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LIFESCIENCES AND HEALTHCARE

Newsletter - August 2026 Edition



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PHARMACEUTICALS

LEGAL AND REGULATORY

Ministry of Health and Family Welfare Invites Comments on Revised Draft National Pharmacy Commission Bill, 2026

On July 1, 2026, the Ministry of Health and Family Welfare ("**MoHFW**") via a public notice bearing No. Z-28020/27/2023-AHS/FTS 8205489, issued a revised draft of the National Pharmacy Commission ("**NPC**") Bill, 2026, incorporating comments received during an earlier round of public consultation, and invited further stakeholder and public comments by July 31, 2026. The Pharmacy Act, 1948 currently governs pharmacy education, registration and professional regulation in India through the Pharmacy Council of India ("**PCI**") and State Pharmacy Councils. The proposed NPC Bill seeks to repeal the Pharmacy Act, 1948 and replace the existing PCI-centred regulatory framework with a National Pharmacy Commission. The proposed National Pharmacy Commission would oversee pharmacy education, institutional assessment and rating, professional licensing, registration and ethical regulation through four specialised boards, while retaining State/Joint Pharmacy Councils for functions including State-level registration. The proposed draft reforms also include a National Exit Test for granting licence to practice Pharmacy as pharmacists and for enrolment in the State Register or the National Register, as the case may be.

https://www.mohfw-dohfw.gov.in/static/uploads/2026/07/e09761311aa45a6e996226aa33b2d87f.pdf

MoHFW Notifies Navi Mumbai Airport as a Port for Import of Drugs under the Drugs Rules, 1945

MoHFW via notification bearing no. G.S.R. 561(E) dated July 2, 2026 has notified Navi Mumbai Airport as a designated port for the import of drugs under the Drugs Rules, 1945. Prior to the amendment, Navi Mumbai Airport was not included among the notified airports for the import of drugs under Rule 43A of the Drugs Rules, 1945. The amendment adds Navi Mumbai Airport to the list of designated airports and is expected to facilitate the movement of pharmaceutical consignments, strengthen logistics infrastructure and provide importers with an additional port of entry for the import of drugs into India.

https://egazette.gov.in/WriteReadData/2026/274223.pdf

Central Drugs Standard Control Organisation Invites Stakeholder Comments on Use of Brand Name Extensions by Pharmaceutical Firms

On July 6, 2026, the Central Drugs Standard Control Organisation ("**CDSCO**") issued a public notice bearing reference no. Enforc-11021(11)/106/2024-eoffice, inviting comments from stakeholders on a proposal concerning the use of brand name extensions by pharmaceutical firms. CDSCO stated that it had received representations alleging that certain companies were marketing different drug

formulations containing different active pharmaceutical ingredients and intended for different therapeutic uses under the same established brand name with varying extensions. The matter was deliberated at the 67th meeting of the Drugs Consultative Committee ("**DCC**") held on November 17, 2025, where members noted that such practices could mislead the consumers and create confusion among prescribers, pharmacists and patients as to the composition and intended use of the medicines, thereby increasing the risk of medication errors.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0MzM=

MoHFW Restricts Exemption for Alcohol-Containing Oral Drug Formulations under the Drugs Rules, 1945

MoHFW has issued a notification bearing G.S.R. 607(E) dated July 8, 2026, notifying the Drugs (Tenth Amendment) Rules, 2026, which amend the Drugs Rules, 1945 ("**Amendment**"). Prior to the Amendment, serial number 10 under Schedule K exempted certain classes of drugs from specified provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945, subject to the conditions prescribed therein. Under Rule 123 of the Drugs Rules, 1945, drugs specified in Schedule K are exempted from the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, to the extent and subject to the conditions specified against each respective entry in Schedule K. Further, prior to the Amendment, there was no exclusion applicable to oral drug formulations containing alcohol based on their alcohol concentration or pack size. The Amendment further amends Schedule K by inserting an exclusion under serial number 10 to provide that all oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles of more than 30 milliliters shall not be covered by the exemption available under the said entry. Correspondingly, the Amendment also amends Schedule H1 by inserting a new entry No. 52 covering all oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles of more than 30 milliliters. Consequently, oral drug formulations containing more than 12% alcohol v/v (Ethyl Alcohol) and marketed in pack sizes exceeding 30 milliliters will no longer be eligible for the exemption available under serial number 10 of Schedule K and will also be regulated under the applicable provisions governing drugs listed in Schedule H1 under the Drugs Rules, 1945.

https://www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ0NTc=

CDSCO Issues Clarification on Jurisdiction for Compounding Applications under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025

On July 21, 2026, CDSCO issued a circular bearing F.No.Legal-13011(11)/17/2026-eoffice(Comp.37331) ("**Circular**"), clarifying the appropriate jurisdiction for submission of applications under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025. The clarification follows observations that applications were being submitted to the Central Compounding Authority even in cases falling within the jurisdiction of State Drug Control Administrations. The

Circular provides that applications must be filed before the competent Compounding Authority based on the authority that drew the sample. Where the sample has been drawn by a State/Union Territory Drugs Inspector, the application must be submitted to the respective State/Union Territory Compounding Authority, whereas applications relating to samples drawn by a Drugs Inspector of CDSCO or offences falling within the jurisdiction of the CDSCO must be submitted to the Central Compounding Authority. The Circular further notes that applications filed before an authority lacking jurisdiction may be returned or rejected and advises stakeholders to verify the competent authority before filing to avoid delays in processing.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1Mjk=

MoHFW Notifies Drugs (Eleventh Amendment) Rules, 2026 to Provide for Debarment of Applicants Submitting Misleading, Fake or Fabricated Documents

MoHFW has issued a notification bearing G.S.R. 706(E) dated July 30, 2026, notifying the Drugs (Eleventh Amendment) Rules, 2026, which further amend the Drugs Rules, 1945. The amendment inserts a new definition of "debarment" under Rule 2(bb), meaning the prohibition, exclusion, or disqualification of any person, firm, or entity from engaging in the import of drugs, manufacture for sale or for distribution, sell, stock or exhibit or offer for sale, or distribute, for a specified period or permanently as a consequence to the violation of statutory provisions. It further inserts new debarment provisions across the Drugs Rules, each providing that an applicant found guilty of submitting misleading, fake or fabricated documents or information may, after being given an opportunity to show cause in writing, be debarred by the applicable regulatory authority for such period as may be deemed fit. Moreover, each of these provisions further provides that an applicant aggrieved by a debarment order may, within thirty days of receipt of the order, appeal to the Government, which may, after such enquiry as it considers necessary and after affording an opportunity of being heard, pass such orders as it considers appropriate.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1NzU=

GOVERNMENT INITIATIVES

CDSCO Approves India's First Dengue Vaccine for Prevention of Dengue

CDSCO, under MoHFW has granted marketing authorisation for Qdenga®, a Dengue Tetravalent Vaccine, manufactured by Takeda GmbH, Germany and imported by Takeda Biopharmaceuticals India Private Limited, making it the first vaccine for prevention of dengue approved in India. The approval was granted following a comprehensive scientific evaluation of the vaccine's quality, safety and efficacy under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945. The vaccine is administered for individuals aged 4 to 60 years and, as a two-dose regimen, at a three months interval. The approval is supported by global clinical studies, and the vaccine has already received regulatory approval in 42 countries, along with World Health Organization (WHO) prequalification, reinforcing India's efforts to strengthen dengue prevention and public health outcomes.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2286883&reg=48&lang=1

Indian Council of Medical Research Licenses Anti-HPV Therapeutic and Two Enteric Vaccine Technologies to Emcure Pharmaceuticals Limited and Biological E Limited

The Indian Council of Medical Research ("**ICMR**"), announced that, under its Medical Innovations Patent Mitra initiative, it had licensed three indigenous biomedical technologies to leading Indian pharmaceutical and vaccine manufacturers for further development, manufacturing and commercialisation. The first technology, SHetA2, is a first-in-class anti-HPV (human papillomavirus) therapeutic candidate for the treatment of Cervical Intraepithelial Neoplasia (CIN), developed jointly by Dr. Showket Hussain of ICMR's National Institute of Cancer Prevention and Research and Dr. Doris M. Benbrook of the Stephenson Cancer Center, University of Oklahoma, USA. The candidate selectively targets and eliminates HPV-induced precancerous and cervical cancer cells while sparing healthy tissue, with potential as a safe, affordable and minimally invasive treatment option. Accordingly, SHetA2 has been licensed to Emcure Pharmaceuticals Limited. The remaining two technologies are next-generation enteric vaccine candidates developed by Dr. Santasabuj Das and his team at ICMR's National Institute of Research in Bacterial Infections in Kolkata, and have been licensed to Biological E Limited.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2286902&reg=48&lang=1

Indian Pharmacopoeia Commission Signs MoU with Uttar Pradesh Promote Pharma Council to Strengthen Quality and Regulatory Standards

On July 14, 2026, the Indian Pharmacopoeia Commission ("**IPC**") signed a Memorandum of Understanding ("**MoU**") with the Uttar Pradesh Promote Pharma Council ("**UPPPC**") during the YEIDA MedTech Investors Meet & Site Visit 2026 at the India Expo Mart, Greater Noida, to strengthen the pharmaceutical and medical device ecosystem in Uttar Pradesh. Under the MoU, IPC and UPPPC will jointly work to strengthen quality standards and regulatory compliance in the medical device and pharmaceutical industries, promote awareness across the Indian Pharmacopoeia, pharmacovigilance and materiovigilance, conduct joint training programmes and stakeholder awareness initiatives, and encourage innovation and research. The partnership also envisages support for Micro, Small, and Medium Enterprises through digital tools for adverse event reporting, and post-market surveillance initiatives to enhance patient safety.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2284706&reg=3&lang=1

INVESTMENTS

Warburg Pincus LLC Acquires Integrace Private Limited

On July 15, 2026, Warburg Pincus LLC ("**Warburg Pincus**"), a U.S. based private equity firm, acquired Mumbai-based Integrace Private Limited ("**Integrace**"), a domestic pharmaceutical formulations company. Integrace has established a therapy-focused portfolio with a strong presence in the orthopedics and gynecology segments and a network of professionals specialised in healthcare across India. Following the acquisition, the former Managing Director of Merck Sharp and Dohme (MSD) and Abbott India Limited, Rehan Khan will assume the role of Chief Executive Officer to lead Integrace. The acquisition reflects Warburg Pincus' continued investment in India's pharmaceutical sector and its strategy of building a scaled, therapy-focused domestic formulations platform.

https://warburgpincus.com/2026/07/15/warburg-pincus-acquires-integrace-an-orthopedics-and-gynecology-focused-pharmaceuticals-company/

MEDICAL DEVICES AND MEDTECH

LEGAL AND REGULATORY

CDSCO Issues Final Guidance Document on Medical Device Software under MDR, 2017

On July 21, 2026, CDSCO issued a circular bearing F.No.MED-16028/2/2025-eoffice, releasing the final Guidance Document on Medical Device Software ("**Guidance Document**") under the Medical Devices Rules, 2017 ("**MDR, 2017**"). The Guidance Document is intended to align India's regulatory framework for medical device software with globally harmonised regulatory practices. The Guidance Document provides clarity on the regulatory expectations applicable to medical device software, including classification principles, safety and performance requirements, documentation standards, quality management considerations, and post-market obligations. The Guidance Document is expected to facilitate consistent implementation of the MDR, 2017, support regulatory compliance for manufacturers and other stakeholders, and promote innovation, patient safety, product quality, and timely market access for medical device software in India.

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1MTM=

GOVERNMENT INITIATIVES

Department of Pharmaceuticals Invites Proposals under the Scheme for Strengthening of Medical Device Industry (SMDI)

The Department of Pharmaceuticals ("**DoP**"), Ministry of Chemicals and Fertilizers, by issuing a revised notice dated July 23, 2026, invited proposals under the Scheme for Strengthening of Medical Device Industry ("**SMDI**") to promote domestic manufacturing, reduce import dependence, and strengthen innovation in the medical devices sector. Applications were invited under key sub-schemes, including the Marginal Investment Scheme for Reducing Import Dependence and the Medical Device Clinical Studies Support Scheme. The initiative is expected to enhance domestic manufacturing capabilities and strengthen India's medical device ecosystem.

https://pharma-dept.gov.in/sites/default/files/Revised_Notice_SMDI_24-07-2026_0.pdf

INVESTMENTS

CARPL.ai Technologies Private Limited Raises USD 10 Million in Series A Funding

On July 23, 2026, **CARPL.ai Technologies Private Limited** ("**CARPL.ai**") announced the successful completion of its USD 10 million Series A funding round, led by the **International Finance Corporation**, a member of the **World Bank Group**, with participation from **Stellaris Venture**

Partners and other investors. According to the announcement, the funding will be used to advance product innovation, expand CARPL.ai's global partner ecosystem, and support commercial growth across all emerging markets including North America, Latin America, Europe, Asia-Pacific and other. The announcement further states that the investment aligns with the World Bank Group and International Finance Corporation's objective of supporting digital health innovation by strengthening engineering, product development and artificial intelligence capabilities in India for deployment to healthcare providers worldwide. It also notes that the funding is expected to accelerate the adoption of artificial intelligence-powered diagnostic solutions and reinforce India's role in the global health technology ecosystem.

https://carpl.ai/news/carplai-raises-10mn-led-by-ifc-to-accelerate-healthcare-ai-adoption-globally

HEALTHCARE AND HOSPITALS

LEGAL AND REGULATORY

National Medical Commission Proposes Amendments to Regulations Governing Establishment of New Medical Institutions

On July 8, 2026, the National Medical Commission ("**NMC**") via notification no. M-27011/01/2025-MARB(LEGAL)/NMC notified draft amendments to the Establishment of New Medical Institutions, Assessment & Rating Regulations, 2023 ("**Regulation**"). The amended regulations may be called Establishment of New Medical Institutions Assessment & Rating (Amendment) Regulations, 2026 ("**Amended Regulation**"). Some of the key changes include the insertion of a new Clause 9(k) which requires all infrastructure to be fully complete at the time of application and any temporary arrangement for hospital or college building shall not be permitted. The Amended Regulation also tightens the requirements relating to incomplete applications by providing that such applications shall be rejected outright, without an opportunity to cure the deficiencies by inserting first proviso after Explanation 3, under clause 9. In addition, Clause 31(c) of the Regulation has been amended to extend the withholding or rejection provision to applications for an increase in seats, whereas the provision was previously limited to applications under new schemes.

https://egazette.gov.in/WriteReadData/2026/274346.pdf

GOVERNMENT INITIATIVES

Sports Injury Centre, Safdarjung Hospital and Sports Authority of India Sign MoU to Strengthen Sports Medicine and Athlete Care

On July 10, 2026, the Sports Injury Centre ("**SIC**"), Safdarjung Hospital, under MoHFW, and the Sports Authority of India ("**SAI**") signed a Memorandum of Understanding in order to strengthen sports medicine and healthcare services for Indian athletes and support staff. The collaboration aims to establish an integrated athlete healthcare ecosystem by combining SIC's clinical expertise in sports medicine and healthcare with SAI's nationwide athlete support network. The partnership will focus on enhancing sports injury prevention, treatment, rehabilitation, diagnosis, and sports science support, while also promoting medical education, joint research, capacity building, and the development of evidence-based treatment protocols and injury prevention strategies. The Memorandum of Understanding is expected to strengthen institutional collaboration between the health and sports sectors and support the development of specialised sports medicine infrastructure and research for Indian athletes, enabling athletes to achieve peak performance.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2283405&reg=48&lang=1

National Health Authority Concludes National Review Meeting on Ayushman Bharat Pradhan Mantri Jan Arogya Yojana and Ayushman Bharat Digital Mission, Charts Roadmap for Next Phase of Health Reforms

On July 18, 2026, the National Health Authority ("**NHA**"), under the MoHFW, concluded a two-day National Review Meeting held on July 17–18, 2026 at Madhya Pradesh Bhawan, New Delhi, on the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana ("**AB PM-JAY**") and the Ayushman Bharat Digital Mission ("**ABDM**"). The meeting brought together officials from the Ministry, NHA, State Health Agencies and other stakeholders to review implementation progress and chart the roadmap for the next phase of health sector reforms. The second day's deliberations focused on financial sustainability and strengthening of public healthcare institutions under AB PM-JAY, including revised grant-in-aid guidelines and fund utilisation practices, as well as the use of health analytics and artificial intelligence to support evidence-based planning. Participants also discussed the National Health Claims Exchange as a mechanism to enable faster settlement of approved AB PM-JAY claims for empanelled hospitals, and the National Medical Commission's efforts to integrate Hospital Management Information Systems with ABDM standards across medical colleges.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2286071&reg=3&lang=1

IndiaAI and Ministry of AYUSH Sign Memorandum of Understanding to Accelerate AI Innovation in Traditional Healthcare

IndiaAI, under the Ministry of Electronics and Information Technology ("**MeitY**"), signed a Memorandum of Understanding ("**AI MoU**") with the Ministry of AYUSH to accelerate the adoption of Artificial Intelligence ("**AI**") across India's traditional medicine ecosystem. Under the collaboration, the Ministry of AYUSH will on board AIKosh, India's sovereign AI repository, and contribute eligible anonymised health research artefacts, including metadata, datasets, toolkits, AI models and use cases, subject to applicable data-sharing policies and regulatory requirements. Eligible stakeholders from the AYUSH ecosystem will also be able to access India's AI computing infrastructure through the IndiaAI Compute ecosystem to support AI research and the development of scalable healthcare solutions. The AI MoU is valid for an initial period of two years, with provision for automatic renewal upon mutual agreement, and does not involve any financial commitment or liability for either party. The collaboration is intended to enable evidence-based research, knowledge management and innovation across areas including medicinal plants, drug administration and capacity building within the AYUSH ecosystem.

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2292413&reg=3&lang=1

INVESTMENTS

Manipal Health Enterprises Limited Files Red Herring Prospectus for Initial Public Offering

Manipal Health Enterprises Limited filed its Red Herring Prospectus dated July 23, 2026 for an initial public offering ("**IPO**") comprising a fresh issue of equity shares aggregating up to INR 8,000 crore

and an offer for sale of up to 21,613,834 equity shares by its promoters, Imperius Healthcare Investments Pte. Ltd. and Manipal Education and Medical Group India Private Limited, along with existing investors including TPG SG Magazine Pte. Ltd., Novo Holdings Invest Asia A/S, Phoenix Bear Investments, LLC and others. The bid period for the IPO issue opened for subscription from July 29, 2026 and closed on July 31, 2026.

https://www.manipalhospitals.com/assets/pdf/Manipal-Health-Enterprises-Limited-RHP.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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