



Luthra *and* Luthra
LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

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Pharmaceuticals

LEGAL AND REGULATORY

DGHS clarifies loan license requirement for outsourced sterilization under MDR; CDSCO seeks updated list of veterinary drug approvals

The Directorate General of Health Services (“**DGHS**”) on June 05, 2025 addressed concerns raised by stakeholders regarding the need for a loan license when outsourcing sterilization activities to another licensed facility under the Medical Device Rules, 2017 (“**MDR**”). The issue was discussed in the 61st Drugs Consultative Committee (“**DCC**”) meeting held earlier in 2023, where it was decided to constitute a sub-committee to examine the matter further.

The sub-committee recommended that a loan license is not required for outsourcing sterilization if the final product is released from the actual manufacturing site with complete quality checks. The sterilization must be done under a third-party agreement with a facility holding a valid MDR license for the specific device, and the sterilization site’s license number should appear on the product label. These recommendations were accepted in the 65th DCC meeting held on December 20, 2024, subject to submission of supporting documents to the licensing authority, and later endorsed by the 92nd Drugs Technical Advisory Board (“**DTAB**”) meeting on April 24, 2025.

Additionally, the Central Drugs Standard Control Organization (“**CDSCO**”) on June 24, 2025 requested all State Licensing Authorities (“**SLA**”) / the Food and Drug Administration to provide an updated list of approved drug products including antibiotics, Fixed Dose Combination (“**FDCs**”), and their premixes for veterinary use approved by their respective offices. Such information would be required for preparing a comprehensive list required by various national and international regulatory agencies including the EU regulation, World Organization of Animal Health (“**WOAH**”) and other ministries.

cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3OTk=

cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NDk=

CDSCO Issues Notice on the Development of a Structured Antimicrobial Use Reporting Framework

The veterinary division of the CDSCO, on June 05, 2025 issued a public notice to extend support for the development of a structured Antimicrobial Use (“**AMU**”) reporting framework which will



focus on systematic control of data related to the production, sale, and import of antibiotics and information on registered veterinary pharmaceutical companies, and other relevant stakeholders.

To facilitate the implementation of this initiative, the CDSCO proposed to constitute a joint working group which is proposed to serve as a collaborative mechanism to coordinate efforts, and streamline the process of AMU data collection, reporting, and monitoring on national level.

In this regard, the drugs controllers of all states and union territories were requested to nominate a nodal officer from their respective jurisdictions to act as the point of contact for all matters pertaining to AMU data collection and coordination with the joint working group. They were further requested to provide a list of veterinary pharmaceutical companies involved in the manufacturing, distribution, and sale of such antibiotics within their respective jurisdictions.

cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4MDA=

INVESTMENTS

CCI approves combination involving acquisition in Aakash Educational Services Limited by Manipal Health Systems Private Limited and Manipal Education and Medical Group India Private Limited

The Competition Commission of India (“**CCI**”), through a press release dated June 24, 2025 has approved a strategic combination involving the acquisition of Aakash Educational Services Limited (the **Target Company**) by Manipal Health Systems Private Limited and Manipal Education and Medical Group Private Limited (collectively, the **Acquirers**).

The transaction involves acquisition of equity shares from individual shareholder Mr. J. C. Chaudhry in the Target Company, a public unlisted company incorporated under the Companies Act 1956.

The Target Company operates as a leader of educational service providers, offering coaching exercises across multiple academic levels including preparatory coaching for competitive examinations, scholarship tests, and entrance examinations. It provides educational services through diversified delivery modes including classroom-based coaching, online learning platforms, distance learning and hybrid learning programs, covering academic support for classes 8-12 with a specialized focus on science stream preparations.

Both acquiring entities are Indian registered companies, owned and controlled by resident Indians. Manipal Health Systems operates in hospital management and healthcare services delivery, while Manipal Education and Medical Group functions under the Manipal umbrella, potentially creating synergies between medical education and healthcare delivery segments.



The detailed order from the CCI regarding the terms and conditions of the transaction is awaited.

<https://www.cci.gov.in/search-filter-details/7118>

Med-tech, Hospitals and Healthcare

LEGAL AND REGULATORY

CDSCO mandates online submission of WHO COPP applications through ONDLS portal

The CDSCO on June 25, 2025, announced a significant regulatory facilitation regarding the issuance of the World Health Organization (“**WHO**”) Certificate of Pharmaceutical Product (“**COPP**”), which is to be submitted exclusively through the Online National Drug Licensing System (“**ONDLS**”) portal.

In this regard, all the manufacturing units have been directed to submit their applications for WHO Good Manufacturing Practices (“**GMP**”) COPP through ONDLS portal from July 15, 2025 and physical applications will not be entertained from the said date. The step wise procedure for registration with ONDLS is annexed to the circular. This is aimed at increasing efficiency, traceability, and ease of access while maintaining compliance with WHO norms.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI4NTA=

West Bengal Assembly passes bill to regulate private healthcare costs

The West Bengal Legislative Assembly on June 17, 2025 passed the Clinical Establishments (Registration, Regulation, and Transparency) (Amendment) Bill, 2025 (the “**Bill**”) to control treatment costs in private medical facilities and protect patients from inflated or hidden charges. The Bill states that “every clinical establishment must strictly follow fixed rates and charges including the package rates for investigation, bed charges, operation theatre procedures”. It mandates adherence to fixed and package rates, advance estimates for treatments outside these packages, and regular communication of updated charges every 24 hours. The bill further states that the final invoice amount cannot exceed estimates beyond a state-specified margin.

The Bill also introduces mandatory electronic medical records, including e-prescriptions and detailed discharge summaries, to be maintained and shared with the government when required. The Bill is now awaiting the Governor’s assent, after which it will be officially implemented across the state of West Bengal.

<https://www.thehindu.com/news/national/west-bengal/west-bengal-assembly-passes-bill-on-transparency-in-medical-costs-in-private-facilities/article69705713.ece>



GOVERNMENT INITIATIVES

DoP issues modifications to the operational guidelines of sub-scheme “Capacity Building and Skill Development for Medical Devices” under the scheme “Strengthening of Medical Device Industry”

The Department of Pharmaceuticals (“DoP”), under the Ministry of Chemicals and Fertilizers, issued an amendment on June 9, 2025, modifying the provisions of the sub-scheme “Capacity Building and Skill Development for Medical Devices,” which falls under the larger “Strengthening of Medical Device Industry” scheme introduced on November 8, 2024. Major changes include reimbursement of 75% of the course cost, up to INR 21 crores, “as and when expenditure is incurred,” allowing for phased reimbursements.

Further amendments include revisions to clause 4.3.2, which originally allowed financial support for diploma and skill development students through trainee institutes, now specifying that such support will be reimbursed quarterly. Clause 4.6, which required refunding grants if programs were discontinued or if conditions were violated, now clarifies that non-recurring expenses already incurred and claimed will not need to be refunded. Lastly, clause 4.10, which previously allowed withdrawal of support if student admissions were below 50%, is revised to state that support will be withdrawn if admissions fall below 30% of the approved annual intake in the first year or below 50% in the second or third year, as per the DoP’s final approval.

[Corrigendum dated 9.6.2025.pdf](#)

INVESTMENTS

IIT Delhi and AIIMS signed MoU to establish Centre of Excellence to promote research using AI to find solutions in healthcare

The Indian Institute of Technology (“IIT”) Delhi signed a memorandum of understanding (“MoU”) with the All India Institute of Medical Sciences (“AIIMS”) to establish a Centre of Excellence (“CoE”) to research artificial intelligence solutions in healthcare. The institutes were awarded a grant of INR 330 crore by the Ministry of Education under its ‘Make AI in India, Make AI Work for India’ initiative.

This partnership has the potential to use AI adequately and promote affordable healthcare and support other key national health programs. The forementioned CoE will look at a minimum of five national health programs for cancer, maternity, childcare, blindness, and tuberculosis among others.

https://www.business-standard.com/health/iit-delhi-aiims-launch-ai-centre-of-excellence-for-healthcare-125060400872_1.html



Other Relevant Sectors

LEGAL AND REGULATORY

FSSAI issues draft notification on standards for cheese powder

The Food Safety and Standards Authority of India (“**FSSAI**”), under the Ministry of Health and Family Welfare, Government of India, issued a draft notification dated June 4, 2025, proposing amendments to the Food Products Standards and Food Additives Regulations, 2011. The draft introduces a specific standard for cheese powder, which is to be incorporated under a new sub-regulation (2.1.17(a)). The proposed standard defines cheese powder as “dried product obtained from cheese or cheese slurry, made by blending cheese with potable water, milk, cream, or butter oil.” The said rules clarify that the said ‘product’ should be white, white with a greenish tinge, or light cream in colour, and must be free from lumps (except those that easily break under slight pressure) and scorched particles.

Additionally, the draft rules mandate that cheese powder must comply with existing standards as per Appendix B and the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011. The manufacturing, processing, and handling of the product must adhere to hygienic practices outlined in Schedule 4 of the Licensing and Registration of Food Businesses Regulations, 2011. Labelling requirements must comply with the Food Safety and Standards (Labelling and Display) Regulations, 2020.

To facilitate stakeholder participation, FSSAI has invited objections and suggestions from the public, which must be submitted within 60 days from the date of publication in the Official Gazette.

https://www.fssai.gov.in/upload/uploadfiles/files/Notification%20dt%2004_06_2025-Cheese%20powder%20draft.pdf

FSSAI notifies First Amendment to Alcoholic Beverages Regulations, 2025

FSSAI vide notification dated June 20, 2025, effective from January 1, 2026 has issued the First Amendment to the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018 (**Amendment**). A key addition is the definition and applicable standards for “alcoholic ready-to-drink beverages,” which are flavored drinks with 0.5% to 15% alcohol, made from spirits or their blends, with permitted additives, and may be carbonated.

The Amendment also revises the classification of Indian liquors into plain and blended types, and introduces honey wine or mead as a new category with 4% to 15.5% alcohol. Further, “Nitro Craft Beer,” containing both CO₂ and N₂, has also been added under the purview of the said rules.

<https://www.fssai.gov.in/upload/notifications/2025/06/685a81f260140Food%20Safety%20and%20Standards%20Alcoholic%20Beverages%20First%20Amendment%20Regulations%202025.pdf>



The Central Consumer Protection Authority issues advisory to e-commerce platforms on “dark patterns”

The Central Consumer Protection Authority (“**CCPA**”), under the Ministry of Consumer Affairs, Food & Public Distribution, issued an advisory on June 7, 2025, directing all e-commerce platforms to conduct self-audits within three months to identify and remove “dark patterns” from their interfaces. These dark patterns are deceptive design practices that mislead or manipulate consumers into making unintended choices.

As per the CCPA advisory, platforms are also encouraged to submit self-declarations affirming that they are not engaging in any such misleading practices. As per the Press Information Bureau, notices have already been issued to several platforms found violating the norms. This move of the CCPA aligns with the Guidelines for Prevention and Regulation of Dark Patterns, 2023, which define 13 specific dark patterns such as false urgency, drip pricing, disguised advertisements, subscription traps, and interface interference among others. To monitor implementation and compliance, a joint working group comprising officials from various ministries, regulators, consumer organizations, and national law universities has also been constituted.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2134765>



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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