

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

UNSTARRED QUESTION NO:3990

ANSWERED ON:26.08.2011

OTC SALE OF ANTIBIOTICS

Lagadapati Shri Rajagopal;Punia Shri P.L. ;Ramasubbu Shri S.;Singh Shri Uma Shanaker

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

- (a) whether the Government proposes a new policy by including a separate Schedule HX under the Drugs and Cosmetics Rules for a number of antibiotics in order to stop/restrict their Over-the- Counter (OTC) sale across the country;
- (b) if so, the details thereof alongwith the mechanism proposed for the purpose;
- (c) the extent to which such policy is likely to deal with irrational use of antibiotics and also adverse effects of commercialisation in health care sector;
- (d) whether there has been opposition to this move from certain quarters; and
- (e) if so, the details thereof alongwith the steps taken/proposed to address the concerns of various stakeholders in the matter?

Answer

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

(a) to (c): 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. It 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 Procedures for microbial identification and for reporting, 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 as Schedule HX 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.

(d) & (e): 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. Certain objections to the proposed move have, however, been received from certain quarters. Once the draft rules are published, the said objections would also be examined comprehensively alongwith the comments received as per the due procedure for the amendment of the Drugs and Cosmetics Rules, as provided under the Act.