GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:378
ANSWERED ON:23.11.2012
SPURIOUS AND SUBSTANDARD DRUGS
Das Gupta Shri Gurudas;Dubey Shri Nishikant ;Lingam Shri P.;Mahendrasinh Shri Chauhan ;Swamygowda Shri N Cheluvaraya Swamy

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

(a) whether attention of the Government has been drawn to manufacturing and marketing of spurious and substandard drugs in several parts of the country;

(b) if so, the details thereof;

(c) the number of raids conducted along with the number of such cases detected and action taken against the offenders during each of the last three years and the current year so far, State/UT-wise;

(d) whether the Government proposes to establish drug recall system to allow pharmaceutical companies to withdraw defective products from the market within a stipulated time frame; and

(e) if so, the details thereof along with the other measures taken/proposed by the Government to tackle the menace of spurious and substandard drugs and award of stringent punishment to the offenders?

Answer

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

(a & b): Isolated cases of spurious drugs are detected by the State Drugs Control Departments through continuous surveillance and drawing of samples for test. There are, however, no reports of any large scale presence of the spurious drugs in the country. A survey to assess the extent of spurious drugs conducted in 2009 revealed that the extent of drugs found spurious was 0.046% only.

(c): A statement giving the details of the raids conducted and action taken during each of the last three years and the current year by the State Drugs Control Authorities is annexed.

(d) & (e): Under schedule M of the Drugs and Cosmetics RuleS 1945, the manufacturer is required to devise a prompt and effective product recall system of defective products for timely information of all concerned up to the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard. The Government has taken following steps to check Spurious/Sub-standard Drugs.

1. The Drugs and Cosmetics Act, 1940 has been amended by the Drugs & Cosmetics (Amendment) Act 2008 providing more for stringent penalties for manufacture of spurious and adulterated drugs. 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 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 in respect of movement of spurious drugs to the regulatory authorities.

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.