

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

UNSTARRED QUESTION NO:394

ANSWERED ON:02.03.2005

CLINICAL TRIALS

Choudhary Shri Nikhil Kumar;Danve Shri Raosaheb Patil

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

- (a) whether the union Government proposes to relax rules pertaining to clinical trials on patients ;
- (b) if so, the details thereof;
- (c) whether non-certified formulations of multi-national pharmaceutical companies are likely to be tested indiscriminately on innocent Indians after relaxing the relevant rules ; and
- (d) if so, the policy measures being taken by the Government to safeguard the interests of innocent Indian patients?

**Answer**

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

(a) to (d) There is no proposal to relax Rules pertaining to Clinical Trial on patients. On the contrary, Schedule Y of Drugs & Cosmetics Rules which prescribes norms for clinical trials has recently been revised, to prescribe in clear terms, the responsibilities of investigators, Ethics Committees and Sponsors. The revised Schedule-Y has also prescribed specific requirements to ensure patients safety by way of obtaining consent form from patients etc.

The above initiatives are aimed at precluding any indiscriminate testing of non-certified formulations of multinational pharmaceutical companies on innocent Indian people.