

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

UNSTARRED QUESTION NO:3664

ANSWERED ON:11.12.2009

SURVEY ON SPURIOUS DRUGS

Bapurao Shri Khatgaonkar Patil Bhaskarrao;Gangaram Shri Awale Jaywant;Jaiswal Shri Gorakh Prasad ;Jindal Shri Naveen;Joshi Shri Pralhad Venkatesh;Sidhu Shri Navjot Singh;Singh Rajkumari Ratna;Yaskhi Shri Madhu Goud

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

- (a) whether the Government has recently conducted nationwide surveys on the extent of spurious and sub-standard drugs in the country;
- (b) if so, the findings thereon indicating the losses occurred to original manufacturers on account of this;
- (c) the steps taken or proposed to be taken by the Government on the basis of the findings;
- (d) whether the Central Drugs Standard Control Organisation (CDSCO) and the Drug Controller General of India (DCGI) lack manpower to conduct operations against such activities; and
- (e) if so, the details thereof; and corrective measures taken in this regard?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRVEDI)

(a): Yes. In a survey conducted by Central Drugs Standard Control Organisation (CDSCO), 24,136 samples of 61 fast moving brands of 9 therapeutic categories from the sale outlets of different stratum (i.e. metro cities, Big cities, district Head Quarters, towns and villages) were collected. The survey has revealed that the extent of spurious drugs is 0.045% only.

(b): The manufacture of spurious drugs is an undercover and localized activity. Its extent of availability has been found to be very low. It is therefore, not possible to measure the impact in terms of losses occurred to original manufacturer.

(c): The following steps have been taken by Government to check the manufacture, sale or marketing of spurious and sub-standard drugs in the country:

1. The Drugs and Cosmetics Act, 1940 has been amended under Drugs & Cosmetics (Amendment) Act 2008 passed by the Parliament on 5th December 2008 and has come in to force since 10th Aug, 2009. Under this Act stringent penalties for manufacture of spurious and adulterated drugs have been provided. Certain offences have been made cognizable and non-bailable.
2. A Whistle Blower Policy has been started 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.
3. The Port and Zonal Offices of the CDSCO are actively involved in the detection of cases of the spurious drugs in the country.
4. A meeting with the Directorate of Revenue Intelligence, Commissioner Customs and all the Port officers was held on 23-06-2009 to sensitize the concerned departments about the import of fake drugs in the country and for taking action for absolute confiscation and prosecutions in cases of import of spurious drugs.
5. In the 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940, held on 10th December, 2008, the States were requested to play pro-active role in assessing the extent of spurious drugs in the country.
6. In the 40th meeting of DCC held on 29.6.2009, 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 adopted for the purpose of uniform implementation of the Drugs and Cosmetic Act in the country. The guidelines have been placed on the web site of CDSCO.
7. Under a Capacity Building Project through World Bank, assistance was provided to upgrade testing facilities and to establish new drug testing laboratories to enhance the capacity of the laboratories to test large number of samples. Under this project 23 States and 6 Central Drug laboratories have been strengthened.

(d)&(e): The manufacture and sale of drugs is under the purview of the State Drug Control Authorities. The CDSCO, however,

coordinate their activities for interstate investigations. To strengthen the manpower of CDSCO for having extra vigilance in operations against such activities, 169 posts of Drugs Inspectors for CDSCO have been sanctioned against the present posts of 32 Drugs Inspectors.