

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

UNSTARRED QUESTION NO:6597  
ANSWERED ON:06.05.2010  
INTRODUCTION OF SCHEDULE M  
Meghwal Shri Bharat Ram

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

(a) the financial affect on the viability of the small and medium pharma industries in the country due to introduction of provision of schedule M and Good Laboratory Practices on them; and

(b) the steps taken by the Government to meet the financial requirements of small and medium pharma manufacturing, units set up before 2001 to upgrade them to global standards?

**Answer**

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b) Schedule M of Drugs and Cosmetics Rules, 1945 has been made mandatory from 1st July, 2005 for all Pharma Enterprises. The up-gradation to Schedule `M` by a small and medium pharma enterprise normally requires a sum of Rs.20.00 lakhs to Rs.2.00 crore depending upon the capital cost and the size of the unit. The Department of Pharmaceuticals and Ministry of MSME are coordinating their efforts for assisting medium and small pharma units. The Department of Pharmaceuticals, in collaboration with the Development Commissioner, MSME of the Ministry of Micro, Small & Medium Enterprises(MSME) introduced a Credit Linked Capital Subsidy Scheme (CLCSS) for Financial Assistance to pharma SSI units for upgradation and compliance of schedule `M` standards as per the Drugs and Cosmetics Rules 1945 of the Drugs and Cosmetics Act 1940. Under this scheme, 15% capital subsidy is provided up to a loan of Rs. 1.0 crore as per the guideline of the scheme. Further several awareness workshops were organized to help them understand requirement for technical upgradation and to make them schedule `M` compliant. Good Laboratory Practices (GLP) is not yet mandatory and the financial aspect is not yet estimated.