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Drugs regulator needs urgent rejig, says panel

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At a time when Indian pharmaceutical firms are under scrutiny for poor manufacturing processes, a new report says the drug regulator is short on manpower, infrastructure and needs an urgent reorganisation.

The expert committee headed by Ranjot Roy Chaudhary, set up by the Government to suggest reforms in drugs regulation and clinical trials, has said in its report that the problems with the current drug regulatory system in the country have been well identified and remedial measures suggested.

"Unfortunately, these have never been seriously looked into. No infrastructural improvement whatsoever, in respect of personnel, has occurred in CDSCO," it said.

The Central Drugs Standard Control Organisation, headed by the Drugs Controller General of India (DCGI) is responsible for monitoring drugs safety, approving manufacturing and import of new drugs, permitting clinical trials and other activities.

The panel has noted a severe shortage of manpower in CDSCO. According to the report, the organisation handles nearly 20,000 applications each year for various statutory approvals, of which over 2,000 are for new drugs.

The current manpower of six Deputy Drugs Controllers (DCs) and 18 Assistant Drugs Controllers (ADCs), assisted by 75 drug inspectors and 55 technical data associates on contractual basis is far short of the actual manpower requirement proposed by the Hathi Committee in 1975 and the Mashelkar Committee in 2003, the report noted.

The panel said that for creating a strong, efficient and effective drugs control authority the CDSCO, which is plagued by "poor infrastructure and manpower", needs to be reorganised.

The panel has said that the CDSCO should be upgraded to a separate organisation/authority, with the DCGI at par with heads of similar organisations. "This will overcome the current malady of lack of functional and financial autonomy," it said.

The panel noted that this lack of autonomy is one of the biggest bottlenecks in decision-making and causes enormous delays. It also noted a severe lacuna in expertise related to regulatory issues. "Till in-house expertise is developed as in other regulatory agencies such as the US Food and Drug Administration and European Medicines Agency, expertise of subject specialists may be utilised on a contractual basis," the committee has recommended.

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