

CDSCO forms expert panel to regulate AI use in drug discovery: DCGI

DCGI Rajeev Raghuvanshi says the panel includes AI experts and will discuss how AI used in drug discovery should be evaluated, approved and regulated

The Central Drugs Standard Control Organisation (CDSCO) has created an expert committee to discuss ways to regulate the use of artificial intelligence (AI) in drug discovery, Drugs Controller General of India (DCGI) Rajeev Raghuvanshi said on Friday.

“Regulation of AI in healthcare is a subject that is being discussed by all agencies globally,” Raghuvanshi said, addressing the 8th CII Pharma and Lifesciences Summit in New Delhi.

He added that the committee includes AI experts, and discussions include how to evaluate, approve and regulate AI in drug discovery. However, Raghuvanshi did not share any timeline or terms of reference for the expert committee.

The announcement comes just a month after the CDSCO issued a guidance document detailing how software-based medical devices, including AI-enabled products, will be regulated under the Medical Devices Rules (MDR), 2017.

Stating that the role of software in healthcare is becoming increasingly critical, the guidance document stated that any software, whether alone or in combination, intended by the manufacturer for medical purposes and defined as a medical device under the Drugs and Cosmetics Act, 1940, and MDR, 2017, is regulated as a medical device.

Raghuvanshi added that the apex regulatory body is aiming to start the Digital Drugs Regulatory System (DDRS) within a month.

The DDRS is a unified, single-window digital platform aimed at overhauling India's pharmaceutical and medical device regulation. “12 companies had bid for developing the system. The technical presentations are over, and the financial viability will be checked within the next seven to ten days,” Raghuvanshi said.

The new system will be designed to streamline complex processes, from registration and clinical trial approvals to import-export licensing and supply-chain traceability. It will bring central and state regulators, laboratories, and allied agencies onto a unified, real-time digital architecture.

He added that the industry will see a lot of AI interventions, simplified processes and data analytics to help the regulator with internal processes, which will increase the ease of doing business.

Raghuvanshi added that the CDSCO is looking at approving new-age therapies to increase their availability in India. “India’s third CAR-T therapy is in the final stages of approval, while an indigenous gene therapy will soon be starting its phase-1 trials,” he said.

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