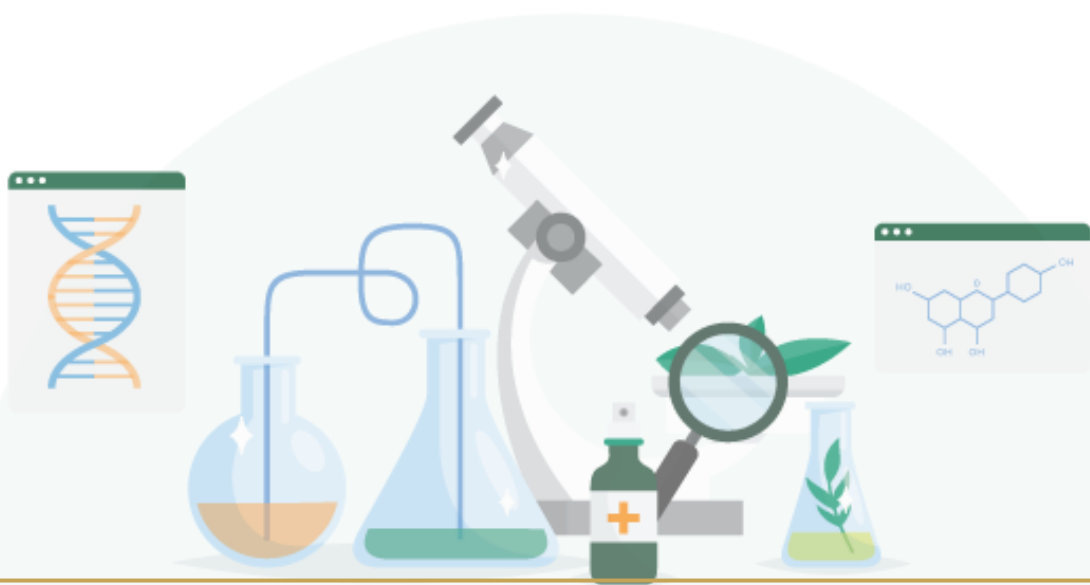


Luthra and Luthra
LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE NEWSLETTER

September 2025 Edition





Pharmaceuticals

LEGAL AND REGULATORY

NPPA Fixes Retail Prices of 9 New Drugs

The National Pharmaceutical Pricing Authority (“NPPA”) has fixed the retail price, exclusive of Goods and Services Tax, if any, of 9 drugs in relation to the formulation specified in the notification with the strength, unit and name of manufacturer, and marketing company. The 9 drugs include Aceclofenac, Paracetamol and Thiocolchicoside Tablets manufactured by Innova Captab and Macleods Pharmaceuticals, Ibuprofen and Paracetamol Suspension manufactured by Shiva Biogenetic Pharmaceuticals and Mankind Prime Labs, among others.

The mentioned retail price is applicable only to the individual manufacturer / marketer who has applied for the same by submitting Form-I for price fixation / revision as stipulated under Drugs (Prices Control) Order, 2013 (“DPCO”).

In case the retail price of any of the mentioned formulations is not complied with, as per the price notification, then the concerned manufacturer/marketing company will be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

Read More:

<https://nppa.gov.in/uploads/tender/b030fb3c3ca505b363f0ce02a1e51e16.pdf>

Amendment to the Uniform Code for Pharmaceuticals Marketing Practices, 2024

The Department of Pharmaceuticals has issued amendments to the Uniform Code for Pharmaceuticals Marketing Practices 2024 (“UCPMP”) to simplify reporting of monthly marketing expenditure and reduce administrative burden on the industry:

Key Amendments:

- Revised to include detailed provisions for the valuation of free samples by both manufacturers and purchasers.
- Omitted the requirement to upload details of the complaints received on UCPMP portal, as well as the requirements to upload Ethics Committee for Pharma Marketing Practices (“ECPMP”)’s final decision on the website of the Department of Pharmaceuticals.
- Introduced new requirements for the annual disclosure of marketing expenditure.
- Added specific provisions for Data Storage and Security.
- Annexure Updates – Previous Annexures replaced with revised formats for disclosure.

Read More:

<https://pharma-dept.gov.in/sites/default/files/Circular%20No.%203%20of%202025%20and%20UCPMP%202024%20as%20amended.pdf>



CDSCO Invites Comments on Consideration of the Proposal Regarding Problem Faced by the Blind or Visually Impaired People to Read Medicines Tablets/Capsules Strips

The Central Drugs Standard Control Organization (“CDSCO”) has invited public comments on a proposal to improve accessibility of medicines for blind and visually impaired persons. The initiative arose from representations highlighting the difficulty such individuals face in identifying medicines and expiry details on tablet or capsule strips.

Following deliberations in the 58th Drugs Consultative Committee (“DCC”) meeting, a sub-committee was constituted to examine the issue, which recommended introducing Braille labelling on drug packs initially on a voluntary basis. Priority is to be given to medicines commonly used by visually impaired persons, such as eye drops, while excluding products administered under healthcare supervision like injectables and vaccines. The sub-committee also advised that Braille artwork be validated by recognized agencies, with labelling following international readability standards (minimum 9-point Times New Roman font and 3 mm line spacing). Additionally, marketing authorization holders should make package information leaflets available in accessible formats upon request and retailers should verbally guide visually impaired customers regarding dosage, drug name and expiry.

In the 66th DCC meeting held on 17 June 2025, further suggestions were added, such as providing Braille cards with bulk packaging containing more than 10 units and incorporating QR codes linked to voice assistance on medicine packs.

Read More:

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

INVESTMENTS

Roche Pharma Partners with 10 Government Hospitals to Bolster Clinical Trial Capabilities in India

The Advanced Inclusive Research (“AIR”) Site Alliance is Roche's flagship global initiative designed to expand access to clinical trials for underrepresented populations. Already implemented in the United States of America, the U.K., Canada and Africa, the AIR Site Alliance is now active in India.

Under this initiative, nearly 400 professionals have been trained, comprising investigators, ethics committee members and other resources as per global Good Clinical Practice standards. By equipping leading government hospitals with global-standard clinical trial capabilities, Roche Pharma aims to bring innovations faster to India.

India accounts for 17% of the world's population and 20% of the global disease burden, yet fewer than 4% of global clinical trials are conducted in the country. This initiative aligns with CDSCO priorities to boost participation of government sites in Phase 3 and 4 trials.

Read More:

<https://www.thehindu.com/business/roche-pharma-partners-with-10-govt-hospitals-to-bolster-clinical-trial-capabilities-in-india/article70046752.ece>



Med-Tech and Medical Device

LEGAL AND REGULATORY

Amendment to the Uniform Code for Marketing Practices in Medical Devices 2024

The Department of Pharmaceuticals has issued amendments to the Uniform Code for Marketing Practices in Medical Devices 2024 (“UCMPMD”) to simplify disclosure:

Key Amendments:

- Revised to include detailed provisions for the valuation of free samples by both manufacturers and purchasers.
- Omitted the requirement to upload details of the complaints received on UCPMP portal, as well as the requirements to upload Ethics Committee for Pharma Marketing Practices (“ECPMP”)’s final decision on the website of Department of Pharmaceuticals.
- Introduced new requirements for the annual disclosure of marketing expenditure.
- Added specific provisions for Data Storage and Security.
- Annexure Updates – Previous Annexures replaced with revised formats for disclosure.

Read More:

https://pharma-dept.gov.in/sites/default/files/ucmpmd%20circular%20with%20amended%20code_1_0.pdf

GOVERNMENT INITIATIVES

ICMR Licenses Nine Health Technologies to Industry Partners at India MedTech Expo 2025

The Indian Council of Medical Research (“ICMR”) has licensed nine advanced technologies to industry partners under its Medical Innovations – Patent Mitra initiative at the India MedTech Expo 2025, resulting in 17 licensing deals. Launched on 8 March 2025 with support from NITI Aayog, the Department of Pharmaceuticals, and DPIIT, the initiative aims to streamline patenting, enhance IP support, and accelerate the transfer of publicly funded health innovations to industry for widespread impact.

Some of the technologies licensed during the ceremony included:

- Multistage Malaria Vaccine – licensed to Indian Immunologicals, Techinvention Lifecare, Panacea Biotech, Biological E, and Zydus Lifesciences.
- Diagnostic ELISA kits for the detection of IgM antibodies against Japanese Encephalitis, Dengue, and Chikungunya – licensed to Diatek Healthcare, Medsource Ozone Biomedicals, and Matrix Labs.
- Novel vaccines – a glycoconjugate Salmonella vaccine and an oral Shigella vaccine based on Multi-Serotype Outer Membrane Vesicles, both licensed to Biological E Limited.

Read More:

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2163759>

Punjab Launches AI-Based Screening Devices for Early Cancer Detection



Punjab has launched a first-of-its-kind Artificial Intelligence enabled screening devices for early detection of breast cancer, cervical cancer and refractive errors. According to Indian Council of Medical Research's ("ICMR") National Cancer Registry Programme, 42,288 new cancer cases have been reported in Punjab in 2024, which is a 7% increase from the previous year of 2023. Whereas, as per the National Family Health Survey data, only 0.3% of women aged 30 to 49 have ever been screened for breast cancer and just 2.4% for cervical cancer in the state.

Punjab's Health Minister said that to reverse these trends, the AI-based devices have been launched, which will be used in primary health settings with an aim to conduct at least 600 eye check-ups and 300 breast and cervical cancer screenings per day for early detection.

Read More:

<https://www.newsonair.gov.in/punjab-launches-ai-based-screening-devices-for-early-cancer-detection/>

DPIIT Signs MoU with Pfizer Limited to Strengthen India's Healthcare Innovation Ecosystem

The Department for Promotion of Industry and Internal Trade ("DPIIT"), Ministry of Commerce and Industry, signed a Memorandum of Understanding ("MoU") with Pfizer Limited.

The collaboration aims to accelerate the lab-to-market journey of innovative healthcare products by extending both financial and non-financial support to start-ups. Under the partnership, the Pfizer INDovation program will empower DPIIT-recognized start-ups with grants of up to ₹60 lakhs each, along with a tailored 18-month incubation program delivered by Social Alpha. The program will provide dedicated acceleration tracks covering clinical validation, regulatory approvals, and go-to-market strategies. Start-ups will also gain access to expert mentorship, infrastructure, and global networks, in addition to exposure at Pfizer's Research and Development facilities in Chennai, enabling them to strengthen innovations with advanced industry insights.

The initiative will support 14 pioneering MedTech start-ups innovating in screening, diagnostics, health monitoring, and treatment enablers, with a particular focus on non-communicable diseases, oncology, brain health, maternal and child health, and immunisation.

Read More:

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2163676>

INVESTMENTS

Poly Medicure Limited Announces Acquisition of Citieffe Group

Poly Medicure Ltd, an India based medical device company operating in medical consumables market, announced signing of a definitive agreement to acquire 100% stake in Medistream SA consisting of Citieffe SRL and its step-down subsidiaries in United States of America and Mexico, at an enterprise value of INR 324 Crores (EUR 31 Million) (majority stake with Archimed; a Europe based healthcare focused PE fund).

This strategic acquisition provides Poly Medicure with an entry point into the large global orthopaedics market, particularly in the trauma and extremities segment.

Read More:



https://www.polymedicure.com/wp-content/uploads/2025/09/Poly-Medicure-Citieffe-Acquisition_Press-Release-1.pdf

Zealthix Raises USD 1.1 Million Seed Funding to Expand SaaS Healthcare Platform

Zealthix Technologies Private Limited, a SaaS-based healthcare platform, has raised USD 1.1 million in seed funding led by Unicorn India Ventures, with participation from AlphaGen Venture Capital. The funds will be used to scale operations, boost revenue growth, and enhance the platform's technology to further digitise and streamline India's healthcare ecosystem.

Founded in 2023, Zealthix offers a cloud-based middleware platform that helps insurers and payers manage OPD and comprehensive healthcare plans, enabling cashless OPD networks and interoperable digital infrastructure. In the past year, the start-up has gained 20 paying clients, including insurers, brokers, and care plan companies, and integrated its OPD stack with several partners. Over the next year, Zealthix plans to expand partnerships with healthcare providers and further develop its OPD stack to help payers launch and manage health products efficiently through customisable digital tools.

Read More:

<https://www.ptinews.com/story/business/zealthix-raises-usd-1-1-million/2941011>

Healthcare and Hospitals

LEGAL AND REGULATORY

DGHS Issues, then Withdraws, Controversial Circular Regarding the Use of the Title “Dr.” by Physiotherapists

On 9 September, 2025, the Directorate General of Health Services (“DGHS”) had issued a circular stating that physiotherapists were not medical doctors and therefore could not use the title of “Doctor” or “Dr.” next to their names. However, within hours, the DGHS withdrew the directive, stating that the issue required further examination and consultation, effectively allowing physiotherapists to continue using “Dr.” for now.

The move follows earlier confusion stemming from the National Commission for Allied and Healthcare Professionals' March 2025 curriculum, which permitted the use of “Dr.” along with the suffix “PT.” The Indian Medical Association (IMA) criticized the government's quick U-turn, calling it inconsistent and misleading, noting that some state High Courts have previously ruled against physiotherapists using the prefix.

Read More:

<https://www.newindianexpress.com/nation/2025/Sep/11/centre-makes-another-u-turn-says-physiotherapists-can-still-use-dr-as-a-prefix>

INVESTMENT

InvAscent Invests in Apex Hospitals

InvAscent, through its India Life Sciences Fund IV (ILSF IV), has invested INR 2,300 million in Apex Hospitals Private Limited, a Jaipur-based multi-specialty hospital chain focused on critical care. The deal



includes a complete secondary exit for existing investor Somerset Indus Capital Partners and a primary infusion to support Apex's expansion across Rajasthan and nearby states.

Apex Hospitals operates seven hospitals with over 600 beds, offering advanced secondary and tertiary care across specialties anchored around critical care and credible ICU care, particularly in underserved Tier 2 and Tier 3 cities.

Read More:

<https://www.invascent.com/news-press/>

Novo Nordisk Teams Up with Apollo Clinics for Obesity Care

Novo Nordisk has partnered with Apollo Clinics to launch a nationwide Comprehensive Obesity Management Program aimed at tackling India's growing obesity crisis through a structured, multi-tiered care model. The collaboration will integrate a complete obesity care framework across select Apollo Clinics, featuring healthcare professional (HCP) training through the *We Learn Obesity Education Series*, in-clinic diagnostic tools, and capability-building modules for dietitians, physiotherapists, and behavioural specialists.

Apollo Clinics will contribute its expertise in chronic condition management by providing infrastructure, clinical pathways, and digital patient support tools, while the program will include patient awareness campaigns, educational materials, and QR-enabled tools linking users to BMI and waist-to-height ratio calculators for personalised care pathways.

Read More:

<https://www.thehindubusinessline.com/news/novo-nordisk-teams-up-with-apollo-clinics-for-obesity-care/article69999543.ece>

Other Important Updates

LEGAL AND REGULATORY

Display of Revised MRP on Unsold Pre-Packaged Stock Following GST Revision

The Central Government, under Rule 33 of the Legal Metrology (Packaged Commodities) Rules, 2011, has permitted manufacturers, packers and importers to revise and declare the new retail sale price ("MRP") on unsold pre-packaged stock that was manufactured, packed, or imported before a change in GST rates. The revised MRP, reflecting the increase or reduction in tax due to GST changes, may be declared in addition to the existing MRP through stamping, stickers, or online printing.

This permission is valid until 31st December 2025 or until the stock is exhausted, whichever comes earlier, subject to the following conditions:

1. The original MRP must remain visible, and the revised price cannot overwrite it.
2. The price difference between the original and revised MRP must correspond only to the change in tax—it cannot exceed the increase or ignore a reduction in GST.
3. Companies must issue at least two newspaper advertisements and notify dealers and Legal Metrology authorities (Central and State/UT) on the price change.



Additionally, old packaging materials or wrappers printed before the GST revision may continue to be used until 31st December 2025 (or until exhausted), provided that corrected MRPs reflecting the revised tax rates are displayed using stamps, stickers, or online printing.

Read

https://consumeraffairs.gov.in/public/upload/admin/cmsfiles/whatsnews/Permission_to_the_manufacturers_or_packers_or_importers_of_pre-packaged_commodities_to_declare_the_revised_retail_sale_price_MRP_on_the_unsold_stock_-_Change_in_GST_rates_of_GoodsServices_-_reg_whatsnews.pdf

More:**Introduction of “Ayurveda Aahara” as a New Kind of Business (KoB) under FSSAI**

The Food Safety and Standards Authority of India (“FSSAI”) has introduced a new Kind of Business (“KoB”) in its Food Safety Compliance System (“FoSCoS”) for “Ayurveda Aahara”, effective from 1st September 2025.

Key points in the notification include a definition for ‘Ayurveda Aahara’, a Central Licence eligibility with an annual fee of Rs. 7500 (excluding GST). Additionally, four Ayurveda Aahara categories and mandatory documents required for their approval have been listed. The notification also specifies inspection checklist and licensing document requirements.

Read More:

<https://fssai.gov.in/upload/advisories/2025/09/68b685259cb03Order%20dated01stSeptember2025-Introduction%20of%20new%20KoB-Ayurveda%20aahara.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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