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CDSCO signals shift towards smarter, risk-based regulation to ease doing business for Indian pharma

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Regulators and industry at iPHEX 2026 call for proportionate enforcement and simpler compliance



The Central Drugs Standard Control Organisation (CDSCO) is moving towards a smarter, risk-based regulatory approach that reduces and prioritises intervention, simplifies processes and applies greater proportionality to compliance, while continuing to safeguard the quality, safety and efficacy of medicines, Dr Ranga Chandrashekhar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare, Government of India, said during a panel discussion at iPHEX 2026 organised by Pharmexcil.

Speaking at a session focused on rationalising criminal provisions governing business and regulatory compliance, Dr Chandrashekhar said CDSCO has examined the drug approval pathway to identify areas where regulatory intervention can be reduced without compromising quality.

He pointed to measures where certain requirements have moved from prior approval to prior intimation, including manufacturing for test and analysis before approval, helping reduce processing time. He also said that for BA/BE studies clinical study designs are standardised and adequate guidance is provided enabling prior intimation for generation of data for export purpose.

He also highlighted CDSCO's increasing use of digital systems, dashboards and supervisory mechanisms to reduce processing time and improve oversight.

Referring to the Jan Vishwas framework, Dr Chandrashekhar said certain procedural and record-keeping offences have been reviewed to ensure that the regulatory response is proportionate to the nature of the lapse, with compounding the offences with monetary penalties available in appropriate cases while retaining deterrence.

Raja Bhanu, Director General, Pharmexcil, said, "For Indian pharmaceutical companies, particularly exporters and MSMEs, regulatory clarity and predictability are critical to competitiveness. A smarter, risk-based approach can reduce avoidable compliance burden while maintaining the standards expected in global markets. This balance between strong regulation, ease & speed of doing business will be important as India strengthens its position as a trusted pharmaceutical partner worldwide."

The discussion reflected a broad convergence that ease of doing business in pharmaceuticals does not mean weaker regulation, but a more risk-based and proportionate framework that simplifies compliance for legitimate businesses while retaining strong safeguards around quality, safety and serious violations.The discussion formed part of iPHEX 2026, the 12th edition of India's flagship pharmaceutical exhibition, organised by Pharmexcil with the support of the Department of Commerce, Ministry of Commerce and Industry, Government of India, under the Bharat Health Global Expo 2026 at Bharat Mandapam, New Delhi.