

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

**LOK SABHA
UNSTARRED QUESTION NO. 161
TO BE ANSWERED ON 15TH DECEMBER, 2017**

ANTI-MICROBIAL RESISTANCE

**161. SHRIMATI SANTOSH AHLAWAT:
SHRI SUMEDHANAND SARSWATI:
SHRI R. DHRUVA NARAYANA:
SHRI NALIN KUMAR KATEEL:
SHRI D.K. SURESH:**

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

- (a) whether the Government proposes to roll out prescription audits as part of a multi-pronged strategy against antimicrobial resistance or antibiotic resistance;
- (b) if so, the details thereof;
- (c) whether the Government also proposes to ban OTC sale of antibiotics, if so, the details thereof;
- (d) whether the Government plans to direct all the hospitals and pharmacists to upload all the prescriptions issued and received by them for evaluation by central agency; and
- (e) if so, the details of existing mandatory protocols and guidelines for hospitals and pharmacists?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)**

(a) & (b): Ministry of Health and Family Welfare has developed strategic National Action Plan on antimicrobial resistance containment in consultation with all relevant stakeholders. Optimizing the use of antimicrobials is one of the key strategies in this plan including prescription auditing.

(c): Import/ manufacture, sale, distribution of drugs including antibiotics are regulated under the provisions of Drugs & Cosmetics Act and Rules. Antibiotics are included in Schedule H & H1 of the Drugs & Cosmetics Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner.

The Drug & Cosmetics Rules, 1945 have since been amended in the year 2013 incorporating a new, namely, Schedule H1 under the Drugs & Cosmetics Rules, 1945 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 labeled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labeled 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.”

(d): No.

(e): Does not arise.