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

LOK SABHA
UNSTARRED QUESTION NO. 2186
TO BE ANSWERED ON 31ST JULY, 2026

STRENGTHENING DRUG SAFETY AND REGULATION

2186. THIRU D M KATHIR ANAND:

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

(a) the factors considered by the Government while bringing cough syrups and other syrup-based medicines under prescription-only sale and the implications of this decision for patient safety, drug regulation and public health;

(b) the provisions governing quality control, licensing, testing, inspection and post-marketing surveillance of pharmaceutical products, including cough syrups and other frequently used medicines;

(c) the details of the number of inspections conducted, drug samples tested, manufacturing licences suspended or cancelled and prosecutions initiated in cases involving substandard, contaminated or unsafe medicines during the recent period;

(d) the coordination mechanism among Central and State drug-control authorities for enforcement of prescription requirements, monitoring of pharmacies and prevention of unauthorised sale of prescription medicines; and

(e) the policy measures introduced by the Government to strengthen drug-safety standards, improve regulatory oversight, enhance public awareness against self-medication and reinforce confidence in the country's pharmaceutical sector?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE

(SMT. ANUPRIYA PATEL)

(a) to (e): As per the Drugs and Cosmetics Act, 1940, and Drugs Rules, 1945, all drugs including cough syrups covered under Schedule X, H and/or H1 are required to be sold by retail on the prescription of a Registered Medical Practitioner (RMP) only. Further, Schedule K to the said Rules provided an exemption for sale of cough syrups in villages with a population not exceeding 1,000 persons and where no dealer was licensed under the said Act. However, the Government vide notification G.S.R 477 (E) dated 09.06.2026, has amended the Drugs Rules, 1945, withdrawing the said exemption to enhance regulatory control and promote rational use of cough syrup in the interest of patient safety.

The manufacturing, sale and distribution of drugs including cough syrups and other frequently used medicines in the country are regulated under the provisions of Drugs &

Cosmetics Act, 1940 and rules thereunder through a system of licensing and inspection by the State Licensing Authorities (SLAs). SLAs are legally empowered to take action against erring license holders in case of violation of provisions of the said Act and Rules. Post-marketing surveillance of drugs is also undertaken through pharmacovigilance activities, market surveillance and testing of drug samples by the Central and State Drug Regulatory Authorities.

Further, in order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 1040 premises since December, 2022 and based on findings, more than 950 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities. More than 1100 cough syrup manufacturers have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

As per information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last three years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	Number of prosecution cases for manufacturing, sale and distribution of spurious/adulterated drugs
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961
2025-26	1,41,322	3,012	283	779*

* Provisional figure

State Licensing Authorities carryout periodic inspections or as per risk-based approach from time to time of the licensed premises for verification of compliance with the provisions of the Act and rules thereunder. Actions such as suspension and cancellation of licences, prosecutions in the court of law are taken against the erring firms by the State Licensing Authorities.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken following policy measures to strengthen drug-safety standards in the country:

(i). The Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for

pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024 and for manufacturers having turnover of less than Rs. 250 Cr from 01.01.2026.

(ii). In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by Central and State Drugs Inspectors. These guidelines provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.

(iii). Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25, 20551 persons have been trained.

(iv). CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(v). List of batches of certain drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). In the cases concerning quality or safety of drugs as and when reported, action is taken by the licensing authorities concerned under the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

(vi). In order to strengthen monitoring, public awareness to prevent harm arising from inappropriate use of GLP-1 receptor agonists, National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), organized a meeting with representatives from Marketing Authorisation Holders (MAHs) and Adverse Drug Reaction Monitoring Centers (AMCs) on 20th May, 2026 and 22nd March, 2026, respectively, to sensitize the stakeholders about the safety of Semaglutide (Ozempic) and other GLP-1 receptor agonists and reporting of suspected Adverse Drug Reactions (ADRs) to the PvPI. Awareness posters have also been posted on IPC social media handles to encourage healthcare professionals and the public to report ADRs associated with GLP-1 receptor agonists including Semaglutide.

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