

## NIH suspension will not affect us claims health minister

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In order to strengthen the regulatory provisions and the monitoring mechanism of clinical trials in the country, Drugs and Cosmetics Rules, 1945 have been amended recently. The National Institute of Health (NIH), had raised concerns about how these new requirements will be implemented, particularly the specific provision related to compensation.

However, the the union minister of health and family welfare, Ghulam Nabi Azad in parliament on August 28, 2013, tried to dispel the fears. "NIH have suspended enrolment of participants in 35 international trials in India. This will, however, not affect this country's health programme and domestic pharma industry. The drug trial policy has been evolving in course of time. Government has been trying to strengthen the regulatory mechanism to ensure proper drug trials," claimed Azad.

These amendments that were made during the early half of this year include:

- A.** Amendment vide Gazette Notification G.S.R. 53 (E) dated January 30, 2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.
- B.** Amendment vide Gazette Notification G.S.R. 63(E) dated February 01, 2013, specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.
- C.** Amendment vide Gazette Notification G.S.R No. 72(E) dated February 08, 2013, specifying requirements and guidelines for mandatory registration of Ethics Committee.