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

LOK SABHA
UNSTARRED QUESTION NO. 3261
TO BE ANSWERED ON 4TH AUGUST, 2017

SPURIOUS DRUGS

3261. SHRI SADASHIV LOKHANDE:
SHRI S.P. MUDDAHANUME GOWDA:
SHRI SATYAPAL SINGH:
SHRIMATI NEELAM SONKER:

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

(a) whether the Government has taken note of the extent of circulation of spurious, sub-standard, expired and banned drugs in the market, State/UT-wise;

(b) the measures taken/proposed to be taken by the Government to strengthen the drug regulatory and monitoring mechanism in order to check the marketing and manufacturing of spurious, substandard, expired and banned drugs in the country;

(c) whether the Central and State Drug Control Organisation have asked manufacturers to recall medicines which are categorized as spurious, sub-standard, expired drugs and not of standard quality and if so, the details thereof and the reaction of the drug manufacturers thereto; and

(d) the other corrective measures taken/proposed to be taken by the Government in this regard?

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

(a): In order to ensure the quality of drugs in the country, both the Central Drugs Standard Control Organisation (CDSCO) and the state drug regulators pick up a large number of samples of drugs from all over the country and have them tested and analysed in the laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the prescribed standards. The details of the drugs that do not meet the standards are immediately notified by the Central or State regulator concerned.

(b): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

(c): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provision of the Act and Rules including product recall.

(d): As in (b) above.

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