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

RAJYA SABHA UNSTARRED QUESTION NO. 2194 TO BE ANSWERED ON 01ST JANUARY, 2019

DRAFT RULES ON ONLINE SALE OF DRUGS

2194. SHRI RIPUN BORA:

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

- (a) whether it is a fact that Government has come up with draft rules on the sale of drugs by e-pharmacies, if so, the details thereof;
- (b) the manner in which the e-pharmacies were regulated till date and whether Government has carried out any surveys on the number of e-pharmacies; and
- (c) the manner in which Government would ensure or plans to ensure that spurious drugs are not sold through e-pharmacies?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY)

(a): The Government has published draft rules vide G.S.R. 817 (E) dated 28th Aug 2018 for inviting comments from public/stakeholders for amendment to the Drugs and Cosmetics Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy.

The draft rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e-pharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.

(b): The manufacture, sale and distribution of drugs in the country is 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. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

There are no specific provisions under the Drugs and Cosmetics Rules regarding regulation of sale of drugs through e-pharmacies. All matters relating to sale of drugs including through online will continue to be regulated in accordance with provisions of the Drugs and Cosmetics Rules, 1945 as amended from time to time.

Government has not carried out any surveys on the numbers of e-pharmacies.

(c): The draft e-pharmacy rules have been framed under the Drugs & Cosmetics Act, 1940 which has adequate provisions to safeguard against sale of spurious drugs.