

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

**LOK SABHA
UNSTARRED QUESTION NO. 376
TO BE ANSWERED ON 03RD FEBRUARY, 2017**

OVER-THE-COUNTER SALES OF DRUGS

376. SHRIMATI PRATYUSHA RAJESHWARI SINGH:

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

- (a) whether the Government has proposed measures to prevent over-the counter sales of drugs included in Schedules H and H1 of the Drugs and Cosmetics Act, 1940 and if so, the details thereof;
- (b) whether Central Drugs Standard Control Organization (CDSCO) ensure that Schedule H and Schedule H1 drugs are not sold over-the-counter;
- (c) if so, the steps taken by CDSCO in this regard;
- (d) whether all drugs used for treating drug resistant tuberculosis included in Schedule H1; and
- (e) if not, the reasons therefor?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)**

(a): Drugs listed in Schedule H, and H1 to the Drugs and Cosmetics Rules, 1945 are required to be sold by retail on the prescription of a Registered Medical Practitioner only. The complete details of drugs included in schedule H1 are also required to be recorded in a separate register at the time of supply.

(b) & (e): Under Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder, the regulatory control over sale of drugs is exercised through a system of inspection and licencing by the State Licensing Authorities appointed by the respective State Governments. Licencees are required to comply with the conditions of Licence. State Licensing Authorities are empowered to take action in case of any violation of the conditions of Licence including conditions specified for sale of drugs included in Schedule H and H1.

(d) & (e): 11 anti tuberculosis drugs have been included in Schedule H1 w.e.f. 01.03.2014 through an amendment in the Drugs & Cosmetics Rules, 1945 after following due procedure and consultation with Revised National Tuberculosis Control Program (RNTCP) of India. The Schedule can be amended as and when new drugs are required to be included in the Schedule.