

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

UNSTARRED QUESTION NO:3281

ANSWERED ON:31.08.2012

UNREGISTERED PHARMACEUTICAL MANUFACTURERS/SHOPS

Bhagat Shri Sudarshan;Ganpatrao Shri Jadhav Prataprao;Gorakhnath Shri ;Singh Rajkumari Ratna

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

- (a) whether the Government has taken note of a large number of unregistered pharmaceutical manufacturers and medicalshops being run in the country;
- (b) if so, the details thereof along with the reaction of the Government thereto;
- (c) the number of unregistered pharmaceutical manufacturers and medical shops detected/identified by the Central Drugs Standard Control Organization (CDSCO) in the country along with the action taken/proposed against them during the last three years and the current year so far, State/UT-wise;
- (d) whether attention of the Government has been drawn to sale of generic medicines as branded medicines by certain pharmaceutical companies/shops and if so, the details thereof during the said period; and
- (e) the steps taken/proposed by the Government to strengthen the monitoring mechanism to keep an eye on the functioning of such unregistered pharmaceutical manufacturers and medical shops and sale of generic medicines as branded medicines by them?

Answer

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

(a) & (b): There are no reports of large number of unregistered pharmaceutical manufacturers and medical shops in the Country. Manufacture and sale of drugs without a valid license is an offence under the provisions of Drugs and Cosmetics Act, 1940. Stray cases of violation of the provisions of the said Act are detected by the Regulatory Authorities and action taken by them as per the law.

(c) The CDSCO has detected 7 cases of manufacture and sale of drugs without a license during the last 3 years. A Statement containing the State/UT-wise details of action taken in this regard is annexed.

(d): The Drugs and Cosmetics Act, 1940 and Rules made thereunder regulate the quality of the drugs manufactured and sold in the country as well as drugs imported into the country to be sold. Manufacturers or importers are free to market their products either under a generic name or under a brand name.

(e): The Government during the last few years has taken the following measures to strengthen the monitoring mechanism to prevent violations of the provisions of the Act and the Rules:

1. The Drugs and Cosmetics Act, 1940 has been amended by the Drugs & Cosmetics (Amendment) Act 2008 providing for stringent penalties for manufacture of spurious and adulterated drugs to make it deterrent for the anti-social elements from indulging in such activities. Certain offences have also been made cognizable and non-bailable.

2. The guidelines have been framed 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.

3. The Drugs & Cosmetics (Amendment) Act, 2008 also provided for the setting up of designated courts for speedy trial of drug related offences. 14 States / Union Territories have already set up such Courts.

4. A Whistle Blower Scheme has been initiated by the Government to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs.

5. 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.

6. The manpower and other infrastructure of the Drugs Control Departments, both at the Centre and in the States / UTs are continuously being strengthened.

Cases of unregistered pharmaceutical manufacturers and medical shops detected in the last 3 years and current year by CDSCO and

the action taken thereon:

Year 2009-10

Nil

Year 2010-11

S.No. State No. of Cases Action taken

1 Tamil Nadu 01 Prosecution launched

Year 2011-12

S.No. State No. of Cases Action taken

1 Delhi 02 Prosecution launched
in 1 case.

2 Karnataka 04 Prosecution launched
in 3 cases.

Year 2012 (till date)

NIL