Luthra and Luthra

LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

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PHARMACEUTICALS

LEGAL AND REGULATORY

NPPA Revises Ceiling Prices of Scheduled Formulations under NLEM

The National Pharmaceutical Pricing Authority (**NPPA**), on 26 March 2025, issued an Office Memorandum to revise the Wholesale Price Index (**WPI**) by +1.74028%. Consequently, on 27 March 2025, the NPPA revised the ceiling price of 748 scheduled formulations under the National List of Essential Medicines (**NLEM**). The purpose of the NLEM is to ensure that the medicines in the list are available at affordable prices so the larger public has access to them. Moreover, on the same day, the NPPA further revised the ceiling price of 152 scheduled formulations under the NLEM. Thus, the NPPA has increased the prices of more than 900 scheduled formulations by 1.74028%. As a result, drug manufacturers may also increase the maximum retail prices of these medicines based on this WPI without the prior approval of the Government.

Office Memorandum [F. NO. 8(131)/2025/DP/NPPA/DIV.II]:
https://www.nppaindia.nic.in/uploads/tender/28410c5da1d6bd5e48e9816ba26096c7.pdf

Order no. S.O. 1489(E):
https://www.nppaindia.nic.in/uploads/tender/83cfb8c85fc0ceeae3ca5063d1c2c763.pdf

Order no. S.O. 1487(E):
https://www.nppaindia.nic.in/uploads/tender/7e147593c7ef922a1ecb4c6bea03fa9e.pdf

Central Drugs Standard Control Organization Issues NSQ Drugs and Spurious Drugs Alert for February, 2025

On 29 March 2025, the Central Drugs Standard Control Organisation (**CDSCO**) issued the 'not of standard quality' (**NSQ**) drugs and spurious drugs list for the month of February 2025. In the alert list issued for February, the CDSCO classified 103 drugs and formulations as NSQ. Popular medicines like Azithromycin Oral Suspension I.P., Amoxycillin & Clavulanate Potassium for Oral Suspension I.P., Paracetamol & Serratiopeptidase Tablets, Levocetirizine Dihydrochloride Tablets IP, and many more failed to meet the quality standards. Moreover, in the spurious drugs list, the CDSCO classified Telma H as a spurious drug. Spurious drugs are falsified or counterfeit medicines made to resemble a drug from another drug company, usually a popular one, in order to deceive the public by exploiting the popularity of the original product. Some of the medicines in the lists are prescribed to treat common conditions like bacterial infections, headaches, allergies, and hypertension. The NSQ drugs list and spurious drugs list are published on the CDSCO website to raise public awareness so the consumers can avoid buying such drugs.

Central NSQ Alert:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTM=

State NSQ Alert:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTQ=

Spurious Drugs Alert:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2MTI=

INVESTOR NEWS

Sun Pharmaceutical Industries Ltd. Acquires Checkpoint Therapeutics, Inc.

Sun Pharmaceutical Industries Ltd., a specialty generics company headquartered in Mumbai, has entered into an agreement to acquire Checkpoint Therapeutics Inc., a U.S. company that focuses on immunotherapy and targeted oncology. The proposed transaction is worth $355 million and is expected to be completed in the second quarter of 2025. As per the agreement, Sun Pharmaceutical Industries Ltd. will acquire all outstanding shares of Checkpoint Therapeutics Inc., and Checkpoint Therapeutics Inc.'s stockholders will receive interest-free cash payments equivalent to $4.10 per share. The deal will further expand Sun Pharmaceutical Industries Ltd. oncology portfolio and consolidate its position as a leading global pharma franchise.

https://sunpharma.com/wp-content/uploads/2025/03/SEIntimationAcquisitionCheckpointFinal.pdf

HEALTH-TECH, HOSPITALS, HEALTHCARE

LEGAL AND REGULATORY

CDSCO Introduces Online Registration Mandate for Clinical Research Organizations

The Ministry of Health and Family Welfare (**MoHFW**) issued the New Drugs and Clinical Trials (Amendment) Rules, 2024 on 19 September, 2024. These rules require Clinical Research Organizations (**CRO**) to compulsorily register with the Central Licensing Authority before conducting clinical trials or bioavailability/bioequivalence studies. In compliance with the same, on 4 March, 2025, CDSCO issued a public notice introducing online registration for CROs on the SUGAM portal. Starting from April 1, 2025, all CROs will be required to complete their online registration by paying a registration fee of Rs. 5 lakh. This initiative aims to streamline the process of CRO registration by improving regulatory oversight and ensuring that only compliant organizations operate in the clinical research field.

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/CRO%20registration.pdf

ICMR Publishes Addendum to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

The Indian Council of Medical Research (**ICMR**) has published an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. This initiative aims to ensure ethical rigour and regulatory compliance in research that explores the integration of traditional and modern medical practices. The addendum introduces the following key measures:

- Ethics Committees overseeing such research must now include two AYUSH subject-matter experts, with at least one being external to the institution
- Informed consent standards have been strengthened, requiring that research participants receive clear, tailored information about Integrative Medicine interventions
- Research involving non-codified traditional medicines must follow the entire prescribed regulatory approval processes as per applicable rules/regulations/guidelines

https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1740984016_icmraddendumethicalrequirementsforresearchinintegrativemedicine.pdf

GOVERNMENT INITIATIVES

MoHFW Issues National Guidelines on Medical Oxygen Management

The MoHFW issued the National Guidelines on Medical Oxygen Management at a workshop held at the All India Institute of Medical Sciences (**AIIMS**), Delhi, on 27 March, 2025. The introduction of the National Guidelines on Medical Oxygen Management, represents a major advancement in enhancing the country's medical oxygen infrastructure and standardizing best practices across healthcare facilities. These detailed guidelines offer a framework for the efficient procurement, storage, and administration of medical oxygen, thus, emphasizing patient safety, capacity building, and emergency preparedness.

https://pib.gov.in/PressReleasePage.aspx?PRID=2115648

INVESTOR NEWS

Everhope Oncology Pvt. Ltd. Secures Investment of USD 10 Million

Narayana Hrudayalaya Ltd., in partnership with W Health Ventures GP LLC and 2070 Health Inc., has launched Everhope Oncology Pvt. Ltd., a joint venture focused on revolutionizing cancer care in India. With plans to expand to ten cities within the next three years, the initiative has secured an

investment of $10 million to establish medical and surgical oncology centers in Delhi and Mumbai. Everhope Oncology Pvt. Ltd. aims to address challenges of delay in cancer treatment due to lack of sufficient oncologists and healthcare infrastructure in India by establishing dedicated chemotherapy facilities and specialized surgical centres. The venture is expected to leverage technology by implementing an AI-driven clinical decision support system and an electronic health record system.

https://www.bseindia.com/xml-data/corpfiling/AttachLive/51622aa2-fd19-4022-b20d-e2d0984a0459.pdf

MED-TECH

GOVERNMENT INITIATIVES

Department of Pharmaceuticals Releases Expression of Interest under PRIP Scheme

The Department of Pharmaceuticals (**DoP**) has released an Expression of Interest (**EOI**) under the Scheme for Promotion of Research & Innovation in Pharma MedTech Sector (**PRIP**). The PRIP Scheme was launched with a total financial outlay of Rs. 5,000 crore with the aim to strengthen India's position as a global hub for research and development in the Pharma MedTech sector. To facilitate the goals of the PRIP Scheme, the Department of Pharmaceuticals invites Expression of Interest from interested entities such as a proprietary firm or partnership firm or limited liability partnership, startups or a company/group of companies registered in India for project funding under the PRIP scheme. The DoP claims that this EoI has been designed to provide the aforementioned entities with an opportunity to co-shape India's journey towards becoming an R&D innovation hub, by soliciting their inputs on:

- Current R&D projects in the scheme's priority areas for PRIP funding consideration
- Challenges in execution of R&D projects
- Actions to strengthen the R&D ecosystem for Pharma and MedTech innovation in India.

https://pharma-dept.gov.in/sites/default/files/PRIP%20Scheme_Expression%20of%20Interest_0.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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