

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

Dear Healthcare Professional,

Novo Nordisk A/S [affiliate to include country specific information to reflect global or local company name] in agreement with the European Medicines Agency and the <National Competent Authority> 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:

- 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 [affiliate to include country specific **presentation** information] are made aware of this issue and that patients at risk of running out of Ozempic® [affiliate to include country specific **presentation** information] 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 [contact details to be updated by affiliate] or to local authorities [to be modified according to national requirements].

**Company contact point**

Further information can be obtained by contacting <local Novo Nordisk affiliate contact details to be added by affiliate>.

Novo Nordisk A/S [affiliate to include country specific information to reflect global or local company name] 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

Medical Director

## Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
<b>Medicinal product(s)/active substance(s)</b>	Ozempic(semaglutide) solution for injection in pre-filled pen.
<b>Marketing authorisation holder(s)</b>	Novo Nordisk A/S
<b>Safety concern and purpose of the communication</b>	The purpose of the communication is to notify healthcare professionals (HCPs) of continued shortages of Ozempic. Delayed awareness of the out-of-stock situation may result in patients missing the required doses, which may have clinical consequences such as hyperglycaemia.
<b>DHPC recipients</b>	Target group for this letter are prescribing HCPs that treat patients with diabetes. Inclusion of pharmacists or other HCPs to the recipients will be determined in conjunction with each national competent authority as needed.
<b>Member States where the DHPC will be distributed</b>	While all member states will be contacted, the DHPC letter will only be distributed in agreement with each national competent authority as not all countries may be impacted by shortages.
Timetable	Date
<b>DHPC and communication plan (in English) agreed by CHMP</b>	17 <sup>th</sup> February 2023
<b>Submission of translated DHPCs to the national competent authorities (NCA) for review</b>	27 <sup>th</sup> February 2023
<b>Agreement of translations by national competent authorities</b>	6 <sup>th</sup> March 2023
<b>Dissemination of DHPC</b>	13 <sup>th</sup> March 2023