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भारत सरकार

Financial Express, Delhi
Tuesday 11th March 2014, Page: 3
Width: 5.35 cms, Height: 23.88 cms, a4, Ref: pmln.2014-03-11.40.26

SC asks govt to give details on adverse effects of clinical trials

fe Bureau

New Delhi, March 10: Raising concern over deaths due to clinical trials of drugs, the Supreme Court on Monday asked the Centre to provide all the data on deaths and serious adverse effects caused due to such trials done by the pharma majors.

It also asked the government to review New Chemical Entities/Global clinical trials as per its last year's October order.

A bench headed by Justice RM Lodha sought information on 506 people who were adversely affected due to such trials and also on whether compensation was paid to 89 people who died. Besides, it also sought details on drugs approved for clinical trails between 2012 and 2013.

It observed that there was a need to find a solution for development of medicines and how to improve human lives.

Counsel Sanjay Parikh told the court that neither the Technical Committee nor the Apex Committee had given details of their evaluation as per the three parameters orders by the apex court's order of October 21, 2013 and instead they had merely rubber stamped their decisions. The three parameters which be followed are safety and efficacy, particularly in terms of risk and benefit to patient; innovation vis-à-vis existent therapeutic option and unmet need in the country

Parikh also raised the point that the Technical Committee includes Dr Ranjit Roy Choudhary who is the chairman of Task Force for Research in Apollo Hospital which has conducted 300 clinical trials.

Clin'd Research.