

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

UNSTARRED QUESTION NO:445

ANSWERED ON:09.08.2012

SPURIOUS DRUGS

Singh Rajkumari Ratna;Sinh Dr. Sanjay

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

- (a) whether any survey has been conducted to assess the extent and quantum of spurious drugs available especially in rural and non-metro cities of the country;
- (b) if so, the details thereof;
- (c) the corrective action taken to weed out this menace;
- (d) whether the Government is considering to bring a legislation for making it compulsory for the chemist shops to issue bills against sale of medicines so as to effectively control the spurious drugs;
- (e) if so, the details thereof; and
- (f) if not, the reasons therefor?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b): A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health, through Central Drugs Standard Control Organization. Samples were drawn from different stratum in various regions in the country. 24,136 samples of 52 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers from over 100 different Pharmacy outlets in different regions of the country and located in each stratum viz. Metros, big cities, district, towns and villages were collected. The survey revealed that the extent of drugs found spurious was 0.046% only. The report of the survey is available on the CDSCO website www.cdsc0.nic.in.

(c): The Government, has taken following steps to check the menace of Spurious/ Sub-standard Drugs.

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008. Stringent penalties for manufacture of spurious and adulterated drugs have now been provided to make it deterrent for the antisocial elements to indulge in manufacture of spurious drugs. Certain offences have also been made cognizable and non-bailable.

2. Whistle Blower Policy has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities. The details of policy are available at the website of CDSCO (www.cdsc0.nic.in).

3. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for implementation. The guidelines are available on the web site of CDSCO (www.cdsc0.nic.in).

4. The inspectorate staff has been instructed to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

5. The State / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases. Some of the States have already set up designated special Courts for trial of cases related to spurious and substandard drugs.

(d): The Drugs and Cosmetics Rule, 1945 provides that the supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars:

(a) Name, address and sale licence number of the dealer,

(b) Serial number of the cash / credit memo,

(c) The name and quantity of the drug supplied.

Carbon copies of cash / credit memos shall be maintained by the licensee as record.

(e) & (f): In view of reply to (d), does not arise.