

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

UNSTARRED QUESTION NO:2219
ANSWERED ON:14.03.2007
CLINICAL TRIAL REPORTS
Hasan Chaudhary Munawwar

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

- (a) whether clinical trial reports are prepared by medical advisers of drug producers and the investigators put their signatures only;
- (b) if so, the details thereof; and
- (c) the details of the arrangements made by Drug Control Authority to monitor such allegations?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a)&(b) : Schedule Y of Drugs and Cosmetic Rule, prescribes the role of Sponsor and Investigator as follows:

Responsibility of Sponsor –The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines, as well as with all applicable statutory provisions. Standard operating procedure should be documented to ensure compliance with GCP and applicable regulations.

Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the Prescribed periodicity.

Responsibilities of the Investigator (s) – The Investigator (s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of the Schedule Y.

(c)In case of any report of non-compliance of Schedule Y of D&C Rules, & GCP Guidelines investigation by the competent authority is initiated. In case any irregularity is confirmed marketing authorization for relevant drugs can be withdrawn/ suspended.