

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

UNSTARRED QUESTION NO:2156
ANSWERED ON:06.12.2006
DRAFT NOTIFICATION FOR GOOD LABORATORY MANUFACTURING PRACTICES
Chowdhury Shri Adhir Ranjan

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

- (a) whether a new draft notification for good laboratory manufacturing practices has been issued by the Government;
- (b) if so, the details thereof;
- (c) whether it is likely to lead to closure of a large number of small scale pharma units due to financial constraints; and
- (d) if so, effective steps taken by the Government in this regard?

Answer

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

(a) Yes, sir.

(b) Union Ministry of Health have published Gazette Notification vide GSR 634 (E) dated 13.10.2006, eliciting views of the public before finalization of the draft rules intended to be amended as Schedule L-1 under the Drugs and Cosmetics Rules, 1945 to incorporate Good Laboratory Practices and Requirements of premises and equipments. However, Good manufacturing practices have already been notified under Schedule M to the said Rules.

(c) No such reports are available with the Government which indicate that amendment of such rules would lead to closure of small scale Pharma units due to financial constraints etc.

(d) Does not arise.