Manufacture and supply of substandard drugs in India

1695. SHRI SAMBHAJI CHHATRAPATI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the World Health Organization (WHO) in a study has identified India also as one of the countries which manufactures and supplies substandard and falsified drugs;

(b) if so, the details thereof;

(c) whether Government has any plan to take a serious call on the outcome of the study; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (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.

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

(c) and (d) The Govt. 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 and 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 CDSCO *(www.cdsco.nic.in)*.

(iv) Guidelines for taking action on samples of drugs declared spurious or not of stands quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008 were forwaraed 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.

(vii) The Government has approved the strengthening of drug regulatory system in the country both at the Central and State level.

(viii) The Drugs and Cosmetics Rules, 1945 have been amended *vide* Gazette notification no. G.S.R. 1337 (E) dated 27.10.2017, making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. Further, the licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

Making warning labels on fast food compulsory

1696. SHRI PARIMAL NATHWANI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) Government's plan to put warning labels on fast food in the country;

(b) which are the countries making warning labels on fast food compulsory and having legal support;