

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

UNSTARRED QUESTION NO:220
ANSWERED ON:01.12.2004
BIO-EQUIVALENCE CENTRES
Paraste Shri Dalpat Singh

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

- (a) Whether Bio-Equivalence centres in the country are being run without any approvals ;
- (b) If so, the details thereof;
- (c) Whether the volunteers for these studies are being hired against the norms ; and
- (d) If so, the action being taken by the Drug Controller General of India (DCGI) to stop it?

Answer

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

(a) to (d): Bio-equivalence studies with drug formulations are required to be carried out as per norms prescribed under Drugs and Cosmetics Rules involving human volunteers. Bio-equivalence centers are required to get the approval from Institutional Ethics Committee and protocol etc. from the office of Drugs Controller (India).

Bio-equivalence centers are required to follow Good Clinical Practice norms for hiring or including human volunteers in the study. The Centres are also required to follow the norms prescribed under the guideline namely `Ethical Guidelines for Biomedical Research for Human Subjects` issued by Indian Council of Medical Research (ICMR). No specific complaint regarding Bio-equivalence centers has been received in this Ministry.