

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:4330  
ANSWERED ON:22.03.2013  
ETHICS COMMITTEES FOR CLINICAL TRIALS  
Bishnoi Shri Kuldeep

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

- (a) whether the Government has laid down any rules/regulations for constitution and composition of Ethics Committees to safeguard the rights, safety and wellbeing of subjects in clinical trial;
- (b) if so, the details thereof;
- (c) the mechanism put in place by the Government to ensure constitution and composition of Ethics Committees as per the rules/regulations;
- (d) the details of cases of contravention of the aforesaid rules/regulations which have come to the notice of the Government during the last three years and the current year along with the action taken/proposed thereon; and
- (e) the measures being taken by the Government for mandatory registration of Ethics Committees and to make them more accountable and transparent while approving clinical trials?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (e): The Drugs and Cosmetics Rules, 1945 have been amended vide Notification G.S.R No. 72(E) dated 8.2.2013 incorporating Rule 122DD and amending the Appendix VIII of Schedule Y for registration of Ethics Committee. This amendment provides details about the functioning of the Ethics Committee as well as the requirements and guidelines for their registration. The constitution and composition of Ethics Committee will be as per the provisions laid down in the Rule. As per Rule 122DD, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with the Drugs Controller General (India) [DCG(I)]. The Ethics Committee shall review and accord its approval to a clinical trial and also carry out review of the trial at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice (GCP) Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects. The Ethics Committee shall allow Inspectors or officials authorised by the DCG(I) to inspect their facilities, records, documents etc. If the Ethics Committee fails to comply with any of the conditions of registration, DCG (I) may suspend or cancel the registration of the Ethics Committee.

So far, no such cases of contravention, of the aforesaid Rule 122DD have been reported.