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India to examine drug approval procedures

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India sets up committee to examine drug approval procedures

Bangalore: India has set up a committee to examine the validity of scientific and statutory basis adopted for approval of new drugs without clinical trials. The government announced the decision to set up the committee after a report by the Parliamentary Standing Committee on glaring irregularities in the functioning of the Central Drugs Standard Control Organization (CDSCO).

India's Minister of Health and Family Welfare Mr Ghulam Nabi Azad made the announcement.

The committee will comprise renowned scientific figures such as Dr V M Katoch, secretary and DG, ICMR; Dr P N Tandon, president, National Brain Research Centre, Department of Biotechnology, Manesar; and Dr S S Aggarwal, former director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.

The committee has also been asked to outline appropriate measures to bring about systemic improvements in the processing and grant of statutory approvals and suggest steps to institutionalize improvements in other procedural aspects of functioning of the CDSCO. The committee has been asked to submit its report within a period of two months.

The Parliamentary Standing Committee report placed various allegations regarding drugs being approved without the necessary clinical trials and various doctors siding with pharma companies to submitting identical recommendations for a particular drug.

The standing committee report has also made recommendations and observations on various aspects such as organizational structure and strength of CDSCO, approval of new drugs, ban of drugs, approval of fixed dose combinations, pharmacovigilance, spurious and sub-standard drugs.