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

LOK SABHA UNSTARRED QUESTION NO. 2114 TO BE ANSWERED ON 12TH DECEMBER, 2025

SALE OF ANTI-DEPRESSANTS

2114. SHRI SRIBHARAT MATHUKUMILLI:

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

- (a) whether the Government maintains data on the number of anti-depressant drugs sold in the country during the last five years and if so, the details thereof, year-wise and State/UT-wise;
- (b) the details of anti-depressant drugs currently approved, available and marketed in the country;
- (c) whether the Government is aware that anti-depressants are being prescribed for off-label uses in the country and if so, the details thereof;
- (d) whether the Government has put in place safeguards and regulatory measures to prevent misuse or inappropriate prescription of anti-depressants for off-label indications and if so, the details thereof; and
- (e) the current status of the draft rules on the regulation of sale and distribution of drugs through e-pharmacy platforms, first notified in 2018?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (d): Sale of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and the Rules made thereunder, by the State Governments through a system of licensing and inspection. State Licensing Authorities (SLAs) are legally empowered to take action against violation of provisions of the said Act and Rules. Data related to the sale of anti-depressant drugs in the State/UTs is not maintained centrally.

During the last three years, Central Drugs Standard Control Organisation (CDSCO) has approved seven anti-depressant drug products for use in country. Drugs, including anti-depressants, are approved along with their indication(s), dosage form, route of administration, and strength in accordance with the regulatory framework.

Various notices/Advisories/Letters have been issued to all State Drugs Controllers, other stakeholders for strict compliance of the requirements of Drugs and Cosmetics Act and

Rules made thereunder and for raising awareness in the public regarding adverse effects of misuse of drugs.

(e) In order to comprehensively regulate online sale of medicines, the Government of India has published draft rules vide its notification dated 28.8.2018, inviting comments from public and stakeholders on amendments to the Drugs 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.
