GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 4231

TO BE ANSWERED ON THE 28th March, 2017

Quality of Drugs

4231. SHRI B. SENGUTTUVAN:

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

(a) whether the Government is aware of the observation made by the US Department of Food and Drugs Administration in the annual conference of the drugs manufacturers' forum to the effect that the drugs sold in India lacks quality and efficacy;

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

(c) whether any drug or drugs manufactured by any Indian pharmaceutical company was found to fall short of the desired norms when tested for quality and if so, the details thereof; and

(d) the details of the proactive steps likely to be taken by the Government to ensure that the drugs sold in India are up to the international quality and efficacy?

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) to (d): Report has appeared in the press that Director, United States Food and Drug Administration (USFDA) India office, had raised concerns about the quality and efficacy of medicines being sold in India.

As per information received from States/U.Ts Drug Controllers, during last three years, the extent of Not of Standard quality/ spurious/ adulterated drugs reported in the country is as under;

S. no	Year	No. of drugs samples tested	No. of samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of samples declared spurious / adulterated	% of drugs samples declared spurious/ adulterated
1.	2013-14	72717	3028	4.16	118	0.16
2.	2014-15	74199	3702	4.98	83	0.11
3.	2015-16	74,586	3703	4.96	234	0.31

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Further, the extent of 'Not of Standard Quality' (NSQ) and spurious drugs in the recently (2014-16) held country wide survey was observed to be 3.16 % and 0.0245 % of the 47012 drug samples tested during the said survey. Drugs manufactured in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of inspection & licensing. All Licensees are required to comply with the quality standards as prescribed under Second Schedule of Drugs & Cosmetics Act, 1940. However,the Government of India has taken the following steps to strengthen regulatory mechanism for Manufacturing, sale and distribution of drugs in the country.

1. 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.

2. 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.

3. 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 CDSCO (www.cdsco.nic.in).

4. 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.

5. 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.

6. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 474 in 2017.

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