

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:2223
ANSWERED ON:14.12.2004
DRUGS AND COSMETICS ACT, 1940
Chowdhury Shri Adhir Ranjan;Khaire Shri Chandrakant Bhaurao

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether small scale units have major role in bringing down the prices of essential medicines in the country;
- (b) whether due to changes in the Drugs and Cosmetics Act, 1940, these small pharmaceutical units are suffering;
- (c) if so, the details thereof and the reasons therefor; and
- (d) the steps taken by the Government to ensure survival of small scale drug units in the country?

Answer

THE MINISTER OF CHEMICALS AND FERTILIZERS & MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

(a)to(d): The Drugs and Cosmetics Act 1940 has not been amended in the recent past. It was last amended in 1995. However, Schedule M to the Drugs and Cosmetics Rules, 1945 relating to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products was amended vide GSR 894(E) dated 11.12.2001 for maintenances of quality control in production of drugs. The difficulties expressed by the manufacturers especially those belonging to small scale sector in respect of some provisions relating to additional space etc., was further examined and a Gazette notification GSR 738(E) containing Draft Rules providing appropriate relaxation has been published on 8.11.04.

Financial assistance is available for technology upgradation to small scale drug and pharmaceutical units under Credit Linked Capital Subsidy Scheme. Small scale industry units are exempted from implementing prices for some of the formulations for which Government fixes prices under the provisions of the Drugs (Prices Control) Order, 1995, as per Gazette Notification S.O. No.134(E) dated 2nd March 1995.