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

LOK SABHA
STARRED QUESTION NO. 11
TO BE ANSWERED ON THE 15TH DECEMBER, 2017
OVER-THE-COUNTER SALE OF DRUGS

***11. SHRI BAIJAYANT JAY PANDA:**

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

(a) whether the Government has taken any steps to prevent over-the-counter sale of drugs included in Schedules H and H1 of the Drugs and Cosmetics Act, 1940;

(b) if so, the details thereof;

(c) whether the Central Drugs Standard Control Organisation (CDSCO) has the responsibility of ensuring that Schedule H and Schedule H1 drugs are not sold over-the-counter;

(d) if so, the details thereof including the steps taken by CDSCO in this regard; and

(e) whether all drugs used for treating drug resistant tuberculosis have been included in Schedule H1, if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (e) : A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 11* FOR 15TH DECEMBER, 2017

(a) & (b):- Sale and distribution of drugs in the country is regulated as per the provisions under the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945 made thereunder. As per the said Rules, drugs specified in Schedule H, H1 or Schedule X cannot be sold except on and in accordance with the prescription of a Registered Medical Practitioner (RMP).

(c) & (d):- The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Licensees are required to comply with all the conditions of license. SLAs are legally empowered to take stringent action against violation of any provision of the Act and Rules.

While State authorities are primarily responsible for regulation of manufacture, sale and distribution of drugs, Central Drugs Standard Control Organisation (CDSCO) is mainly responsible for approval of New Drugs, Clinical Trials, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations, etc.

CDSCO from time to time sensitizes State Licensing Authorities to ensure compliance of various provisions of the Drugs & Cosmetics Act and Rules including measures to ensure that Schedule H and H1 drugs are not sold without prescription of R.M.P.

(e)**:** All the drugs for treating drug resistant tuberculosis have been included in Schedule H1 except Kanamycin, Streptomycin and Ofloxacin, which are already included in Scheduled H to the Drugs & Cosmetics Rules, 1945. Eleven anti tuberculosis drugs have been introduced in the Schedule H1 w.e.f. 1.03.2014 through amendment in Drugs & Cosmetics Rules, 1945 following due procedures and consultation with Revised National Tuberculosis Control Program (RNTCP) of India.

*****