GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 4692
TO BE ANSWERED ON 23RD MARCH, 2018

STANDARDS FOR DRUGS

4692. SHRI KESINENI NANI:

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

(a) whether it is a fact that a number of Indian companies have received observations, warning letters and import alerts from the United States Food and Drug Administration (USFDA);

(b) if so, the major reasons highlighted under these observations;

(c) the existing mechanism for monitoring of such companies;

(d) whether there are major disparities between the standard of testing of pharmaceutical and drugs by the USFDA and the Central Drugs Standard Control Organizations; and

(e) if so, the details thereof along with the steps being taken by the Government to bring a convergence so as to achieve higher standards for pharmaceuticals and drugs manufactured in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(ASHWINI KUMAR CHOUBEY)

(a) & (b): No such data is available. However, it may be noted that warning letters/ import alters from any overseas regulatory agency, including USFDA, are directly sent to the companies.

(c) to (e): For export of drugs, Indian Pharmaceutical Companies are required to comply with the regulatory provisions of importing country. The standards of drugs to be followed are specified in respective pharmacopoeia. These standards are continuously upgraded from time to time.

Government has taken/is taking following measures to establish strict enforcement regime for stringent prosecution/penalties in cases of manufacture, supply and sale of drugs as well as non-adherence to the quality norms prescribed:

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 and setting of special Courts.

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2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. Twenty two States have set up designated special Courts.

3. A Whistle Blower Scheme has been announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country.

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 April, 2008) to **510** (in 2018).

7. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

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