

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

UNSTARRED QUESTION NO:1269  
ANSWERED ON:18.07.2014  
ANTIMICROBIAL ANTIBIOTIC DRUGS  
Venugopal Dr. Ponnusamy

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

- (a) whether cases of drug resistant infections arising out of widespread and indiscriminate use of antimicrobial/ antibiotic drugs are on the rise in the country;
- (b) if so, the details thereof;
- (c) whether the Government has received any report/recommendations in this regard;
- (d) if so, the details thereof; and
- (e) the measures being taken by the Government to address the problems of multi drugs resistance due to widespread and indiscriminate use of antimicrobial/ antibiotic drugs in the country?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a) to (e): Concerns have been expressed in respect of development of antimicrobial resistance in pathogens, even to the newer, more potent anti-microbial drugs, on account of increased availability and use of antibiotics across the country. A Task Force was constituted by the Government to recommend measures to address 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. The Drug & Cosmetics Rules, 1945 have since been amended vide Gazette Notification No GSR 588 (E) dated 30-08-2013 incorporating a new, namely, Schedule H1 under the Drugs & Cosmetics Rule containing 46 drugs which include antibiotic drugs, Anti TB drugs and certain habit forming drugs. The drugs falling under Schedule H1 are required to be sold in the country with the following conditions:

(1) the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

(2) The drug specified in Schedule H1 shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labelled with the following words in a box with a red border: "Schedule H1 Drug-Warning:- 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."