Govt. officially extends revised schedule M deadline for SMEs until Dec 2025

On 12th February 2025, the government officially extended the deadline for small drug manufacturers to comply with the revised Schedule M regulations, setting the new deadline for December 31, 2025. This final notification followed a draft issued in January. The Ministry of Health and Family Welfare (MoHFW) announced that small and medium manufacturers with a turnover of 250 crore or less were given a conditional extension, provided they submitted their upgradation plan in Form A to the Central License Approving Authority within three months from February 11, 2025.

The decision came after small drug manufacturer associations, such as the Confederation of Indian Pharmaceutical Industry (CIPI), urged the government for a two-year extension, citing financial and operational challenges. Originally, the revised Schedule M, which upgraded “good manufacturing practices” to “good manufacturing practices and requirements of plan and equipment,” had been in effect since June 2024 for larger manufacturers with a turnover exceeding 250 crore.

Stakeholder concerns over infrastructure improvements, personnel training, and financial constraints led to the extension. Before this decision, nearly 5,000 of the 8,500 MSME pharmaceutical units in India risked closure. The government maintained that the updated Schedule M aimed to enhance pharmaceutical quality and safety, improving both domestic operations and global competitiveness.

Govt plans 10,000 more Janaushadhi Kendras by 2027

On 13th February 2025, the government decided to intensify efforts to expand its flagship initiative, Janaushadhi Kendras (JAKs), to provide affordable medicines. As per the Department of Pharmaceuticals (DoP), the government planned to increase the number of JAKs by approximately 67% over the next two years, targeting 25,000 centers by March 2027. This marked a 66.6% rise from the existing 15,000 centers as of January 2025. However, a previous parliamentary statement by the then Union Minister of State for Chemicals and Fertilizers, Bhagwanth Khuba, had set the deadline for achieving this target by March 2026.

JAKs offered medicines 50-80% cheaper than branded alternatives and had registered net sales of ₹1,606 crore in FY24 -25. For the upcoming fiscal year, the ministry aimed to establish 5,000 additional centers, taking the total count to 20,000, with an expected sales growth of ₹2,200 crore in FY25 -26.

In addition to the JAK expansion, the government significantly increased the budget for the Promotion of Research and Innovation in Pharma MedTech (PRIP) scheme by 227%, from ₹75 crore to ₹245 crore. Furthermore, ₹1,000 crores were allocated for three bulk drug parks, and ₹100 crore was earmarked to establish Centers of Excellence (CoEs) across all seven National Institutes of Pharmaceutical Education and Research (NIPERs).

India & Indonesia collaborate on traditional medicine quality assurance

On 14th February 2025, the Union Minister of State (Independent Charge) for the Ministry of Ayush, Prataprao Jadhav, announced that an MoU was signed between the Pharmacopoeia Commission for Indian Medicine & Homeopathy (PCIM&H), the Ministry of Ayush, and the Indonesian Food and Drug Authority. According to an official statement, the collaboration aimed to elevate global standards in traditional medicine.

Highlighting the significance of the MoU, Minister Jadhav stated that it would ensure the safety, efficacy, and quality of traditional medicines while promoting a scientifically regulated approach. Secretary of the Ministry of Ayush, Vaidya Rajesh Kotecha, emphasised that the partnership fostered knowledge exchange, and capacity building, and strengthened the global role of traditional medicine. PCIM&H, an IS/ISO 9001:2015 certified institution, played an important role in maintaining quality standards.

The MoU was exchanged in the presence of Prime Minister Narendra Modi and Indonesia's President, with Dr. S. Jaishankar representing India. Key provisions included regulatory information exchange, capacity-building initiatives, technical visits, joint training programs, and international collaborations. Officials from both countries stressed that the partnership marked a milestone in integrating traditional medicine into global healthcare and enhancing its regulatory framework.

Kerala launches Nayanamritham 2.0: AI-powered eye disease screening

The Government of Kerala, in collaboration with Remidio, launched Nayanamritham 2.0, an AI-assisted program aimed at screening chronic eye diseases on 18th February 2025. This initiative was the first of its kind to be led by a state government, focusing on improving early detection and enhancing accessibility to eye care across Kerala. Building on the success of Nayanamritham 1.0, which had introduced diabetic retinopathy (DR) screening at Family Health Centers with expert interpretation by ophthalmologists, Nayanamritham 2.0 took a significant step forward. The new phase empowered optometrists with Remidio's AI-enabled fundus cameras, which instantly classified cases as referable or non-referable, ensuring faster diagnoses and timely referrals.

In addition to DR, the updated program also included screening for glaucoma and age-related macular degeneration (AMD). The initiative had expanded its reach to Community Health Centers, Taluk Hospitals, and District Hospitals, making comprehensive eye care more widely available.

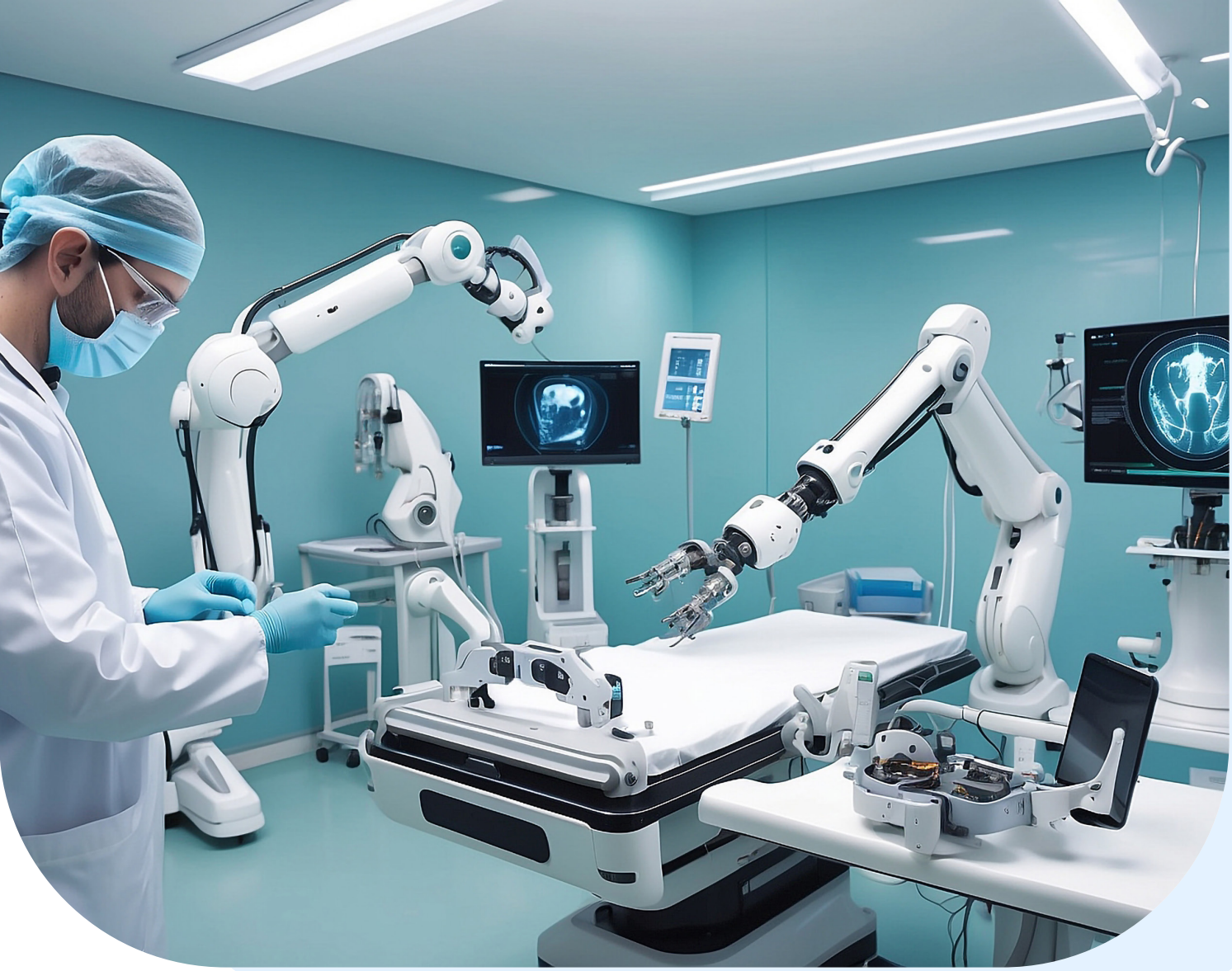
At the launch event, Dr. Bipin Gopal, Deputy Director, DHS, Government of Kerala, highlighted that AI was designed to empower healthcare providers rather than replace them. With this initiative, Kerala set a global precedent for integrating AI into ophthalmic care, improving early detection, reducing preventable blindness, and strengthening its healthcare system.

Kerala launches India's first expired medicine disposal program

On 19th February 2025, the Kerala government launched a pioneering programme to collect expired and unused medicines from homes and dispose of them scientifically. The State Drugs Control Department introduced the initiative, titled 'nPROUD' (New Programme for Removal of Unused Drugs), making Kerala the first state in India to implement such a project at the government level. Health Minister Veena George inaugurated the initiative on February 22 in Kozhikode.

As part of the project, unused medicines were collected directly from homes, and designated disposal facilities were set up. Initially, the programme was implemented in Kozhikode Corporation and Ulliyeri Panchayat, with plans for statewide expansion. Smt. Veena George highlighted that improper disposal of medicines led to antimicrobial resistance, health hazards, and environmental pollution. The Drugs Control Department had taken up this initiative as no adequate system previously existed for the scientific collection and processing of unused drugs.

The project followed the provisions of the Biomedical Waste Management Act and Rules. Medicines were collected through home visits at scheduled intervals, and the public could also deposit them in designated blue boxes. With support from local bodies and Haritha Karma Sena members, the collected medicines were scientifically processed at the Kerala Enviro Infrastructure Limited (KEIL) waste treatment plant, approved by the Central and State Environment Departments.



AIIMS Delhi installs surgical robot, advancing robotic-assisted surgery in India

On 19th February 2025, the All India Institute of Medical Sciences (AIIMS) in Delhi recently installed a surgical robot in its General Surgery Department, marking a significant step toward integrating advanced medical technology into public healthcare. This initiative was part of a broader effort to expand the use of robotic-assisted surgeries in India. According to estimates by the data and analytics company GlobalData, the market for robotic surgical systems was projected to grow at a compound annual growth rate (CAGR) of around 10 percent through 2036.

A report by GlobalData indicated that India was expected to hold a 6 percent share of the Asia-Pacific robotic surgery market in 2024. Government initiatives played a crucial role in supporting the adoption of this technology in public hospitals, driving market growth. The newly installed surgical robot at AIIMS Delhi provided surgeons with a magnified, three-dimensional view of the surgical site and robotic arms that enhanced precision in complex procedures. Robotic-assisted surgeries were associated with greater accuracy, fewer errors, and improved patient outcomes. However, widespread adoption depended on factors such as cost and the availability of specialized training.

Additionally, the Apollo Cancer Centre in Kolkata had successfully performed India's first robotic-assisted excision of a rare prostatic stromal tumor, showcasing the expanding role of robotic surgery in treating complex conditions. These advancements signaled a shift toward making cutting-edge surgical technology more accessible across both public and private healthcare sectors.

WHO adds traditional medicine to ICD-2025 for global integration

On 20th February 2025, the World Health Organisation (WHO) introduced a new module dedicated to traditional medicine conditions in its 2025 update to the International Classification of Diseases (ICD-11), marking a significant milestone in the global integration of traditional healthcare practices. According to the Indian government, this update followed a year of testing and deliberations after the launch of ICD-11 TM-2 in January 2024 for Ayurveda, Siddha, and Unani systems of medicine.

The Ministry of Ayush stated that the inclusion of traditional medicine in WHO's internationally recognized health framework ensured that Ayurveda, Siddha, and Unani were officially documented and categorized alongside conventional medical conditions. This development elevated their status in global health reporting, research, and policymaking. Vaidya Rajesh Kotecha, Secretary of the Ministry of Ayush, described the ICD-11 update as a significant step toward integrating traditional medicine into mainstream healthcare and improving evidence-based policymaking.

Dr. Robert Jakob, Team Leader of WHO's Classifications and Terminologies Unit, emphasized that the update improved interoperability and accuracy, benefiting national health systems. By allowing dual coding, the new module enabled comprehensive data collection on traditional medicine diagnoses, thereby enhancing research and healthcare strategies worldwide. The initiative strengthened the credibility and visibility of Ayurveda, Siddha, and Unani on a global platform.

Indian Pharmaceutical Alliance hosts 10th Global Pharmaceutical Quality Summit 2025

The Indian Pharmaceutical Alliance (IPA) hosted the 10th Global Pharmaceutical Quality Summit on 27th – 28th February 2025 at J.W. Marriott Juhu, Mumbai, bringing together industry leaders, regulators, and experts to discuss the future of pharmaceutical quality and manufacturing. Themed "Navigating the Next Decade for Global Excellence," the summit featured an inaugural session led by Mr. Nilesh Gupta, Chair of IPA's Quality Forum, followed by a keynote address by Mr. Arvind Virmani, Member, NITI Aayog, and remarks by Mr. Rajeev Raghuvanshi, Drug Controller General of India. A key highlight was the CEOs panel discussion, where industry leaders from Cipla, Lupin, Sun Pharma, and Zydus Lifesciences shared insights on India's global leadership in pharma.

Despite challenges such as tariff threats, policy shifts, and evolving technologies, industry leaders remained optimistic about growth opportunities. Discussions focused on India's role in making advanced therapies like gene therapy affordable, with Mr. Pankaj Patel advocating global collaboration for supply chain security. Mr. Dilip Shanghvi emphasized innovation in both synthetic chemistry and biological advancements, while Mr. Nilesh Gupta highlighted the necessity of complex generics. Mr. Umang Vohra envisioned India's expansion in emerging therapies like CAR-T cell therapy. The launch of McKinsey's report reaffirmed India's position as the largest supplier of generics. The summit reinforced India's commitment to quality, innovation, and regulatory excellence for sustained global leadership.

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