

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

**LOK SABHA  
UNSTARRED QUESTION NO.444  
TO BE ANSWERED ON 21<sup>ST</sup> JULY, 2023**

**REGULATION OF SALE OF MEDICINES WITHOUT PRESCRIPTION**

**444: SHRI NALIN KUMAR KATEEL:  
SHRIMATI SUMALATHA AMBAREESH:  
SHRI D.K. SURESH:**

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

- (a) whether the Government is aware of the number of medicines including antibiotics being sold without proper prescription by chemists across the country;
- (b) if so, the details thereof;
- (c) whether the Government has any proposal to take stringent steps to regulate over-the-counter sale of medicines without prescription; and
- (d) if so, the details thereof alongwith the response of the Government in this regard?

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

(a): 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 State Government through a system of licensing and inspection. SLAs are legally empowered to take action against violation of provisions of the said Act and Rules.

(b) to (d): CDSCO and Ministry of Health and Family Welfare have taken various measures in this regard.

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 sold in the country with the following conditions:

- (i) The supply of a drug specified in Schedule H1 is 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 are maintained for three years.

(ii) The drug specified in Schedule H1, is labelled with the symbol Rx which is in red and conspicuously displayed on the left top corner of the label, and is 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

The State Drugs Controllers/other stakeholders have been sensitized in this regard. Various notices/Advisories/Letters have been issued to all 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.

\*\*\*\*\*