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LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

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PHARMACEUTICALS

LEGAL AND REGULATORY

Mandatory Registration required for Clinical Research Organisations

The Ministry of Health and Family Welfare has issued a notification amending the New Drugs and Clinical Trials Rules, 2019 (**"NDCT Rules"**). The New Drugs and Clinical Trials (Amendment) Rules, 2024 (**the "NDCT Amendment Rules"**), which will come into effect on 01 April 2025, introduces several critical changes aimed at enhancing the oversight of clinical trials in India, with a particular focus on the role of Clinical Research Organisations (**CROs**) in clinical trials.

One of the major changes brought in by the NDCT Amendment Rules is the mandatory registration requirement for CROs. Earlier, under the NDCT Rules, only bioavailability and bioequivalence study centres were required to register with the Central Licensing Authority (**CLA**). Upon this amendment coming into effect, all CROs will have to register with the CLA before conducting any clinical trial, bioavailability, or bioequivalence study on new or investigational drugs in human subjects.

Notification No. G.S.R. 581 (E):
cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwMTM=

Central Drugs Standard Control Organisation (CDSCO) Flags 49 Drugs for Failing Quality Test and Declares 4 Drugs as Spurious

The CDSCO in its monthly alert list issued for September 2024, declared 49 drugs, including popular and commonly used medicines like Nimesulide & Paracetamol Tablets by Innova Captab Limited, Pantoprazole Gastro-resistant Tablets by Alkem Health, Cefpodoxime Tablets by Aristo Pharmaceuticals Pvt. Ltd., Amoxicillin and Potassium Clavulanate Tablets by Alkem Health, Ciprofloxacin Tablets by Cadila Pharmaceuticals Limited as Not of Standard Quality (**NSQ**).

Moreover, 4 drug samples (Tamsulosin and Dutasteride Tablets (**UrimaxD**), Calcium and Vitamin D3 Tablets I.P (**SHELCAL 500**), Pantoprazole Gastro-Resistant and Domperidone Prolonged Release Capsules I.P. (**PAN-D**), Nandrolone Decanoate Injection IP 25mg/ml (**DecaDurabolin 25 Inj**) were declared as spurious in another alert list by CDSCO. Spurious drugs are falsified medicines made to resemble another drug company, usually some popular brand, in order to deceive the public by exploiting the popularity of the original product.

NSQ drugs link:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwODQ=

Spurious drugs link:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwODI=

Maximum Retail Price (MRP) and Reduction in GST Rates of three Anti-cancer Drugs

In consonance with the Government's commitment to ensure the availability of drugs at affordable prices, the National Pharmaceutical Pricing Authority (**NPPA**) issued an office memorandum on 28 October, 2024. directing the reduction of maximum retail price (**MRP**) of 3 anti-cancer drugs (Trastuzumab, Osimertinib and Durvalumab). This was done as a result of the announcement made in the Union Budget for the year 2024-25, exempting these 3 anti-cancer medicines from customs duty. Moreover, the GST rates on these 3 drugs has also reduced from 12% to 5%.

Office memorandum link:

https://www.nppaindia.nic.in/uploads/tender/52b2593ccf4a36153b1e4d44bd825336.pdf

Tax rate notification: https://gstcouncil.gov.in/sites/default/files/2024-10/ctr-05-2024.pdf

GOVERNMENT INITIATIVES

India May Change Strip Color for all Antimicrobials Drugs to Blue

In a meeting held in September 2024, the Drugs Technical Advisory Board (**DTAB**) deliberated on a proposal for addition of blue strip / box for providing antimicrobial resistance (**AMR**) warning on the label of the antimicrobial products, for keeping special focus on antimicrobials, which may lead to reduction in AMR. DTAB has decided to suitably amend the labelling requirements under Drugs Rules, 1945.

This proposed amendment is aimed at tackling the growing threat of AMR, which caused an estimated 300,000 to 1.04 million deaths in India in 2019, according to the Global Research on Antimicrobial Resistance project.

www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjM3MQ==

Health Ministry Releases Draft Guidelines on Good Clinical Practices for Clinical Trials

The CDSCO has issued a draft guideline on Good Clinical Practices (**GCP**). The guidelines are designed to standardize and improve clinical trial procedures across India by emphasizing ethical considerations, transparency, and patient safety, aiming to align India's clinical trial practices with

international standards. The draft covers various aspects of clinical trials, from protocol development to data management, and calls for stringent oversight to ensure the safety and integrity of the trials.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE4OTU=

MED-TECH AND MEDICAL DEVICE

LEGAL AND REGULATORY

Uniform Code for Marketing Practices in Medical Device, 2024

The Department of Pharmaceuticals released the much-awaited Uniform Code for Marketing Practices in Medical Devices (**"MD Marketing Code"**) earlier this year in September. The primary aim of the MD Marketing Code is to provide an outline and a framework to the medical device industry for marketing their products through promotions, brand reminders, samples, workshops, interaction with healthcare professionals, etc. The MD Marketing Code requires medical device companies to align their promotional activities with regulatory standards and encourages medical device associations to enhance oversight of marketing practices.

https://pharmaceuticals.gov.in/sites/default/files/UCMPMD_0.pdf

GOVERNMENT INITIATIVES

Prime Minister Launched Drone Services at 11 Tertiary Care Institutions

To expand healthcare services in rural and hard-to-reach areas, the Prime Minister on 29 October 2024, launched drone services at 11 Tertiary Care Institutions. These are AIIMS Rishikesh (Uttarakhand), AIIMS Bibinagar (Telangana), AIIMS Guwahati (Assam), AIIMS Bhopal (Madhya Pradesh), AIIMS Jodhpur (Rajasthan), AIIMS Patna (Bihar), AIIMS Bilaspur (Himachal Pradesh), AIIMS Raebareli (Uttar Pradesh), AIIMS Raipur (Chhattisgarh), RIMS Imphal (Manipur) and AIIMS Mangalagiri (Andhra Pradesh). Moreover, a Helicopter Emergency Medical Services from AIIMS Rishikesh was also launched in order to help deliver speedy medical care by stabilising and treating trauma victims during flight and onsite. It will cover Uttarakhand and nearby areas within 100 nautical miles.

https://pib.gov.in/PressReleasePage.aspx?PRID=2069266

Prime Minister Inaugurates 5 Projects under Production Linked Incentive (PLI) Scheme for Medical Devices and Bulk Drugs

On 29 October, 2024, the Prime Minister inaugurated 5 projects under PLI scheme for medical devices and bulk drugs at Vapi (Gujarat); Sultanpur, (Hyderabad); Bengaluru, (Karnataka); Kakinada (Andhra Pradesh) and Nalagarh (Himachal Pradesh). These units will manufacture high-end medical devices, such as body implants, critical care equipment, and important bulk drugs like Penicillin-G and Clavulanic Acid. The Prime Minister also laid the foundation stone for 4 Centres of Excellence at NIPER –Ahmedabad (Gujarat) for Medical Devices; NIPER Hyderabad (Telangana) for Bulk Drugs; NIPER, Guwahati (Assam) for Phytopharmaceuticals; and NIPER – Mohali (Punjab) for Anti-Bacterial Anti-Viral Drug Discovery and Development. These initiatives support the 'Make in India' initiative and support India's goal of reducing import dependence by enhancing local research and manufacturing capabilities in medical devices and bulk drugs.

https://www.pmindia.gov.in/en/news_updates/pm-launches-inaugurates-and-lays-the-foundation-stone-of-multiple-projects-related-to-health-sector-worth-over-rs-12850-crore/

HEALTH-TECH, HOSPITALS AND HEALTHCARE CENTRES

LEGAL AND REGULATORY

Supreme Court Clarifies Standards for Medical Negligence

On 25 October, 2024, the Supreme Court in the case, **Neeraj Sud and Ors. v. Jaswinder Singh and Ors. MANU/SC/1158/2024**, noted that simply because a patient has not responded favourably to a surgery or a treatment administered by a doctor, or if the surgery has failed, the doctor cannot be held liable for medical negligence. A doctor will be held liable for negligence only when he does not have the requisite qualification or skill or when he fails to exercise reasonable care when giving the treatment. This decision by the Supreme Court overturns a National Consumer Disputes Redressal Commission (**NCDRC**) verdict that had found a doctor and Postgraduate Institute of Medical Education and Research (**PGIMER**) guilty of negligence in an eye surgery case from 1996. Thus, the Supreme Court held that post-surgery complications alone are not sufficient grounds for proving negligence.

https://api.sci.gov.in/supremecourt/2011/35971/35971_2011_17_1501_56737_Judgement_25-Oct-2024.pdf

GOVERNMENT INITIATIVES

Prime Minister Launched U-WIN Portal for Digitalisation of Immunisation Services for Pregnant Women and Children

In consonance with the objective of the India's Universal Immunisation Programme (**UIP**), the U-WIN digital platform was launched in October 2024 to capture each and every vaccination event of all pregnant women and children. This Made-in-India digital platform will benefit 2.9 crore pregnant women and 2.6 crore infants annually by fully digitalising the complete vaccination process. It will also ensure the timely administration of life-saving vaccines to pregnant women and children (from birth to 16 years). India's UIP is - part of the Reproductive and Child Health Program under the National Health Mission. It is one of the largest public health programs in the world under which vaccination is being provided free of cost to all pregnant women and children. Vaccination can be availed against 12 vaccine preventable diseases.

https://mohfw.gov.in/press-info/7828

The Union Health Ministry Approves Introduction of New Shorter and More Efficacious Treatment Regimen for Drug-Resistant TB in India

The Union Health Ministry of India has approved the introduction of the BPaLM regimen, a new and more effective treatment for multi-drug-resistant tuberculosis (**MDR-TB**) under the National TB Elimination Program (**NTEP**). This four-drug combination (Bedaquiline, Pretomanid, Linezolid, and Moxifloxacin) offers a shorter, safer, and more effective treatment, reducing the duration of treatment from 20 months to just six months. This move supports India's goal of eliminating TB by 2025 and is expected to benefit the country's 75,000 drug-resistant TB patients while also lowering treatment costs.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2052515

INVESTMENTS

Yatharth Hospital Acquires Majority Stake in MGS Infotech

Yatharth Hospitals and Trauma Care Services Ltd, one of the leading private super specialty hospitals in North India, has entered into an agreement for the acquisition of a 60% stake in MGS Infotech Research and Solutions, Faridabad, Haryana. This acquisition will enhance Yatharth Hospitals positioning as the leading healthcare provider, with the largest bed capacity in the Faridabad region. This is the second acquisition in this year by Yatharth Hospitals. The first acquisition took place in February 2024, where Yatharth Hospitals acquired a 100% stake in the Faridabad-based 175-bed Asian Fidelis Hospital.

https://www.yatharthhospitals.com/news/acquires-majority-stake-in-400-bedded-hospital-in-

Faridabad#:~:text=Under%20the%20terms%20of%20the,152%20crores

HEALTH ADVERTISING

LEGAL AND REGULATORY

Illegal to Advertise 'Miraculous' Ayurveda, Siddha, Unani, and Homeopathy (ASU&H) Drugs

The AYUSH Ministry has issued a public notice reiterating that it is illegal to advertise Ayurveda, Siddha, Unani, and Homeopathy drugs claiming "**miraculous or supernatural effects**" for the treatment of diseases, since such advertisements can "**mislead and endanger**" public health. The Ministry further clarified that it does not grant manufacturing licenses to any ASU&H manufacturers or companies for the sale of their medicines. Moreover, as per the provisions of the Drugs & Cosmetics Act, 1940 and its rules, the manufacturing licenses for sale of any ASU&H medicine/drug is granted by the State/ Union Territory Licensing Authority (**SLA**) of the respective State/ Union Territory.

https://aiia.gov.in/wp-content/uploads/2024/09/Public-Notice-ASU-H-medicines.pdf

OTHER IMPORTANT UPDATES

LEGAL AND REGULATORY

Guidelines for Prevention and Regulation of Greenwashing or Misleading Environmental Claims, 2024

The Central Consumer Protection Authority has notified the Guidelines for Prevention and Regulation of Greenwashing or Misleading Environmental Claims, 2024 (**"Greenwashing Guidelines"**). The Greenwashing Guidelines is aimed to operate in furtherance to the Guidelines for Prevention and Regulation of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022.

The Greenwashing Guidelines have laid down conditions which must be adhered to in case of using environmental claims in any form of advertising. Any advertisements suggesting environmental friendly attributes will now have to be accurate and substantiated. No environmental claims such 'eco-friendly', 'organic', 'natural', etc. can be made without adequate qualifiers and disclosures.

https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/Greenwashing_Guidelines.pdf

Ministry of Environment, Forest and Climate Change Published the Ecomark Rules, 2024

On 1 October, 2024, the Ministry of Environment, Forest and Climate Change published the Ecomark Rules, 2024 (**"Ecomark Rules"**) which replaces the Ecomark Scheme of 1991. The Ecomark Rules are in alignment with the **'LiFE'** (Lifestyle for Environment) Mission announced by the central government in 2021. The Ecomark Rules will be implemented by the Central Pollution Control Board in partnership with the Bureau of Indian Standards. Products such as cosmetics, several types of oils, soaps, detergents, food items, plastic items and packaging materials must adhere to specific environmental criteria under the Ecomark Rules to ensure minimal environmental impact. The Ecomark Rules are expected to encourage the demand for environment-friendly products, promote lower energy consumption, accurate labelling, environmentally friendly production of items, and prevent misleading information about products.

https://moef.gov.in/storage/tender/1727787383.pdf

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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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