

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

UNSTARRED QUESTION NO:2517
ANSWERED ON:07.12.2012
SHORTAGE OF DRUG INSPECTORS
Gowda Shri D.B. Chandre;Jeyadural Shri S. R.

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

- (a) whether there is gap between the required and existing number of drug inspectors and many States have expressed their inability to allocate more funds to strengthen the regulatory infrastructure;
- (b) if so, the details thereof along with the reaction of the Government thereto, State/UT-wise;
- (c) whether any recommendation has been made for the appointment of one drug inspector for every 25 manufacturing units and one for every 100 pharmacies;
- (d) if so, the details thereof along with the follow up action taken/proposed by the Government thereon; and
- (e) the other steps taken and funds earmarked by the Government to address the issue?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (e): An Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, then DG, CSIR was set up by the Ministry of Health and Family Welfare for comprehensive examination of Drug Regulatory issues in the country. The committee in its report submitted in 2003 had pointed out the following problems in the drugs regulatory system in the country:

- (a) inadequate or weak drug control infrastructure at the State and Central level
- (b) inadequate drugs testing facilities
- (c) shortage of drug inspectors
- (d) non-uniformity of enforcement
- (e) lack of specially trained cadres for specialised regulatory areas
- (f) non-existence of data bank and non-availability of accurate information.

The Committee recommended the strengthening of drug control organizations for effective implementation of the law. It also recommended that the requirement of appropriate staff could be considered as 1 inspector for 50 manufacturing units and 1 inspector for 200 sales units.

Faced with the aforesaid deficient status of the State drug control departments, the Central Government has envisaged a Centrally Sponsored Scheme during the 12th Five Year Plan to help them in upgrading their infrastructure, both physical and human resources.

The Scheme would be funded by the Centre and the States.

During the financial year 2012-2013, a token provision of Rs. 2 crore has been kept in the budget of the Ministry for the purpose.

The required interventions in the direction of strengthening the infrastructure of State drug control departments will include:

- (i) Strengthening of manpower.
- (ii) Strengthening of physical infrastructure
- (iii) Reviving non-operational / partly operational drug testing facilities to enhance their capacity
- (iv) Sharing information about drugs and sub-standard drugs with the drugs controllers of other States/UTs
- (v) Providing training to enforcement officials

(vi) Creating data base on Drug Regulation and introducing IT enabled services.