

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

UNSTARRED QUESTION NO:3295

ANSWERED ON:01.08.2014

USE OF ANTIBIOTICS

Mullappally Shri Ramachandran;Rudy Shri Rajiv Pratap

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

- (a) whether India has emerged as the world's largest consumer of antibiotics and, if so, the details thereof;
- (b) the details of the antibiotics usage in the country vis-a-vis other countries during each of the last three years;
- (c) whether the Government has assessed the overall impact of the excessive use of antibiotics in the country and, if so, the details and the outcome thereof; and
- (d) the measures being taken by the Government to review the current situation regarding manufacture, use and misuse of antibiotics in the country?

Answer

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

(a) to (d): Comparative data regarding antibiotic consumption in India and other countries is not maintained. There has been a 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. The Government, therefore, constituted a Task Force to recommend measures to address the problem of multi-drug 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 included inter alia insertion of 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. The Task Force also recommended development of 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, the Drugs & Cosmetics Rules, 1945 were amended vide Gazette Notification G.S.R. 588(E) dated 30.08.2013 thereby introducing a new Schedule H1 containing certain 3rd and 4th generation antibiotics, certain habit forming drugs and anti-TB drugs. These drugs 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 warning 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 in retail without the prescription of a Registered Medical Practitioner.

In addition, the Government has framed a comprehensive policy to address the problem of multi- drug resistance due to widespread and indiscriminate use of antimicrobial / antibiotic drugs in the country. The National Policy for Containment of Antimicrobial Resistance has been formulated by the Ministry of Health & Family Welfare for this purpose. The policy has also been widely disseminated among all the States and Union Territories. The Government has also decided to implement a National Programme on Containment of Anti-Microbial Resistance during the 12th Five Year Plan for rational use of antibiotics in hospitals and training & capacity building of professionals in relevant sectors.