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LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE

Newsletter - May 2026 Edition

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Pharmaceuticals

LEGAL AND REGULATORY

Indian Pharmacopoeia Commission Issues the Draft Version of National Formulary of India, 2026

The Indian Pharmacopoeia Commission has released the draft National Formulary of India, 2026, a guidance document aimed at promoting rational use of medicines and addressing antimicrobial resistance. The National Formulary of India, 2026 serves as an essential reference for healthcare professionals, providing evidence-based guidance on therapeutic choices, dosage forms, and safe prescribing practices across clinical settings for major drug classes, prominently including analgesics, antipyretics and anti-inflammatory drugs. By placing the draft in the public domain, the government has invited feedback from stakeholders, including healthcare professionals, industry experts, and the public.

https://ipc.gov.in/images/Biologics/NFI-2026-for-website.pdf

GOVERNMENT INITIATIVES

Department of Pharmaceuticals Organises Webinar on AI-Driven Innovations

As part of Sādhana Saptah 2026, the Ministry of Chemicals and Fertilisers' Department of Pharmaceuticals ("**DoP**") hosted a webinar on "AI and Emerging Technologies in Pharmaceuticals and Regulations" on April 4, 2026. The talk emphasised how artificial intelligence is changing the pharmaceutical industry, especially in the areas of drug research, clinical trials, and regulatory procedures. The webinar, which was presented by Prof. Manoj Kumar of the National Institute of Pharmaceutical Education and Research (**NIPER**), Mohali, centered around important uses of AI, such as drug design, toxicity prediction, target discovery, and data-driven clinical research. Professor Kumar went into detail on the increasing use of AI in polypharmacology and multi-target drug development, AI-driven drug design and de novo molecule synthesis, and the prediction of 3D protein structures and drug-target interactions. The webinar also emphasised the necessity of developing government systems' capacity to use AI for evidence-based regulatory decision-making, expedited approval processes, and improved post-market surveillance and drug safety monitoring.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2249011&reg=3&lang=1

Department of Pharmaceuticals Organises 9th edition of India Pharma 2026

The 9th edition of India Pharma 2026, organised by the DoP, concluded on April 14, 2026, after two days of extensive deliberations aimed at strengthening India's pharmaceutical and biopharma ecosystem. The event consisted of sessions encompassing pharmaceutical financing and forward-looking pathways for innovation-led growth in the sector. The event consisted of more than 800 delegates, over 60 speakers engaging in 10 sessions, including 6 plenary sessions, supported by over 20 partner organisations. The valedictory address, delivered by Shri Satyaprakash T L, Joint Secretary, DoP noted that discussions across sessions focus on the next phase of growth: funding, infrastructure, and speed. Speakers, including Shri Dilip Shanghvi of Sun Pharmaceutical Industries noted that although India has positioned itself as a global

leader in generics and vaccines, the next phase lies in advancing innovative medicines and cutting-edge science.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2251887&reg=3&lang=1

INVESTMENTS

Rubicon Research Limited Acquires 85% Stake in Arinna Lifesciences Limited

Rubicon Research Limited ("**Rubicon**") has obtained an 85% equity interest in Arinna Lifesciences Limited ("**Arinna**") for around Rs. 175.92 crore, at an enterprise valuation of Rs. 200 crore, signifying Rubicon's strategic foray into India's central nervous system therapeutic sector. Established in 1999 as an integrated pharmaceutical company with capabilities spanning research and development, manufacturing, and commercialisation of differentiated products, Rubicon seeks to leverage Arinna's portfolio of over 60 chronic therapy brands and its established distribution network of more than 4,000 prescribers to expand its domestic presence. The purchase, done on a cash and debt-free basis, with Rubicon purchasing shares at Rs. 158.53 per share, enables Rubicon to scale its differentiated offerings, including specialised goods through Arinna's distribution infrastructure.

https://nsearchives.nseindia.com/corporate/9823522970_15042026172232_SEPressReleaseIntmationRubiconResearch15Apr2026.pdf

Sun Pharmaceutical Industries Limited Acquires Organon & Co.

Sun Pharmaceutical Industries Limited ("**Sun Pharma**") and Organon & Co. ("**Organon**") have reached a definitive agreement whereby Sun Pharma will purchase all of Organon's outstanding shares in an all-cash transaction for USD 14.00 per share, with an enterprise valuation of USD 11.75 billion. Organon is a multinational healthcare company with a portfolio of more than 70 products in the areas of general medicines and women's health, including biosimilars. These products are marketed in 140 countries and are supported by six manufacturing facilities located throughout the European Union and emerging markets. Subject to regulatory clearance and Organon's stockholder approval, the deal is anticipated to conclude in early 2027.

https://sunpharma.com/wp-content/uploads/2026/04/PR-Sun-Organon-announcement-Apr-26.pdf

Medical Devices and Med-Tech

LEGAL AND REGULATORY

Ministry of Health and Family Welfare Issues Draft Amendments to the Medical Devices Rules, 2017

The Ministry of Health and Family Welfare released draft amendments to the Medical Devices Rules, 2017, ("**MDR**") on April 10, 2026. Key amendments include insertion of a new clause to Rule 44, of the MDR which stipulates that in case of medical device manufacturer who outsourced the sterilization process of

medical devices at the site of another facility, the license number of the sterilization site should be mentioned on label of the device. The sterilization site license number added on the label of the medical device must be preceded by the words "Sterilization sites Manufacturing License Number" or "Ster. Mfg. Lic. No." or "S.M. L". Moreover, a Ninth Schedule is proposed to be added to the MDR, which prescribes fees for medical device testing and evaluation.

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

Department of Pharmaceuticals Amends the Uniform Code for Marketing Practices in Medical Devices, 2024

On April 30, 2026, the Department of Pharmaceuticals issued a circular bearing reference no. 31026/51/2024-MD (Part File), amending the Uniform Code for Marketing Practices in Medical Devices, 2024 ("**UCMPMD Amendment**"), in order to reduce the compliance burden for the medical device industry with respect to foreign training events of healthcare professionals ("**HCPs**").

- Prior to the UCMPMD Amendment, under Clause 6.2(i) of the Uniform Code for Marketing Practices in Medical Devices ("**UCMPMD**"), the conduct of Continuing Medical Education ("**CME**"), Continuing Professional Development ("**CPD**"), training, or otherwise for conference, seminar, workshop, etc. in foreign locations was prohibited except for advanced clinical trainings in exceptional circumstances like non-availability of trainers or equipment and products within the country. For trainings conducted at foreign locations, detailed justification, along with details of participating HCPs, duration and location of training, trainers, equipment and facilities to be used, expenditure to be incurred on travel and boarding etc. had to be submitted to the DoP at least three (3) months in advance before the scheduled date, and only on specific approval of the DoP such foreign trainings were allowed to be permitted.

- Post the UCMPMD Amendment, the earlier requirement of seeking specific prior approval from the DoP at least three (3) months in advance has been omitted and the amended Clause 6.2(i) now requires medical device companies to share details of the proposed foreign training, including justification, participant details, and estimated total expenditure at least one (1) month in advance with their respective Industry Associations. Moreover, it is the responsibility of the medical device company to adhere to all the provisions of the UCMPMD in letter and spirit, while planning and organizing such training programmes. Any violation shall be dealt with in accordance with provisions contained in Sections 12 and 13 of the UCMPMD (relating to penalties and reference, and appeal, respectively).

- Before the UCMPMD Amendment the provision of travel facilities by companies, whether inside or outside the country, to HCPs was limited to only speakers for a CME or CPD program. Post the UCMPMD Amendment, the provision of providing such travel facilities has now been widened to include participants in a training program as well.

- Before the UCMPMD Amendment, provision of hospitality by companies, representatives or any person acting on their behalf towards HCPs was limited to only speakers of a CME or a CPD program. Post the UCMPMD Amendment, the provision of providing hospitality has been widened to include participants in a training program as well.

- Lastly, in the note following Clause 8.4, the regulation that will prevail in the case of any items missing under the UCMPMD, has been changed from "*Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002*" to the "*National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023*".

https://pharma-dept.gov.in/sites/default/files/UCMDMD%20circular%201-2026%2BUCMDMP%20code%20as%20amended%20on%2030.4.2026%20%281%29_0.pdf

GOVERNMENT INITIATIVES

Ministry of Health and Family Welfare Launches Mobile Application to Strengthen Clinical Workflow of Community Health Officers

On April 13, 2026, the Ministry of Health and Family Welfare launched a mobile application to support Community Health Officers and strengthen digital service delivery at the primary healthcare level. Developed by the Indian Council of Medical Research, the app functions as a comprehensive clinical decision-support and job-aid tool for Community Health Officers deployed at Sub-Centre Ayushman Arogya Mandirs, by offering them step-by-step guidance for outpatient care, including diagnosis, referral, and pre-referral management. The application also integrates features such as patient registration, electronic health records, teleconsultation, and follow-up tracking, enabling better continuity of care. The application is structured into three key sections (Workflows, Assessment Tools, and Treat and Counsel) and uses a colour-coded system where red indicates an immediate threat to life requiring urgent referral, orange suggests specialist evaluation, yellow covers conditions manageable at the Sub-Centre Ayushman Arogya Mandirs with or without teleconsultation, and Green denotes mild cases manageable at the facility level.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2251582&reg=3&lang=1

Healthcare and Hospitals

LEGAL AND REGULATORY

National Medical Commission Issues Draft Registration of Medical Practitioners and Licence to Practice Medicine (Amendment), Regulations 2026.

On April 7, 2026, the National Medical Commission released draft version of the Registration of Medical Practitioners and Licence to Practice Medicine (Amendment), Regulations 2026 ("**Draft Regulations**"). Some of the key amendments introduced by the Draft Regulations includes a definition for the term "Armed Forces Medical Services (**AFMS**)" and a framework for managing professional misconduct matters involving Armed Forces Medical Services practitioners. If an allegation of professional misconduct or

medical negligence is made against a medical practitioner serving in the Armed Forces Medical Services, then the State Medical Council with which the practitioner is registered shall have the jurisdiction to decide the matter upon the recommendation of the State Medical Council within whose territorial jurisdiction the cause of action arose.

https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Gazette%20Notification%20dated%2007.04.2026.pdf

GOVERNMENT INITIATIVES

The Union Ministry of Health and Family Welfare Convened the First BRICS Health Working Group Meeting, 2026

On April 15, 2026, the Ministry of Health and Family Welfare convened the inaugural BRICS Health Working Group (**HWG**) meeting of 2026, themed *"Building for Resilience, Innovation, Cooperation and Sustainability,"* The session brought together health officials and subject matter experts from BRICS member countries to advance multilateral public health cooperation. The deliberations focused on tuberculosis research networks, inter-jurisdictional coordination among medical product regulatory authorities, an integrated early warning mechanism for infectious disease surveillance, digital health infrastructure supporting continuity of care, and improving digital health architectures to enable access to remote and vulnerable communities. Moreover, the meeting focused on key aspects, such as promoting healthy lifestyles, wellness, mental health, and traditional medicine systems.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2252335&reg=3&lang=1

National Health Authority Conducts Chintan Shivir on Ayushman Bharat Pradhan Mantri Jan Arogya Yojana and Ayushman Bharat Digital Mission in Pune

National Health Authority has conducted a two-day Chintan Shivir in Pune, aimed at evaluating the implementation and advancement of two flagship government initiatives, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana ("**AB PM-JAY**") and the Ayushman Bharat Digital Mission ("**ABDM**"). The retreat served as a platform for senior officials and key stakeholders to collectively examine achievements to date, identify operational hurdles, and deliberate on measures to enhance the efficiency of digital health infrastructure and healthcare service delivery across the country. For instance, Shri Rajeev Topno, Additional Chief Secretary, Government of Gujarat, noted the state's experience in consolidating clinical governance under AB PM-JAY by stating that Gujarat has implemented robust gatekeeping mechanisms such as Online Tumor Board Certification, alongside data-driven monitoring. These measures have led to improved clinical appropriateness, mitigate unnecessary procedures, and significant cost efficiencies.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2253329&reg=3&lang=1

Other Updates

FSSAI Issues Advisory Prohibiting Use of Ashwagandha Leaves in Food Products

On April 16, 2026, the Food Safety and Standards Authority of India ("**FSSAI**") issued an advisory bearing reference no. F. No. RCD-15001/11/2021-Regulatory-FSSAI ("**FSSAI Advisory**") prohibiting the use of Ashwagandha (*Withania somnifera*) leaves in crude, extract, or any other form in food products. Under Schedule IV of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 ("**FSSAI Regulations**") the FSSAI has specified the list of plants or botanicals permitted to be used in the food products in India. As per Schedule IV of the FSSAI Regulations only the use of Ashwagandha roots and their extracts as per the prescribed limits is permitted. However, since certain manufacturers are using Ashwagandha leaves and its extracts in their products, the FSSAI issued the FSSAI Advisory reinforcing that the use of Ashwagandha leaves in crude, extract, or any other form is not permitted under the FSSAI Regulations. Thus, all food business operators have been advised to comply with the FSSAI Advisory and the FSSAI Regulations, non-compliance with the same will lead to regulatory action under the Food Safety and Standards Act, 2006 and the regulations thereunder.

Earlier, along similar lines, the Ministry of AYUSH issued an advisory bearing reference no. T-13020/4/2022-DCC-Part(2) dated April 15th 2026, noting that despite an earlier directive in October, 2021, directing AYUSH drug manufacturers, exporters, sellers to not use Ashwagandha leaves either in crude or extract or any other form in AYUSH drugs/ products, certain manufacturers still continue to use Ashwagandha leaves in their products.

Accordingly, the Ministry of AYUSH directed all AYUSH drug/ product manufacturers, exporters, sellers to:

- Use only Ashwagandha roots in crude or extract or any other form in single or as an ingredient in compound AYUSH drugs/products.

- Not use Ashwagandha leaves, in crude, extract, or any other form, in AYUSH drugs/products.

- Ensure compliance with the provisions of Rule 161 of the Drugs Rules, 1945, which requires that the plant parts used in the drugs/products must be clearly mentioned on the label.

https://fssai.gov.in/upload/advisories/2026/04/69e0d84fcac2fAdvisory%20on%20non%20use%20of%20ashwagandha%20leaves%20in%20crude%20or%20extract%20or%20any%20other%20form%20in%20food%20products-%20reg.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.

The Team

PRADNESH WARKE
Partner
Email – p.warke@luthra.com

RAVI RAJ SHEKHAR
Senior Associate
Email – r.shekhar@luthra.com

PRAGNA YENDURI
Associate
Email – syenduri@luthra.com

PRAGYA RANI
Associate
Email – prani@luthra.com

TANAY JHA
Associate
Email – t.jha@luthra.com

OFFICES

NEW DELHI
1st and 9th Floors, Ashoka Estate,
24 Barakhamba Road, New Delhi - 110 001
T: +91 11 4121 5100
F: +91 11 2372 3909
E: delhi@luthra.com

MUMBAI
20th Floor, Indiabulls Finance Center,
Tower 2 Unit A2, Elphinstone Road,
Senapati Bapat Marg, Mumbai - 400 013
T: +91 22 4354 7000
F: +91 22 6630 3700
E: mumbai@luthra.com

BENGALURU
3rd Floor, Onyx Centre, No. 5, Museum Road,
Bengaluru - 560 001
T: +91 80 4112 2800 / +91 80 4165 9245
F: +91 80 4112 2332
E: bengaluru@luthra.com

HYDERABAD
Serene Towers,
House No. 8-2-623/A,
Road No. 10, Banjara Hills,
Hyderabad, Telangana - 500034
T: +91 40 7969 6162
E: hyderabad@luthra.com

CHENNAI
Prestige Palladium Bayan,
8th Floor, Greams Road, Nungambakkam Division,
Egmore, Chennai - 600 006,
Tamil Nadu
T: +91 95604 88155
E: chennai@luthra.com