

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

UNSTARRED QUESTION NO:2284

ANSWERED ON:24.08.2012

ANTIBIOTIC POLICY

Krishnaswamy Shri M.;Punia Shri P.L. ;Siricilla Shri Rajaiah

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

- (a) whether the Government has developed any comprehensive policy which addresses the problem of multi drugs resistance arising out of widespread and indiscriminate use of antimicrobial/antibiotic drugs in the country;
- (b) if so, the details thereof indicating the salient features of the said policy;
- (c) the action taken/proposed by the Government to resolve objections received from different quarters against the said policy;
- (d) whether the Government has finalised operational guidelines and put in place a regulatory mechanism to implement the said policy; and
- (e) if so, the details thereof and if not, the reasons therefor?

Answer

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

(a) to (e): On account of the growing public health concern regarding antimicrobial resistance in pathogens on account of increased availability and use of antibiotics across the country meant for human, animal and industrial consumption, 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 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 the sale of antibiotics, curtail the availability of Fixed Dose Combinations, start colour coding of third generation of antibiotics and restrict their access only to tertiary care hospitals. It also recommended to develop standardized Antimicrobial Susceptibility Testing methodology, develop detailed Standard Operating Procedure for microbial identification and for reporting and training of doctors, etc. Based on the recommendations of the Task Force, a notification has been published in the Gazette of India for comments containing the draft amendments to the Drugs & Cosmetics Rules, 1954 for taking out all antibiotics, TB drugs and certain habit forming drugs from the existing Schedule 'H' of the said Rules and putting them in a separate new Schedule 'HI' stipulating that the container of the substance specified in such Schedule 'HI' will be labeled with a symbol 'Rx' which shall be in red colour and conspicuously displayed on the left corner of the label with the warning ;"It is dangerous to take this prescription except in accordance with medical advice and not to be sold by retail without the prescription of the Registered Medical Practitioner.'