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

LOK SABHA
UNSTARRED QUESTION NO. 942
TO BE ANSWERED ON 22ND JULY, 2016

SUB-STANDARD MEDICINES

942. SHRIMATI KOTHAPALLI GEETHA:

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

(a) whether bar coding for medicines, training for drug manufacturers and an integrated approach towards zero tolerance for sub-standard medicines in the country is on the anvil and if so, the details thereof;

(b) whether the Government ensures that awareness among manufacturers and 287 †Original notice of the question received in Hindi. training is a part of holistic approach to deal with sub-standard medicines, if so, the details thereof;

(c) whether there is any system to check the medicines that are brought from other countries to India or the ones sold there; and

(d) if so, the details thereof and if not, the reasons therefor?

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

(a) & (b): 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 State and Central laboratories to upgrade their analytical capabilities and skill sets. As far as bar coding is concerned, a draft notification had been issued on 03.06.2015 to invite objections and suggestions from the stakeholders. The notification was, however, not finalized keeping in view the reservations expressed by manufacturers including regarding the high cost of bar coding. Separately, CDSCO has commenced risk based inspections of manufacturing facilities. These measures will help in substantially reducing the incidence of 'Not of Standard Quality' drugs.

(c) & (d): Requirements of import & registration under the Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder are to be complied with before import of drugs into India. For import of any drug into the country, the foreign manufacturing site and the drug to be imported are required to be registered and Import Licence is required to be obtained from CDSCO. Such permissions/licences are granted only after due scrutiny.