

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

UNSTARRED QUESTION NO:4144
ANSWERED ON:21.12.2005
REGULATING CLINICAL RESEARCH
Rao Shri Sambasiva Rayapati

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

- (a) whether the Government has set up a panel of regulators, mostly eminent doctors and researchers to inspect research sites in their zones;
- (b) if so, the details thereof;
- (c) whether a two day workshop on good clinical practice for the regulators was held at AIIMS in October , 2005; and
- (d) if so, the extent to which these steps are likely to be helpful to regulate clinical research?

Answer

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

(a) to (d) Yes, Sir. Among the various measures taken by the Government to regulate Clinical Trials in the country, initiatives have also been taken to undertake regulatory inspections of clinical trial sites. For this, a training workshop was held in October, 2005 in coordination with Department of Pharmacology, AIIMS, New Delhi to prepare a panel of experts from different parts of the country. This step would enable the regulatory agency i.e. Central Drugs Standard Control Organisation to ascertain the status of conformity to the principles of Good Clinical Practices (GCPs) by the sponsors and clinical investigators involved in Clinical Trials.