Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

FEBRUARY 2025 EDITION

Pharmaceuticals

LEGAL AND REGULATORY

The Ministry of Health and Family Welfare Notifies the Drug Amendment Rules 2025

The Ministry of Health and Family Welfare (**MoHFW**), on 11 February 2025, released the Drugs Amendment Rules, 2025. The said rules extend the deadline for implementing the revised Good Manufacturing Practices (**GMP**) under Schedule M of Drugs Rules, 1945, for small and medium drug manufacturers to December 31, 2025. The previous deadline was 28 December 2024. The rules have also provided Form A, which is the application for seeking extension for compliance with the revised Good Manufacturing Practice, under Schedule M. This form must be submitted within 3 months from 11 February 2025 to the Central Licensing Authority. This extension serves as a relaxation for small and medium drug manufacturers by providing them with adequate time to ensure compliance with the revised GMP.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI1MTk=

GOVERNMENT INITIATIVES

The MoHFW Launches the Annual Nationwide Mass Drug Administration Campaign for Lymphatic Filariasis Elimination

On 10 February 2025, the MoHFW launched the Annual Nationwide Mass Drug Administration (**MDA**) Campaign for Lymphatic Filariasis Elimination. The campaign focuses on the door-to-door administration of anti-filarial medication, ensuring that every eligible individual is administered the prescribed medicine to stop the spread of the disease. Lymphatic Filariasis is a parasitic disease transmitted by infected mosquitoes which can lead to physical disabilities such as swelling of the limbs and scrotal swelling. The MDA campaign will cover 111 endemic districts across 13 states: Andhra Pradesh, Assam, Bihar, Chhattisgarh, Gujarat, Jharkhand, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Odisha, Uttar Pradesh, and West Bengal.

https://pib.gov.in/PressReleasePage.aspx?PRID=2101250

INVESTMENTS

Go Digit General Insurance Ltd. Acquires a Stake in Dr. Reddy's Laboratories Ltd.

Go Digit General Insurance Ltd. acquired a 0.32% stake in the pharmaceutical company, Dr. Reddy's Laboratories Ltd. through a cash infusion of Rs. 30.06 crore. Go Digit General Insurance Ltd. is an insurance provider offering vehicle insurance, travel insurance and home insurance. Dr. Reddy's Laboratories Ltd. is a leading multinational pharmaceutical company based in India

that manufactures and markets a wide range of pharmaceuticals. The investment made by Go Digit General Insurance Ltd. in this pharmaceutical company aligns with a broader trend of insurance firms diversifying their services and expanding into the healthcare sector.

https://www.bseindia.com/xml-data/corpfiling/AttachLive/50284655-3072-4de9-aa5c-35ca44923145.pdf

Med-Tech

LEGAL AND REGULATORY

The Ministry of Consumer Affairs Issues the Draft Legal Metrology (Packaged Commodities) Amendment Rules, 2025

On February 10, 2025, the Ministry of Consumer Affairs published the draft of Legal Metrology (Packaged Commodities) Amendment Rules, 2025. The aim of these proposed amendments is to implement provisions regarding the packaging and labelling of medical devices, in consonance with the Medical Devices Rules, 2017. It shall be noted that the proposed amendment provides relief to the medical device companies from following provisions regarding principal display panel under the Legal Metrology (Packaged Commodities) Rules, 2011. Principal display panel refers to the surface area on a packaged commodity where the information as required under the Legal Metrology (Packaged Commodities) Rules, 2011 are displayed.

https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/Draft%20Amendment%20in%20PCR%20-%20medical%20device.pdf

Health-Tech, Hospitals, Healthcare

GOVERNMENT INITIATIVES

Ministry of Ayush Launches “Shatavari– For Better Health” Campaign

In efforts to raise awareness about the health benefits of medicinal plants, a species-specific campaign titled “Shatavari– For Better Health” was launched by Ministry of Ayush in February 2025. Shatavari, is known for its numerous health benefits, particularly in supporting women’s health and enhancing immunity. Through this campaign, the plant is hoped to receive focused attention, ensuring that the benefits of Shatavari reaches wider audiences across the nation. The campaign marks another step in the Ministry of Ayush’s continued efforts to promote traditional medicine and medicinal plants in India.

https://pib.gov.in/PressReleasePage.aspx?PRID=2100345

MoU between Ministry of Ayush and DoSJE to Promote Geriatric Healthcare and Combat Substance Abuse

On 12 February, 2025, the Ministry of Ayush and the Department of Social Justice and Empowerment (**DoSJE**) signed a Memorandum of Understanding (**MoU**) in New Delhi. The aim of the MoU is to implement Ayush-based interventions to promote geriatric healthcare and tackle substance abuse. The MoU would enable the Ministry of Ayush and DoSJE to foster innovative initiatives for promoting the health of senior citizens, reducing the demand for drugs, addressing substance abuse, and aiding mental rehabilitation. Moreover, the MoU aims to enable research on the therapeutic benefits of traditional healthcare practices in improving geriatric health, mental health and for preventing substance abuse.

https://pib.gov.in/PressReleasePage.aspx?PRID=2102271

Ministry of Health & Family Welfare Launches an Intensified Special Non-Communicable Diseases Screening Campaign

In order to mitigate the burden of non-communicable diseases (**NCDs**) in India, the MoHFW launched an Intensified Special NCD Screening Campaign. The campaign is expected to operate from 20 February 2025 to 31 March 2025, to conduct 100% screening of individuals aged 30 years and above for prevalent NCDs, such as diabetes, hypertension, and common cancers. The campaign will take place across Ayushman Arogya Mandirs (**AAMs**) and various healthcare facilities nationwide, under the National Programme for Prevention and Control of Non-Communicable Diseases (**NP-NCD**). Through this campaign, frontline workers will conduct community visits to ensure maximum screening coverage. Data on screening, treatment, and follow-ups will be uploaded on the NP-NCD Portal on a daily basis. States and union territories will also provide updates to the MoHFW by 6 PM daily, in order to enable continuous monitoring and technical support.

https://pib.gov.in/PressReleasePage.aspx?PRID=2104884

INVESTMENTS

Avendus Future Leaders Fund Acquires a Stake in La Renon Healthcare Pvt. Ltd.

Avendus Future Leaders Fund (FLF), has acquired a minority stake worth INR 160 crore in La Renon Healthcare Private Limited. This transaction marks FLF's first investment in its newly launched Future Leaders Fund III. La Renon Healthcare is a pharmaceutical company based in Ahmedabad that caters majorly to Nephrology, Neurological Disorders, Critical Care, Gynaecology, Ortho, Gastroenterology, Urology, Respiratory and Cardio Metabolic. Avendus Future Leaders Fund is a private strategies fund of the Avendus Group. Through this transaction the Avendus Group has diversified into the healthcare and life sciences space.

https://www.avendus.com/india/newsroom/avendus-future-leaders-fund-iii-makes-maiden-investment-in-la-renon-healthcare

11 Companies Invest in Green Pharma City Project at BioAsia 2025 in Telangana

BioAsia 2025 is a life sciences and health-tech event hosted by the Government of Telangana which unites global leaders across the life sciences sector to nurture cross-border collaborations and the adoption of cutting-edge technologies which are revolutionising healthcare delivery on a global scale. During this event, the Telangana government announced investments of INR 5,445 Crore by 11 companies in its Green Pharma City project. The Green Pharma City project is a large-scale industrial initiative aimed at creating a dedicated pharmaceutical manufacturing hub near Hyderabad. The investments received by these 11 companies will aid in funding the project and promoting the healthcare sector in the state.

https://www.telangana.gov.in/news/news-and-press-releases/2025/02/cm-sri-a-revanth-reddy-minister-sri-d-sridhar-babu-inaugurate-bioasia-2025-at-hicc-hyderabad/

Other Important Updates

LEGAL AND REGULATORY

FSSAI Issues Draft Food Safety and Standards (Labelling and Display) Amendment Regulations, 2025

The Food Safety and Standards Authority of India (**FSSAI**) notified the draft of Food Safety and Standards (Labelling and Display) Amendment Regulations, 2025 on 17 February 2025. The draft regulations require packaged foods to provide information regarding per serve percentage (%) contribution to Recommended Dietary Allowance (**RDA**) in bold letters with relatively increased font size for added sugar, saturated fat and sodium content. Moreover, all milk and milk-based products would be required to contain a milk logo on the packaging as per the design specifications in the draft regulations. Lastly, coffee-chicory mixtures would have to depict the percentage of coffee and chicory content on the front of the package, in capital letters within a rectangular box on the principal display panel.

https://fssai.gov.in/upload/uploadfiles/files/Draft%20FSS_Labelling%20and%20Display_Amendment%20Regulations_2025.pdf

FSSAI Issues Draft Food Safety and Standards (Laboratory and Sample Analysis) Amendment Regulations, 2025

The FSSAI notified the draft of Food Safety and Standards (Laboratory and Sample Analysis) Amendment Regulations, 2025. Some of the key changes introduced by the draft regulations

are strict deadlines for food testing and adoption of internationally recognised methods if FSSAI manuals do not contain the specific protocols. Food analysis reports must be submitted within 14 days of receiving the sample for analysis and detailed reasons must be given to the designated officer and the commissioner in case of any delays. The draft regulations note that the manuals of the method of analysis adopted by the FSSAI shall be used for analysing the samples of food articles. However, in case the method for analysing any parameter is not available in these manuals, the food laboratory would be allowed to adopt a validated method of analysis prescribed by "AOAC/ ISO / Pearson's/ Jacob/ IUPAC/ Food Chemicals CODEX/ BIS/ Codex Alimentarius/ Woodmen/ Winton-Winton/ Joslyn" or any other internationally recognised regulatory agencies.

https://fssai.gov.in/upload/uploadfiles/files/Draft%20FSS_Laboratory%20and%20Sampling%20Analysis_Amendment%20Regulations_2025.pdf

FSSAI Issues Draft Food Safety and Standards (Vegan Foods) Amendment Regulations, 2025

The FSSAI notified the draft of Food Safety and Standards (Vegan Foods) Amendment Regulations, introducing changes regarding vegan food compliance. The draft regulations mandate vegan food imports to have a certificate from the exporting country's recognised authority, as per the form annexed in the draft rules. The form requires the exporting country's recognised authority to provide details and declarations regarding the products. Some of these declarations are aimed to ensure that the products have not been involved in any animal testing for any purpose including safety evaluation, unless provided by any regulatory authority; the stages of production, processing, and distribution of the food products are in conformity with Good Manufacturing Practices; and the storage and production line of vegan and non-vegan raw is separate.

https://fssai.gov.in/upload/uploadfiles/files/Draft%20FSS_Vegan%20Foods_Amendment%20Reg_2025.pdf

The Ministry of Environment, Forest and Climate Change Notifies the Battery Waste Management Amendment Rules, 2025

The Ministry of Environment, Forest and Climate Change (**MoEFCC**) notified the Battery Waste Management Amendment Rules, 2025 on 24 February 2025. The purpose of the amended rules is to regulate battery waste by promoting collection, recycling, and disposal of such wastes. The rules require the producers of batteries to print a barcode or Quick Response (**QR**) code containing the Extended Producer Responsibility registration number on:

- battery or battery pack; or
- equipment having battery or battery pack; or
- packaging of battery or battery pack; or
- packaging of the equipment having battery or battery pack; or
- bulk packaging of batteries or battery packs, not for retail sale;

Moreover, the Extended Producer Registration number must be printed on the product information brochure. Further, the rules note that marking of hazardous substances like cadmium and lead found in batteries is not required if the metal concentration of cadmium and lead in the battery is less than or equal to 0.002% (20 parts per million) and 0.004% (40 parts per million) by weight, respectively.

https://moef.gov.in/uploads/pdf-uploads/pdf_67c141239b5a22.27180537.pdf

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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