CENTRAL DRUGS STANDARD CONTROL ORGANIZATION'S ADVISORY ON PROMOTION OF PRESCRIPTION DRUGS

On March 10, 2026, the Central Drugs Standard Control Organization ("**CDSCO**") issued an advisory bearing ref. no. SEC-11011(11)/45/2025-eoffice, reiterating that manufacturers and importers of drugs must ensure that the manufacture, sale, distribution, and promotion of drug products comply with the approved indications, conditions of permission, labelling requirements, and other statutory provisions under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

The advisory flags concerns that certain pharmaceutical companies may be engaging in direct or indirect promotional practices, including surrogate marketing, digital outreach, and disease awareness initiatives in relation to GLP-1 receptor agonists and other prescription medicines used for obesity and metabolic disorders.

The advisory cautions any form of advertisement, whether direct or indirect, which:

- promotes prescription-only medicines to the general public
- overstates therapeutic effectiveness,
- suggests guaranteed weight-loss outcomes,
- minimizes the importance of lifestyle interventions like diet and exercise, or
- encourages demand for pharmacological therapy

may constitute as misleading promotion and could invite regulatory action under the Drugs Rules, 1945.

Through the advisory, CDSCO aims to safeguard public health by preventing misleading marketing practices and ensuring that vulnerable populations are not exploited through promotion of prescription drugs. In light of the CDSCO's increasing focus on promotional practices in the pharmaceutical sector, companies may consider reviewing their marketing, therapy awareness, and digital outreach materials to assess compliance with the applicable regulatory framework and mitigate potential enforcement risks.

Read more at:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM5NjI=

This update is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Subsequent New Drugs Division)

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Advisory

Under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945 made thereunder, all manufacturers and importers of drugs are required to ensure that manufacture, sale, distribution, and promotion of drug products strictly conform to the approved indications, conditions of permission, labeling requirements, and other statutory provisions.

It has been brought to the notice of this Directorate that certain pharmaceutical companies may be engaging in direct or indirect (surrogate) promotional activities, including disease awareness campaigns, digital media outreach, and other communications, relating to GLP-1 receptor agonists and similar prescription drugs indicated for obesity and metabolic disorders.

In this regard, it is clarified that:

1. Prescription drugs, including GLP-1 receptor agonists, are required to be prescribed by Registered Medical Practitioners/specialists as per approved indications and conditions of marketing authorization.
2. Any form of advertisement, whether direct or indirect, which:
   - Promotes prescription-only medicines to the general public,
   - Exaggerates therapeutic efficacy,
   - Suggests assured or guaranteed weight loss outcomes,
   - Downplays lifestyle modification measures (diet, exercise, behavioural interventions), or
   - Induces demand for pharmacological therapy,

   may amount to misleading promotion and may attract action under relevant provisions of the Drugs Rules, 1945, including principles underlying Schedule J of the said rules.
3. Obesity is a chronic metabolic condition requiring comprehensive management, including lifestyle interventions. Pharmaceutical therapy, where indicated, must not be projected in a manner that undermines public health initiatives promoting diet control, physical activity, and preventive healthcare measures.

Any promotional activity, including so-called "awareness campaigns," that functions as a surrogate advertisement for prescription-only drugs shall be viewed seriously and may be treated as irrational or misleading marketing practice.

Accordingly, all manufacturers, importers, and marketing authorization holders are hereby advised to:

- Ensure strict compliance with the Drugs and Cosmetics Act, 1940 and Rules made thereunder.
- The Prescribing Information/ Patient information leaflet/ Product Information Sheet (PIS) shall prominently display the details of authorized personnel and the authorized office code. The PIS shall also provide a dedicated contact number along with a complaint / ticket reference mechanism for addressing consumer queries and facilitating reporting.
- Advertisement including surrogate advertisement of the said product shall be strictly prohibited. This prohibition shall extend to any form of direct or indirect promotional activity in print, electronic, digital, social media, or any other public platform that is intended, directly or indirectly, to promote the product to the general public. Further, any promotional activity carried out under the pretext of disease awareness, influencer engagement, corporate campaigns or similar activities that create brand recall/product visibility of the prescription product, shall also be treated as violations.
- All manufacturers and Marketing Authorization Holders shall be strictly comply with all applicable ethical and regulatory norms, including ethical marketing practices, to ensure that vulnerable populations are not exploited.
- To mitigate any residual risk, the firms to submit comprehensive Risk Management Plan (RMP) which shall ensure continued safety monitoring and implementation of appropriate risk minimization measures.

In view of above all stakeholders are advised to adhere with this advisory in public interest.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To

1. **All Stakeholders & CDSCO Website**
2. **Advertising Standards Council of India (ASCI)**