

# Drug industry frets as just 9 trials get approval

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The new drug advisory committee has approved only nine clinical trials — five global clinical trials and four trials in fixed-drug combinations — making the clinical trial industry wary of the government's lukewarm response.

So far, in 2014, 107 trials have been approved. However, in 2012, 262 trials were approved. There were 23 proposals, but only 13 were cleared. The technical committee evaluated all the recommendations and found that only drugs for biologicals, fixed-dose combinations and other new combinations required trials.

A senior industry

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— DR PREETI REDDY,  
Mahavir Research Centre

source said, "These were 23 cases before the technical committee. Of these, 13 were global clinical trials of non-communicable diseases and 10 were related to clinical trials for approval of new drugs."

The industry has to follow several guidelines and they have to ensure

the patient is not harmed. There are strict checks for the set parameters, along with the increasing day-to-day cost of monitoring and also video-recording of reactions to drugs.

Dr Preeti Reddy of Mahavir Research Centre said, "The strict approach of the Drug Controller General of India is welcome but it must ensure that after proper approvals, trials are not stopped due to any complaints. There is a need for new drugs."

The Supreme Court has also said proposals for global clinical trials have to be evaluated on the basis of risk of assessment versus benefit to the patients and unmet medical needs in the country.

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Clinical trials