

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

STARRED QUESTION NO:36

ANSWERED ON:20.11.2009

SPURIOUS DRUGS

Gawali Patil Smt. Bhavana Pundlikrao ;Roy Shri Nripendra Nath

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

- (a) whether the Government is aware of the reports of the London-based International Policy Network and Business Monitor International that pronounced India as one of the largest producers of fake/spurious drugs;
- (b) if so, the facts thereof and the reaction of the Government thereto;
- (c) the names of the companies and the persons found guilty for manufacturing and selling such drugs and the action taken against them during the last three years and the current year, State/UT-wise; and
- (d) the further steps taken/being taken by the Government to check, detect and punish manufacturers and traders of fake/spurious drugs?

**Answer**

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

(a) to (d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 36 FOR 20TH NOVEMBER, 2009

(a) Yes, Sir. The International Policy Network report pertains to the availability of spurious drugs in various regions of the world. In the Indian context, it has referred to a report of ASSOCHAM.

(b) The report of ASSOCHAM is not based on any survey or findings but has taken into account the drop in annual turnover by about 25% of the original manufacturers. The drugs samples tested all over the country during the last five years revealed that approximately 0.3% to 0.4% of around 40,000 samples tested per annum were found spurious. A recent survey carried out by Central Drugs Standards Control Organisation (CDSCO) on the basis of the statistical principles provided by Indian Statistical Institute (ISI), Hyderabad to assess more accurate extent of spurious drugs in the country has revealed that the extent of spurious drugs is further much below this level (about 0.045%).

(c) A Statement showing the number of samples tested, declared spurious, prosecutions launched, persons arrested and approximate value of drugs seized during the years 2005-2006, 2006-2007 and 2007-2008 as obtained from the State Licensing Authorities is at Annexure-I. The information in respect of year 2008-09 has been received from some of the State Drugs Controllers and the same is at Annexure-II.

(d) The following steps have been taken by Government to check the sale 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 announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy, 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. At the Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940, the States were requested to play a pro-active role in assessing the extent of spurious drugs in the country and
6. 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.

8. Cases of import of bulk drugs from unregistered sources originating from China have recently been detected involving the following Indian companies and which have already been handed over to the Central Bureau of Investigation (CBI) for further investigations:

(i) M/s J.B. Khokhani & Co.

(ii) M/s. Envee Drugs Private Limited

(iii) M/s Sheetal Pharma

(iv) M/s C.J. Shah & Co.

9. In another three such cases involving the following Indian companies, it has been decided to hand over the investigation to the CBI

(i) M/s. Kawalal & Co.

(ii) M/s Adcock Ingram Limited

10. Yet another case involving Shri Vinayak Trading Company, Mumbai, has been detected for selling spurious Miglob Injection manufactured by a Chinese company and imported and marketed by VHB Life Sciences Ltd, Mumbai, has been detected.

11. Again, a raid was conducted by the officers of the CDSCO (North Zone) on 10/11/09 and 12 shops were raided in Bhagirath Palace, New Delhi.