



Mitigation measures recommended by EMA/MSSG


Multistakeholder workshop on shortages of GLP-1 receptor agonists

Presented by
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Background information

- Recommendations were adopted by MSSG on 12 June
- Extensive consultations across the network and with patients and healthcare professionals
- Recommendations were published on 26 June accompanied by various communication activities



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Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products on shortage of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

1. Introduction

A shortage of medicines containing Glucagon-Like Peptide-1 (GLP-1) receptor agonists is affecting EU Member States since 2022 and will continue throughout 2024. The shortage involves the medicinal products Ozempic (semaglutide), Saxenda (liraglutide), Trulicity (dulaglutide) and Victoza (liraglutide). The shortage is due to an increased demand for these medicines in conjunction with other causes, such as manufacturing capacity constraints. These medicines are either authorised for the treatment of diabetes (Bydureon (exenatide), Byetta (exenatide), Lyxumia (lixisenatide), Ozempic, Trulicity, Rybelsus (semaglutide) and Victoza) or weight management under certain conditions¹ (Saxenda, Wegovy (semaglutide)) or both indications (Mounjaro (tirzepatide)²).


Excessive off-label use for cosmetic weight loss of some of these medicines has raised concerns. This relates to use for weight management in people without obesity or people with overweight who do not have weight related health problems. This use has been mentioned frequently in the news and social media and is exacerbating existing shortages with serious consequences for public health.

In the case of Ozempic, the prolonged shortage and ongoing high demand for the medicine have been linked to reports of falsified Ozempic. In October 2023, national competent authorities identified falsified Ozempic in the supply chain. EMA published information alerting patients and healthcare professionals of falsified Ozempic identified in the supply chain and the potential serious health consequences linked to its use.

EMA and the EU regulatory network are closely monitoring the shortages through the SPOC WP (Medicines Shortages Single Point of Contact working party) and MSSG (Executive Steering Group on Shortages and Safety of Medicinal Products). In addition to holding regular meetings with marketing

¹ For GLP-1 receptor agonists that are approved for weight management, they are indicated together with diet and physical activity in adults who have obesity (BMI of 30 kg/m² or more) or overweight (BMI between 27 and 30 kg/m²) and have weight-related health problems such as diabetes, abnormally high levels of fat in the blood, high blood pressure or obstructive sleep apnoea (frequent interruption of breathing during sleep). In addition, Saxenda can be used in adolescents from 12 years of age with obesity (BMI of 30 or more) who weigh more than 60 kg.

² Mounjaro is a long acting glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 receptor agonist.

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Recommendations to Marketing Authorisation Holders

- **Get approval from regulatory authorities for promotional activities on GLP-1 receptor agonists, where applicable.** Every promotional action should also be accompanied by awareness campaigns on weight management and educational activities on the ongoing shortage and implications for clinical practice.
- **Increase manufacturing capacity**
- **Implement effective short term mitigation activities, in particular controlled distribution**
- Continue engaging with regulatory authorities to ensure coordination and effective implementation of mitigation measures.
- Involve the SPOC WP and MSSG proactively in all decisions impacting supply and availability.

Recommendations to Member States

- Implement mitigation measures and measure their effectiveness in order to optimise measures to mitigate shortages.
- **Exchange information via the SPOC WP to facilitate this.**
- Consider, jointly with marketing authorisation holders, implementation of **controlled distribution** at national level, where possible.
- **Develop guidelines to facilitate prioritisation** (together with experts and learned societies) of patients who require these medicines during shortages.
- These guidelines can help ensure that patients in need receive access to these essential treatments during times of limited supply.

Recommendations to Healthcare Professionals

- Bydureon, Byetta, Lyxumia, Ozempic, Rybelsus, Trulicity and Victoza are indicated for **diabetes** only, Saxenda and Wegovy are indicated for **weight management** in people with obesity or overweight with weight-related health issues as an adjunct to diet and exercise. Mounjaro is authorised for both diabetes and weight management. **Any other use represents off-label use which is worsening existing shortages.**
- **Excessive off-label use of some GLP-1 receptor agonists** puts at risk the availability of these medicines for their approved uses.
- Healthcare professionals should prescribe these medicines in line with authorised use(s) only, taking into account national guidance

Recommendations to Healthcare Professionals

- GLP-1 receptor agonists **are not approved for and should not be used for cosmetic weight loss, i.e. use for weight loss in people without obesity or people with overweight who do not have weight related health problems.** Healthcare professionals should consider offering these people lifestyle advice instead.
- Pharmacists should dispense these medicines according to the guidelines applicable in their Member State, which may impose certain restrictions (e.g. number of packs per prescriptions).
- If a GLP-1 receptor agonist is not available, doctors should switch patients to another suitable alternative based on clinical judgement.

Recommendations to Patients and Members of the public

- If patients are already being treated with these medicines and they are not available, their doctor may need to switch them to another treatment.
- These medicines are only available with a prescription and should only be used under medical supervision. **Using these medicines without medical supervision can put your health at risk.**
- GLP-1 receptor agonists are **not for short-term use** and like all medicines they can have side effects. The most common side effects include problems with the digestive system, such as diarrhoea and nausea (feeling sick).
- People looking for advice on weight loss should always consult a healthcare professional and seek advice from qualified sources. Weight management should be primarily based on diet and physical exercise.

Recommendations to Patients and Members of the public

- GLP-1 receptor agonists that are being sold by online websites could be **falsified** and therefore can have serious consequences for health.
- People should not try to purchase these medicines online without a medical prescription.
- Patients who buy these medicines online should use **pharmacies that are registered** with the national competent authorities in the EU Member States, to reduce the risk of buying sub-standard or falsified medicines.
- More information on buying medicines online in the EU can be found here: <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview/buying-medicines-online>

Summary and next steps



Recommendations adopted on 12 June 2024



Commitment to work with all stakeholders to implement recommendations



Today's workshop will be used to identify points for further discussions

Any questions?

Further information

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