

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

UNSTARRED QUESTION NO:743

ANSWERED ON:22.10.2008

CLINICAL TRIALS BY MNCS IN INDIA

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

- (a) whether India has become the top destination in Asia for clinical trials of foreign drugs;
- (b) if so, the details thereof and the reasons therefor;
- (c) whether there is presently any law in force to regulate/monitor such trials;
- (d) if so, the details thereof; and
- (e) the steps taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE(DR. ANBUMANI RAMADOSS)

(a): Clinical Research has emerged as a very promising area in the country during last few years. Several leading multinational Pharmaceutical companies are conducting their clinical trials through Clinical Research Organisations(CROS).

(b): The increased clinical trial flow to India is the result of several fundamental strengths such as : diverse genetic pool, Large patients pool with diseases such as cardiovascular, diabetics and psychiatric disorders, which are prevalent in industrialized countries, drug-naïve population and good hospitals where trials can be undertaken. Low cost in conducting trials, etc.

(c) to (e) : In respect of the regulation of clinical trials in India, Government has streamlined the provisions under Drugs and Cosmetics Rules for conduct of Clinical trials. Rules -A to E have been amended for this purpose. Schedule Y of Drugs and Cosmetics Rules have also been amended in 2005 . Good Clinical Practice (GCP) guidelines have been published in 2001.