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

RAJYA SABHA UNSTARRED QUESTION NO. 1399 TO BE ANSWERED ON 14th MARCH, 2017

LEGAL FRAMEWORK FOR E-PHARMACY BUSINESS

1399. SHRI BHUPENDER YADAV:

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

(a) whether any proposals have been considered for framing separate guidelines for the sale of medicines online (epharmacy) in order to outline a legal framework for e-pharmacy business, if so, the details thereof;

(b) whether Government plans to amend the Drugs and Cosmetics Act, 1940 to differentiate between online and offline pharmacies, if so, the details thereof;

(c) the steps taken by Government to address the problem of validity of prescriptions in epharmacy business; and

(d) the difficulties faced by start-ups in the ease of doing e-pharmacy business and the steps taken by Government to address these problems?

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

(a) & (b): In view of the concerns raised on the sale of drugs over internet, the Drugs Consultative Committee (DCC) in its 48^{th} meeting held on 24^{th} July, 2015, constituted a sub-committee to examine the issue of sale of drugs on internet. The Sub-Committee, in its report, has inter alia recommended:-

- Creation of a National Portal to act as the nodal platform for transacting and monitoring online sale of drugs.
- Necessity of evolving a mechanism to register e-pharmacies.
- Geographical restrictions for operation of e-pharmacies.
- Mechanism for verification of authenticity through a link to the National Portal.
- Existing licensees carrying out retail sale of drugs would also be able to register on the National Portal for carrying out online sale of drugs.
- As certain categories of drugs viz. the Narcotic and Psychotropic drugs, tranquilizers, habit forming drugs and Schedule X drugs that are prone to being abused or misused to be excluded from sale through e-pharmacies.
- Amendment of Drugs & Cosmetics Rules, 1945 for effective monitoring and proper enforcement of the Drugs & Cosmetics Act, 1940 for achieving its aims and objectives.

(c) & (d): Any sale of medicine in the country continues to be regulated as per provisions of the Drugs and Cosmetics Rules, 1945 as amended from time to time. In terms of the provisions of the said Rules, drugs specified in Schedules H, H1 and X cannot be sold except on, and in accordance with the prescription of a Registered Medical Practitioner from a licensed premises. Therefore, any sale of such drugs other than from a licensed premise is not in conformity with these rules. Further, other requirements such as noting the name and address of seller and date on which medicines are dispensed can also not be met in many cases.

Currently, e-pharmacies which do not meet the requirements of Drugs and Cosmetics Rules, 1945 including those relating to sale from a licensed premises and maintaining necessary records, are not permitted.