

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA
STARRED QUESTION No. 289
TO BE ANSWERED ON THE 28TH MARCH, 2023

Selling medicines without prescription

289 Shri Rajeev Shukla:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether the Ministry is aware of several medicines, including antibiotics, being sold by medicine shops across the country without prescription;
- (b) if so, whether the Ministry has taken steps to regulate over-the-counter sale of medicines without prescription; and
- (c) if so, the details thereof and if not, the reasons therefor?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(DR. MANSUKH MANDAVIYA)**

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

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (c) OF STARRED QUESTION NO. 289 FOR REPLY ON 28.03.2023

(a): The subject matter pertains to the Department of Health and Family Welfare (DoHFW). As informed by DoHFW, the sale of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder by the State Licensing Authorities (SLAs) appointed by the State Government through a system of licensing and inspection. SLAs are legally empowered to take action against violation of provisions of the Act and Rules.

(b) & (c): Central Drugs Standard Control Organisation (CDSCO) and Ministry of Health and Family Welfare have taken various measures in this regard. Major such measures are as under:-

(I) The Drug & Cosmetics Rules, 1945 was amended vide GSR 588 (E) 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: -

- i. 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.
- ii. The drug specified in Schedule H1, 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 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.

(II) The State Drugs Controllers/other stakeholders have been sensitized from time to time in this regards. Various notices/Advisories/Letters have been issued to all the State Drugs Controllers, other stakeholders for strict compliance of the requirements of Drugs and Cosmetics Act and Rules made there under and raising awareness in the public regarding adverse effects of misuse of drugs including antibiotics.

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