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

LOK SABHA UNSTARRED QUESTION NO.†2985 TO BE ANSWERED ON 17TH MARCH, 2023

QUALITY OF ONLINE MEDICINES

†2985: SHRI GHANSHYAM SINGH LODHI:

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

(a) whether the Government is aware of the online sale of medicines;

(b) if so, the companies which are selling medicines online;

(c) the details of the online companies selling medicines without license including their names and the number of years since when they have been selling their medicines;

(d) the States in which the network of online selling of medicines exists; and

(e) the manner in which the Government plans to control the quality of online medicines?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) to (e): As informed by Central Drugs Standard Control Organisation (CDSCO), various representations are received raising concerns regarding sale of drugs through online, internet or other electronic platforms including various mobile applications, in contravention to the provisions of the Drugs and Cosmetics Act, 1940.

Based on findings in representations CDSCO issued Show Cause Notices on 08.02.2023 & 09.02.2023 to 31 firms engaged in the online sale of the drugs.

The cases concerning quality of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940. The State Licensing Authorities (SLAs) are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

2. States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

3. The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

4. To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

5. The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

6. The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.
