Update on Ozempic (semaglutide) and Victoza (liraglutide): Supply shortage

Dear Healthcare Professional,

Novo Nordisk [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 the injectable glucagon-like peptide-1 receptor agonist (GLP-1 RA),
 Ozempic, coupled with capacity constraints at some of our manufacturing sites have led to shortages, including out-of-stock situations.
- The supply situation for the lower strengths of Ozempic, 0.25 mg and 0.5 mg, has deteriorated with intermittent shortages for all strengths expected into Q4 2024.
- It is therefore recommended to continue limiting treatment initiation of new patients on Ozempic until the supply situation improves; this is expected in September 2024.
- Novo Nordisk temporarily reduced the supply of Victoza (once daily) in Q4 2023 to increase the
 supply of Ozempic (once weekly) therefore optimizing the use of the production capacity. This is
 expected to allow treatment of a greater number of patients. Although the supply of Victoza has
 improved in all EU/EEA countries since Q1 2024, some countries still experience intermittent
 shortages. To ensure patients who are already on treatment can continue with it, no new
 patients should be started on Victoza.
- The supply shortages are not related to a quality defect or a safety issue.
- In case Ozempic or Victoza are not available for patients currently on treatment, patients should be safely switched to another injectable GLP-1 RA, or other suitable alternative, based on your clinical judgement and local guidelines.

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.

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.

Any other use, including for weight management, represents off-label use and places the availability of Ozempic and Victoza for the indicated population at high risk. These medicines should be prescribed in line with authorised use(s) only, taking into account guidance issued by national authorities in their Member State or applicable national therapeutic guidelines.

Call for reporting

Adverse events including medication errors relating to Ozempic and Victoza 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 recognizes the concern this is causing people living with type 2 diabetes mellitus. 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 continues to work diligently to increase and improve the stability of supply for Ozempic and Victoza to minimize the impact on patients. We sincerely apologize for this situation and the uncertainty this may cause.

Yours Sincerely

Medical Director

Medicinal product(s)/active substance(s) Marketing authorisation holder(s) Purpose of the communication Purpose of the communication Discernification for the lower strengths of Ozempic and Victoza: 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. The supply situation for the lower strengths of Ozempic 0.25 mg and 0.5 mg has deteriorated, with intermittent shortages for all strengths expected into Q4 2024. For Victoza, some countries still experience intermittent shortages. The supply shortage is not related to a quality defect of the products or a safety issue. DHPC recipients Target group for this letter is general physicians and specialists that treat patients with diabetes (e.g., endocrinologists). Adding pharmacists or other health care providers to the recipients will be determined in conjunction with each national competent authority as needed. Member States where the DHPC will be determined in agreement with national competent authorities in individual Member States, as not all Member States maybe impacted by supply shortages.	DHPC COMMUNICATION PLAN		
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Timetable Date	the DHPC will be distributed	national competent authorities in individual Member States, as not	

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	22 July 2024
Submission of translated DHPCs to the national competent authorities for review	29 July 2024
Agreement of translations by national competent authorities	5 August 2024
Dissemination of DHPC	9 August 2024