GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:358 ANSWERED ON:06.12.2013 SALE OF DRUGS Bais Shri Ramesh:Kumar Shri P.

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

- (a) the number of medicines notified by the Government which cannot be sold without doctors' permission in the country;
- (b) whether the Government proposes to impose restriction on over-the-counter sale of certain new medicines in the country;
- (c) if so, the details thereof; and
- (d) the other measures being taken by the Government to check the indiscriminate use of antibiotics and other drugs, including antituberculosis drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

- (a) to (d): Under the Drugs & Cosmetics Rules, drugs specified under Schedule H and Schedule X are required to be sold by retail on the prescription of a Registered Medical Practitioner only. At present Schedule H & Schedule X contains 510 & 15 drugs, respectively. Recently, a new Schedule H1 has been introduced through Gazette notification GSR 588 (E) dated 30-08-2013, which contain certain 3rd and 4th generation antibiotics, certain habit forming drugs and anti-TB drugs. These drugs are required to be sold in the country with the following conditions:
- (1) 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.
- (2) The drug specified in Schedule H1 shall 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 a box with a red border:
- "Schedule H1 Drug-Warning:
- -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."