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 shortages which are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it will be sufficient to meet full 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 as further detailed in the 'Background section' of this document. Any other use, including for weight management, is considered off-label 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
- 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, not least because Novo Nordisk is aware of the limited availability
 of other injectable GLP-1 RAs
- 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. 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