

CDSCO proposes fresh framework for software-based medical devices

On 22nd October 2025, in a move to align India's regulatory framework for medical device software with global standards, the Central Drugs Standard Control Organization (CDSCO) released draft guidelines for granting licences to manufacture or import such devices. The Drugs Controller General of India (DCGI) stated that the draft guidance was prepared to bring greater clarity on the regulatory aspects of medical device software and to harmonize India's requirements with international practices.

The 76-page document provided detailed guidance on definitions, classifications, applicable standards, quality management systems, and licensing authorities. It also included directions for clinical investigations and performance evaluations of software used in in vitro diagnostics (IVDs). The draft was opened for public comments for 30 days.

The Medical Technology Association of India (MTAI) welcomed the step but emphasized the need for clearer evaluation protocols and algorithm change management for AI/ML-based devices. It also urged CDSCO to streamline compliance for low-risk Software as a Medical Device (SaMD). MTAI Chairman Pavan Choudary said the draft reflected CDSCO's commitment to fostering safe, innovative, and globally competitive MedTech software. Currently, the Medical Devices Rules, 2017, outline technical and quality standards for Software in a Medical Device (SiMD) and SaMD in India.





National Human Rights Commission seeks report from Health Ministry, FSSAI on reuse of cooking oil

On 25th October 2025, the National Human Rights Commission (NHRC) issued a notice to the Union Health Ministry and the Food Safety and Standards Authority of India (FSSAI) over a complaint highlighting the alleged widespread reuse of cooking oil across the country. The Commission directed both authorities to conduct a probe and furnish a state-wise report, along with an action taken report within two weeks.

The complaint, filed by the founder of Sarthak Samudayik Vikas Evam Jan Kalyan Sanstha in Bhopal, raised serious concerns about the repeated reuse or resale of cooking oil by small hotels, roadside eateries, and food vendors, despite FSSAI's Repurpose Used Cooking Oil (RUCO) campaign. The complainant warned that such practices posed severe public health risks, including cancer, heart disease, and liver disorders, and contributed to water and soil contamination.

Taking cognisance of the issue under Section 12 of the Protection of Human Rights Act, 1993, the NHRC bench, headed by member Mr. Priyank Kanoongo, viewed the allegations as potential human rights violations. The Commission directed the authorities to strictly enforce existing regulations, improve waste oil management systems, and initiate awareness campaigns on the dangers of reused cooking oil.

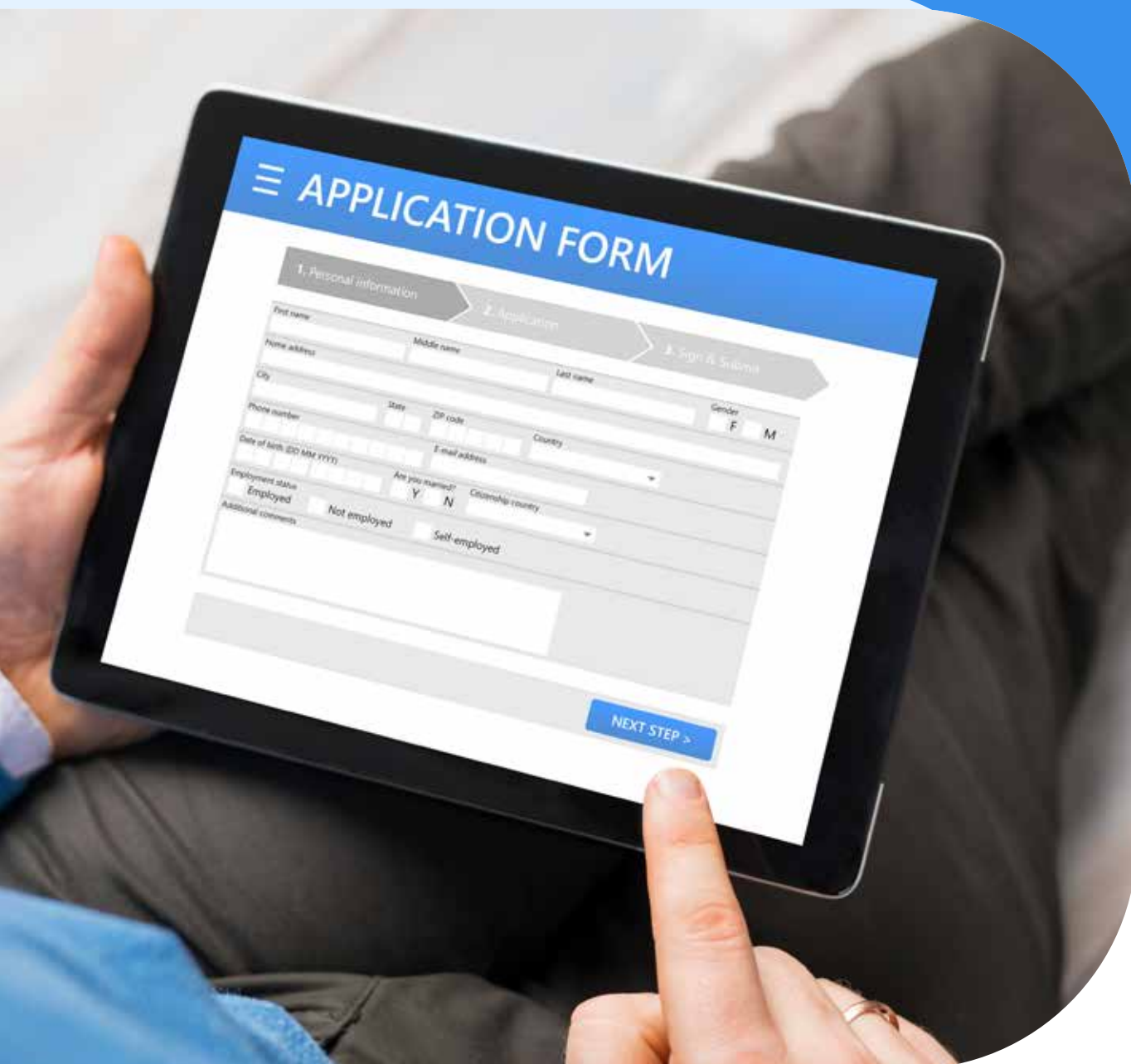


12 states record better sex ratio at birth than national average, says Union Health Minister J P Nadda

On 28th October 2025, Union Health Minister J P Nadda chaired the 31st Central Supervisory Board meeting and said India had made notable progress in reducing sex-based discrimination, with 12 states recording a sex ratio at birth (SRB) above the national average of 917. The board reviewed implementation of the Pre-Conception and Pre-Natal Diagnostic Techniques (PC-PNDT) Act and assessed steps taken since the previous meeting. Citing the 2021–23 Sample Registration Survey, Mr. Nadda noted that SRB had improved from 899 in 2016–18 to 917 in 2021–23.

The meeting focused on combating misuse of medical technologies for sex determination and on preventing pre-birth sex-selective elimination. Members highlighted improved enforcement through court cases, inspections and facility registrations. Mr. Nadda urged more state-level sensitisation workshops to address emerging technology-driven challenges such as portable diagnostic devices, genetic testing and online advertisements promoting sex determination. He also called for regular state interactions and sharing of best practices.

Officials praised proactive measures by states including Madhya Pradesh, Rajasthan, Karnataka, Uttarakhand and Haryana, which had conducted sting operations and formed task forces. Union Health Secretary Punya Salila Srivastava and Minister of State Savitri Thakur reaffirmed commitment to women's and children's welfare, cited the role of Beti Bachao Beti Padhao, and urged collective action and greater participation from the medical community to enforce the PC-PNDT Act.



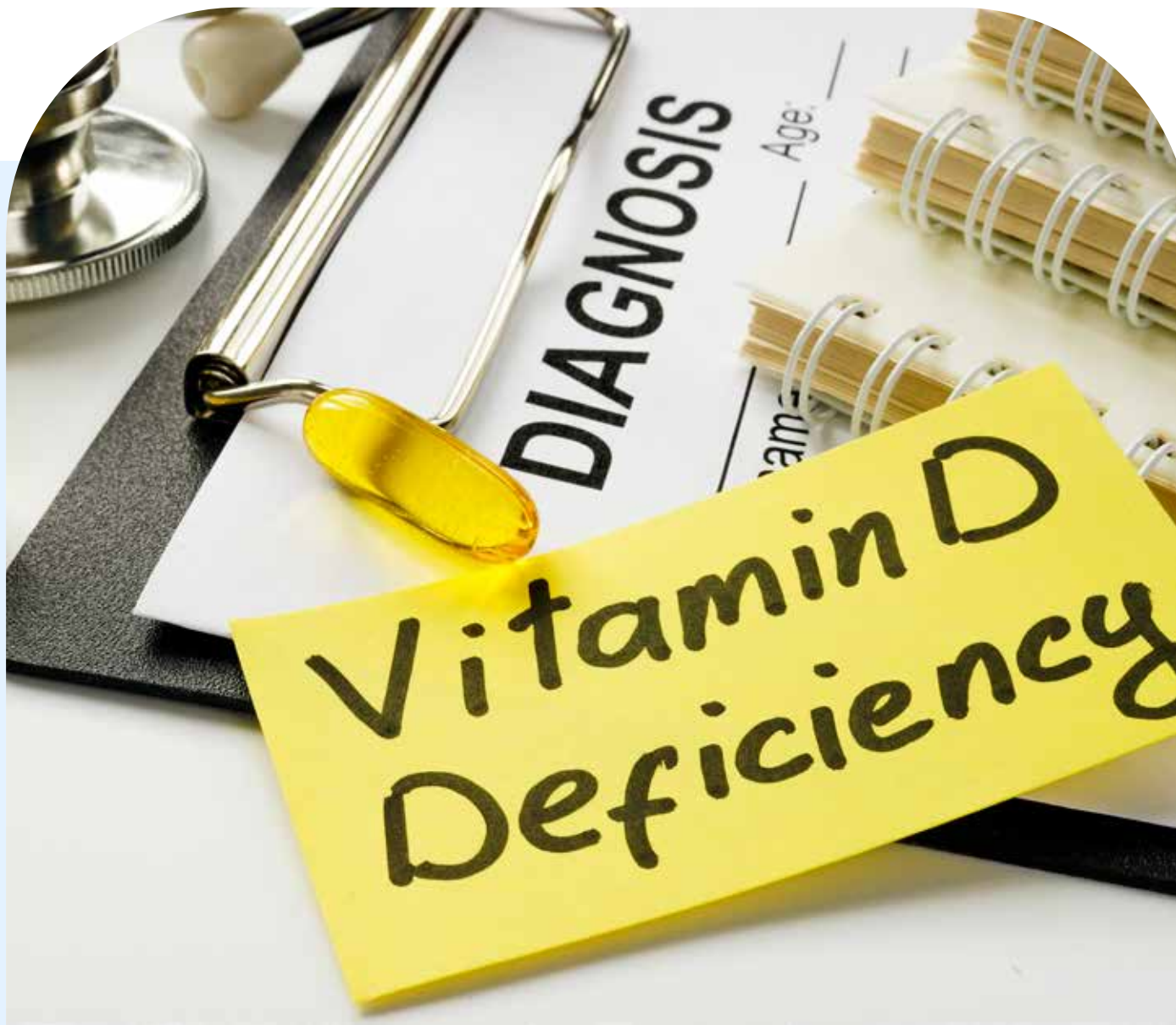
Centre moves to penalise drugmakers for fake data in approval process

On 30th October 2025, The Union Health Ministry notified draft rules that would bar drugmakers if they were found to have submitted misleading, fake, or fabricated information while seeking product marketing approvals. Under amendments to the 1945 rules, the Ministry empowered central and state drug regulators to debar applicants from the licensing process for a period deemed fit after conducting enquiries and affording an opportunity to be heard. Concerned applicants were given 30 days from receipt of an order to submit written representations explaining why the order should not be issued. The notification stated that the government might, after such enquiry, pass appropriate orders. The draft rules were opened for objections and suggestions from stakeholders until November 27. The changes followed a recommendation by the Drugs Technical Advisory Board, which had urged that debarment be added alongside suspension or cancellation of products where fabricated or misleading data had been used. Previously, applicants suspected of data fabrication were typically pursued under relevant sections of the Indian Penal Code, but licensing authorities had not frequently disclosed such cases. Regulators and observers had long flagged data integrity as a weakness in emerging markets and the draft aimed to strengthen regulatory action and deter submission of falsified data.

Study finds widespread Vitamin D deficiency among Indians despite slight improvement

On 30th October 2025, a nationwide study by Metropolis Healthcare Limited found that 46.5% of Indians tested were vitamin D deficient and a further 26% were insufficient, highlighting widespread inadequacy. The analysis was based on more than 2.2 million test results collected between 2019 and January 2025. Regionally, South India recorded the highest deficiency at 51.6%, with Kerala, Puducherry and Tamil Nadu each exceeding 50%. Central India followed at 48.1%, North India at 44.9% and West India (including Maharashtra) at 42.9%, while the Northeast reported the lowest rate at 36.9%, a disparity the study attributed to greater outdoor activity and varied diets there.

The report showed a gradual national improvement, with deficiency levels declining from roughly 51% in 2019–20 to about 43% in 2023–24, but experts warned that urbanisation, reduced sunlight exposure and poor diets continued to drive the problem. Adolescents (13–18 years) emerged as the most affected group, with a 66.9% deficiency rate, signalling a growing public-health concern. Gender gaps narrowed, as 46.9% of women and 45.8% of men were found deficient. Metropolis leaders emphasised the silent but significant health impacts of vitamin D deficiency and recommended paired testing (calcium and parathyroid hormone) to identify underlying causes and guide preventive action.



Ayurveda sector valued at USD 43 billion, poised for major growth: Ayush Secretary

On 30th October 2025, Ayush Ministry Secretary Vaidya Rajesh Kotecha said the Indian Ayurveda economy was valued at USD 43 billion as he addressed the Kerala Health Tourism and Global Ayurveda Summit and Expo 2025 organised by CII. He noted that Ayurveda and traditional healthcare systems were poised for a major transformation and were projected to contribute five per cent to India's GDP by 2047, up from about 1.1 percent currently. Kotecha added that investment proposals worth USD 1.2 billion were already in the pipeline and praised Kerala's pioneering role in Ayurveda.

Union Minister of State for Ayush Prataprao Jadhav, speaking online, lauded Kerala's Ayurveda care and infrastructure, while Kerala Industries Minister P Rajeev outlined state initiatives to position Kerala as a global healthcare destination and to integrate Ayurveda with modern medicine. CII Global Ayurveda Summit chairman Dr Sajikumar projected that Kerala's Ayurveda economy would grow to Rs 60,000 crore by 2031 from Rs 15,000 crore at present, and that the sector could reach Rs 5 lakh crore by 2047 in line with the Viksit Bharat vision. CII leaders emphasised South India's strong healthcare capabilities and Kerala's strengths in wellness, with organisers highlighting the sector's resilience and its potential to drive economic growth through investment, integration of traditional and modern care, and promotion of holistic health tourism.



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