GLP-1 receptor agonists: EMA/MSSG communication and engagement activities

Multistakeholder workshop on shortages of GLP-1 receptor agonists

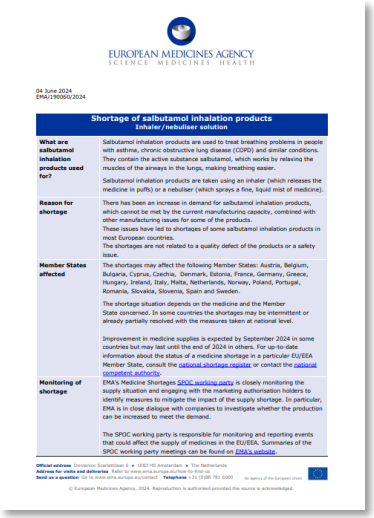
Presented by Juan Garcia Burgos, Inga Abed and Giulia Gabrielli
Stakeholders and Communication Division

An agency of the European Union

Challenges linked to GLP-1 receptor agonists shortages

- Unmet demand for weight loss medicines
- Off-label use for cosmetic weight loss
- Social media influence
- Risk of falsification and counterfeits
- Need to raise awareness using new tools
- Challenge of change behaviour through communication

Summary of communication activities

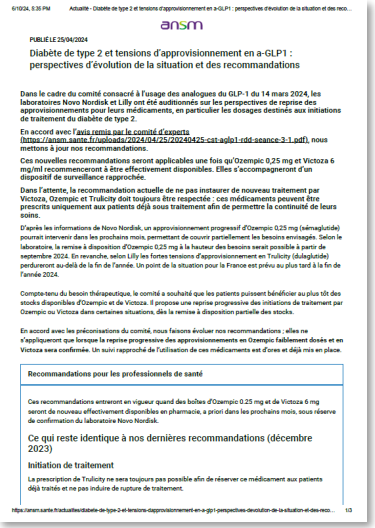


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 June 2024
EMA/190060/2024

Shortage of salbutamol inhalation products
Inhaler/nebuliser solution

What are salbutamol inhalation products used for?	Salbutamol inhalation products are used to treat breathing problems in people with asthma, chronic obstructive lung disease (COPD) and similar conditions. They contain the active substance salbutamol, which works by relaxing the muscles of the airways in the lungs, making breathing easier. Salbutamol inhalation products are taken using an inhaler (which releases the medicine in puffs) or a nebuliser (which sprays a fine, liquid mist of medicine).
Reason for shortage	There has been an increase in demand for salbutamol inhalation products, which cannot be met by the current manufacturing capacity, combined with other manufacturing issues for some of the products. These issues have led to shortages of some salbutamol inhalation products in most European countries. The shortages are not related to a quality defect of the products or a safety issue.
Member States affected	The shortages may affect the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden. The shortage situation depends on the medicine and the Member State concerned. In some countries the shortages may be intermittent or already partially resolved with the measures taken at national level. Improvement in medicine supplies is expected by September 2024 in some countries but may last until the end of 2024 in others. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the national shortage register or contact the national competent authority.
Monitoring of shortage	EMA's Medicine Shortages SPOC working party is closely monitoring the supply situation and engaging with the marketing authorisation holders to identify measures to mitigate the impact of the supply shortage. In particular, EMA is in close dialogue with companies to investigate whether the production can be increased to meet the demand. The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU/EEA. Summaries of the SPOC working party meetings can be found on EMA's website



6/10/24, 8:36 PM Actualité - Diabète de type 2 et tensions d'approvisionnement en a-GLP1 : perspectives d'évolution de la situation et des reco...

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PUBLIÉ LE 25/04/2024

Diabète de type 2 et tensions d'approvisionnement en a-GLP1 : perspectives d'évolution de la situation et des recommandations

Dans le cadre du comité consacré à l'usage des analogues du GLP-1 du 14 mars 2024, les laboratoires Novo Nordisk et Lilly ont été auditionnés sur les perspectives de reprise des approvisionnements pour leurs médicaments, en particulier les dosages destinés aux initiations de traitement du diabète de type 2.

En accord avec l'avis remis par le comité d'experts (https://ansm.sante.fr/uploads/2024/04/25/20240425-cat-aglo1-rdd-seance-3-1.pdf), nous mettons à jour nos recommandations.

Ces nouvelles recommandations seront applicables une fois qu'Ozempic 0,25 mg et Victoza 6 mg/ml recommenceront à être effectivement disponibles. Elles s'accompagneront d'un dispositif de surveillance rapprochée.

Dans l'attente, la recommandation actuelle de ne pas instaurer de nouveau traitement par Victoza, Ozempic et Trulicity doit toujours être respectée : ces médicaments peuvent être prescrits uniquement aux patients déjà sous traitement afin de permettre la continuité de leurs soins.

D'après les informations de Novo Nordisk, un approvisionnement progressif d'Ozempic 0,25 mg (sémaglutide) pourrait intervenir dans les prochains mois, permettant de couvrir partiellement les besoins envisagés. Selon le laboratoire, la remise à disposition d'Ozempic 0,25 mg à la hauteur des besoins serait possible à partir de septembre 2024. En revanche, selon Lilly les fortes tensions d'approvisionnement en Trulicity (dulaglutide) perdureront au-delà de la fin de l'année. Un point de la situation pour la France est prévu au plus tard à la fin de l'année 2024.

Compte-tenu du besoin thérapeutique, le comité a souhaité que les patients puissent bénéficier au plus tôt des stocks disponibles d'Ozempic et de Victoza. Il propose une reprise progressive des initiations de traitement par Ozempic ou Victoza dans certaines situations, dès la remise à disposition partielle des stocks.

En accord avec les précisions du comité, nous faisons évoluer nos recommandations : elles ne s'appliqueront que lorsque la reprise progressive des approvisionnements en Ozempic faiblement dosés et en Victoza sera confirmée. Un suivi rapproché de l'utilisation de ces médicaments est d'ores et déjà mis en place.

Recommandations pour les professionnels de santé

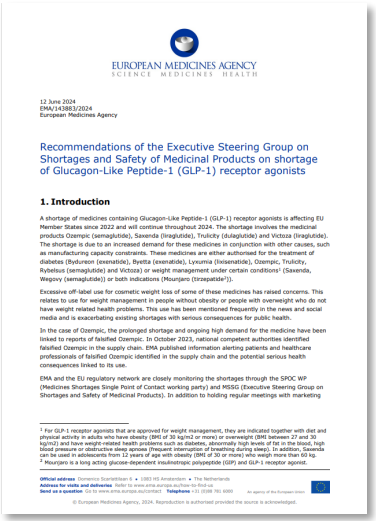
Ces recommandations entreront en vigueur quand des boîtes d'Ozempic 0,25 mg et de Victoza 6 mg seront de nouveau effectivement disponibles en pharmacie, a priori dans les prochains mois, sous réserve de confirmation du laboratoire Novo Nordisk.

Ce qui reste identique à nos dernières recommandations (décembre 2023)

Initiation de traitement

La prescription de Trulicity ne sera toujours pas possible afin de réserver ce médicament aux patients déjà traités et ne pas induire de rupture de traitement.

https://ansm.sante.fr/actualites/diabete-de-type-2-et-tensions-dapprovisionnement-en-a-glp1-perspectives-evolution-de-la-situation-et-des-reco... 1/3



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2024
EMA/143883/2024
European Medicines Agency

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 conditions[1] (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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Publication of shortage catalogue and DHPCs on EMA website

Communication campaigns national level

MSSG recommendations

Summary of Messages

Healthcare professionals

- GLP-1 receptor agonists
  - are approved to treat diabetes and/or weight loss in obesity and weight-related health conditions
  - should be prescribed in line with their authorised use(s) and national guidance
- are not approved for cosmetic weight loss

Patients and members of the public

- GLP-1 receptor agonists are
  - prescription medicines and should only be used under medical supervision
  - Diabetes and obesity are chronic diseases and GLP-1 receptor agonists are intended for long-term treatment;
  - Like all medicines, they can cause side effects
- High demand leads to the risk of falsification
  - falsified copies are available online
  - using falsified medicines can have serious health consequences
  - do not purchase without a medical prescription
- People considering weight loss should consult an HCP

Communication activities

Publications

News announcement on EMA website

Human Medicines newsletter

Multistakeholder workshop on shortages of GLP-1 receptor agonists

Press briefing

Live stream – 26 June

Social media

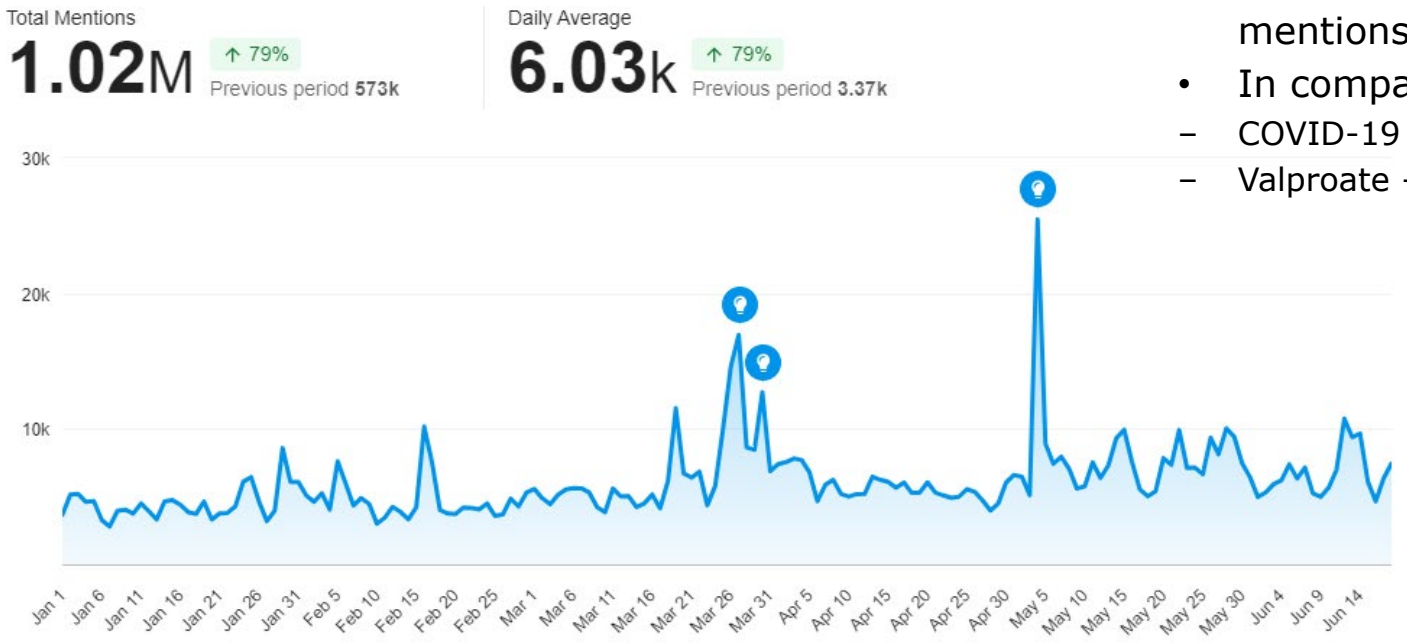
Social media listening

Social media posts and video

Instagram Live session (planned)

Joint inter-agency video campaign on falsified medicines (planned)

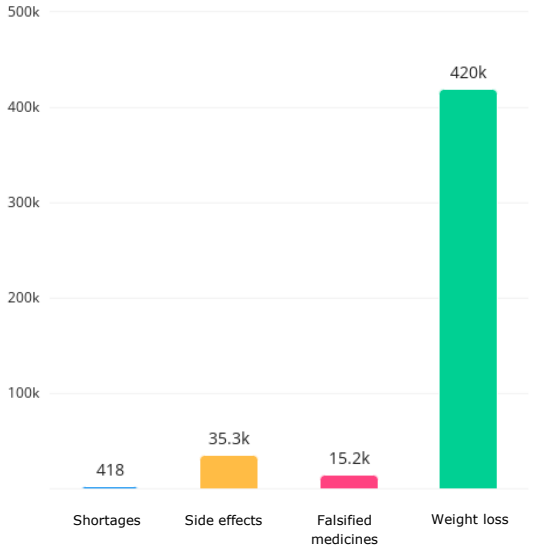
Social media listening



- GLP-1 receptor agonist mentions
- In comparison:
  - COVID-19 vaccines - 12M
  - Valproate – 20k

Social media listening - themes

- Thematic comparison of topics of interest to EMA
- Analysis of peaks:
  - Peaks often related to celebrity mentions or news shared by top media outlets
  - Discussion also driven by: pricing and affordability, effectiveness for weight loss, side effects (digestive issues but also muscle loss, unintended pregnancy), financial investments, personal experiences
- Analysis of key words:
  - Globally mentions of weight loss, specific products or celebrity names
  - In the EU also advertisement of online sales of medicines

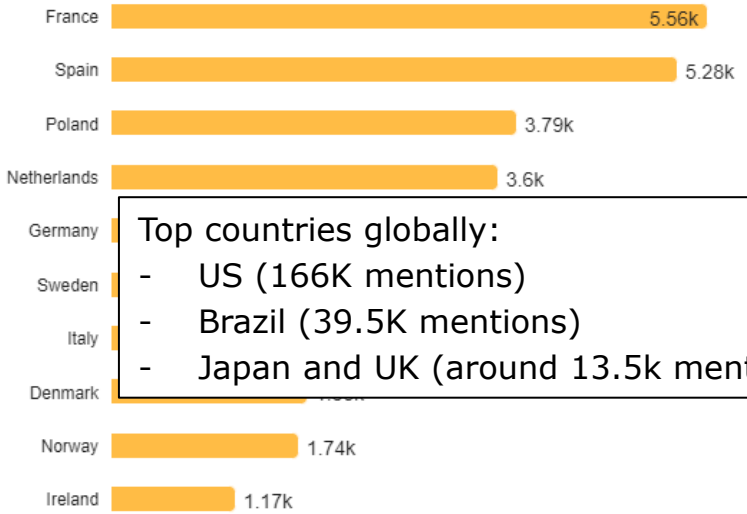


Social media listening

Mentions by age and gender

Male	44.8%	45
Female	33.1%	33
Unknown	22.1%	22

Top 10 EU countries by mention



Top countries globally:
- US (166K mentions)
- Brazil (39.5K mentions)
- Japan and UK (around 13.5k mentions)

Help us to make an impact

Consistency of the messages are key

Relay the messages
in multiple languages

Disseminate the messages through all available channels
social media, websites, newsletters

Help us reach specific audiences
young people who use social media for information about health, especially on diet and body image

Any questions?

Further information

Juan.Garcia@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
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