

<date>

Direct Healthcare Professional Communication (DHPC)

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

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 intermittent shortages which are expected to continue into 2023
- 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

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.

Higher than expected demand has resulted in a shortage of Ozempic®. The shortages will be intermittent and continue into 2023. 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>.

Final version agreed with EMA

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. At Novo Nordisk we are working around the clock to maximise existing production while investing heavily in new capacity to remedy these shortages. We sincerely apologise for this unfortunate situation and any inconvenience it may cause.

Yours Sincerely

Medical Director

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Ozempic®(semaglutide) solution for injection in pre-filled pen
Marketing authorisation holder(s)	Novo Nordisk A/S
Safety concern and purpose of the communication	The purpose of the communication is to notify healthcare professionals (HCPs) of possible intermittent 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
DHPC recipients	Target group for this letter is prescribing HCPs that treat patients with Diabetes. Adding pharmacists or other HCPs to the recipients will be determined in conjunction with each national competent authority as needed
Member States where the DHPC will be distributed	All members states will be contacted but DHPC letter will only be distributed in agreement with each national competent authority as not all countries may be impacted by intermittent shortages
Timetable	
Date	
DHPC and communication plan (in English) agreed by PRAC	30 th September 2022
DHPC and communication plan (in English) agreed by CHMP/CMDh	30 th September 2022
Submission of translated DHPCs to the national competent authorities (NCA) for review	5 th to 10 th October 2022
Agreement of translations by national competent authorities	~1-3 days dependent upon respective NCA
Dissemination of DHPC	1-3 days after final agreement with NCA