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**IMPORTANT MEDICINE
SAFETY INFORMATION**

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Ozempic® (semaglutide) and Victoza® (liraglutide): Supply shortage

November 2023

Dear Healthcare Professional,

Novo Nordisk Ireland in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Victoza® and Ozempic® Summary

- Increased overall demand for Ozempic® and Victoza® injectable glucagon-like peptide-1 receptor agonists (GLP-1 RAs) coupled with capacity constraints at some of our manufacturing sites have led to shortages, including out of stock situations. In addition, to facilitate increasing supply of Ozempic®, Novo Nordisk has decided to temporarily reduce the supply of Victoza®. The shortage situation for Ozempic® and Victoza® will deteriorate in Q4 2023.
- For Ozempic®, intermittent shortages are expected throughout 2024. For Victoza®, shortages are expected at least until Q2 2024.
- The supply shortages are not related to a quality defect of the products or a safety issue.
- Where Ozempic® or Victoza® is not available for patients currently treated with one of these respective products, patients should be safely switched to another injectable GLP-1 RA, or other suitable alternative, based on clinical judgement and market availability.

Victoza® Supply in Ireland

- A shortage of Victoza® (2 and 3-pen packs) is expected from early December 2023.** A return to stock is expected **Q2 2024**.
- No new patients should be started on Victoza® until at least Q2 2024**, when supply is expected to normalize, and available product should only be used to continue treatment of patients currently treated.

Ozempic® Supply in Ireland

- Novo Nordisk will limit the supply of the starting dose for Ozempic® (0.25 mg)**, which is expected to limit the initiation of new patients, to mitigate the increasing demand on the maintenance doses (Ozempic® 0.5 mg and 1 mg). **It is recommended to limit initiations of new patients during the shortage and until the supply situation improves, which is expected in Q1 2024.** Any other use, including for overweight/obesity treatment, represents off-label use and currently places the availability of Ozempic® for the indicated population at high risk.
- To ensure long-term continuity of stable supply of Ozempic® to the Irish market, Novo Nordisk release a proportional level of Ozempic® stock to secondary wholesalers on a month-by-month basis. Secondary wholesalers have also implemented proportional allocations at pharmacy level to ensure continuity of supply. As a result of the above actions, supply may not meet demand at pharmacy level and will result in intermittent delays in receiving stock of Ozempic® by pharmacies.

Background

Ozempic® and Victoza® are indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- As monotherapy when metformin is considered inappropriate due to intolerance or contraindications;
- In addition to other medicinal products for the treatment of diabetes.^{1,2}

Victoza® is also indicated for adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.²

Any other use, including for overweight/obesity treatment, represents off-label use and currently places the availability of Ozempic® and Victoza® for the indicated population at high risk.

Call for reporting

Adverse events including medication errors relating to Ozempic® and Victoza® or alternative Novo Nordisk products should be reported to the Novo Nordisk Medical Department at complaintireland@novonordisk.com or Tel: 01 8629700 or to the Health Products Regulatory Authority at www.hpra.ie.

Company contact point

Further information can be obtained by contacting Novo Nordisk Limited, Ireland on 01 8629700 or infoireland@novonordisk.com.

Novo Nordisk recognises the uncertainty and concern this is causing people living with type 2 diabetes mellitus. Novo Nordisk Ireland will continue to provide updates on this supply situation to the HPRA and Health Service Executive as new information becomes available.

Novo Nordisk is working diligently to manage supply of Ozempic® and Victoza® in order to minimise the impact of this increase in demand. We sincerely apologise for this unfortunate situation and any inconvenience it may cause.

Please ensure all relevant staff are made aware of the content of this letter.

Yours sincerely

Dr. Donna Sexton

Clinical, Medical and Regulatory Director



www.medicines.ie

References:

1. Novo Nordisk. Ozempic® (semaglutide)
Summary of Product Characteristics (SmPC).
Revision date 03/2023



www.medicines.ie

2. Novo Nordisk. Victoza® (liraglutide)
Summary of Product Characteristics (SmPC).
Revision date 07/2023

Ozempic®, Victoza® and the Apis bull logo are registered trademarks owned by Novo Nordisk A/S.
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