

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 1307
TO BE ANSWERED ON THE 18th December, 2018

Substandard Drugs

†1307. SHRI DHARMENDRA YADAV:
DR. SHRIKANT EKNATH SHINDE:
DR. PRITAM GOPINATH MUNDE:
SHRI VINAYAK BHAURAO RAUT:
SHRI ADHALRAO PATIL SHIVAJIRAO:
SHRI SHRIRANG APPA BARNE:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether certain drugs manufactured by renowned/major companies have been found to be of substandard quality during the last six months in the country;
- (b) if so, the details thereof along with the names and details of the said companies, State-wise;
- (c) the action taken/being taken by the Government against these companies;
- (d) whether drug regulators of seven States have found that 27 medicines sold by 18 major drug companies in India were of substandard quality during the last three years; and
- (e) if so, the facts thereof and the action taken/being taken against these companies?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS;
MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI MANSUKH L. MANDAVIYA)**

(a) to (c): The import, manufacturing, sale and distribution of drugs are regulated in the country under the provisions of Drugs and Cosmetics Act 1940 and Rules thereunder. Under the said Act and Rules thereunder, manufacturing, sale and distribution of drugs are regulated in the country through a system of licensing and inspection. License for manufacturing, sale and distribution of drugs are granted by State Licensing Authorities appointed by respective State Governments. The State Licensing Authorities are empowered to take action against the manufacturing/sale/distribution of Substandard /Spurious Drugs in the country. Details of instances of drugs samples declared as Not of Standard Quality/Spurious/Adulterated/Misbranded by Central Drugs Testing

Laboratories are regularly uploaded on monthly basis in CDSCO website (www.cdsco.gov.in), under the heading “Drug Alert”.

In such cases, for the drugs, which have been declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, the matter is referred to concerned State Licensing Authorities to take necessary action under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

(d) & (e): Earlier in 2016, a news article appeared in the “Indian Express” dated 28.11.2016 under the title “27 medicines sold by top firms “fail” quality tests in seven States. Pursuant to the News Article, CDSCO had requested all the seven (07) State Licensing Authorities (SLAs) to take necessary action under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

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