

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

**LOK SABHA  
UNSTARRED QUESTION NO. 3567  
TO BE ANSWERED ON 13<sup>TH</sup> MARCH, 2026**

**SALE OF ANTIDEPRESSANT DRUGS**

**3567. SHRI TANGELLA UDAY SRINIVAS:**

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

- (a) the details of the data on the sale of antidepressant drugs maintained during the last five years, year-wise and State/UT-wise;
- (b) the list of antidepressant drugs currently approved and marketed in the country;
- (c) the safeguards in place to regulate prescription practices, including off-label use;
- (d) whether any monitoring or audit mechanism exists to track prescription trends, misuse or adolescent consumption and if so, the details thereof;
- (e) the number of adverse drug reactions reported in relation to antidepressants during the last five years, year-wise; and
- (f) the current status of rules regulating sale of prescription drugs, including Schedule H, H1 and psychotropic medicines, through e-pharmacy platforms along with enforcement actions taken?

**ANSWER**

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

(a) to (e): 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. As per market data available with National Pharmaceutical Pricing Authority (NPPA) Department of Pharmaceuticals (DoP), the sales as reported under “anti-depressants and mood” category for the last five years is as under:

Year	Sales Value (in ₹in Cr.) based on Maximum Retail Price
2021	2,442.41
2022	2,820.74
2023	3,137.62
2024	3,478.35
2025	3,648.78

(Source- Pharmarack database December 2025)

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.

The Indian Pharmacopoeia Commission (IPC) as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) collates and analyses, Individual Case Safety Reports (ICSRs) related to adverse drug reactions. The year-wise distribution of ICSR is given below:

<b>Calendar Year</b>	<b>Number of Adverse Drugs Reactions (ADR) Reports of Antidepressant Drugs</b>
2021	666
2022	1271
2023	1836
2024	2063
2025	1798

(f) 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.

Isolated complaints regarding sale of drugs by e-pharmacies without proper prescription etc. have been received. As and when such complaints are received, based on the merit, the matter is referred to the concerned State Licensing Authority for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945, as the State Licensing Authorities are empowered to take action in case of any violation of the conditions of sale licenses.

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