

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

UNSTARRED QUESTION NO:908

ANSWERED ON:25.11.2011

ANTIBIOTIC POLICY

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

- (a) the steps taken so far by the Government to rationalize and regulate antibiotics in the market;
- (b) whether the Government has withheld the notification to introduce Schedule H1, aimed at imposing strict curbs on the sale of antibiotics in the country;
- (c) if so, the details thereof alongwith the reasons therefor; and
- (d) the time by which antibiotic policy is likely to be finalised in the country?

Answer

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

(a) to (d): A Task Force was constituted by the Government to recommend measures to attend to the problem of multi drugs resistance arising out of widespread and indiscriminate use of antimicrobial drugs in the country and to assess, review and suggest measures on anti-microbial resistance. The Task Force has recommended various steps to rationalize the use of antibiotics in the country. The recommendations include, inter alia, a separate Schedule under the Drugs and Cosmetics Rules to regulate sale of antibiotics, curtailing the availability of Fixed Dose combinations, start colour coding of third generation of antibiotics and restrict their access only to tertiary care hospitals. It has also recommended to develop standardized Antimicrobial Susceptibility Testing methodology, develop detailed Standard Operating Procedure (SOPs) for microbial identification and for reporting and training of doctors, etc.

The Drugs Consultative Committee in its meeting held on 28th October, 2010 also recommended that a new Schedule may be incorporated under the Drugs and Cosmetics Rules, 1945 and along with antibiotics it should include other categories of drugs like anti-TB drugs and certain habit forming drugs which are commonly misused. It was also recommended that these drugs should be sold on double prescriptions where one copy of the prescription is to be retained by the chemist for one year. This will help in auditing the sale of such drugs. The DCC agreed to the recommendations of the Task Force that third generation of antibiotics should be permitted to be sold to the tertiary care hospitals only. Meanwhile, numerous objections to the proposed move have, however, been received from different quarters. The draft rules for insertion of the proposed new Schedule have not yet been published for inviting the comments of the public / stakeholders as required under the Drugs & Cosmetics Act, 1940.