GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1039
ANSWERED ON:30.07.2010
SPURIOUS DRUGS
Bajwa Shri Partap Singh;Patil Shri C. R. ;Verma Shri Sajjan Singh

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

(a) the details of any study/survey conducted in regard to prevalence of spurious and sub-standard drugs in the country;

(b) the measures taken to protect the interests of original innocent manufacturers from counterfeits;

(c) whether the Government proposes to bring about stringent rules and reforms to check this menace;

(d) if so, the details thereof; and

(e) the details of drug manufacturers against whom action has been taken during the last three years and the current year, State-wise?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a): To assess the extent of spurious drugs in the country, a survey was conducted in the year 2009 by the Central Drugs Standard Control Organization (CDSCO). The statistical principles for the survey were provided by Indian Statistical Institute, Hyderabad. Under this survey 24,136 samples of 61 brands of drugs belonging to 9 therapeutic categories of 29 manufacturers from over 100 different pharmacy outlets in different regions of the country and located in each stratum viz. metros, big cities, district, towns and villages were collected. The survey has revealed that the extent of drugs found spurious was 0.046% only.

(b) to (d): Following steps have been taken by the Government to check the menace of spurious and adulterated drugs in the country:

(i) The Drugs and Cosmetics Act, 1940 has been amended by the Drugs & Cosmetics (Amendment) Act 2008, whereby more stringent penalties for manufacture and trade of spurious and adulterated drugs have been provided. Certain offences have been made cognizable and non-bailable.

(ii) The industry and other stakeholders represented against possible misuse of the enhanced provisions by the law enforcement agencies. To allay their apprehensions, detailed guidelines on implementation of these amended provisions, as approved by the Drugs Consultative Committee, have been issued and conveyed to the State Governments.

(iii) Schedule M to the Drugs and Cosmetics Rules, 1945 pertaining to Good Manufacturing Practices was amended in 2001 to make it mandatory, and at par with the international standards, for the manufacturers of drugs to comply with the requirements of this Schedule for quality control of the drugs manufactured by them.

(iv) A Whistle Blower Scheme 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 the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

(e): Statements containing the State-wise data for the last three years and the current year on the number of the samples tested, declared spurious and sub-standard and the number of persons arrested, as collected from the State Drugs Controllers, are annexured.