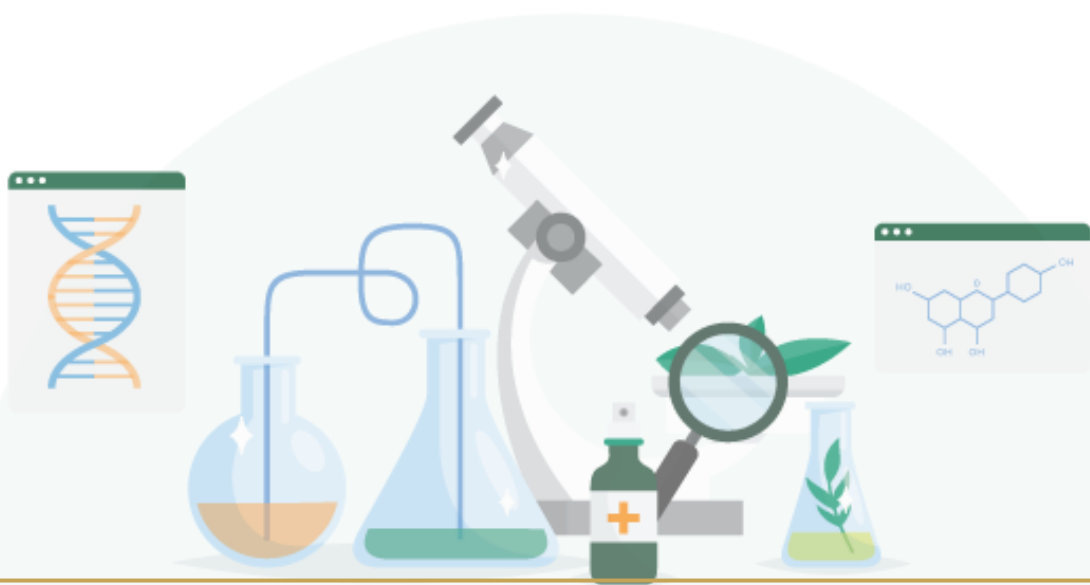


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## LIFESCIENCES AND HEALTHCARE

*Newsletter - December 2025 Edition*



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## Pharmaceuticals

### LEGAL AND REGULATORY

#### I. Supreme Court Calls for National Policy to Address Inconsistencies in Organ Transplantation

On 19<sup>th</sup> November 2025, the Supreme Court in the case *Indian Society of Organ Transplantation v. Union of India*, issued a series of directions to the Union and State governments, aimed at strengthening India's organ transplantation framework and addressing the inconsistencies between States when it comes to regulation and procedure for organ donation. The court highlighted critical inconsistencies in the implementation of the Transplantation of Human Organs and Tissues Act, 1994 (“THOTA”), particularly its 2011 amendments noting that Andhra Pradesh was yet to implement the amendments issued in 2011 and Karnataka, Tamil Nadu, and Manipur have not yet adopted the THOTA's 2014 Rules. The bench stressed upon the necessity of consistent allocation criteria across the country. It also directed the Union Government to draft guidelines after consulting with National Organ and Tissue Transplant Organization (“NOTTO”) for protecting live donors and preventing exploitation.

[https://api.sci.gov.in/supremecourt/2025/1331/1331\\_2025\\_1\\_14\\_66128\\_Judgement\\_19-Nov-2025.pdf](https://api.sci.gov.in/supremecourt/2025/1331/1331_2025_1_14_66128_Judgement_19-Nov-2025.pdf)

#### II. The Department of Pharmaceuticals Issued a Public Notice Regarding Exemption of Drugs from Global Tender Enquiry

On 21<sup>st</sup> November 2025, the Department of Pharmaceuticals (“DoP”) issued a public notice seeking objections from Indian manufacturers on the proposed addition of patented and proprietary medicines and formulations to the Global Tender Enquiry (“GTE”) exemption list, which permits procurement from overseas suppliers when there is no domestic production. Indian manufacturers have been asked to submit objections, if any, (based on their domestic manufacturing capacity) against the inclusion of the formulations specified in the aforementioned public notice in the GTE exemption list.

[https://pharma-dept.gov.in/sites/default/files/Public%20Notice%20dated%2021.11.2025\\_0002%20Final.pdf](https://pharma-dept.gov.in/sites/default/files/Public%20Notice%20dated%2021.11.2025_0002%20Final.pdf)

#### III. Pharmacy Council of India Directs State Pharmacy Councils to Submit Consolidated Data of Pharmacists

On 6<sup>th</sup> November 2025, the Pharmacy Council of India (“PCI”) instructed all State Pharmacy Councils (“SPC”) to furnish data on registered pharmacists in a prescribed format. The information is required to enable the National Health Authority (“NHA”) to compile a unified national database of pharmacists under the Health Professional Registry (“HPR”). The PCI is collaborating with the NHA to integrate pharmacists into the HPR and to ensure the continuous maintenance and updating of records as mandated under Section 15(A) of the Pharmacy Act, 1948. This provision requires the PCI to maintain a Central Register of pharmacists, incorporating names of all individuals registered with SPC and updating it regularly based on additions and changes reported by the States. Accordingly, all State authorities are expected to comply fully and submit accurate data within the stipulated timeframe.

<https://pci.gov.in/media/documents/15-42020-PCI.pdf>



## GOVERNMENT INITIATIVES

### **I. India Reiterates Commitment to Patient Safety through Global #MedSafetyWeek 2025 Campaign**

The #MedSafetyWeek campaign, first launched in 2016, seeks to educate the public on why, how, and where to report suspected side effects. The 2025 edition, marking its tenth anniversary, was the largest to date, with 130 organizations across 117 countries sharing messages in over 60 languages. The National Coordination Centre – Pharmacovigilance Programme of India (“NCC-PvPI”), Indian Pharmacopoeia Commission (“IPC”) participated in the tenth edition of the global #MedSafetyWeek campaign, held from 3<sup>rd</sup> to 9<sup>th</sup> November 2025, along with 130 partner organizations worldwide. This year’s campaign carried the core message: “*Everyone has a role to play in medicines safety. By reporting suspected side effects, you and I can help make medicines safer for everyone.*” The initiative aimed to raise awareness among patients, families, and healthcare professionals about the importance of reporting suspected side effects of medicines.

<https://mohfw.gov.in/?q=en/press-info/9569>

### **II. CCRAS Launches SIDDHI 2.0 to Strengthen Research-driven Innovation in Ayurveda Pharma Sector**

Scientific Innovation in Drug Development, Healthcare & Integration (“SIDDHI 2.0”) is a national industry research interface platform established to accelerate evidence-based Ayurvedic product development. On 25<sup>th</sup> November 2025, The Central Council for Research in Ayurvedic Sciences (“CCRAS”), Ministry of Ayush, launched the second edition of its flagship industry–research interface initiative, SIDDHI 2.0, in Vijayawada. The two-day national conclave has been organized by the Regional Ayurveda Research Institute (“RARI”), Vijayawada, in collaboration with the Confederation of Indian Industry, Vijayawada Zone. By simultaneously fostering scientific innovation and industry collaboration, SIDDHI 2.0 establishes the groundwork for a modern, evidence-based, and scalable Ayurvedic ecosystem that aligns with India’s broader vision of holistic healthcare.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2194439&reg=3&lang=1>

### **III. Indian Pharmacopoeia Commission Signs MoU with Jharkhand State Pharmacy Council**

On 15<sup>th</sup> November, 2025, the Indian Pharmacopoeia Commission (“IPC”), Ghaziabad, an autonomous institution under the Ministry of Health and Family Welfare, Government of India, signed a Memorandum of Understanding (“MoU”) with the Jharkhand State Pharmacy Council (“JSPC”), to strengthen collaborative efforts aimed at promoting the safe and rational use of medicines, enhancing pharmacovigilance and materiovigilance activities, and advancing patient safety initiatives across the state of Jharkhand. The MoU was signed by Dr. V. Kalaiselvan, Secretary-cum-Scientific Director, IPC, and Shri Prasanth Kumar Pandey, Registrar-cum-Secretary, JSPC, in the presence of representatives from both organizations. The partnership envisions strengthening the utilization of the National Formulary of India (“NFI”) as a standard reference document across healthcare facilities in Jharkhand and promoting its systematic use by pharmacists to support rational dispensing and safe medication practices. The collaboration between IPC and JSPC reflects a shared commitment to improving medication safety and strengthening public health systems through structured capacity-building and the promotion of evidence-based pharmacy practice.

<https://mohfw.gov.in/?q=en/press-info/9587>



## Medical Devices and Med-Tech

### LEGAL AND REGULATORY

#### I. Requirement of license issued by CDSCO in procurement of Medical Devices

On 17<sup>th</sup> November 2025, the Central Drugs Standard Control Organization (“CDSCO”) issued a circular noting that various procurement agencies including hospitals are demanding USFDA/CE certification as one of the requirements of technical bid for procurement of medical devices in the country. Currently no medical devices can be sold in India without valid license obtained from licensing authorities, according to the Medical Devices Rules, 2017 under the Drugs and Cosmetics Act, 1940. Based on the risk, medical devices are classified in four categories that is low risk in Class A, low to moderate risk in Class B, moderate to high risk in Class C, and high risk in Class D.

The manufacturing license for risk Class A and Class B medical devices and sale license for all risk class of medical devices are issued by the concerned state licensing authorities. The import license for all risk class of medical devices and manufacturing license for risk Class C and Class D is issued by the central licensing authority based on the detailed review and conformance of quality management system in manufacturing of medical devices. Thus, CDSCO requested that all the procurement agencies including hospitals shall mandate CDSCO license or license issued by Indian licensing authorities as a part of the requirements for procurement of medical devices, without which medical devices cannot be sold in India.

[cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTM2NDE=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2NDE=)

### GOVERNMENT INITIATIVES

#### I. Regional Open Digital Health Summit 2025 Convenes to Advance Interoperability and GenAI for Global Health

On 19<sup>th</sup> November 2025, the Regional Open Digital Health Summit 2025 was inaugurated, bringing together policymakers, technologists, public health leaders, and global experts from across the WHO South-East Asia Region (“SEAR”). The aim of this three-day summit was to accelerate the adoption of open, interoperable, and standards based digital health ecosystem across the region. Highlighting India’s advancements in using GenAI for health, the Union Health Secretary said, “Across the nation, AI-enabled surveillance and diagnostics are helping us identify diseases faster, predict outbreaks earlier and support frontline health workers in the most remote parts of the country.” The Regional Open Digital Health Summit 2025 is expected to deliver actionable outcomes, including country-specific digital health roadmaps, enhanced technical capacity, and strengthened regional governance frameworks.

<https://mohfw.gov.in/?q=en/press-info/9601>



## Healthcare and Hospitals

### LEGAL AND REGULATORY

#### **I. CDSCO Directs Mandatory Display of PvPI QR Code and Toll-Free Adverse Drug Reaction Reporting Number at All Pharmacies**

On 20<sup>th</sup> November 2025, the CDSCO instructed all State and Union Territory Licensing Authorities to ensure that every retail and wholesale pharmacy displays the designated PvPI QR code at a prominent location within their premises and the toll-free number 1800-180-3024 shall also be displayed to facilitate easy reporting of adverse events or adverse drug reactions by the public and healthcare professionals. This directive aims to strengthen pharmacovigilance, enhance patient safety, and raise awareness about adverse drug reactions.

[cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTM2NDI=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM2NDI=)

### GOVERNMENT INITIATIVES

#### **I. Three-day Workshop on National Consultation on Nursing Policy Priorities and Best Practices**

On 14<sup>th</sup> November 2025, Union Ministry of Health and Family Welfare, in collaboration with Jhpiego and the World Health Organization (“WHO”), concluded the three-day National Consultation and Experience Sharing Workshop on Nursing Policy Priorities and Best Practices in India, in New Delhi. The workshop underscored the importance of systematic workforce planning and management. States and experts recommended the adoption of scientific planning tools to determine appropriate staffing levels, improve deployment, and ensure optimal nurse-to-patient ratios across various levels of care. Deliberations also highlighted the need to create clear and progressive career pathways enabling nurses to take on advanced practice, public health, and leadership roles. The event concluded with a shared resolve to take forward the recommendations and continue building an empowered, skilled, and motivated nursing workforce that can meet the evolving health needs of the nation.

<https://mohfw.gov.in/?q=en/press-info/9585>

#### **II. India Anchors Global Efforts on Evidence-based Traditional Medicine Ahead of WHO Summit**

The Ministry of Ayush, Government of India, together with the World Health Organization (“WHO”), organized an Ambassadors’ Reception in New Delhi on 10<sup>th</sup> November 2025 as a precursor to the 2<sup>nd</sup> WHO Global Summit on Traditional Medicine, which will take place from 17–19 December 2025 in New Delhi. Dr. Catharina Boehme, Senior Advisor to the WHO Director-General, emphasized that nations should ensure strong ministerial-level participation at the Ministerial Roundtable and called for a renewed collective commitment to developing health systems that are accessible, affordable, inclusive, and grounded in scientific evidence. The Ministry of Ayush also requested all missions to support and enable robust participation from their respective governments in the 2<sup>nd</sup> WHO Global Summit on Traditional Medicine in December.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2188383&reg=3&lang=1>



### III. Union Health Minister Launches National Action Plan on Antimicrobial Resistance 2.0

On 18<sup>th</sup> November 2025, Union Minister of Health and Family Welfare, unveiled the second edition of the National Action Plan on Antimicrobial Resistance (“NAP-AMR”). The launch event was attended by the Principal Scientific Advisor, Union Health Secretary, Secretary - Department of Health Research and Director General of Health Services. In his remarks, the Union Health Minister stressed that the misuse and excessive consumption of antibiotics have become widespread, making immediate corrective action essential. Further, the Principal Scientific Advisor outlined several national efforts to curb AMR, noting that Kerala and Gujarat have become the first states to prohibit over-the-counter sales of antibiotics. He also mentioned that certain antimicrobials and pesticides have been barred from agricultural use.

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2191165&reg=3&lang=2>

#### INVESTMENTS

### I. Lord’s Mark India Acquires 85% Stake in Renalyx Health Systems

Lord’s Mark Industries Ltd., a group focused on diversified healthcare and technology, has announced its acquisition of an 85% stake in Renalyx Health Systems Private Limited, a med-tech innovator based in Bengaluru that has developed India's first indigenous, AI- and cloud-enabled smart hemodialysis machine. Renalyx will act as the research and development division of Lord’s Mark Industries, concentrating on innovative medical devices targeting kidney and liver health. This acquisition is a significant move for Lord’s Mark Industries as it seeks to advance into cutting-edge medical technologies that tackle the increasing prevalence of chronic kidney disease in India. Renalyx’s premier hemodialysis machine boasts features like real-time remote monitoring, cloud-based clinical connectivity, and smart analytics, which facilitate hospitals, dialysis centers, and practitioners in providing safer, more dependable, and affordable renal therapy. Lord’s Mark Industries Ltd. is positioned to develop its homegrown dialysis infrastructure, improve clinical results, and broaden access to high-quality renal care from Tier 1 to Tier 3 regions.

[https://bsmedia.business-standard.com/\\_media/bs/data/announcements/bse/24112025/c672c1c7-7b92-475d-b66a-d0db24e14d11.pdf](https://bsmedia.business-standard.com/_media/bs/data/announcements/bse/24112025/c672c1c7-7b92-475d-b66a-d0db24e14d11.pdf)

### II. MOVIN Enters India’s Healthcare Logistics Services

On November 26, 2025, MOVIN Express Pvt. Ltd., a joint venture between InterGlobe Enterprises and UPS, announced its entry into India’s rapidly expanding healthcare logistics market, which is estimated to be worth USD 7.5 billion. The company will provide end-to-end temperature-controlled services for the pharmaceuticals, MedTech, and diagnostics industries, initially operating in 50 cities across India. MOVIN Healthcare is committed to offering specialized temperature-controlled packaging that can maintain temperatures of (2 to 8°C) for refrigerated items, (15–25°C) for ambient controlled goods, and (-80 to -20°C) for dry ice frozen shipments, which are essential for vaccines, pharmaceuticals, and materials for clinical trials. Shipments will be securely managed and monitored in real-time, backed by a control tower that operates around the clock.



[https://www.movin.in/sites/default/files/2025-11/Final%20Press%20Release\\_MOVIN%20Domestic%20India\\_Healthcare%20launch\\_12%20November%202025%20%28004%29.docx.pdf](https://www.movin.in/sites/default/files/2025-11/Final%20Press%20Release_MOVIN%20Domestic%20India_Healthcare%20launch_12%20November%202025%20%28004%29.docx.pdf)

## Other Updates

### I. FSSAI-CBIC Integration under SWIFT 2.0 Streamlines Food Import Clearance

On 12<sup>th</sup> November 2025, the Food Safety and Standards Authority of India (“FSSAI”) completed the integration of its Food Import Clearance System (“FICS”) with the Central Board of Indirect Taxes and Customs (“CBIC”) via the ICEGATE platform as part of the upgraded SWIFT 2.0 programme. FICS had previously been integrated into CBIC’s ICEGATE platform under SWIFT 1.0. This enhanced integration represents a major step forward in advancing the Government’s objectives of improving the ‘Ease of Doing Business’ and streamlining trade processes. After the successful pilot launch of the FSSAI–CBIC linkage under SWIFT 2.0, the system is now set for phased implementation across key food import locations throughout the country. This will help create a more seamless, technology-driven import clearance framework.

[https://fssai.gov.in/upload/uploadfiles/files/Press%20Release%20SWIFT%202\\_0%20First%20Draft.pdf](https://fssai.gov.in/upload/uploadfiles/files/Press%20Release%20SWIFT%202_0%20First%20Draft.pdf)



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