

## Overview of the supply situation of GLP-1 receptor agonists

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Multistakeholder workshop on shortages of GLP-1 receptor agonists

Presented by  
Klaus Kruttwig, Medicines and Medical Devices Shortages Specialist, TRS-SAM, EMA

# Outline

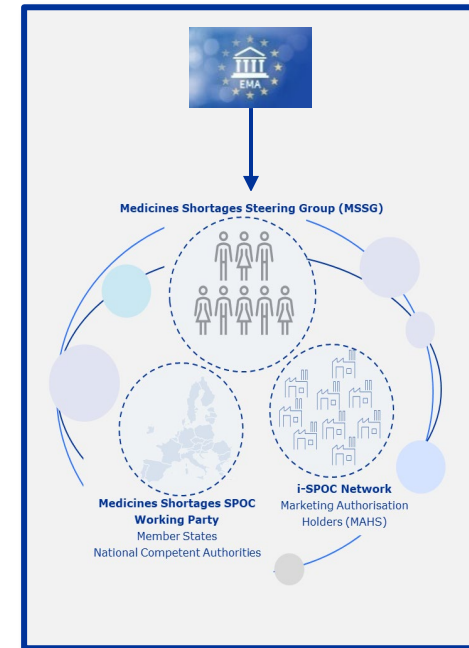
- ① Monitoring and mitigating shortages of medicines and management of public health emergencies/major events
- ② Shortages of GLP-1 RA - overview
- ③ Current mitigation and shortage management activities

# Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events



Regulation (EU) 2022/123 applicable from **1 March 2022**

- Provides a framework for activities established by EMA to monitor and **mitigate potential and actual shortages of medicines**.
- Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis) and for monitoring of events, including medicine shortages, which might lead to a crisis situation (public health emergencies or major events).
- Establishes “**Medicines Shortages Steering Group**” (MSSG) – supported by **Working Party of Single Points** of Contacts in the **Member States** (SPOC WP) and network of contact points from pharmaceutical companies (I-SPOC Networks).
- Foresees **European Shortages Monitoring Platform** (ESMP) by Feb 2025.



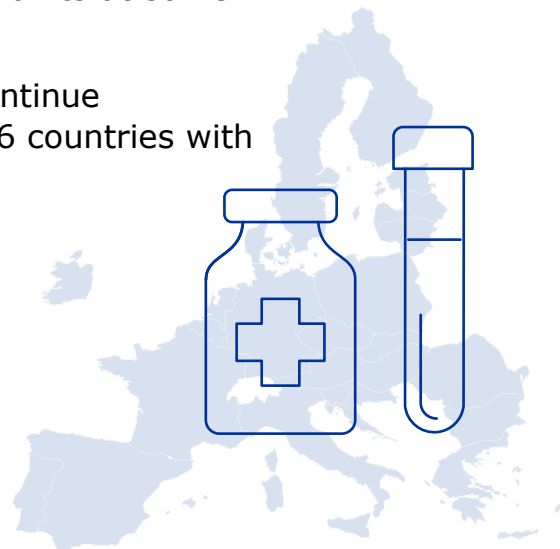
# Shortages of GLP-1 receptor agonists – overview (1/2)

## Shortages of Ozempic (semaglutide) and Victoza (liraglutide)

- **Shortages of Ozempic:** ongoing since 2022, for Victoza since 2023. It is uncertain when supplies will be sufficient to fully meet demand.
- **Root cause:** multifactorial, related to increased demand and capacity constraints at some manufacturing sites.
- In Q4 2023, **supply situation deteriorated**. Shortages for Ozempic will continue throughout 2024. Resupply of Victoza started earlier in 2024 with currently 6 countries with intermittent shortages

## Selected MAH mitigation measures:

- The MAH limited **supply of Ozempic 0.25 mg** to decrease initiations of new patients during shortage.
- To facilitate increasing supply of Ozempic, the MAH decided to **temporarily reduce the supply of Victoza**.



# Shortages of GLP-1 receptor agonists – overview (2/2)

## Shortages of Saxenda (liraglutide)

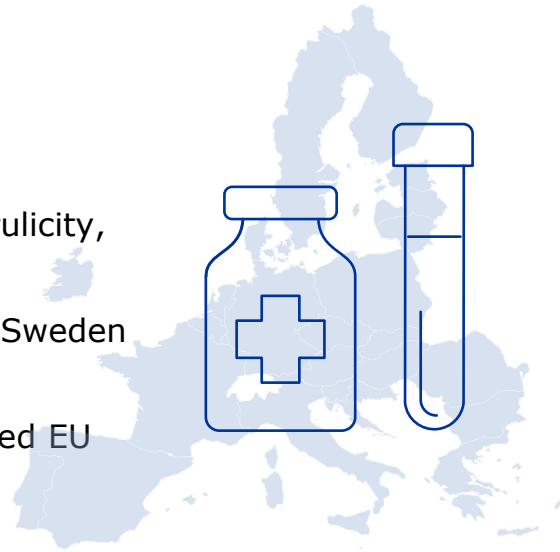
- Intermittent shortages are still ongoing in Austria, Finland and Italy. Shortages expected to continue until **end of 2024**

## Shortages of Rybelsus (semaglutide)

- Started in 2023, **resolved** in January 2024.

## Shortages of Trulicity (dulaglutide)

- Started in 2023 and **ongoing**. There has been an increase in demand for Trulicity, which has led to intermittent supply shortages.
- Austria, Belgium, Finland, Hungary, Italy, Netherlands, Portugal, Spain and Sweden are currently affected or are at risk of being affected.
- Shortages are expected to continue at least until end of 2024 in most affected EU Member States.



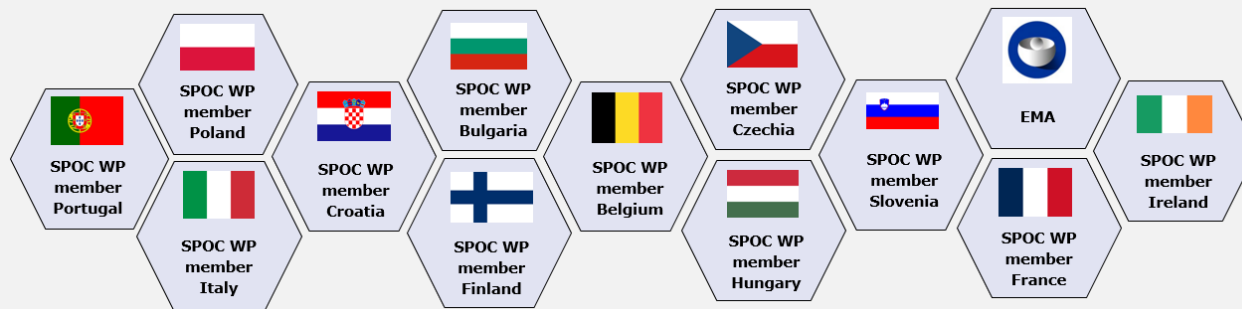
# Current mitigation and shortage management activities



**Discussions at MSSG and SPOC WP** to determine underlying mechanisms and measures that could improve availability of GLP-1 RA.



**Regular discussions** are held between **EMA and MAHs** including a dedicated **SPOC WP Subgroup** of member states who are working closely with EMA on this issue:



# Current mitigation and shortage management activities



EMA and the SPOC WP are engaging with **GLP-1 receptor agonists MAHs** to gain a comprehensive understanding of the **entire market situation** including **current and anticipated shortages**.



Discussions in the **Drug Shortages Global Regulatory Working Group**.



EMA **coordination of stock redistribution** amongst EU member states to avoid immediate patient-level stock-outs.



Extensive **communication at EU and national level**, including DHPCs, shortage catalogue entries, and response to media and public queries.



Assessment and granting of regulatory flexibilities to MAHs, if appropriate



Exchange of good practice examples between EU/EEA countries and international

# Any questions?

## Further information

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[klaus.kruttwig@ema.europa.eu](mailto:klaus.kruttwig@ema.europa.eu)

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

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