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

LOK SABHA
UNSTARRED QUESTION NO. 1122
TO BE ANSWERED ON 24TH JULY, 2026

USE OF DIABETES DRUG OZEMPIC

1122. SMT. KANIMOZHI KARUNANIDHI:

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

(a) whether the Government is aware of the growing use of certain GLP-1 class drugs, such as Ozempic, which are approved for the treatment of diabetes, being increasingly used off-label or without proper medical oversight, and the concerns raised regarding potential misuse for non-diabetic purposes, if so, the details thereof; and
(b) whether the Government proposes to strengthen monitoring, prescription guidelines, public awareness and vigilance mechanisms to prevent harm arising from inappropriate use of such medications and if so, the details thereof?

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

(a): Drugs such as Ozempic, are required to comply with safety, quality and efficacy requirements under the New Drugs and Clinical Trials Rules, 2019 prior to approval for manufacture/import or marketing. Such approvals are granted by the Central Drugs Standard Control Organisation (CDSCO) based on evaluation of clinical data and other scientific evidence generated under the provisions of said rules.

CDSCO has approved GLP-1 receptor agonist drugs in India strictly for the indications of Type 2 Diabetes Mellitus (T2DM) in adults and chronic weight management in adults with specified medical conditions.

In view of the potential misuse by non-diabetes individuals, the prescription and use of such drugs have been restricted exclusively to endocrinologists and internal medicine/ specialists. Initiation and continuation of therapy are required to be undertaken only under the strict supervision and monitoring of the treating specialist physician. This regulatory safeguard is intended to prevent inappropriate use and to ensure that these drugs are administered strictly under qualified medical supervision, thereby mitigating risks associated with misuse and unsafe consumption.

In addition, CDSCO has issued an Advisory dated 10.03.2026 to all concerned stakeholders, emphasizing strict compliance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, and directing that manufacture, sale, and distribution strictly conform to approved indications and conditions of permission.

(b): CDSCO has issued an advisory dated 27.03.2026 directing State/UT Drugs Controllers to ensure strict adherence to the conditions of approval and the warnings specified on the approved product labels for GLP-1 based weight loss drugs. It further emphasizes that the manufacture/import, distribution, wholesale and retail sale and dispensing of such drugs shall take place only through authorized channels and strictly in accordance with the approved indications and labelling.

The advisory also directs the State/UT Drugs Controllers to initiate appropriate regulatory action in cases involving diversion of products, leakage into unauthorized supply channels, promotional practices influencing the supply chain, or any non-compliance with the conditions of approval. In addition, they have been advised to undertake active monitoring of print, electronic, digital, social media and outdoor advertising platforms to detect non-compliant advertisements or surrogate promotional activities relating to these drugs.

Wherever violations are detected, appropriate action initiated under the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the Drugs and Cosmetics Act, 1940 and the Rules made thereunder against the manufacturers, importers, marketers or any other entities.

Following steps has been taken by National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), to strengthen monitoring, public awareness to prevent harm arising from inappropriate use of GLP-1 receptor agonists

(i). NCC-PvPI 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.

(ii). All AMCs under PvPI across the country have been sensitized through emails and posters to closely monitor and report ADRs associated with semaglutide and other GLP-1 receptor agonists.

(iii). 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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