Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

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Pharmaceutical

LEGAL AND REGULATORY

DGTR Initiates Anti-Dumping Investigation on Imports of Bromo OTBN from China

The Directorate General of Trade Remedies (**DGTR**) has initiated an anti-dumping investigation on imports of *4-(Bromomethyl)-2'-cyanobiphenyl* (**Bromo OTBN**), an intermediate used in the manufacture of antihypertensive drugs such as Losartan and Telmisartan, originating from China.

The probe follows an application filed by Neogen Chemicals Ltd., alleging large-scale dumping of the chemical at unfairly low prices, causing material injury to the domestic industry through price suppression, reduced market share, and under-utilized capacity. The application was submitted in accordance with provisions of the Customs Tariff Act, 1975, and the Customs Tariff (Identification, Assessment and Collection of Anti-Dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995,

DGTR has noted that the goods produced domestically are identical in physical and chemical properties, manufacturing process, functions, and uses to those imported from China, and are treated as a "like article" for the purpose of this investigation.

Read More:
https://www.dgtr.gov.in/en/anti-dumping-cases/anti-dumping-investigation-concerning-imports-4-bromomethyl-2-cyanobiphenyl-also

Bangalore Raises Alarm to CCI Over Anti-Competitive, Non-Compliant Medicine Ads by Unregulated Online Pharmacies

The Bangalore District Chemists and Druggists Association (**BDCDA**) has called on the Competition Commission of India (**CCI**) against anti-competitive and non-compliant pharmaceutical advertising by unregulated online pharmacy platforms. According to BDCDA, these platforms use aggressive digital marketing through Facebook, Instagram, WhatsApp, and other mobile applications, misleading consumers and violating established pharmaceutical advertising norms.

BDCDA president warned that such practices bypass the role of licensed pharmacists, encourage irrational self-medication, accelerate antimicrobial resistance (**AMR**), and increase risks of counterfeit and habit-forming drug abuse. In its representation, BDCDA has urged CCI to initiate a detailed investigation into the functioning, algorithms, and pricing models of online pharmacies and Medplus, invoking the Competition Act, 2002.

Read More:
https://www.bdcda.in/navigation-single/222

CDSCO issues Public Notice for Mandatory Online Submission of Test Licence Applications

The Central Drugs Standard Control Organisation (**CDSCO**) has issued a public notice dated July 09, 2025 directing that all applications for clinical trial (Phase I, II, and III) for cell and gene therapeutics products shall be made through the online SUGAM portal system. The CDSCO has also provided user manual and video tutorial for filing of clinical trial applications on the portal which is now available on CDSCO website.

As a result of the aforesaid, CDSCO has informed that offline submissions of clinical trial applications will no longer be accepted after July 10, 2025.

Read More:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4OTc=

NPPA Notifies Retail Price of 71 Formulations

The National Pharmaceutical Pricing Authority (**NPPA**) has notified the retail prices of 71 formulations as per the Drugs Prices Control Order (**DPCO**), 2013. This includes retail prices for anti-cancer drug trastuzumab for Injection - each lyophilized vial containing trastuzumab (In House) (375 mg), a, a trehalose dihydrate Ph. Eur. (340.91mg), L-Histidine HCL monohydrate Ph. Eur. (8.44 mg), L-Histidine Ph. Eur. (5.45 mg), polysorbate 20 IP (1.53 mg) from Reliance Life Sciences at Rs 11,966.64 per vial, and antibacterial fixed dose combination (**FDC**) of ceftriaxone 2000 mg, disodium edetate 74 mg and sulbactam 1000 mg powder for solution for Infusion marketed by Tyykem Pvt Ltd at Rs. 1,036.6 per vial.

The NPPA also fixed a separate retail price of ₹6.96 per sachet (excluding GST) for GlaxoSmithKline (**GSK**) Asia's combination of paracetamol 500 mg and phenylephrine HCl 10 mg. The decision follows recommendations of the Multidisciplinary Committee (**MDC**) of experts in line with Para 11(3) of the Drugs (Prices Control) Order, 2013, which allows separate pricing for formulations not specified in Schedule I. GSK had sought a higher special price of ₹27 per sachet citing advantages such as faster solubility, disintegration, improved absorption, and better patient compliance, particularly for those with swallowing difficulties. The NPPA, in its 134th Authority meeting on June 26, 2025, accepted the MDC's recommendation and notified the retail price.

Read More:
https://nppa.gov.in/uploads/tender/75d29bebb2daf2afeba5135b6e42f8f5.pdf

https://nppa.gov.in/uploads/tender/b84c87bfcc4e6d6788482ab161474c08.pdf

GOVERNMENT INITIATIVES

Karnataka Signs 5-year MoU with Germany to Boost Lifesciences Start-ups and Innovation

Karnataka has signed a five-year memorandum of understanding (**MoU**) on July 09, 2025 with the German state of Bavaria to strengthen cooperation in lifesciences and technology. The agreement, inked by state minister M.B. Patil and Dr. Florian Herrmann of the Bavarian State Chancellery, covers biotechnology, medical technology, artificial intelligence, quantum technology, higher education, and skill development.

The collaboration includes co-funded biotech R&D grants, joint innovation hubs through Berlin and Bavaria partnerships, and initiatives in climate-friendly pharma manufacturing, precision medicine, AI-driven drug discovery, and bioprocessing. The MoU aims to enhance collaboration in biologics, biosimilars, medical devices, contract research and manufacturing, lab technology, clinical trials, data analytics, and green R&D. A Berlin office in Bengaluru will be launched in 2026 to further catalyse start-up support and deepen Karnataka's role as a hub for lifesciences and high-tech partnerships with Germany.

Read More:
https://www.pharmabiz.com/NewsDetails.aspx?aid=179022&sid=1

CDSCO Issues Guidance Document for Subject Expert Committees to Streamline Evaluation Process

CDSCO has released Version 1.0 of the Subject Expert Committees (**SECs**) Guidance Document dated July 17, 2025, providing a detailed framework for the functioning of SECs, their members, and applicant stakeholders in the review process. The document outlines the step-by-step procedures for scientific evaluation, voting mechanisms, and preparation of minutes to ensure transparency, fairness, and predictability in regulatory decision-making.

The guidelines emphasise rigorous risk–benefit assessment, consistency across therapeutic areas, and timely recommendations within seven working days. They require SECs to reach scientifically sound consensus decisions, with any conflicting views escalated to the Technical Committee for final resolution. Clinical trial waivers must be explicitly recorded as "Yes" or "No" with detailed justification in line with the New Drugs Clinical Trials Rules, 2019, and Medical Devices Rules, 2017.

The document also highlights SEC members' obligations to maintain confidentiality, declare conflicts of interest, keep abreast of scientific advances, and ensure deliberations remain limited to product safety, efficacy, and quality. CDSCO, acting as moderator, will ensure structured, balanced discussions and timely dissemination of final minutes to stakeholders.

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/SEC%20guidance%20document.pdf

Healthcare and Hospitals

LEGAL AND REGULATORY

NMC Releases Framework for Ethical Conduct of Live Surgeries

National Medical Commission (**NMC**) on July 26, 2025 issued new guidelines to regulate the conduct and broadcast of live surgeries in India (**Guidelines**). These Guidelines are issued in response to a petition filed before the Supreme Court in the case of Rahil Chaudhary and Others v. Union of India, which raised concerns about Live Surgical Broadcasts (**LSB**) conducted by private hospitals.

As per the Guidelines, sponsors and supervisors of live surgeries must have indemnity insurance coverage and the supervisors or their authorized team members must belong to the same specialty and be part of the operating team. Foreign Medical Practitioners (**FMPs**) are required to obtain temporary permission from the Ethics and Medical Registration Board (**EMRB**) or NMC, following the nomination of a specialty expert team for approval, and must also secure prior permission from the concerned State Medical Council, provided that, LSB should not be used for promotion of the operating surgeon, hospital or product brand. Only Registered Medical Practitioners (**RMPs**) or FMPs practicing modern medicine with at least 5 (five) years of experience after specialty certification are permitted to perform live surgeries.

Further, strict patient selection criteria have been prescribed, excluding high-risk cases, incomplete investigations, or unusual anatomical features. It should be noted that patients cannot receive financial incentives, though insurance coverage is allowed, and complications must be treated free of cost. Comprehensive informed consent is required, covering risks, anonymity, and withdrawal rights, while confidentiality and zero patient charges are emphasized. Surgeons must adhere to SOPs, manage post-operative care for at least 24 hours, and ensure that broadcasts serve only educational and not commercial purposes.

Read More:
https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Public%20Notice%20dt%2026-07-2025%20with%20Live%20Surgery%20Guidelines.pdf

MoHFW Circular on Discontinuation of the Term "Paramedical" and Adoption of "Allied and Healthcare"

Ministry of Health and Family Welfare (**MoHFW**) through the National Commission for Allied and Healthcare Professions (**NCAHP**), issued a circular dated July 1, 2025, directing the discontinuation of the term "Paramedical" in all official correspondence, policies, advertisements, training programmes, institutional titles, recruitment notifications, and educational materials.

This directive follows the enactment of the National Commission for Allied and Healthcare Professions Act, 2021 (**Act**), which formally adopted the term "Allied and Healthcare" to define, standardize, and recognize such professionals under a unified regulatory framework. Accordingly, all State Governments, Union Territories, universities, and institutions have been advised to replace the term "Paramedical" with "Allied and Healthcare" as defined in the Act.

Read More:
https://ncahp.abdm.gov.in/documents/Orderdt_01-07-2025.pdf

GOVERNMENT INITIATIVES

NMC Issues Compliance Directions to Medical Colleges for Maintenance of Authentic Patient Records

NMC released a public notice mandating all medical colleges to maintain authentic patient records linked to the Ayushman Bharat Health Account ID (**ABHA-ID**) for every patient registered in their associated hospitals. The notice requires that all inpatient records must include the name and signature of both the unit faculty and senior residents, and that all investigative reports require a faculty signature from the relevant department. The NMC has expressly warned that these requirements will be actively monitored during assessments, with the potential for strict action, including penalties against faculty and the institution if any fake records are detected. While ABHA-ID registration remains mandatory, medical colleges are directed not to deny treatment to patients lacking this ID.

Read More:
https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Public%20Notice%20dt%2026-07-2025.pdf

INVESTMENTS

Apollo Hospitals and Siemens Healthineers Collaborate to Strengthen Liver Healthcare Through AI

Apollo Hospitals and Siemens Healthineers have formalized a research collaboration to advance innovation in liver healthcare through artificial intelligence (**AI**) and imaging technologies. The initiative focuses on developing advanced diagnostic solutions to improve patient pathways in liver disease management, from early detection and risk stratification to monitoring intervention and therapy response. The collaboration builds on memorandum of understanding signed in 2024, followed by the Master Research Agreement (**MRA**) in March 2025. The recent signing of the MRA Addendum in Hyderabad on July 23, 2025, is reported to be a key milestone in strengthening the partnership's research in diagnostic and interventional ultrasound imaging.

The partnership brings together Apollo's clinical expertise and Siemens Healthineers' technological strengths, aiming to address the growing burden of Metabolic Dysfunction-Associated Steatotic Liver Disease (**MASLD**), earlier known as NAFLD, which affects 9% to 32% of India's population, particularly those with obesity and diabetes.

https://www.apollohospitals.com/corporate/apollo-in-the-news/apollo-hospitals-and-siemens-healthineers-join-hands-to-combat-liver-disease-in-india-by-pioneering-ai-and-imaging/

Med-Tech and Medical Devices

LEGAL AND REGULATORY

MoHFW Notice on Mandatory Medical Device Safety Monitoring Committees in Medical Institutions

The NMC issued a public notice on July 13, 2025, directing all medical colleges and institutions to establish a Medical Device related Adverse Event Committee (**MDAEC**) to monitor and address adverse events linked to medical devices. This initiative aligns with the Materiovigilance Programme of India (**MvPI**), launched in 2015 by the MoHFW to ensure patient safety through systematic reporting and analysis of medical device-related incidents. Medical institutions are further required to register their MDAECs with the Indian Pharmacopoeia Commission (**IPC**). The website of all medical institutions shall also indicate the name of the Coordinator/Convenor of the MDAEC and additional members with date of registration.

The notice also reminded the medical institutions to update the Pharmacovigilance Committee members' names on their websites by July 31, 2025.

Read More:
https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Public%20Notice%20dt%2013-07-2025.pdf

Department of Consumer Affairs Releases Draft Rules for Clinical Electrical Thermometers for Continuous Measurement

The Legal Metrology Division of the Department of Consumer Affairs vide notification dated 31 July 2025 issued the Draft Legal Metrology (General) Fourth Amendment Rules, 2025. These Draft Rules propose to insert Part XII in the Legal Metrology (General) Rules, 2011, specifically addressing technical and metrological requirements for Clinical Electrical Thermometers for Continuous Measurement.

The draft rules outline reference conditions, and measuring parameters, technical and metrological requirements, measurement ranges, and permissible errors, testing and conformity assessment procedures, labelling and marking requirements, such as manufacturer's identification, type/model, batch/serial number, and relevant units of measurement, among others to ensure compliance with prescribed standards. The draft is open for public consultation till August 30, 2025.

Read More:
https:///public/upload/admin/cmsfiles/whatsnews/Draft_Rules_for_Clinical_Electrical_Thermometers_for_Continuous_Measurement_-_comments_from_stakeholders__reg_whatsnews.pdf

Department of Consumer Affairs Releases Draft Rules for Non-Invasive Non-Automated Sphygmomanometers

The Legal Metrology Division of the Department of Consumer Affairs (Ministry of Consumer Affairs, Food & Public Distribution) has, via a notification on 31 July 2025, issued the Draft Legal Metrology (General) Fourth Amendment Rules, 2025 to set technical and safety standards for manual blood pressure monitors (Non-Invasive Non-Automated Sphygmomanometers). The draft is open for stakeholders' consultation till August 30, 2025.

The draft rules aims to amend the Legal Metrology (General) Rules, 2011 by replacing PART VII-A in the Eighth Schedule with detailed provisions for mechanical/manual blood pressure monitors. It defines the scope, terminology (including auscultatory method, cuff, manometer, rapid exhaust valve, tamper proofing), and technical setup of sphygmomanometers. Further, additional technical and construction specifications such as unit requirements structure of the cuff and pneumatic system, and tamper-proofing standards have been included in the draft.

Read More:
https://consumeraffairs.gov.in/public/upload/admin/cmsfiles/whatsnews/Draft_Rules_for_Non-Invasive_Non-Automated_Sphygmomanometers-_comments_from_stakeholders__reg_whatsnews.pdf

Cosmetics

LEGAL AND REGULATORY

The MoHFW issues notification amending Cosmetics Rules, 2020

The MoHFW has notified the Cosmetics (Amendment) Rules, 2025, introducing various clarifications and compliance requirements under the Cosmetics Rules, 2020. The amendment provides clarity on labelling by clarifying "use before" as the first day of the mentioned month and "date of expiry" as the last day of the month. It also designates the Central Drugs Laboratory as the Central Cosmetics Laboratory to function as the testing and appellate authority.

Further, licensees under the Cosmetics Rules, 2020 are now required to maintain batch and raw material testing records for three years or six months after expiry, whichever is later. A new provision also empowers the State Licensing Authority to suspend or cancel licences for non-compliance, with an appeal mechanism to the State Government.

For exports, cosmetic labels must comply with the importing country's laws, and in cases where manufacturer details cannot be disclosed, a code number approved by the State Licensing Authority may be used.

Read More:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI5ODY=

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.

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