

DRAP ALERT NO. Nº I/S/7-23-24

# FALSIFIED PRODUCT ALERT

**Date:** 12<sup>th</sup> July, 2023

#### **Target Audience:**

- Regulatory Field Force
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics.
- Pharmacists and Chemists at Distribution, Institutional suppliers
- General Public

#### **Problem Statement:**

Glucagon-like Peptide 1 Receptor Agonists (GLP-1-RA) are a class of Pharmaceuticals indicated to manage Diabetes type II. In Pakistan, only a single brand i.e. Ozempic injection manufactured by Novo Nordisk is registered by DRAP and is available as a "prescription only" product.

There has been a surge of online information promoting the use of GLP-1 RA products for weight loss which is its unapproved use and this situation is encouraging risky procurement behaviors. Numerous online sources offer GLP-1 RA products for sale without requiring a prescription. The quality and safety of these medical products manufactured and distributed in poorly controlled environments (such as the internet) cannot be assured.

Due to stated reasons, an increased demand resulting in a global shortage of these products has risen which may create environments favorable for availability of falsified medical products. Reports have been received to WHO regarding an increase in availability of falsified GLP-1-RA products in the past six months. It is possible that several versions of falsified GLP-1 RA – regardless of brand name – are in circulation and available online.

#### **Threats to Public Health: -**

Falsified medical products have been known to lack efficacy and/or cause toxic reactions. They are neither approved nor controlled by DRAP and may have been produced in unhygienic conditions by unqualified personnel, contain unknown impurities, and are sometimes contaminated with bacteria. It is also possible that people living with diabetes type II who miss treatment due to unavailability of GLP-1-RA products may also suffer clinical consequences.

DRAP, Islamabad

+ 92 51 910 73 17

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gsms@dra.gov.pk

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## Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these products. Endocrinologists and Pharmacists present at heath care facilities are requested to remain vigilant and inform patients of procuring medical products only from authorized channels.

Adverse reactions or quality problems experienced with the use of any such product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this <u>link</u>. Further information of reporting problems to DRAP is available on this <u>link</u>.

### Advice for Consumers / General public: -

To ensure the authenticity, consumers should always obtain medical products from the authorized licensed pharmacies /outlets. The authenticity of these products should be carefully checked and If the consumer has any doubt, advice must be sought from your pharmacist.

In case if a consumer has experienced any problem related to taking or using these drug product(s), they should cease the use of the product in question immediately and contact their Physician or Pharmacist and should also report the incident to the Drug Regulatory Authority of Pakistan.

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