

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:101

ANSWERED ON:30.11.2012

SALE OF DRUGS

Sayeed Muhammed Hamdulla A. B. ;Sugumar Shri K.

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

- (a) whether the Government has taken note of irrational use of antibiotics across the country;
- (b) if so, the details thereof;
- (c) whether the Government proposes necessary amendments in the Drugs and Cosmetics Rules including imposition of restriction on over-the-counter sale of certain antibiotic and anti-tuberculosis drugs in the country;
- (d) if so, the details thereof; and
- (e) the manner in which the above amendments are likely to benefit the patients and will be enforced across the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 101 FOR 30.11.2012

(a)&(b) Yes, Madam. Irrational use of antibiotics in the country is a public health concern.

(c)&(d) Yes, Madam. The Government has published draft rules vide Gazette notification GSR 228 (E) dated 20-03-2012 for amending the Drugs and Cosmetics Rules, 1945 for insertion of a new Schedule H1 containing 91 drugs including 73 antibiotics, 13 habit forming drugs and 4 anti-TB drugs.

(e) Such amendment in the Rules would help enforcement in a more focused manner and restrict the indiscriminate use of antibiotics. Under this new provision in the Drugs and Cosmetics Rules, the drugs included in the Schedule H1 would be required to be labeled with the following warning in a box with a red border that "It is dangerous to take this preparation except in accordance with the medical advice. Not to be sold by retail without the prescription of a Registered Medical Practitioner."