

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
STARRED QUESTION NO. 386  
TO BE ANSWERED ON THE 19<sup>TH</sup> JULY, 2019  
CONSUMPTION OF ANTIBIOTICS**

**\*386. DR. (PROF.) KIRIT PREMJI BHAI SOLANKI:**

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

(a) whether India is one of the largest consumers of antibiotics in the world, if so, the details thereof and the reasons therefor;

(b) whether there has been an increase in the resistance to antibiotics during the past three years and if so, the details thereof;

(c) whether the Government has identified the key factors responsible for such rising antibiotic and antimicrobial resistance, if so, the details thereof and if not, the reasons therefor;

(d) whether the Government has taken measures to regulate the human consumption of antibiotics or issued any guidelines to restrict the over-the-counter availability of certain antibiotics and if so, the details thereof; and

(e) whether the Government has made the dispensing of certain antibiotics over the counter punishable and if so, the details thereof?

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

(a) to (e): A statement is laid on the Table of the House

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA  
STARRED QUESTION NO. 386\* FOR 19<sup>TH</sup> JULY, 2019**

(a): As per a report available in public domain, the Drug Controller General of India has reported that in the year 2015, U.S.A, France and Italy were leading High Income Country (HIC) consumers of antibiotics while India, China and Pakistan were the leading Low and Middle Income Country (LMIC) consumers.

(b): Increase in the resistance to antibiotics like third generation cephalosporins, fluoroquinolones and carbapenems is observed in the AMR surveillance network of ICMR.

(c): High burden of bacterial infections leading to higher use of antibiotics; overuse and misuse of antibiotics in humans and animals; syndromic management of infectious diseases due to poor utilization / access to microbiology labs for culture and antimicrobial sensitivity testing; over the counter availability of antimicrobials; prescribing antimicrobials for viral infections, such as, colds and influenza; use of antimicrobials for animals and fish as growth promoters; inadequate management of pharmaceutical waste; inadequate infection control, sanitary conditions and inappropriate food-handling are the key factors for rising antimicrobial resistance.

(d): Antibiotics are included in Schedule H of the Drugs and Cosmetics Rules, 1945 and are required to be sold in retail only under the prescription of a Registered Medical Practitioner. To further regulate the human consumption and restrict over the counter availability of certain antibiotics, the Drugs & Cosmetics Rules, 1945 were amended in August 2013, incorporating a new Schedule H1 wherein 24 third/fourth generation antimicrobials are covered. The supply of these drugs need to be recorded in a separate register giving name and address of prescriber, patient and name of drugs and quantity supplied. The records shall be maintained for 3 years and be open for inspection. Schedule H1 drugs also have specific labelling requirements.

(e): Sale and distribution of drugs are regulated under the provisions of the Drugs and Cosmetics Act, 1940 & Rules, 1945 made thereunder. License for sale and distribution of drugs are granted by State Licensing Authorities appointed by respective State Government. State Licensing Authorities are empowered to take action against any violations of the conditions of license including over the counter sale against guidelines.

