



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Glucagon-like Peptide-1 (GLP-1) Receptor Agonists (RA)

EMA Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP)
Working Parties joint meeting

Presented by Romana Micovcakova and Klaus Kruttwig on 28 February 2024
Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

An agency of the European Union





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
- ④ Question to HCPWP and PCWP

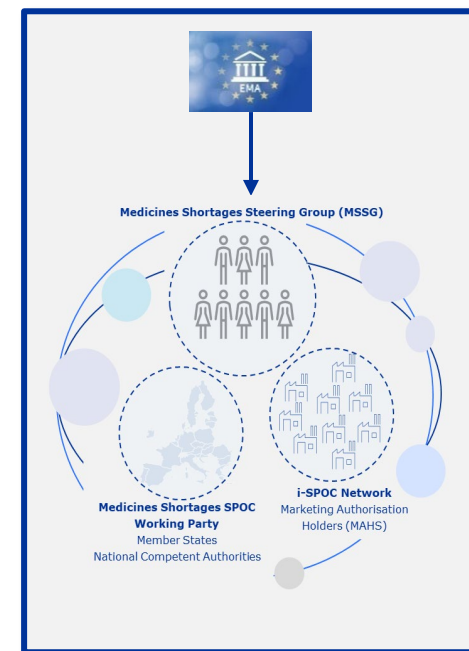


Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events



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 a Network of contact points from pharmaceutical companies (I-SPOC Networks).
- Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by Feb 2025.



Shortages of GLP-1 RA – overview (1/2)

- **Shortages of Ozempic** (semaglutide) have been ongoing since 2022. It is uncertain when supplies will be sufficient to fully meet demand.
- **Root cause** appears to be multifactorial, related to increased demand and capacity constraints at some of the manufacturing sites.
- In Q4 2023, EMA was informed about further **deterioration of the supply situation for Ozempic and Victoza** (liraglutide), continuing throughout 2024 for Ozempic, and at least until Q2 2024 for Victoza.

Selected MAH mitigation measures for Ozempic:

- The MAH is **limiting the supply and availability of Ozempic 0.25 mg** to decrease initiations of new patients during the shortage and until the supply situation improves.
- To facilitate increasing supply of Ozempic, the MAH decided to **temporarily reduce the supply of Victoza**.

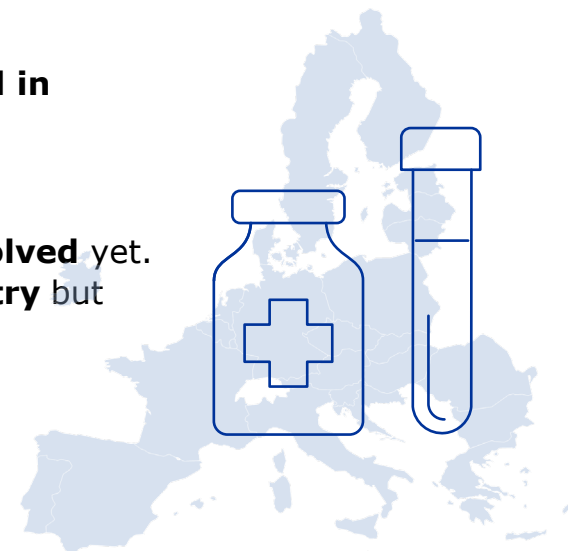
MAH = Marketing Authorisation Holder





Shortages of GLP-1 RA – overview (2/2)

- Intermittent **shortages of Saxenda** (liraglutide) are still ongoing in Finland, Germany, Norway and Sweden and are expected to be resolved by the end of March 2024 in most affected countries except Finland, where they may continue **until the end of 2024**.
- **Shortage of Rybelsus** (semaglutide) **started in 2023 and was resolved in January 2024**.
- Shortage of **Trulicity** (dulaglutide) started in 2023 and **has not been resolved** yet. At the moment, the shortage of Trulicity is only **reported in one EU country** but other countries may be affected intermittently.



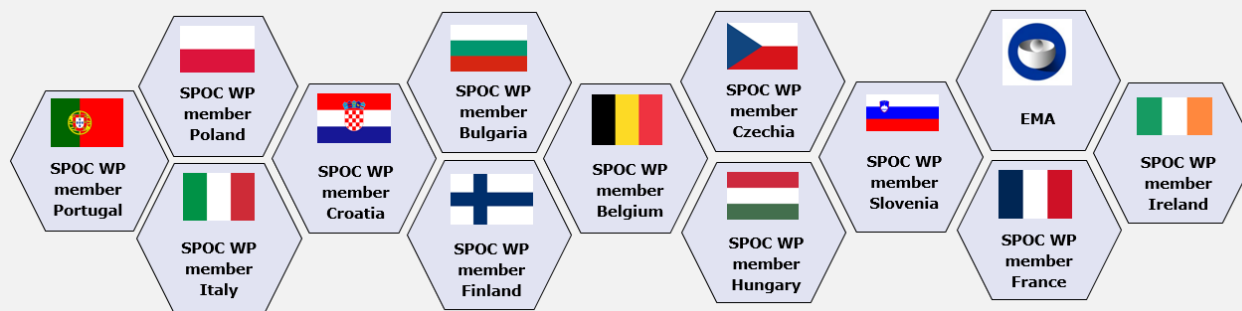
Current mitigation and shortage management activities



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 RA 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.



A **survey** has been sent to the **Working Group of Communication Professionals** (WGCP) to analyse specifically the EU/EEA countries communication activities.



Question to HCPWP and PCWP

The MAH is limiting the supply of the **starting dose for Ozempic** (0.25 mg), which is expected to limit the initiation of new patients, to **mitigate** the increasing demand on the maintenance doses (Ozempic 0.5 mg and 1 mg).

What is your experience with this mitigation measure?



Any questions?

Further information

klaus.kruttwig@ema.europa.eu

romana.micovcakova@ext.ema.europa.eu

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

Telephone +31 (0)88 781 6000

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