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

RAJYA SABHA
UNSTARRED QUESTION NO. 2824
TO BE ANSWERED ON 17TH MARCH, 2026

UNREGULATED SALE AND MISLEADING PROMOTION OF WEIGHT-LOSS AND WEIGHT-GAIN DRUGS

2824 MS. SWATI MALIWAL:

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

(a) whether Government has assessed rising use and unauthorised sale of prescription drugs, anabolic steroids and nutraceutical/herbal products marketed for weight loss or weight gain and findings thereof;

(b) whether products claiming weight reduction, muscle gain or fat loss are required to demonstrate efficacy and safety through independent clinical evaluation and if so, the details of products assessed and results thereof;

(c) the number of product bans, market recalls and prosecutions undertaken under relevant statutes in last three years; and

(d) whether Government proposes mandatory health warnings, restrictions on influencer promotion and a publicly accessible list of banned/investigated products to prevent misleading claims and protect consumers?

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

(a) to (d): All drugs intended for therapeutic use, including those claiming effects such as weight reduction or metabolic modification, 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 three drugs for obesity/weight management in the country i.e., Orlistat, Tirzepatide and Semaglutide.

These drugs are required to be sold in retail on the prescription of endocrinologist or Internal Medicine/ specialists only as per the conditions of approval issued by CDSCO. All

drugs should be used/consumed in accordance with recommendations for use and under medical supervision.

Under the Drugs and Cosmetics Act, 1940, and Rules thereunder, the license for Sale and Distribution of drugs are granted by the State Licensing Authority appointed by the State Government. Licensee is required to comply with all the conditions of license. State Licensing Authorities are empowered to take action on violation of any conditions of such licenses. As per the conditions of license, sales of Drugs shall be effected only by or under the personal supervision of a registered pharmacist and no person can sale by retail the Schedule H, H1 and X drugs without prescription of Registered Medical Practitioner (RMP).

To regulate the usage and prevent self-abuse of steroids, which may contribute to health issues, following steps have been taken by the Government:

(i) The Drugs Rules, 1945 were amended vide G.S.R. 277(E) dated 23.03.2018 for inclusion of 14 steroids under Schedule H of Drugs Rules, 1945.

(ii) The Drugs Rules, 1945 were amended vide G.S.R 408(E) dated 26.04.2018 mentioning that the salts, esters, derivatives and preparations containing steroids or Hydroquinone for topical or external use shall also be covered under Schedule H.

Food Safety and Standards Authority of India (FSSAI) has notified Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. These regulations prescribe standards for Nutraceuticals, Health Supplements, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food. The products categorized under Food for Special Medical Purpose (FSMP) are required to carry a mandatory advisory warning stating “Recommended to be used under medical advice only” in bold letters along with a warning that the product is not for parenteral use.

Actions such as product bans, market recalls and prosecutions against erring manufacturers/sellers are undertaken by the concerned State Authorities under relevant act. Details regarding the same are maintained by the respective State/UT authorities.

On 10.03.2026, CDSCO issued an advisory to all the concerned stakeholder against any promotional activity, including so-called "awareness campaigns," that functions as a surrogate advertisement for prescription drugs including Glucagon-like peptide-1 (GLP-1) receptor agonists, to attract action under relevant provisions of the Drugs Rules, 1945, including principles underlying Schedule J of the said rules.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder encompass the provisions for prohibition of misleading advertisements and exaggerated claims of drugs and medicinal substances including Ayush medicines.

Ministry of Ayush issued an advisory dated 18.04.2024 and directed to all State/UT Ayush Drug Licensing Authorities, all Ayush drug manufacturers/associations, and the National Pharmacovigilance Coordination Centre regarding “Compliance to the labelling provisions for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs/medicines”.

Ministry of Ayush issued a public notice on 08.10.2024, informing the general public about the facts regarding ASU&H drugs/medicines and urging them to avoid patronizing misleading advertisements, which was published in 100 leading newspapers across India in Hindi, English, and several regional languages.

As per existing regulatory framework, all advertisements telecast on private satellite TV channels are required to adhere to the Advertising Code prescribed under the Cable Television Networks (Regulation) Act, 1995 and rules framed thereunder. Rule 7(5) of the Advertising Code inter alia provides that 'No advertisement shall contain references which are likely to lead the public to infer that the product advertised or any of its ingredients has some special or miraculous or super-natural property or quality, which is difficult of being proved.' Appropriate action is taken against the private TV channels when violation of any provision of the Advertising Code is found. Ministry of Information & Broadcasting also issues advisories from time to time to broadcasters for ensuring compliance to the Advertising Code.

The Central Consumer Protection Authority (Central Authority/CCPA) has been established under Section 10 of the Consumer Protection Act, 2019 to regulate the matters related to violation of rights of consumers, unfair trade practices and false or misleading advertisements and protect and enforce the rights of the consumers as a class.

Central Consumer Protection Authority (CCPA), in exercise of the powers conferred by Section 18 of the Consumer Protection Act, 2019, issued "Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022". These guidelines provide for conditions for non-misleading and valid advertisement, bait advertisement, prohibition of surrogate advertisement, children targeted advertisement, disclaimer in advertisement and duties of manufacturer, service provider, advertiser and advertising agency.

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