

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

UNSTARRED QUESTION NO:125

ANSWERED ON:22.02.2013

SURVEY ON SPURIOUS SUB STANDARD DRUGS

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

- (a) whether the Government has conducted any nationwide survey on the extent of spurious, sub-standard and expired drugs in the country;
- (b) if so, the details along with the outcome thereof indicating the estimated losses occurred to the original manufacturers on account of this malpractice;
- (c) the follow up action taken/proposed by the Government thereon;
- (d) whether the Central Drugs Standard Control Organisation (CDSCO) lack manpower to conduct operations against such activities; and
- (e) if so, the details thereof and the corrective measures taken/proposed by the Government in this regard?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b) A nationwide survey to assess the extent of spurious drugs in the country was conducted in the year 2009. 24,136 samples of 62 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers from over 100 different pharmacy outlets in different regions of the country were drawn from different strata in various regions in the country. The survey revealed that only 0.046% of the drugs were found spurious. Survey was related to spurious drugs only which are manufactured clandestinely. The survey did not have reference to assess the losses occurred to the original manufactures on account of this malpractice. Further, on the basis of the information collected by the State Drug Control Departments, the number of samples of drugs declared as not-of standard quality has been found to be around 4.75% only.

(c) The cases of spurious, substandard and expired drugs are investigated by the State Drug Control Departments for violation of the provisions of the Drugs & Cosmetics Rule as and when detected and action is taken by them as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945. The manufacture of spurious drugs being a clandestine activity can be curbed only through continuous surveillance and surprise inspections by the State Drug Control Departments. The inspectorate staff keep strict vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

The Central Government has taken following steps to check the problem of Spurious/Sub-standard Drugs:

1. A new scheme has been prepared by the Central Government for providing assistance for strenghtening of State Drug Control Departments during the 12th Five Year Plan.
2. The Drugs & Cosmetics Act, 1940 has been amended by Drugs & Cosmetics (Amendment) Act, 2008 for making penal provisions under the Act more stringent.
3. The Drugs & Cosmetics (Amendment) Act, 2008 also enabled establishment of special designated courts for trial of offences related to spurious and adulterated drugs. 14 States/UTs have already set up such courts.
4. A Whistle Blower Scheme has been initiated to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this scheme the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

(d) & (e) Strengthening and upgradation of infrastructure and facilities of CDSCO is an continuous and ongoing process depending upon increase in responsibilities and consequent workload. Since 2008, 216 additional posts in the CDSCO have been sanctioned.