GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 666
TO BE ANSWERED ON THE 19th December, 2017

Sub-standard Drugs

666. SHRI ANTO ANTONY:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has taken note of the report of World Health Organisation (WHO) that 1 in 10 medical products in developing countries are substandard or falsified?
(b) if so, the details thereof and the steps taken/being taken by the Government in this regard;
(c) whether the Government has conducted any enquiry in this regard; and
(d) if so, the details and outcome thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): Director-General, WHO Geneva has launched two documents concerning substandard and falsified medical products, at the Graduate Institute, Geneva:

(i) a study on the public health and socioeconomic impact of substandard and falsified medical products ; and

(ii) WHO global surveillance and monitoring system for substandard and falsified medical products

They include estimations on the observed failure rates of sampled medicines in quality surveys carried out 2007-2016 involving over 48,000 samples from 88 Member States. The aggregate observed failure rates in low and middle income countries is estimated at 10.5%.

The Government of India has taken various steps to check the quality of drugs manufactured in the country. Details are as under:

(i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

(ii) The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

(iii) A Whistle Blower Scheme was announced by the Government of India 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 to the regulatory authorities in respect of movement of spurious drugs. The details of policy are available at the website of Central Drugs Standard Control Organization (CDSCO) (www.cdsco.nic.in).

(iv) 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 uniform implementation.

(v) The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

(vi) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2017.

(c) & (d): As per the information received from CDSCO, no enquiry has been conducted by them on this report. In India, with strengthening of Drug regulatory system and continuous improvement in monitoring of quality of drugs, % of Not Of Standard Quality (NSQ) Drugs reported in the country has been reduced from 6.20% in the year 2007-08 to 3.6% in 2016-17.

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