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# LIFESCIENCES AND HEALTHCARE NEWSLETTER

*September 2026 Edition*



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# PHARMACEUTICALS

## LEGAL AND REGULATORY

### Ministry of Health and Family Welfare Amends Rule 89 of the Drugs Rules, 1945

On August 06, 2026, the Ministry of Health and Family Welfare ("**MoHFW**"), introduced the Drugs (Twelfth Amendment) Rules, 2026, further amending the Drugs Rules, 1945. The Notification amends Rule 89 of the Drugs Rules, 1945 by expanding the forms referred to therein from Form 25 and Form 28 to also include Form 25A, Form 25F, Form 28A, Form 28B, Form 28D, Form 28DA, Form 28E and Form 28F. Accordingly, the Notification amendment expands the categories of manufacturing licences whose holders may obtain a licence in Form 29 under Rule 89 of the Drugs Rules, 1945 for the manufacture of drugs for the purposes of examination, test or analysis.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1OTQ=

### Central Drugs Standard Control Organisation Invites Stakeholder Comments on Operational Guidelines for Single Ethics Committee Review of Multi-Centre Research

The Central Drugs Standard Control Organisation ("**CDSCO**") issued a public notice bearing reference no. ETHICS/11/9/2026-eoffice dated August 06, 2026, inviting stakeholder comments on the Operational Guidelines for Single Ethics Committee Review of Multi-Centre Research in India ("**Guidelines**"). The consultation follows the publication by the Indian Council of Medical Research ("**ICMR**") of the Addendum (2026) to the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, which introduces the concept of Single Ethics Review for multi-centre research. The proposed framework is intended to facilitate implementation of the ICMR Addendum, particularly in the context of the requirements prescribed under the New Drugs and Clinical Trials Rules, 2019. CDSCO has invited stakeholders and other interested parties to provide comments and suggestions on the proposed Guidelines.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1Nzg=

### CDSCO Clarifies Application Requirements for Globally Unapproved New Drugs Where Global Clinical Trials Include Indian Subjects

The CDSCO issued a clarification circular bearing reference F. No. ND-11011(13)/2/2026-eoffice dated August 10, 2026, regarding the submission of applications for permission to import and market new drugs which have not been approved anywhere in the world, where Phase III Global Clinical Trials ("**GCTs**") are ongoing or have been completed with participation of Indian subjects under the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**").

The clarification provides that sponsors seeking permission to import and market such new drugs in India are required to submit the requisite applications to the Investigational New Drug Division, CDSCO (HQ), New Delhi, which will be responsible for processing and evaluating such applications in accordance with the applicable regulatory requirements under the NDCT Rules.

https://www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTg=

**CDSCO Issues Notice against Unauthorised Manufacturing and Marketing of Unapproved Drug Products Containing Enclomiphene and Its Combinations**

The CDSCO issued released a public notice bearing reference F. No. ENFORC-12016(11)/2/2026-eoffice-34479 dated August 10, 2026 ("**Notice**"), bringing to notice the unauthorised manufacturing and marketing of drug products containing Enclomiphene and its combinations without obtaining requisite permission from the CDSCO.

The Notice clarifies that Enclomiphene and its combinations have not been approved by the CDSCO for manufacture and marketing in India and cautions that the manufacture, sale, distribution or marketing of such products without the requisite approval is in contravention of the applicable provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019. The Notice directs all State and Union Territory Drugs Controllers to identify manufacturers, marketers, distributors and other entities involved in the manufacture, sale, distribution or marketing of such unapproved drug products and to initiate appropriate regulatory action in accordance with the applicable provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2MDI=

**MoHFW Extends Mandatory Warning Requirement to All Fixed Dose Combinations of Chlorpheniramine Maleate and Phenylephrine Hydrochloride for Children below Four Years**

MoHFW issued a notification bearing reference no. S.O. 4595(E) dated August 18, 2026 ("**FDC Notification**"), extending a mandatory warning label requirement to all formulations of fixed dose combinations ("**FDCs**") containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride. The FDC Notification follows the recommendation of an Expert Committee constituted by the Ministry, which examined FDCs containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride and recommended that the warning be extended to all such formulations manufactured, imported or marketed in India.

The FDC Notification requires manufacturers to display the warning "Fixed Dose Combination shall not be used in children below four years of age" on the drug label, package insert and promotional literature associated with such formulations.

https://egazette.gov.in/WriteReadData/2026/275640.pdf

### MoHFW Proposes Inclusion of Four Drugs in Schedule H1 of the Drugs Rules, 1945

MoHFW issued a notification bearing reference no. G.S.R. 745(E) dated August 19, 2026 ("**Draft Notification**"), to further amend the Drugs Rules, 1945 by inserting Flupentixol, Zopiclone, Gabapentin and Carisoprodol under Schedule H1 of the Drugs Rules, immediately after the existing entry at serial number 52. The Draft Notification subjects Flupentixol, Zopiclone, Gabapentin and Carisoprodol to the regulatory requirements applicable to drugs included in Schedule H1 under the Drugs Rules, 1945. As a result, these drugs are required to be sold by retail only on the prescription of a registered medical practitioner, with the applicable Schedule H1 caution and warning requirements on the label, and pharmacies would be required to maintain a separate record of the sale and supply of such drugs for a period of three years.

https://www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTc=

## GOVERNMENT INITIATIVES

### Indian Pharmacopoeia Commission Recognised by World Health Organization South-East Asia Regulatory Network as Regional Centre of Excellence in Pharmacovigilance and Technical Centre in Quality of Medicines

The Indian Pharmacopoeia Commission ("**IPC**"), under the MoHFW, has been recognised by the World Health Organization South-East Asia Regulatory Network as the Regional Centre of Excellence in Pharmacovigilance and the Technical Centre in Quality of Medicines. The recognition was announced during the 10th Anniversary Meeting of South-East Asia Regulatory Network, held in Kathmandu, Nepal, on August 4–5, 2026. The recognition reflects the IPC's strengthened role in supporting regulatory cooperation and technical collaboration among regulatory authorities in the World Health Organization, South-East Asia Region, including through knowledge exchange, capacity building and harmonisation of approaches relating to medicine quality and pharmacovigilance.

https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2295002&reg=48&lang=1

### IPC Organises First-ever Interactive Meeting with Central Drugs Laboratory, Kolkata, and Launches Seven Nitrosamine Impurities Reference Standards

IPC under the MoHFW, organised an interactive meeting at the Central Drugs Laboratory and Central Cosmetics Laboratory, Kolkata, on the theme "*IP 2026: Perspectives, Suggestions & Way Forward*". The meeting brought together representatives and experts from regulatory authorities and laboratories to discuss developments relating to pharmacopoeial standards, drug quality and the role of Indian Pharmacopoeia Reference Standards and Impurity Standards in ensuring the quality, safety and efficacy of pharmaceutical products. A key development was the launch of seven Indian Pharmacopoeia Nitrosamine Impurities Reference Standards, marking the first such standards

introduced by the IPC. These reference standards are intended to facilitate the accurate detection and quantification of nitrosamine impurities in pharmaceutical products and support drug testing, analytical method validation, quality assurance and regulatory compliance.

https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2303150&reg=48&lang=1

### IPC Organises Scientific Conclave at National Institute of Pharmaceutical Education and Research, Guwahati and Launches Twelve New Reference Standards for Phytopharmaceuticals

IPC under the MOHFW, organised a Scientific Conclave and Interactive Session at the National Institute of Pharmaceutical Education and Research, Guwahati, on August 27, 2026, on the theme "*Indian Pharmacopoeia (IP) 2026: Advancing Quality, Safety, and Innovation in Drugs, Food and Phytopharmaceuticals*". The event marked the first scientific conclave organised by the IPC in the Northeast region and brought together regulators, academics and scientific institutions to deliberate on the standardisation and quality of phytopharmaceuticals.

A key development was the launch of twelve new reference standards for phytopharmaceuticals and medicinal plants, comprising seven Indian Pharmacopoeia Phytochemical Reference Standards and five Indian Pharmacopoeia Botanical Reference Standards. These standards, introduced by the IPC for the first time, are intended to support the evidence-based development, quality control and therapeutic evaluation of plant-based medicinal products.

https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=2304237&reg=48&lang=1

## INVESTMENTS

### Alivus Life Sciences Limited to Acquire 76% Stake in IQGen-X Pharma Private Limited

On August 18, 2026, Alivus Life Sciences Limited ("**Alivus**"), formerly Glenmark Life Sciences Limited, announced the acquisition of a 76% stake in IQGenX Pharma Private Limited ("**IQGenX**") valued at INR 91.2 million. The acquisition is expected to be completed by the end of the current calendar year. The acquisition will enable Alivus to extend its capabilities into advanced formulation development, including complex delivery formats, bioequivalence and stability studies, regulatory filings, and an expanded Contract Development and Manufacturing Organisation (CDMO) service platform covering pre-formulation studies, prototype development, process optimisation, scale-up, clinical supplies, commercial manufacturing, analytical development, method validation, stability programmes and regulatory submission support. Alivus also intends to leverage IQGenX's platform alongside its Active Pharmaceutical Ingredient (API) portfolio, primarily with a focus on oncology, to develop differentiated and niche assets for potential out-licensing across multiple geographies

https://alivus.b-cdn.net/alivus_pdfs/media/Alivus%20_Press%20Release_IQGenX_Final.pdf

# MEDICAL DEVICES AND MEDTECH

## LEGAL AND REGULATORY

### MoHFW Notifies Medical Devices (Second Amendment) Rules, 2026

MoHFW issued amendments via notification bearing reference no. G.S.R. 743(E) dated August 14, 2026 ("**Amendment**"), notifying the Medical Devices (Second Amendment) Rules, 2026, to further amend the Medical Devices Rules, 2017. The Amendment relate to the regulatory requirements for outsourced sterilisation of medical devices, including requirements concerning the disclosure of the manufacturing licence number of the sterilisation site on the label of the medical device. The Amendment also proposes to introduce a Ninth Schedule prescribing fees for testing or evaluation of medical devices and make corresponding amendments to the Medical Devices Rules, 2017.

https://egazette.gov.in/WriteReadData/2026/275637.pdf

### MoHFW Notifies Medical Devices (Third Amendment) Rules, 2026

MoHFW issued notification bearing reference no. G.S.R. 744(E) dated August 14, 2026, notifying the Medical Devices (Third Amendment) Rules, 2026, ("**Third Amendment**") to further amend the Medical Devices Rules, 2017. The Third Amendment inserts "Quality Management System" after the reference to "standards" in Rules 19H and 19J of the Medical Devices Rules, 2017, thus requiring manufacturers and importers of Class A non-sterile and non-measuring medical device to self-certify compliance with the Quality Management System requirements under the Medical Device Rules, 2017 for registration on the Online System for Medical Devices. The Third Amendment also revises the marginal heading of Rule 19 of the Medical Devices Rules, 2017 from "Medical Device Testing Laboratory" to "Government Medical Device Testing Laboratories." Further, the Third Amendment modifies Rule 63(1), proviso (iv) of the Medical Devices Rules, 2017, by inserting the words "or European Union countries" after the existing reference to Japan. Accordingly, the results of clinical investigation may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the European Union countries when applying for permission to import or manufacture medical device which does not have its predicate device.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ2NTU=

## GOVERNMENT INITIATIVES

### 9th Edition of India Medical Device 2026 Commences in New Delhi

The 9th edition of India Medical Device 2026 was held on August 7–8, 2026 at Vigyan Bhawan, New Delhi. Organised by the Department of Pharmaceuticals in association with the Federation of Indian Chambers of Commerce and Industry, the two-day conference was themed "*Towards Viksit Bharat:*

*Advancing India as a Global Hub for Quality Medical Devices*." The discussions focused on increasing domestic value addition, strengthening component manufacturing, promoting advanced medical-device innovation and improving quality standards. The Department of Pharmaceuticals also stressed that India needs to move beyond import substitution and develop an export-oriented medical-device industry capable of competing in global markets. The Drugs Controller General of India highlighted the sector's transition from an import-dependent market toward domestic manufacturing, while emphasising the need to develop indigenous capabilities in high-end Class C and Class D medical devices and in-vitro diagnostics, supported by faster, transparent and predictable regulatory approvals.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2296028&reg=22&lang=1

### Government Releases Knowledge Paper on Artificial Intelligence in MedTech

On August 8, 2026, the Union Minister for Chemicals and Fertilizers and Health and Family Welfare released the knowledge paper "*AI in MedTech: Revolutionizing Healthcare Through Artificial Intelligence*" at 9th Edition of India Medical Device 2026, organized by the Department of Pharmaceuticals. The paper examines the development of AI-enabled MedTech in India and identifies strategic measures to promote its responsible adoption across the healthcare sector. It considers the application of AI in diagnostics, clinical decision support, operational efficiency and medical device innovation, while highlighting the regulatory, policy and ecosystem measures required to facilitate adoption at scale. The paper notes that transitioning AI solutions from successful pilots to routine clinical use will require addressing fragmented health data, limited evidence, evolving regulatory requirements and constrained reimbursement pathways. It further identifies AI-ready data and evidence, lifecycle-based regulation, and appropriate procurement and reimbursement mechanisms as key areas requiring attention to support broader clinical adoption of AI-enabled MedTech.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2296569&reg=48&lang=2

## INVESTMENTS

### Ayati Devices Private Limited Raises INR 15 Crore in Pre-Series A Funding Led by Inflexor Ventures LLP

Bengaluru-based Ayati Devices Private Limited ("**Ayati Devices**"), has raised INR 15 crore (Indian Rupees Fifteen Crores) in a Pre-Series A funding round led by Inflexor Ventures LLP, marking the Ayati Devices' first institutional investment. Founded in 2019, Ayati Devices develops portable diagnostic technologies for screening diabetic foot complications and peripheral vascular disease, with applications intended for primary care centres and diabetes clinics. The newly raised capital will support the expansion of manufacturing capacity, entry into international markets, team growth, and accelerated R&D in AI-powered diagnostics. Ayati Devices has deployed more than 10,000 (ten thousand) devices across over 30 (thirty) countries and has regulatory approvals in India, the US, Sri Lanka, Malaysia and the UAE.

https://www.inflexor.vc/news/ayati-devices-raises-15-crore-pre-series-a-funding-led-by-inflexor-ventures-read-more-at-https-entrepreneur-economictimes-indiatimes-com-news-funding-ayati-devices-raises-15-crore-pre-series-a-funding-led-by-inflexor-ventures-133142047

## HEALTHCARE AND HOSPITALS

### LEGAL AND REGULATORY

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

The National Medical Commission ("**NMC**"), via notification bearing reference no. R. 11061/05/2026-EMRB-Reg. dated August 11, 2026 published a draft of the Registration of Medical Practitioners and Licence to Practice Medicine (Amendment) Regulations, 2026 ("**Draft Amendment**"). A key proposal in the Draft Amendment is the introduction of a centrally generated Unique Identification ("**UID**") number for every registered medical practitioner. Under the proposed Draft Amendment, once a practitioner is registered in the state medical register, the Ethics and Medical Registration Board would generate a UID that would grant registration in the National Medical Register ("**NMR**") and eligibility to practise medicine anywhere in India. The proposed Draft Amendment also prescribes procedure for making application for licence to practice medicine ("**Licence**") and include provisions relating to foreign medical graduates and temporary registration for foreign nationals undertaking postgraduate or super-speciality courses in India. The Licence shall be valid for a period of five (5) years and it needs to be renewed after the validity of the Licence ends.

https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Pre-published%20-%20draft%20of%20(Registration%20of%20Medical%20Practitioners%20and%20Licence%20to%20Practice%20Medicine%20(Amendment)%20Regulations%202026)%20(1).pdf

### GOVERNMENT INITIATIVES

#### Project SARATHI Proposed for Expansion across Healthcare Institutions

On August 1, 2026, Union Health Minister Shri J. P. Nadda reviewed Project SARATHI and discussed taking the volunteer-based patient assistance programme to more hospitals and medical institutions across India. Under SARATHI, trained young volunteers help patients with hospital navigation and other non-medical needs. At Post Graduate Institute of Medical Education and Research, Chandigarh, a Department of Community Medicine study found that the programme helped cut patients' overall navigation time by 26%.

The proposed expansion includes formal volunteer training, integration with MY Bharat, digital tools for tracking participation and gathering patient feedback, and other support mechanisms. Volunteers

will remain limited to non-clinical and non-administrative roles, with the broader goal of developing a practical model that can be replicated across Central Government hospitals and other healthcare institutions.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2293080&reg=48&lang=2

### Government Reviews Progress of Key Health Sector Initiatives Announced in Union Budget 2026–27

On August 27, 2026, Union Minister for Health and Family Welfare, Shri Jagat Prakash Nadda reviewed the progress of key health-sector projects and initiatives announced in the Union Budget 2026–27, with a focus on time-bound implementation, inter-Ministerial coordination, regular monitoring and measurable outcomes. A key focus was the initiative to increase emergency and trauma-care capacity in District Hospitals by 50% through the establishment and strengthening of Emergency and Trauma Care Centres. Three committees were subsequently set up to review different aspects of the emergency and trauma-care initiative, covering infrastructure, medicines, diagnostics and quality; human resources, academic expansion and skill development; and digital systems and pre-hospital care integration. A detailed assessment of gaps in district hospitals against the Indian Public Health Standards has been completed, resulting in 613 district hospitals being placed into phases for implementation according to patient load, infrastructure and overall preparedness. Phase I comprises 160 hospitals, which are expected to be strengthened by March 2027, while 203 hospitals have been placed in Phase II and 250 in Phase III. The review also considered National Emergency Life Support training, which is intended to enhance emergency-care capabilities among healthcare professionals and frontline personnel. The Union Minister for Health and Family Welfare stressed the importance of continued coordination and implementation of programs within set timelines to ensure that the Budget announcements result in measurable outcomes.

https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=2303957&reg=48&lang=2

## INVESTMENTS

### Kohlberg Kravis Roberts & Company to Acquire Medicover India

On August 6, 2026, Kohlberg Kravis Roberts & Company ("**KKR**"), announced the signing of definitive agreements to acquire Medicover India ("**Medicover**"). Medicover operates a multi-specialty hospital network comprising 24 hospitals and approximately 4,800 beds across South and West India, with more than 1,900 doctors and services spanning over 80 clinical specialties. KKR stated that the investment will support the next phase of the business through investments in talent, technology, infrastructure and clinical capabilities. The transaction remains subject to necessary regulatory approvals.

https://media.kkr.com/news-details?news_id=6a6c6df1-c849-4af4-a6a2-4fbef3d757a0

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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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## THE TEAM



**PRADNESH WARKE**
Partner
p.warke@luthra.com



**PRAGNA YENDURI**
Associate
syenduri@luthra.com



**TANAY JHA**
Associate
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
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