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Health Ministry planning to waive off clinical trials for select drugs

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Initially the proposal was to waive off clinical trials for all drugs which are available in these developed markets for at least two years. However, this was met with objections during deliberations by the Drugs and Technical Advisory Board, which usually takes a call on such matters.

In a move to make innovative medicines available for critical diseases like HIV, hepatitis and tuberculosis, the health ministry plans to waive off clinical trials in humans for select drugs which are essential for Indian patients and were approved in developed markets like the US, European Union, Japan, Canada and Australia at least two years ago.

"The recommendations were made by the Ranjit Roy Chowdhary committee some time back. The idea is to take a progressive step in the direction of making essential and innovative medicines available in India at a fast pace," Drugs Controller General of India GN Singh , reported Economic Times.

Though such waivers are still approved by the drug regulator on case to case basis, the ministry now plans to bring in legal provisions under the proposed rules for clinical trials. This will enable the regulator set a standard procedure and criteria for approvals.

The health ministry has sent the proposed rules to the law ministry for vetting. Singh said in some cases the clinical trial waiver may even be extended to cancer drugs but only if they are considered essential for treatment of Indian patients and alternatives are unavailable. Companies, however, will also be required to do post marketing trials and submit data in a specified period after the launch. Initially the proposal was to waive off clinical trials for all drugs which are available in these developed markets for at least two years. However, this was met with objections during deliberations by the Drugs and Technical Advisory Board, which usually takes a call on such matters.

Experts part of the board had said some of these medicines may be effective in patients of other countries but may act differently on Indian patients because of genetic make-up. "Our objective is to ascertain safety and efficacy of the drug in Indian patients...We will still decide on case to case basis and take a call depending on the need and efficacy of the drug," Singh said.