Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

MAY 2025 EDITION

Pharmaceuticals

LEGAL AND REGULATORY

The MoHFW introduces key amendments to the Drugs Rules, 1945 to Ease Compliance and Enhance Quality Oversight in Pharma Sector

Government of India through the Ministry of Health and Family Welfare ("**MoHFW**"), issued a draft notification (G.S.R. 345(E)) on 28th May, 2025, proposing amendments to the Drugs Rules, 1945, under the Drugs and Cosmetics Act, 1940. Key amendments include (i) mandatory bacterial endotoxins or pyrogens testing (as per the latest Indian Pharmacopoeia) for drugs administered directly into the body, such as injections; (ii) Forms 20B, 20G, and 21B will now require drug sales to be personally supervised by a competent person, with any changes in the competent person to be reported to the licensing authority within a month; (iii) The general exemption allowing drug sales to non-medicinal manufacturers (like beverage or confectionery producers) is removed; such sales will now only be permitted for antimicrobial drugs used in processing; and (iv) Drugs under Serial No. 15 of Schedule K are proposed to be excluded from Schedule H. The said draft rules are open to public comments for a period of 30 days from the date of publication and the comments, if any shall be taken into consideration after expiry of 30 days.

Link:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3Nzg=

CDSCO Issues Guidance Document on Safe Disposal of Expired/Unused Medicines

The Central Drugs Standard Control Organisation ("**CDSCO**") on 26th May, 2025, released a detailed guidance document (WI/01/DCC-P-25) titled "Guidance Document On Disposal Of Expired/ Unused Drugs" to help ensure that expired or unused medicines are disposed of safely and responsibly protecting both public health, animal health and the environment. The note outlines recommended disposal methods such as landfill, encapsulation, inertization, sewer disposal, and both medium and high-temperature incineration. It details specific procedures for retailers, distributors, manufacturers, and hospitals for proper drug disposal. Expired or unused medicines must be stored separately in appropriate areas, and transport vehicles must comply with the Motor Vehicles Act, 1988, along with environmental guidelines. To raise public awareness, states may establish "Drug Take Back" systems under the Biomedical Waste Management Rules, 2016, and share a list of medicines (e.g., Diazepam, Oxycodone, Fentanyl) that should be flushed for safety.

Link: Guidance document on disposal.pdf

CDSCO Issues Clarification on Labelling Permissions under Rule 104A for Imported Drugs

The CDSCO issued an Office Memorandum on May 26, 2025, clarifying the process for overprinting, stickering, or stamping of imported drug products under Rule 104A of the Drugs and Cosmetics Rules, 1945. This is in continuation of an earlier circular dated 29 January 2020. It states that:

- The permission for label overprinting/stickering under Rule 104A strictly applies only to imported drugs. This rule cannot be used for labelling activities related to domestically manufactured drugs.
- Only licensed importers holding a valid manufacturing license in their own name are authorised to carry out these labelling modifications.
- Importers must ensure they have adequate infrastructure, including proper storage facilities, labelling areas, and must appoint at least one manufacturing and quality assurance (QA) personnel to the satisfaction of the State Licensing Authority (SLA). Quality control (QC) labs and personnel are not mandatory for this specific labelling activity.
- Any changes made to the label must comply with the Drugs and Cosmetics Rules, and must not obscure the original label. Additionally, the license number and a clear statement describing the nature of the overprinting or stickering activity must be mentioned next to the new information.

Link:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI3NTE=

GOVERNMENT INITIATIVES

Unlicensed Veterinary Drug Factory Busted in Telangana; Rs 3 Lakh Worth of stock Seized

On May 28, 2025, Telangana's Drugs Control Administration, in collaboration with the CDSCO, Hyderabad Zone, uncovered unlicensed manufacturing of veterinary drugs from Siflon Drugs and Pharmaceuticals Ltd., Unit-I, at ALEAP Industrial Estate in Medchal, Malkajgiri District. Acting on a tip-off, officials discovered large quantities of drugs (537 kg of Albendazole Tablets 250mg (Bolus) and 986 kg of Albendazole Granules (Veterinary)) being produced without the necessary drug manufacturing license. Valued at Rs 3 lakhs, the seized stock was sent for chemical analysis. Manufacturing of drugs without a valid license is a cognizable offence under the Drugs and Cosmetics Act, 1940 and the offence is punishable with imprisonment of up to 5 years.

Press Note: https://dca.telangana.gov.in/openfile.php?f=360

INVESTMENTS

Piramal Pharma to Invest $90 Million In US Site Expansions

Piramal Pharma is investing $90 million to expand its manufacturing facilities in the U.S., focusing on its sites in Lexington, Kentucky, and Riverview, Michigan. This move helps meet rising demand from U.S. customers and supports the push for onshoring drug supply.

In Lexington, the company is adding 24,000 sq ft of space, a new laboratory, and commercial-scale production for injectable drugs. The upgrade includes a new filling line, lyophilizers, and advanced equipment, with operations set to begin by late 2027. Meanwhile, the Riverview facility is gearing up to enhance production of payload-linkers, essential for antibody-drug conjugates and other therapies, aiming to be ready by end of 2025.

Piramal is funding the expansion through bank loans and internal accruals for cost efficiency. This move coincides with U.S. President Donald Trump's initiative to lower prescription drug costs.

Link:
https://www.ndtvprofit.com/business/piramal-pharma-to-invest-90-million-in-us-site-expansions

Med-tech, Hospitals, and Healthcare

LEGAL AND REGULATORY

Extension Granted for Submission of Self-Declaration and Marketing Expenditure Details under UCMPMD

Government of India under the Department of Pharmaceuticals and through the Ministry of Chemicals and Fertilizers, has issued a circular dated 28 May 2025, extending the deadline for submission of self-declaration and disclosure of marketing expenditure under the Uniform Code for Marketing Practices in Medical Devices, 2024 (**UCMPMD**). As per Clause 14.3 of UCMPMD 2024, all concerned stakeholders, particularly medical device companies, were required to submit a declaration regarding their marketing practices and expenditure within 2 months from the end of financial year. The new deadline for submission is 31 July 2025, allowing additional time for compliance and documentation. Stakeholders are advised to ensure that the requisite self-declarations and marketing disclosures are submitted to the appropriate authority by the revised date.

Link:
Letter-dated-28.5.2025.pdf

GOVERNMENT INITIATIVES

CDSCO Proposes Ban on Antimicrobial Formulations for Animal Use in Public Interest

Government of India through the Ministry of Health and Family Welfare, issued a draft notification on 22 May 2025 proposing to prohibit the import, manufacture, sale, and distribution of specified antimicrobial drugs and their formulations for use in animals, under Section 26A of the Drugs and Cosmetics Act, 1940. The Government, in consultation with the Drugs Technical Advisory Board, is of the view that the use of certain antimicrobials in animals poses a risk to human health, particularly by contributing to antimicrobial resistance. The notification clarifies that safer alternatives are available for veterinary use, making the restriction necessary and justified in public interest. Stakeholders and the general public may submit objections or suggestions within 30 days of the Gazette publication to the Under Secretary (Drugs), Ministry of Health & Family Welfare.

Link:
https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/2025.05.22_S.O.%202298(E)_Notification%20to%20prohibit%20the%20imporfor%20animal%20use.pdf

INVESTMENTS

Sun Pharma to Invest $100 Million in Commercialising Innovative Drugs in FY25

Sun Pharmaceutical Industries has announced a $100 million investment for FY25 to commercialise new speciality products, strengthening its patented drug portfolio. Sun Pharma is putting more focus on specialty medicines, especially in the United States. After a solid year of growth, the company is now launching new drugs like Leqselvi for hair loss (alopecia areata) and Unloxcyt for a type of skin cancer. These new treatments show Sun Pharma's move towards more advanced, targeted medicines. While the company's revenue continues to grow, its net profit dropped slightly, reportedly due to one-time investment losses. With these steps, Sun Pharma is working to become a major global player in specialty medicines, especially in the United States.

Link:
https://www.livemint.com/companies/sun-pharma-q4-fy25-results-earnings-fy26-specialty-products-growth-dilip-shanghvi-11747925063970.html

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sun-pharma-lines-up-usd-100-mn-to-commercialise-niche-products-this-fiscal/articleshow/121546015.cms?from=mdr

Lupin Partners with SteinCares to Expand Access to Eye Disease Biosimilar in Latin America

Lupin has entered into a licensing and supply agreement with SteinCares to commercialize its biosimilar ranibizumab across Latin America, excluding Mexico and Argentina. Under the deal, Lupin will manufacture the drug, while SteinCares will manage regulatory approvals and distribution. Ranibizumab, a biosimilar to Roche's Lucentis, is used to treat retinal disorders such as neovascular (wet) age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. Lupin has been marketing the biosimilar in India under the brand name RaniEyes since 2022. This collaboration will enhance access to advanced retinal therapies in the target region and is expected to improve access to an important treatment option while reducing healthcare costs for both patients and institutions in Latin America.

Link:
https://steincares.com/ranibizumab-biosimilar-latin america/#:~:text=Mumbai%2C%20Costa%20Rica%2C%20May%2026,Latin%20America%20excluding%20Mexico%20and

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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