

## **KIHT Certification Services (KCS) become the first CDSCO-approved device audit body in Andhra-Telangana**

On 5<sup>th</sup> July 2025, in a significant development, Andhra Pradesh became home to its first-ever CDSCO-notified auditing body for medical devices. The Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, notified KIHT Certification Services (KCS) as the state's first regulatory body authorised to audit manufacturing facilities for Class A and Class B medical devices. Among 14 such notified bodies nationwide, KCS was the only one operational in Andhra Pradesh and Telangana, marking a milestone in the region's quality assurance capabilities.

KCS was housed within the Kalam Institute of Health Technology (KIHT) on the AMTZ campus. While KIHT was established in July 2017 as a Government of India initiative supported by the Department of Biotechnology, KCS was set up in April 2022. It was accredited by the National Accreditation Board for Certification Bodies and offered a wide range of services, including ISO 13485 certification, quality system audits, CE-mark consultancy, and risk management training.

This move provided immediate benefits to domestic medical device manufacturers, particularly MSMEs, by reducing audit-related expenses and eliminating the need for out-of-state inspections. It also supported the broader goal of strengthening India's medical device ecosystem through regional regulatory infrastructure.





## **NMC orders medical colleges to form device safety monitoring panels**

On 15<sup>th</sup> July 2025, the National Medical Commission (NMC) directed all medical colleges across India to constitute committees dedicated to monitoring, assessing, and preventing adverse events related to medical devices. In a public notice, the NMC mandated that these committees be registered with the Indian Pharmacopoeia Commission (IPC). It highlighted that medical devices had become an integral part of healthcare and, in some cases, had caused patient harm, reinforcing the need for a strong monitoring mechanism.

To address this, the Ministry of Health and Family Welfare had launched the Materiovigilance Programme of India (MvPI) in 2015 under IPC to systematically track and mitigate risks associated with medical devices. The initiative aimed to enhance patient safety by collecting and analysing data through a growing network of Medical Device Adverse Events Monitoring Centres (MDMCs) housed in hospitals and medical colleges.

The NMC stated that medical colleges were well-placed to serve as MDMCs due to their clinical and technological exposure. Benefits included academic recognition, professional development, and policy influence. The NMC also instructed that the committee coordinators and members' names be published on the institution's website, with the Medical Superintendent serving as Chairperson. Colleges were asked to complete registration by 31<sup>st</sup> July and update existing pharmacovigilance committee details.



## Delhi Government begins hiring for the state mental health authority after the High Court order

On 21<sup>st</sup> July 2025, the Delhi government began the recruitment process for 11 key posts in the State Mental Health Authority (SMHA), following a Delhi High Court directive issued in December 2024 to expedite the long-pending appointments. The advertised positions included one psychiatrist, a clinical psychologist, a psychiatric social worker, a mental health professional, and a mental health nurse, roles deemed essential for making the SMHA functional under the Mental Healthcare Act, 2017.

Despite the 2017 legislation mandating each state to establish a mental health authority, Delhi's SMHA had remained largely non-functional due to prolonged delays in appointing non-official members. The high court had emphasised the urgency of creating a working regulatory framework, especially in light of rising mental health needs in the capital.

The SMHA is responsible for regulating mental health services, monitoring treatment centres, registering mental health establishments, and safeguarding the rights of persons with mental illness. The urgency of appointments was further underscored by a recent study from AIIMS, published in the Indian Journal of Psychiatry (2024), which revealed that nearly one in three adolescents (aged 15–19) in urban Delhi had experienced an episode of depression or anxiety. The findings highlighted the growing mental health burden among the city's youth.





## **NATHEALTH and EY launched a whitepaper on Streamlining Compliance in the Indian Healthcare Sector, to address healthcare inefficiencies**

On 28<sup>th</sup> July 2025, NATHEALTH – Healthcare Federation of India, in collaboration with EY India, released a whitepaper titled Streamlining Compliance in the Indian Healthcare Sector, which was submitted to NITI Aayog. The document outlined a roadmap for regulatory reform, based on inputs from hospitals, diagnostic centres, and MedTech firms, and aimed to simplify India's fragmented compliance system.

The whitepaper aligned its recommendations with national priorities such as Ease of Doing Business, digital governance, and improved healthcare access. It highlighted that the healthcare sector faced oversight from 10–12 ministries across three tiers of governance, placing it among the top three most compliance-heavy industries in the country.

The study found that 25–30 per cent of compliance requirements changed annually, and 24 per cent of central regulations were healthcare-specific. NATHEALTH proposed a digital single-window compliance platform to address inefficiencies caused by procedural duplication and a lack of standardisation.

The whitepaper identified 85 compliance challenges, with 44 deemed especially burdensome. Segment-specific issues were detailed for hospitals, diagnostics, and MedTech firms. NATHEALTH President Ameera Shah stressed the need for agile regulatory frameworks to support patient-centred care. The paper recommended short-term, medium-term, and long-term strategies for a more transparent, cost-effective, and innovation-friendly compliance ecosystem.

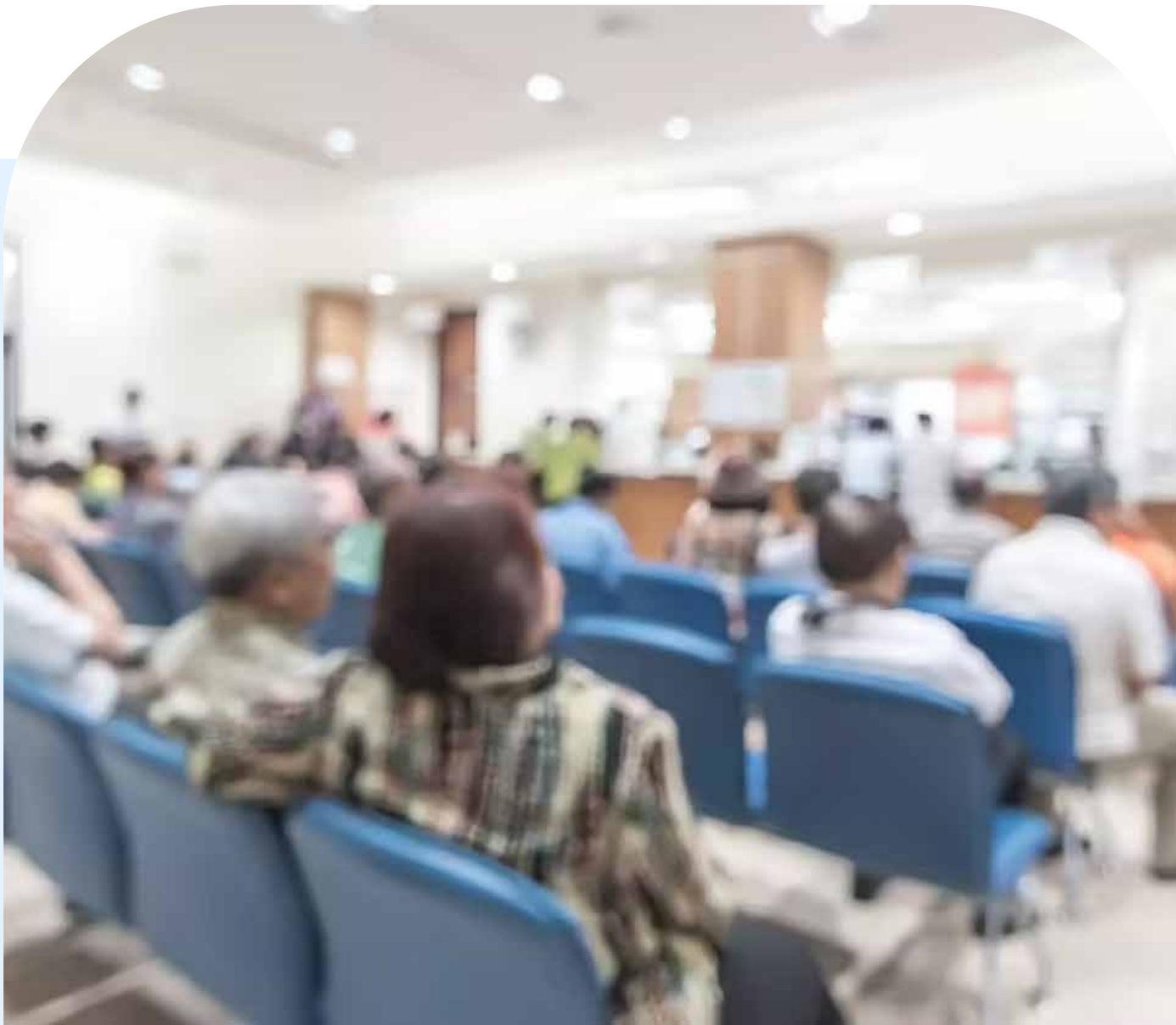
## Delhi Government launches digital OPD appointment system across hospitals

On 24<sup>th</sup> July 2025, Chief Minister Rekha Gupta launched the Health Information Management System (HIMS), describing it as a major step toward digitising healthcare delivery in Delhi. The system enabled patients to book OPD appointments online, access digital OPD slips, and view their medical records in real time, eliminating the need to wait in long hospital queues.

Ms. Gupta also virtually inaugurated 34 Ayushman Arogya Mandirs and eight Jan Aushadhi Kendras during the event at the Delhi Secretariat. Developed with the Union Health Ministry, the HIMS platform was based on the NextGen e-Hospital model and integrated with Ayushman Bharat Health Account (ABHA) IDs. Officials stated that over 93 lakh ABHA IDs had already been generated in Delhi.

The new system went live across 35 government hospitals for OPD services and was slated for phased expansion to all public health institutions. Ms. Gupta said the digital platform connected patients, doctors, and hospitals through a centralised network, improving service delivery and transparency.

She also criticised the previous AAP-led government's healthcare approach, claiming it failed to appoint dedicated medical superintendents or adequately hire doctors and paramedical staff. "We are still searching for their health model," she said, adding that one superintendent had been handling four hospitals.



## ICMR highlights 45% shortage in cancer radiotherapy machines in India

On 25<sup>th</sup> July 2025, in a recent ICMR study published in BMC Cancer highlighted a significant gap in radiotherapy access across India. It found that only 28.5% of cancer patients received radiotherapy, far below the optimal 58.4%. The study, conducted by ICMR-NCDIR Bengaluru, used epidemiological data from the National Cancer Registry and international benchmarks to estimate machine requirements and utilisation gaps.

The burden of breast, head and neck, lung, and cervical cancers alone accounted for 60% of India's radiotherapy needs. The study revealed that radiotherapy use remained low in major indicated sites such as lymphoma, lung, prostate, and breast cancers. At current rates, India had only 794 megavoltage radiotherapy machines, falling short by 45% of the minimum requirement, based on WHO standards of one machine per million population.

The projected need for 2025 ranged between 1,585 and 2,545 machines, depending on clinical benchmarks. The study stressed the need for increased investment in equipment and equitable distribution across regions. It also recommended scaling up indigenous production of radiotherapy units to reduce reliance on imports. Researchers concluded that improved planning, guided by cancer registry data, and early detection efforts were essential for addressing the growing cancer burden in India.





## **Government to set up over 200 cancer day care centres nationwide**

On 27<sup>th</sup> July 2025, the Ministry of Health and Family Welfare achieved a significant milestone by screening over 10.18 crore women aged 30 years and above for cervical cancer across the country, as part of a population-based initiative under the National Health Mission (NHM). The screening was conducted through Ayushman Arogya Mandirs (AAMs), targeting women between 30 and 65 years using the Visual Inspection with Acetic Acid (VIA) method.

Trained health workers carried out the screenings at Sub-Health Centres and Primary Health Centres, while women testing VIA-positive were referred to higher centres for further evaluation. Accredited Social Health Activists (ASHAs) played a key role in identifying at-risk individuals through the Community-Based Assessment Checklist (CBAC), promoting awareness, and encouraging participation in screenings.

The government supported the initiative through targeted awareness campaigns, wellness activities, and public engagement via print, electronic, and social media. States and Union Territories received dedicated NHM funds for awareness generation as per their Program Implementation Plans (PIPs).

A time-bound NCD Screening Campaign conducted from February 20 to March 31, 2025, helped accelerate coverage. According to data from the National NCD Portal, 10.18 crore women out of 25.42 crore eligible females had been screened as of July 20, 2025.





## Cervical Cancer Screen (Co-Testing)

### **Over 10 crore women screened for cervical cancer under Ayushman Arogya Mandirs & National Health Mission**

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## Experts call for urgent action on rising hepatitis burden in India

Only 3% of hepatitis B patients in India were aware of their condition, and less than 1% of eligible individuals received antiviral treatment, according to experts at the 'Illness to Wellness' Awareness Conference held in New Delhi on World Hepatitis Day, i.e., 28th July 2025. The event, organised by the Illness to Wellness Foundation under the theme "Prevention, Diagnosis, and Treatment for Hepatitis," brought together medical professionals, policymakers, and public health advocates to address India's growing hepatitis burden.

Delivering the keynote address, Mr. Rajesh Bhushan, Former Secretary, Ministry of Health & Family Welfare and Chairperson, Illness to Wellness Foundation, called hepatitis a "silent public health crisis" and outlined five urgent priorities: expanded screening, timely hepatitis B birth-dose vaccination, decentralised treatment access, awareness at the community level, and the use of real-time data for intervention. He emphasised the need for collaboration across government, civil society, and the private sector.

In his welcome address, Mr. Anil Rajput, Chairperson of the Foundation's Advisory Council, reinforced the importance of a holistic approach. Health experts at the conference flagged low vaccine coverage among newborns and urged a focus on universal vaccination, early diagnosis, and reducing stigma. The event concluded with a strong call for united national efforts to eliminate hepatitis by 2030.



### **About Avian WE's Healthcare E-Newsletter:**

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