

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

STARRED QUESTION NO:201
ANSWERED ON:07.12.2012
SPURIOUS SUBSTANDARD EXPIRED DRUGS
Ray Shri Saugata;Singh Shri Pashupati Nath

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

- (a) whether sale and marketing of spurious, substandard and expired drugs including ayurvedic/homoeopathic drugs and deaths therefrom have been reported in the country;
- (b) if so, the details thereof indicating the value of drugs and the action taken against the offenders during each of the last three years and the current year, State/UTwise;
- (c) whether the Government has any proposal under consideration for entering into international cooperation and a global treaty to deal with the menace of spurious and substandard drugs reaching the market;
- (d) if so, the details thereof along with the steps taken/proposed to be taken by the Government in this regard; and
- (e) the other measures being taken by the Government to effectively deal with the menace of spurious, substandard and expired drugs?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.201 FOR 7TH DECEMBER, 2012

(a)&(b): Cases of sale of spurious and substandard drugs have been reported by the State / UT Drugs Control Authorities. A statement showing the number of samples tested, number of samples declared not of standard quality, number of samples declared spurious, number of prosecutions launched, number of persons arrested and the approximate value of drugs seized State / UT wise during 2009-10, 2010-11, 2011-12 and from April-July, 2012 is enclosed at Annexures 1 to 4.

The Central Drugs Standard Control Organisation (CDSCO) has not received any report of deaths due to sale and marketing of spurious, sub-standard and expired drugs.

(c)&(d) The Government has no proposal under consideration for entering into international co-operation and global treaty specifically to deal with the menace of spurious and substandard drugs reaching the market.

(e) The Government has taken the following steps to check the problem of spurious / sub-standard drugs.

1. The Drugs and Cosmetics Act, 1940 was amended by the Drugs & Cosmetics (Amendment) Act, 2008 to provide for more stringent penalties for manufacture and trade of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
2. The Drugs & Cosmetics (Amendment) Act, 2008 has also enabled setting up of special designated courts for speedy disposal of cases to deal with the cases of offences under the Drugs and Cosmetics Act. 14 States/UTs have already set up these special Courts.
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.
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. Under this scheme, the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.
5. The state drugs controllers have been regularly requested to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.
6. Overseas inspection of manufacturing sites abroad from where drugs are imported into the country has been initiated. Such

inspections have already been conducted in manufacturing sites situated in China.

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