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

LOK SABHA
UNSTARRED QUESTION NO. 4481
TO BE ANSWERED ON 12TH AUGUST, 2016

BANNED DRUGS

4481. SHRI JYOTIRADITYA M. SCINDIA:
SHRI KAMAL NATH:

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

(a) whether the Government is aware that various global regulatory agencies especially in USA and UK have banned several drugs from India, if so, the details thereof;

(b) whether the Government has identified flaws in the drug regulation regime, if so, the details thereof;

(c) whether the World Health Organization (WHO) has issued number of warnings to drugs manufacturers in India; and

(d) if so, the details thereof and the steps Government proposes to take in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a): For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country. Isolated reports of the drugs not meeting the prescribed standards have appeared in the media and on the websites of the regulatory authorities of foreign countries, etc. from time to time. Information of ban on firms for export of drugs manufactured at their sites is generally not officially communicated to the CDSCO.

(b): The gaps and weaknesses of regulatory regime in the country have been identified. The Government has taken a series of measures to plug the gaps. A proposal for strengthening of drug regulatory system in the country, both at the Central and State levels has been approved at a cost of Rs.1750 crore. Out of this, Rs.900 crore is for strengthening of Central regulatory structures while Rs.850 crore has been approved as the Central Government's contribution for upgrading and strengthening the States' Drug Regulatory System. The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, and to check the marketing and manufacturing of spurious, adulterated, misbranded, sub-standard and expired drugs in the country, the Government has taken a series of measures. These include stringent penalties including making certain offences cognizable and non-bailable;

establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases; announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country; issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or 'not of standard quality'; instructions to the concerned staff to keep a vigil and draw samples of drugs for test and analysis for monitoring the quality of drugs moving in the country; increase in the number of posts in Central Drugs Standard Control Organization (CDSCO); re-equipping the drug testing laboratories with state of art equipment; large scale nation-wide survey to determine the 'not of standard quality' drugs; conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union. Several training programmes have also been conducted for laboratory personnel of the State and Central laboratories to upgrade their analytical capabilities and skill sets. Separately, CDSCO has commenced risk based inspections of manufacturing facilities.

(c): No.

(d): Does not arise.