

28, February 2023

## Direct Healthcare Professional Communication (DHPC)

### Ozempic®(semaglutide) solution for injection in pre-filled pen: supply shortage

Dear Healthcare Professional,

Novo Nordisk A/S, in agreement with the European Medicines Agency and the Medicine Authority of Malta would like to inform you of the following:

#### Summary:

- Increased demand for Ozempic® has led to shortages which are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it will be sufficient to fully meet current demand.
- Delayed awareness of the out-of-stock situation may result in patients missing the required doses, which may have clinical consequences such as hyperglycaemia.
- You are urged to ensure that patients using Ozempic® are made aware of this issue and that patients at risk of running out of Ozempic® are safely switched to another glucagon-like peptide-1 receptor agonist, or other suitable alternatives based on your clinical judgement.
- Ozempic® is only indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic® for the indicated population at risk.

#### Background

Ozempic® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise <sup>(1)</sup>

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.

Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic® for the indicated population at risk.

Higher than expected demand has resulted in a shortage of Ozempic®. The shortages are expected to continue throughout of 2023. While supply will continue to increase, it is uncertain when it will be sufficient to meet full demand. The supply shortage is not related to a quality defect of the product or a safety issue

We kindly request your support to ensure that patients using Ozempic® FlexTouch® [0.25 mg, 0.5 mg and 1 mg] are made aware of this issue and that patients at risk of running out of Ozempic® FlexTouch®

#### Novo Nordisk S.p.A.

Società con socio unico  
Direzione e Coordinamento  
Novo Nordisk A/S (Danimarca)  
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[0.25 mg, 0.5 mg and 1 mg] are switched to another glucagon-like peptide-1 receptor agonist or other suitable alternatives as per market availability.

### Call for reporting

Adverse events including medication errors relating to Ozempic® FlexTouch® or alternative Novo Nordisk products should be reported to Novo Nordisk SpA [via Elio Vittorini 129, 00144 Rome, Italy - Web site <https://www.novonordisk.it/>] or to local authority through ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

### Company contact point

Further information can be obtained by contacting Charles de Giorgio Ltd. Triq il-Kan. Karmenu Pirotta, B'Kara, BKR 1114 Malta. Telephone: (+356) 2560 0500 Fax: (+356) 2560 0200 Website: <https://charlesdegiorgio.com/>

Novo Nordisk AS will continue to provide updates on this supply situation to your local health authority as new information becomes available. Novo Nordisk is working diligently to manage supply of Ozempic® in order to minimise the impact of this increase in demand. We sincerely apologise for this unfortunate situation and any inconvenience it may cause

Yours Sincerely

DocuSigned by:

*Marcella Marcellini*

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Marcella Marcellini

Regulatory and Safety Manager

on behalf of

Amale Chalfoun, MD  
Senior Clinical, Medical and Regulatory Director  
CMR Department- Italy

### References:

1. Novo Nordisk. Ozempic® (semaglutide) Summary of Product Characteristics. Sep 2022

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