow/123075827.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Apollo entities seek CCI nod for recast plan

The entities of Apollo Group are seeking CCI's approval for a composite restructuring plan to separately list its omnichannel pharmacy and digital health businesses within 18-21 months. The proposal involves the demerger of omnichannel pharmacy distribution, Apollo 24|7 digital platform and remote telehealth division of Apollo Hospitals Enterprise (**AHEL**) into a new company-Apollo Healthtech (**AHTL**). Further, Keimed, another group entity shall be merged into the new company. The move is aimed to create a formidable listed omnichannel pharmacy distribution and digital health platform leader in India.

https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/apollo-entities-seek-cci-nod-for-recast-plan/articleshow/123028988.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Med-tech and Medical Devices

LEGAL AND REGULATORY

CDSCO invites comments on standard IVD evaluation protocol drafted by ICMR

The Indian Council of Medical Research (**ICMR**) and the CDSCO have jointly released draft performance evaluation protocols for in-vitro diagnostic (**IVD**) kits under the Medical Devices Rules, 2017. These draft protocols provide a standardized framework to assess the quality, accuracy, sensitivity, specificity, and reliability of IVDs used for detecting and differentiating major respiratory viruses, including Influenza A & B (with/without subtyping), SARS-CoV-2, and Respiratory Syncytial Virus, in single-plex or multiplex molecular assay formats. The protocols, once finalized, will guide manufacturers and testing labs in India to ensure validated and reliable diagnostic performance.

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

Ministry of Consumer Affairs rolls out the Legal Metrology (General) Fifth Amendment Rules, 2025

The Ministry of Consumer Affairs, Food and Public Distribution (Department of Consumer Affairs) has issued the Legal Metrology (General) Fifth Amendment Rules, 2025 on August 07, 2025, under the Legal Metrology Act, 2009. The amendment revises the Eighth Schedule, Part VI, Part C of the Legal Metrology (General) Rules, 2011, specifying standards for thermometers. Key changes include:

- Definition of a complete thermometer as a temperature probe connected to an indicating unit, either as an interchangeable temperature probe with a compatible indicating unit or as a temperature probe and indicating unit permanently connected.
- Adjustment of temperature maintenance requirements from 36.9–37.1°C to 37°C ± 1°C.
- Correction in cross-references within the rules, replacing "5(2)(7)" with "5(2)(i)".

https://egazette.gov.in/(S(qyfmi3ukabq4oo1r3uv4ctdc))/ViewPDF.aspx

INVESTMENTS

CCI approves the proposed acquisition of certain shareholding of Micro Life Sciences Pvt. Ltd. by Platinum Jasmine A 2018 Trust

On August 19, 2025, the Competition Commission of India (**CCI**) approved the proposed acquisition by Platinum Jasmine A 2018 Trust (through its trustee Platinum Owl C 2018 RSC Limited), an investment entity owned by the Abu Dhabi Investment Authority, of certain equity shares of Micro Life Sciences Pvt. Ltd. from Bilakhia Holdings Pvt. Ltd. and via new share subscription, amounting to approximately 3.06% of the Target. Micro Life Sciences and its subsidiaries are primarily engaged in manufacturing and selling medical devices (such as stents, heart valves, orthopedic implants, sutures, staplers, meshes, and intrauterine devices), in-vitro diagnostic analyzers and reagents, self-testing kits (including COVID and pregnancy tests), and specialized medical devices like surgical robots, while also maintaining R&D facilities for diagnostic, orthopedic, endo-surgery, and cardiovascular solutions in India.

https://cci.gov.in/combination/press-release/details/560/0

Cosmetics

LEGAL AND REGULATORY

CCPA Imposes Penalty on Major Cosmetic Companies for Misleading Fat-Loss Claims

The Central Consumer Protection Authority (**CCPA**) has imposed a penalty of INR 3,00,000 (Rupees Three Lakhs) on major two cosmetics and wellness companies for publishing misleading advertisements about fat-loss and slimming treatments using the Cryolipolysis (CoolSculpting) procedure. Cryolipolysis is a non-invasive cosmetic procedure that uses controlled cold temperatures to freeze and destroy fat cells in targeted areas, leading to reduced fat deposits.

The advertisements by the two companies exaggerated claims of drastic and permanent weight loss, which are not supported by the US Food and Drug Administration (**US FDA**) approval, as the procedure is only approved for localized fat reduction in specific body areas for individuals with a BMI of 30 or less. CCPA directed the companies to clearly disclose the targeted body areas, demographic limitations, BMI restrictions, and that the procedure is not for weight loss in all future advertisements and consent forms. CCPA further warned all beauty clinics, wellness centres and service providers in India to strictly follow the Consumer Protection Act, 2019 to avoid penalties and legal proceedings.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2160053

Other Important Updates

LEGAL AND REGULATORY

FSSAI Mandates Display of Coffee-Chicory Mixture Percentage on Labels of Coffee Packages

The Food Safety and Standards Authority of India (**FSSAI**) has notified the Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2025, amending the Food Safety and Standards (Labelling and Display) Regulations, 2020. The amendment, effective from 1st July 2026, updates Schedule-II, paragraph 2, relating to Coffee-Chicory Mixtures. It mandates that packages of coffee-chicory mixtures or instant coffee-chicory blends display the percentage composition of coffee and chicory clearly on the front label.

https://fssai.gov.in/upload/notifications/2025/08/689d8d163d422coffee%20chicory_gazette.pdf

FSSAI in Consultation with Ministry of Ayush Releases Definitive List of Ayurveda Aahara Products under Category A

The FSSAI, in consultation with the Ministry of Ayush, has released a definitive list of **Ayurveda Aahara** products under the Food Safety and Standards (Ayurveda Aahara) Regulations, 2022, bringing India's traditional dietary wisdom into a modern regulatory framework. These regulations recognise foods based on recipes, ingredients, and processes from authoritative Ayurvedic texts, with the list under Note (1) of Schedule B drawn directly from classical texts in Schedule A to ensure authenticity. The initiative provides Food Business Operators (**FBOs**) with a credible reference for manufacturing Ayurveda Aahara products, while a structured process allows for the inclusion of additional Category A products with supporting textual references. Supported by the National Institute of Ayurveda, the compendium has been meticulously curated and scientifically validated, making it a guiding document for manufacturers and ensuring public access to safe, authentic, and time-tested dietary solutions.

Ayurveda Aahara embodies the holistic principles of Ayurveda, emphasising balance, seasonal suitability, and the use of natural ingredients and herbs with therapeutic benefits to support digestion, immunity, and overall well-being. Union Minister Shri Prataprao Jadhav encouraged citizens to adopt these practices as a preventive healthcare measure, while FSSAI and the Ministry of Ayush highlighted that the initiative strengthens consumer trust, aligns traditional knowledge with modern safety standards, and promotes widespread adoption of Ayurveda-based nutrition

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2151745

GOVERNMENT INITIATIVES

FSSAI takes steps to boost food safety standards

The Government of India, through the FSSAI, has strengthened street food safety by enforcing science-based standards, mandating licensing/registration of all Food Business Operators (**FBOs**), and carrying out annual inspections for petty food manufacturers. Under the Food Safety and Standards Act, 2006 and related regulations, every FBO must follow sanitary and hygienic requirements as per their business scale. FSSAI, along with State and UT authorities, conducts continuous surveillance, inspections, and random sampling, taking penal action against violators. To improve compliance and create awareness, FSSAI launched the Food Safety Training and Certification (**FoSTaC**) programme, which includes a specialized course on "Street Food Vending." So far, over 3 lakh street vendors have been trained in food safety practices through this initiative.

Building on these efforts, FSSAI introduced the nationwide "Eat Right India" movement to transform the country's food ecosystem, awarding certificates to ensure hygiene and safety at food outlets. A key initiative under this is the Eat Right Street Food Hub certification programme, which educates and certifies clusters of street vendors while providing IEC materials to enhance visibility and consumer trust—405 hubs have been certified so far. To expand outreach in remote areas, Mobile Food Testing Laboratories (**MFTLs**) have been deployed across 35 States/UTs, offering on-the-spot food testing, training for food operators, and awareness campaigns for the public.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2154157

Medicinal Plants Board, Ministry of Ayush Signs Two Strategic MoUs to Strengthen Conservation and Public Awareness of Medicinal Plants

The National Medicinal Plants Board (**NMPB**), Ministry of Ayush, signed two key MoUs in New Delhi to advance medicinal plant conservation and public engagement, in the presence of Union Minister Shri Prataprao Jadhav. The first MoU, with IshVed-Bioplants Venture, Pune, focuses on conserving rare, endangered, and threatened (**RET**) medicinal plants through tissue culture methods, enhancing cultivation, supply, and value for the Ayush industry. The second tripartite MoU, with All India Institute of Ayurveda (**AIIA**) and AIIMS New Delhi, aims to establish a national medicinal plants garden at AIIMS to raise public awareness, educate patients and students, and promote knowledge-sharing among institutions. Both agreements underscore the Ministry of Ayush's commitment to integrating traditional knowledge with modern science, supporting evidence-based conservation, research, and broader public outreach in India's medicinal plant sector

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2152130

Luthra and Luthra
LAW OFFICES 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.

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

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