GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3285
ANSWERED ON:13.08.2010
CLINICAL TRIAL OF DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the trials of drugs/vaccines are being done on poor patients with the involvement of multi-national companies;

(b) if so, the details thereof;

(c) whether the permission for the clinical trials is accorded by the Drug Controller General of India;

(d) if so, the details of the procedure prescribed for each phase of the trial; and

(e) the details of complaints received in this regard during the last three years and the action taken thereon?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) & (b): Clinical trials on drugs / vaccines are permitted to be conducted in the country in accordance with requirements and guidelines specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule Y of Drugs & Cosmetic Rules. Such trials are conducted by pharmaceutical companies including multi-national companies and by other Organisations, Institutions etc.

(c): Clinical trials as defined under Rule 122 DAA of Drugs and Cosmetics Rules are permitted by Drugs Controller General (India).

(d) Procedure for conducting clinical trials in different phases is prescribed in Schedule Y of Drugs & Cosmetic Rules.

(e): Sometimes complaints regarding clinical trials are received from investigator, Clinical Research Organizations (CRO)/ Sponsor, trial subjects and from other stake holders. There have been complaints of death during clinical trials which may take place due to various reasons. These could be disease related deaths like cancer etc or administration to critical or terminally ill patients or side effects or unrelated causes. Such deaths are investigated for causal relationship by investigator and by medical experts of sponsor. The information collated revealed that there were 132 deaths in the year 2007, 288 in the year 2008 and 308 upto August, 2009. Action on such types of complaints is taken as per Drugs and Cosmetics Rules thereunder.