

**GOVERNMENT OF INDIA  
MICRO, SMALL AND MEDIUM ENTERPRISES  
LOK SABHA**

UNSTARRED QUESTION NO:6323  
ANSWERED ON:04.05.2010  
REPORT OF SUBORDINATE LEGISLATION COMMITTEE  
Bheiravdanji Shri Gadhvi Mukeshkumar;Mahant Dr. Charan Das

**Will the Minister of MICRO, SMALL AND MEDIUM ENTERPRISES be pleased to state:**

- (a) whether concerns have been expressed by various quarters including Committee on Subordinate Legislation (Rajya Sabha) vide 181st report in regard to the instance of closure of small manufacturing units in the event of implementation of the provisions of Drugs and Cosmetics (Amendment) rules, 2001 relating to Good Manufacturing Practices (GMP);
- (b) if so, the details thereof;
- (c) the suggestions/recommendations made in this regard; and
- (d) the corrective steps taken by the Government in this regard?

**Answer**

MINISTER OF STATE (INDEPENDENT CHARGE), MICRO, SMALL AND MEDIUM ENTERPRISES (SHRI DINSHA PATEL)

(a), (b) & (c) The pharmaceutical industry and various forums including Committee on Subordinate Legislative (Rajya Sabha) vide 181st Report have expressed serious concern over the instances of closure of small drugs and pharmaceuticals manufacturing units, allegedly linked with the implementation of the provisions of Drugs and Cosmetics (Amendment) Rules, 2001 relating to Good Manufacturing Practices (GMP). They have recommended that the Government should support small pharmaceutical industries to become Schedule M complaint. Some of their recommendations are for promotion the schemes like Credit Linked Capital Subsidy Scheme (CLCSS), Credit Guarantee Fund Scheme among the small scale drug manufacturers to enable them to access the institutional credit, extension of Certification Reimbursement Scheme to cover the expenditure incurred by the small manufacturers in maintaining the documentation, special package for the small pharma units under the Micro and Small Enterprise Cluster Development Programme to avail the integrated infrastructure facilities, link proposed interest subsidy scheme with the Credit Linked Capital Subsidy Scheme, conduct workshops for the field level enforcement agencies of the Government and the technical personnel of such small manufacturing units to interact and understand the functional constraints in implementing the amended provisions, early finalization of rules pertaining to establishment of funds as provided in the Micro, Small and Medium Enterprises Development Act, 2006 to support the small drug manufacturers, conduct a survey to ascertain the extent of cases of closure of SSIs in pharma sector due to non-compliance of revised Schedule M ever since it became applicable from 1st July, 2005 by Micro, Small and Medium Enterprises (MSMEs) Development Organization along with the Drug Technical Advisory Board.

(d) Government is supporting small manufacturing units in Drugs & Pharmaceuticals Sector through various schemes/programmes such as Credit Linked Capital Subsidy Scheme (CLCSS) to provide incentives to micro and small enterprises for technology up gradation, Credit Guarantee Scheme, ISO-9000/ISO-14001/HACCP Reimbursement Scheme, National Manufacturing Competitive Programme to enhance their productivity and competitiveness, Micro and Small Enterprises - Cluster Development Programme (MSE-CDP).

179 technologies required for Schedule M compliance and National/ International standards in the Drugs & Pharmaceuticals sector were added to the list of eligible technologies under CLCSS on 13.7.2009. 9 State level Awareness Building Workshops have been organised to adopt well established and improved technologies to make them Schedule M compliant under CLCSS. 160 Drugs and Pharmaceuticals Micro and Small Enterprises (MSEs) have availed subsidy of Rs. 7.75 crore since inception of the CLCSS up to March, 2010. The Credit Guarantee Fund Trust for MSEs has provided guarantee cover to 248 drug units amounting to Rs. 36.31 crore under the Credit Guarantee Scheme cumulatively till March, 2010. Under MSE-CDP, soft interventions have been taken up in Basic Drug Cluster at Thane, Pharmaceutical Industry Clusters at Mumbai, Indore, Margao, Cuttack and under hard intervention, a common facility centre is being set up at pharmaceutical cluster, Cuttack. Under this programme, workshops and training programmes are being organized on regular basis for awareness of GMP/Schedule M and some units were assisted for obtaining the certificate for schedule 'M'.