GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:364
ANSWERED ON:22.03.2013
FAKE COUNTERFEIT SUBSTANDARD DRUGS
Angadi Shri Suresh Chanabasappa;Singh Shri Ratan

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

(a) whether as per the reports of the World Health Organisation (WHO) and the Organisation for Economic Cooperation and Development (OECD) a sizeable quantum of the medicines sold in India are fake and most of the fake drugs supplied to the world have their origins in India;

(b) if so, the details thereof and the reaction of the Government thereto;

(c) whether the Government has assessed the results yielded by various measures to check the problem of fake/counterfeit/substandard drugs in the country;

(d) if so, the details thereof indicating the number of specially designated courts set up, cases disposed of and offenders punished thereby and the rewards given under the Whistle Blower Scheme during each of the last three years and the current year, State/ UT-wise; and

(e) the further measures taken/proposed by the Government to curb the menace of fake/ counterfeit/substandard drugs including use of nanotechnology for identifying such drugs in the country?

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.364 FOR 22ND MARCH, 2013

(a)&(b): No such report has been received from WHO stating that a sizable quantum of the medicines sold in India are fake and most of the fake drugs supplied to the world have their origin in India. WHO has clarified in August 2012 that it has not conducted any study regarding fake drugs in the past several years.

The Organisation for Economic Cooperation and Development (OECD), in its report published in 2008, had mentioned about the import of counterfeit drugs from India into the European Union. The statistics mentioned in the report were related to cases of violation of Intellectual Property Rights recorded in 2005 with TAXUD (European Community's Taxation and Custom Union). Such cases were considered as `counterfeit` medicines by European Union. As per the OECD Report, above cases were Intellectual Property Rights (IPR) violations and not related to quality, safety and efficacy of the drugs.

(c): A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Central Drugs Standard Control Organization (CDSCO). The survey was statistically designed by the Indian Statistical Institute, Hyderabad. Under the study, 24,136 samples of 62 brands of drugs were drawn from different outlets spread over the country. The survey revealed that the extent of drugs found spurious was 0.046% only.

Further, as per the information made available by the State Drugs Controllers in respect of the drugs samples tested during last three years, the percentage of substandard drugs varied from 5.70% in 2008-09 to 4.54% in 2011-12.

(d): The Drugs & Cosmetics (Amendment) Act, 2008, enabled setting up of specially designated courts for trial of offences covered under the Drugs & Cosmetics Act, 1940. 16 States / UTs have already set up such courts.

A statement containing the information, made available by the State Drugs Controllers giving the number of samples tested, number of samples declared not-of-standard quality, number of samples declared spurious / adulterated, number of prosecutions launched, number of cases decided, number of persons arrested and approximate value of drugs seized during the last 3 years 2009-2010, 2010-2011, 2011-2012 and 2012-2013 (till December, 2012) is given at Annexure A.

Under the Whistle Blower Scheme, no case has so far been found eligible for any reward so far.

(e) Government has taken the following measures to check spurious/sub-standard drugs in the country:

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. 16 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 have been 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. On the basis of an Order of the Hon'ble High Court of Allahabad in the Criminal (Misc) Writ Petition No. 16212/2008 − Brahmaji vs State of UP and Others, the Government had constituted a Task Force to examine the feasibility of networking and tracking the drugs distribution system in the country from the manufacturer to the retailer to secure the entire supply chain and detect spurious drugs available in the market. Different options through the use of information technology were considered by the Task Force, including providing bar code on the label of the drugs, for identifying and tracking their movement from the manufacturer to the consumer. On the basis of the recommendations of the Task Force and further consultation with the stakeholders, the Government conducted a study with the help of the National Informatics Centre to examine the feasibility of networking and tracking the drugs distribution system in the country from the manufacturer to the retailer by the use of modern information technological tools to detect spurious drugs available in the market.

6. Overseas inspections of drug manufacturing sites to ensure quality of imported bulk drugs were started in 2011.

7. 216 additional posts were created in 2008 and 2009 for strengthening CDSCO headquarters and ports / zonal offices.

8. During the 12th Five Year Plan, substantial provision has been made for further strengthening of the drug regulatory system of the country, both at central and state level.