Epidemiological Alert: Misuse of GLP-1 receptor agonist medications and considerations for the Americas Region

27 February 2026

In recent months, there has been an increase in the number of countries reporting adverse effects of varying severity associated with the misuse of glucagon-like peptide-1 (GLP-1) receptor agonists indicated for the treatment of obesity in adults. In this context, the Pan American Health Organization/World Health Organization (PAHO/WHO) urges Member States to strengthen pharmacovigilance systems, promote timely reporting of adverse events, and implement risk communication actions aimed at both the general population—to promote the proper use of these drugs—and health personnel, to ensure that they are prescribed strictly in accordance with the indications approved by national regulatory authorities, based on an individual clinical assessment and with continuous medical monitoring.

Obesity is recognized by the World Health Organization (WHO) as a chronic disease that requires a comprehensive and sustained approach. In this context, the use of pharmacological interventions should be carefully evaluated within person-centered care models, considering the individual clinical profile, comorbidities, and the benefit-risk ratio of each therapeutic option *(1)*.

Glucagon-like peptide-1 (GLP-1) receptor agonists, including semaglutide, dulaglutide, liraglutide, tirzepatide, beinaglutide, and exenatide, among others, are a class of drugs authorized in several countries for specific indications. These drugs act on mechanisms that regulate appetite and energy metabolism; however, their prescription and use must be strictly in accordance with the indications approved by national regulatory authorities, within a structured clinical management plan and with periodic clinical monitoring *(2)*. The WHO has published global guidelines detailing considerations for the appropriate, safe, and supervised use of GLP-1 drugs *(3)*.

The Expert Committee on the Selection and Use of Essential Medicines recently assisted the WHO in publishing (February 2026) the 24th Edition of the WHO Model List of Essential Medicines. In it, the inclusion of semaglutide, dulaglutide, liraglutide, and tirzepatide was recommended **as additional hypoglycemic therapies in adults with type 2 diabetes and with i) established**

Suggested citation: Pan American Health Organization/World Health Organization. Epidemiological Alert: Misuse of GLP-1 receptor agonist medications and considerations for the Americas Region – 27 February 2026. Washington, D.C.: PAHO/WHO; 2026.

cardiovascular disease or chronic kidney disease; and ii) obesity (BMI[1]≥ 30 kg/m2) that has a significant impact on their health or quality of life. The committee clearly did not recommend the use of these products in patients with obesity and without type 2 diabetes and comorbidities *(4)*.

With regard to the safety of GLP-1 receptor agonists, the most frequently reported adverse effects are gastrointestinal in nature and are generally transient *(2)*. However, less frequent but potentially serious events such as pancreatitis, biliary disease, and intestinal obstruction have been reported (**Table 1**) *(5- 8)*, as well as other rare risks still under evaluation *(2)*. This background underscores that their use should be exclusively under medical prescription and with adequate clinical monitoring. In this regard, there is a clear need to strengthen pharmacovigilance systems, promote timely reporting of adverse events, and generate additional evidence on long-term safety and effectiveness under real-world conditions *(3)*.

Table 1: Serious adverse events associated with GLP-1 RAs and official regulatory sources

Serious adverse event	Summary clinical description	Level of regulatory recognition	Associated risk factors
Acute pancreatitis *(5, 6)*	Inflammation of the pancreas that may manifest as persistent severe abdominal pain, nausea, and vomiting.	Warning included in EMA/FDA technical data sheets	History of pancreatitis, hypertriglyceridemia
Biliary disease (cholelithiasis/cholecystitis) *(7)*	Formation of gallstones or gallbladder inflammation associated with rapid weight loss.	Recognized adverse reaction	Rapid weight loss, obesity
Intestinal obstruction/ileus/ gastroparesis *(6)*	Severe impairment of gastric emptying or intestinal transit.	Post-marketing reports	Previous GI disorders
Worsening of diabetic retinopathy *(5)*	Progression of microvascular complications in patients with diabetes.	Warning in clinical studies	Long-standing diabetes
Risks from counterfeit/unauthorized products *(8)*	Absence of active ingredient, contamination, loss of cold chain.	WHO/NRA alerts	Online purchases, informal channels

EMA, European Medicines Agency; FDA, Food and Drug Administration; WHO, World Health Organization; NRA, National Regulatory Authority.

Source: Adapted from the European Medicines Agency, Food and Drug Administration and World Health Organization *(5- 8)*.

In the Americas Region, various regulatory authorities have issued official communications on the use of these drugs outside of nationally approved indications, as well as on the detection of counterfeit or unauthorized products *(9 - 20)*. The growing demand for these drugs may encourage their sale through unofficial channels, increasing the risk of exposure to products whose quality, safety, and efficacy have not been verified, with a consequent increase in the risk of adverse effects and other associated complications *(2)*.

[1] Body Mass Index (BMI) is a reliable screening tool for assessing a person's weight in relation to their height.

Recommendations for Member States

Unregistered, substandard, and counterfeit medical products pose a threat to public health. Their presence on the market and high probability of consumption by the population can lead to treatment failure, adverse reactions, and increased morbidity and mortality among patients. In addition, these products increase healthcare costs for the population and health systems. Therefore, PAHO/WHO recommends that Member States:

1. Safe clinical use and responsible prescribing

- Ensure that the use of GLP-1 RAs is limited to indications approved by the National Regulatory Authority (NRA), in the context of a comprehensive obesity management plan *(3, 21, 22)*.
- Promote clinical protocols that include *(22)*:
  - Initial assessment of comorbidities,
  - Clear criteria for initiation and discontinuation of treatment,
  - Periodic clinical and metabolic follow-up.
- Training health professionals on potential risks, interactions, relative contraindications, and warning signs *(3)*.

2. Regulatory and pharmacovigilance strengthening

- Strengthen national active and passive pharmacovigilance systems, integrating mechanisms for early detection of adverse events associated with the use of GLP-1 RAs, particularly those related to off-label use, self-medication, or acquisition through unauthorized channels *(3, 23, 24)*.

- Strengthen and widely disseminate national mechanisms for reporting adverse events, ensuring that healthcare professionals, healthcare facilities, marketing authorization holders, and patients are aware of the official channels in place in each country.

- Ensure that all reports of suspected adverse reactions, regardless of the point of entry, are formally channeled and concluded by the NRA or the officially designated National Pharmacovigilance Center, in order to ensure traceability, causality analysis, and benefit-risk assessment.

- Establish specific protocols for the standardized reporting of serious adverse events (e.g., acute pancreatitis, biliary disease, intestinal obstruction, acute renal failure, progression of diabetic retinopathy), including structured clinical follow-up. (*3, 23, 24*).

- Incorporate into surveillance plans the monitoring of regulatory signals currently under international study, such as the progression of diabetic retinopathy, the possible risk of pancreatic cancer, and active surveillance of medullary thyroid carcinoma, clarifying that these events are under evaluation and do not constitute confirmation of a causal relationship *(25)*.

- Promote the timely exchange of information between national regulatory authorities and regional networks for pharmacovigilance and substandard and counterfeit medical products, coordinated by PAHO, to facilitate the detection and coordinated management of emerging signals.

3. Control of the pharmaceutical market and prevention of counterfeit products

- Intensify regulatory inspections of this therapeutic group as a matter of priority, considering its high demand and the increased risk of marketing through informal channels, e-commerce, and social media *(3, 5, 24, 26)*.

- Strengthen supply chain surveillance, including document verification, batch traceability, and control of storage and transport conditions (*5, 24, 26*).

- Disseminate and strengthen national mechanisms for reporting suspected substandard, counterfeit, or unauthorized medical products, ensuring that all information received is formally channeled and evaluated by the NRA.

- Coordinate interagency actions with customs authorities, trade oversight agencies, and control entities to prevent the entry and circulation of unauthorized or counterfeit GLP-1 products (*5, 26*).

- Issue timely public alerts regarding counterfeit batches or unauthorized products detected, and share the information through the relevant regional networks (*5, 24, 26*).

4. Risk communication aimed at the population

- Develop evidence-based public communication strategies that clearly explain that GLP-1 agonist drugs are not cosmetic treatments and that their use should be exclusively under specific medical indications and with close clinical monitoring *(3, 5, 22)*.

- Promote clear messages about warning signs that require immediate medical attention (persistent abdominal pain, severe vomiting, visual disturbances, thyroid symptoms, among others) *(3, 5, 22)*.

- Implement official digital campaigns that warn about the risks of purchasing these products online or through unauthorized channels, and provide information on how to verify product authenticity and how to report adverse events or suspected counterfeiting.

- Ensure that institutional communication reinforces the importance of using only official reporting mechanisms, ensuring that information reaches the NRA in a timely manner.

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