CDSCO powers up Joint Drug Controllers to drive faster approvals

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New Delhi: In a bid to fast-track approvals for import licenses and decisions related to serious adverse events (SAE), the Central Drugs Standard Control Organisation (CDSCO) has delegated licensing authority (LA) powers to Joint Drug Controllers (India).

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Additionally, the order empowers officials to examine and make decisions on compensation payments for severe adverse events—death, persistent disability, etc.—in clinical trials and BA-BE studies, as per the revelant provisions.

Until now, only the DCGI held the central licensing authority powers and announcement of delegation is expected to accelerate the approval process for the respective matters.

Speaking to ETPharma a senior drug controller said, “delegation of powers to Joint Drug Controllers enables faster approvals for import/manufacturing licenses and timely SAE compensation decisions, reducing delays and improving regulatory efficiency-all of which translate to faster product approvals, and improved business confidence for the pharmaceutical industry.”

“This reform strengthens accountability within CDSCO and supports the Government’s “Ease of Doing Business” and “Make in India” initiatives, the regulator added.

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