

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

UNSTARRED QUESTION NO:974
ANSWERED ON:09.03.2005
CASES OF SPURIOUS DRUGS
Bhadana Shri Avtar Singh

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

- (a) whether the Government is aware of the increasing number of cases of spurious drugs in the country;
- (b) if so, the details of the number of such cases detected during each of the last three years, State-wise;
- (c) whether the guidelines issued in this regard earlier by the Government to the State Governments are not proving effective ; and
- (d) if so, the strategy formulated by the Government to put a check on such cases?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): As per the feed back available from the State Drug Controllers, 38824, 43138 and 40862 drugs samples were tested during the periods 2001-02, 2002-03 and 2003-04 out of which 96, 129 and 118 samples were declared spurious.

(b) to (d): Under the Drugs and Cosmetics Act, 1940, the responsibility for regulating manufacture and sale of drugs including taking legal action against the guilty persons rests with the State Governments. As per feed back available from the State Drug Controllers 84 (eighty four) persons were arrested in relation to spurious drugs cases and prosecuted in the appropriate court during the period 1.4.2002 to 30.6.2004. Details of cases detected year-wise and state-wise are not maintained centrally. Manufacture of spurious/counterfeit/fake drugs is primarily a clandestine activity. Trading in counterfeit products including drugs is reported world over. However, keeping in view the serious implications of spurious drugs on public health as well as the loss to genuine industry, the Government has taken the following measures to combat this menace:

(i) The State Governments have been advised from time to time to undertake focused surveillance over possible movement of spurious drugs and detailed guidelines have been provided for this purpose.

(ii) A Capacity Building Project through World Bank assistance has been taken up to provide substantial assistance to State Governments to upgrade drug testing facilities or to establish new drug testing laboratories. It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months.

(iii) Training programmes for regulatory officials of State Governments on logistics of intelligence work, prosecutions etc. have been conducted with the assistance of FDA, Maharashtra.

(iv) In order to ensure efficient information exchange between drug regulatory officers in the country, a countrywide computer-networking project has been undertaken by the Central Government.

(v) Pharma industry and trade has been motivated to fight menace of spurious drugs as a shared responsibility.

(vi) Government of India had constituted a committee of experts on 27th January, 2003 under the Chairmanship of Dr. R.A. Mashelkar, D.G., CSIR to undertake a comprehensive view of the drug regulatory system in the country including evaluation of the extent of spurious and sub-standard drugs and recommended remedial measures to deal with this problem effectively.

The expert committee submitted its final report to the Government in November, 2003. Based on the recommendations given by the committee in its report, Central Government had initiated steps to bring legislation for amending the Drugs and Cosmetics Act, 1940 on the lines suggested by the committee. A bill was introduced in the Lok Sabha in December, 2003 to amend the said Act to provide strictedpenalties to the offenders including a maximum penalty of capital punishment. It was further recommended to make the

offences non-bailable and cognizable and to provide for designated courts for speedy trial of cases. The Cabinet has now accorded approval for the introduction of Drugs and Cosmetics (Amendment) Bill 2005 in the Parliament subject to certain modifications. The Bill is likely to be introduced in the budget session of Parliament.