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

LOK SABHA
UNSTARRED QUESTION NO. 3371
TO BE ANSWERED ON 05th AUGUST, 2022

REGULATION ON USE OF DRUGS

3371: SHRI VISHNU DATT SHARMA:

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

(a) the achievements in fulfilment of aims and targets set in 'National action plan of the year 2017' of the Government to regulate the use of drugs;

(b) whether the Government has any data on the compliance of schedule H1 by pharmacies/drug retailers in the country;

(c) if so, the details thereof; and

(d) if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (d): Central Drugs Standard Control Organisation (CDSCO) has informed that they have taken various regulatory steps in this regard as under:

1. Antibiotics are included in Schedule H1 of the Drugs and Cosmetics Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner. Further in order to regulate the human consumption of antibiotics and further restrict their retail sale without prescription, the Drug & Cosmetics Rules, 1945 have since been amended vide Notification dated 30.08.2013 incorporating a new, namely, Schedule H1 under the Drugs & Cosmetics Rules containing antibiotics, 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:

    a) 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.

    b) The drug specified in Schedule H1, 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 legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG-CAUTION
-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.

2. The Drugs and Cosmetics Rules were amended by the Ministry of Health and Family Welfare, to make a provision that the container of a medicine for treatment of food producing animals shall be labelled with the withdrawal period of the drug for the species on which it is intended to be used.

3. The Department of Animal Husbandry, Dairying and Fisheries has issued a circular to Directors/Commissioners (Animal Husbandry) of all State and UTs on 03.06.2014 and directed judicious use of antibiotics and hormones for the treatment of ailing food producing animals and that the use of antibiotics and hormones in animal feed should also be stopped. Subsequently DCG (I) has also issued an advisory to States/UTs that use of Antibiotics and Hormones in animal feed should also be stopped.

4. Colistin and its formulations have been prohibited for manufacture, sale and distribution for food producing animals, poultry, aqua farming and animal feed supplements.

5. The State Drugs Controllers/other stake holders have been sensitized about concerns regarding sale of prescription drugs by retail without prescription of Registered Medical Practitioners. Various Notices/Advisories/Letters have been issued to State Drugs Controllers and other stake holders for strict compliance of the requirements of Drugs and Cosmetics Act and Rules.

6. In 58th DCC meeting deliberations were made regarding strong implementation of the provisions of the Drug & Cosmetics Act, 1940 and Rules to ensure quality, safety and efficacy of drugs including antibiotics sold in the country and also to ensure that no drugs in Schedule H & H1 are sold by retail without prescription of RMP.

7. Sales and distribution of drugs are regulated under Drugs and Cosmetics Act 1940 & Rules by the State Licensing Authorities (SLAs) appointed by the State Governments. The SLAs are empowered to take action in case of any non-compliance.

8. National action plan on containment of Antimicrobial Resistance (NAP-AMR) was launched on 19th April 2017 and is implemented by various stakeholder ministries and departments. National AMR surveillance network of state medical college labs (NARS-Net) has been established to generate quality data on AMR for priority bacterial pathogens of public health importance.

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