



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 (tirzepatide²)).

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.



authorisation holders of affected GLP-1 receptor agonists, they are also carefully monitoring current and forecasted supply levels. EMA is also exchanging information with its international counterparts.

On 12 April 2024 the MSSG discussed potential recommendations for measures to be undertaken proactively by all stakeholders to mitigate the shortage of GLP-1 receptor agonists and ensure supply of these medicines to patients.

2 Recommendations

2.1 Recommendations to marketing authorisation holders

- MSSG remains committed to collaborating with industry stakeholders and recommends that marketing authorisation holders get approval from regulatory authorities for promotional activities on GLP-1 receptor agonists, where applicable. Every promotional action by marketing authorisation holders should also be accompanied by awareness campaigns on weight management and educational activities on the ongoing shortage and implications for clinical practice.
- Marketing authorisation holders should increase manufacturing capacity and should implement effective short term mitigation activities, in particular controlled distribution together with Member States to ensure that these medicines are available to patients who need them. MSSG recommends marketing authorisation holders to continue engaging with regulatory authorities to ensure coordination and effective implementation of mitigation measures.
- Marketing authorisation holders should involve the SPOC WP and MSSG proactively in all decisions impacting supply and availability of GLP-1 receptor agonists in the EU/EEA.

2.2 Recommendations to Member States

- Member States should implement mitigation measures and measure their effectiveness in order to optimise measures to mitigate shortages. Member States are encouraged to exchange information via the SPOC WP to facilitate this. In particular they should consider, jointly with marketing authorisation holders, implementation of controlled distribution³ at national level, where possible.
- Member States are encouraged (together with experts and learned societies) to develop guidelines to facilitate prioritisation 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.

2.3 Recommendations to healthcare professionals

- The GLP-1 receptor agonists 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.
- The MSSG is concerned about excessive off-label use of some GLP-1 receptor agonists which puts at risk the availability of these medicines for their approved uses. The MSSG therefore recommends that healthcare professionals prescribe these medicines in line with their authorised

³ https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf (p.4)

use(s) only, taking into account guidance issued by national authorities in their Member State or applicable national therapeutic guidelines.

- 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.

2.4 Recommendations to patients and members of the public

- The medicines Bydureon, Byetta, Lyxumia, Ozempic, Rybelsus, Trulicity and Victoza are authorised for diabetes only. Saxenda and Wegovy are authorised for weight management in people with obesity or overweight with weight related health issues as an adjunct to diet and exercise and Mounjaro is indicated for both diabetes and weight management. 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. In particular the use of Ozempic has been mentioned frequently in the news and social media for the use of weight management outside their approved uses. 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 (which may affect more than 1 in 10 people) 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.
- People should be aware that GLP-1 receptor agonists that are being sold by online websites could be falsified and therefore can have serious consequences for their 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>