

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

**RAJYA SABHA  
UNSTARRED QUESTION NO. 122  
TO BE ANSWERED ON 11<sup>TH</sup> DECEMBER, 2018**

**OVERUSE OF ANTIBIOTICS**

**122. DR. T. SUBBARAMI REDDY:  
SHRIMATI AMBIKA SONI:**

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

- (a) whether it is a fact that India is the world's largest consumer of antibiotics and their use has more than double in the last 15 years;
- (b) if so, whether any study has been made against overuse of antibiotics, if so, the details thereof;
- (c) whether the US Food and Drug Administration has warned that overuse of antibiotics can cause mental health problems and serious blood sugar disturbances etc., among the people with diabetes; and
- (d) if so, whether any advisory or guidelines have been issued to use antibiotics only when needed, and the details thereof?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SMT. ANUPRIYA PATEL)**

(a) & (b): As per information with the Drug Controller General of India, the leading High Income Country (HIC) consumers of antibiotics in 2015 were the U.S.A, France and Italy, while the leading Low and Middle Income Country (LMIC) consumers were India, China and Pakistan. Between 2000 and 2015, antibiotic consumption increased from 3.2 to 6.5 billion Defined Daily Doses (DDDs) (103%) in India, from 2.3 to 4.2 billion DDDs (79%) in China and from 0.8 to 1.3 billion DDDs (65%) in Pakistan.

(c): As per U.S. Food and Drugs Administration news release dated 10.07.2018, the Administration requires safety labelling changes for fluoroquinolone class of antibiotics to strengthen the warning about the risks of mental health side effects and serious blood sugar disturbances, including hypoglycemic coma and make these warnings more consistent across the labelling for all fluoroquinolones taken by mouth or given by injection.

(d): In light of the safety issues reported by U.S. Food and Drug Administration, all States/UTs Drug Controllers have been requested to direct the manufacturers of fluoroquinolones under their jurisdiction to mention following cautions in the label/Package insert/Promotional Literature of the drugs.

1. The label of the product should mention following caution :-

This drug may cause low blood sugar and mental health related side effects.

2. Package insert and promotional literature should mention the details as follows :-

“The drug may cause low blood sugar and mental health related side effects. Low blood sugar levels, also called hypoglycaemia, can lead to coma. The mental health side effects are more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are:

- i. disturbances in attention
- ii. disorientation
- iii. agitation
- iv. nervousness
- v. memory impairment
- vi. Serious disturbances in mental abilities called delirium.”