



Multistakeholder workshop on shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

1 July 2024, 11.45-18.30

Hybrid meeting / EMA, Amsterdam

A shortage of medicines containing Glucagon-Like Peptide-1 (GLP-1) receptor agonists has been affecting EU Member States since 2022 and is expected to continue throughout 2024. The shortage is due to an increased demand for these medicines in conjunction with other causes, such as manufacturing capacity constraints. The medicines are authorised for the treatment of diabetes or for weight management under certain conditions or both.

The off-label use for cosmetic weight loss and the emergence of falsified products further complicates the situation, particularly given the competing indications of these medicines.

EMA and the European Network are committed to tackling these shortages, and several actions have been taken at national and EU level; while these actions are helping to manage the situation, it is clear

that they are not enough and that further action is needed to successfully mitigate or end these shortages.

New EU legislation¹ has given EMA additional responsibilities for managing shortages at EU level. As a result, EMA has established an Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to play a central role in coordinating, preventing and mitigating medicine shortages in the EU.

The MSSG acknowledges the complexity of this shortage situation and the fact that it involves many parties and stakeholders, each with varying interests and facing different challenges. Given the limited impact of current measures, the MSSG has organised this multi-stakeholder workshop to bring together all relevant parties to facilitate a common understanding and to jointly discuss and identify possible additional solutions.

Therefore, the objectives of this workshop are as follows:

- Clarify the needs and challenges of the different stakeholder groups in the context of shortages of GLP-1 receptor agonists.
- Share experiences of ongoing activities to mitigate and prevent shortages of GLP-1 receptor agonists.
- Identify novel solutions to mitigate and prevent the shortages of these medicines.
- Strengthen cooperation amongst all stakeholders and improve coordination of activities.
- Discuss and agree on key messages for communication and how to best reach target audiences.

The following mailbox has been set up to **collect** feedback **from stakeholders** in the context of the workshop on shortages of GLP-1 receptor agonists: GLP1_workshop@ema.europa.eu

Feedback could be questions you would like to see addressed during the discussions of the workshop; expectations for specific stakeholders and suggestions for actions.

Although EMA will not individually acknowledge or respond to the contributions made, they will be used to inform EMA's future actions.

¹ Regulation (EU) 2022/123

Multistakeholder workshop on shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

Chaired by Emer Cooke (EMA) and Karl Broich (HMA)

12:15 Technical checks

12:30 Welcome and opening speech

Welcome and introduction 10'

Emer Cooke (EMA) and Karl Broich (HMA)

Outline of the day and objectives 5'

Monica Dias (EMA)

12:45 Session 1: Setting the scene

Chair: Karl Broich (HMA)

Overview of the supply situation of GLP-1 receptor agonists 10'

Klaus Kruttwig (EMA)

Clinical impact of shortages 15'

Francesco Giorgino (EASD)

Euan Woodward (EASO)

Round table discussion with concerned stakeholders and partners 30'

Elisabeth Dupont (IDF Europe)

Jaqueline Bowman (PA-AP)

Ancel.la Santos (BEUC)

Stefano del Prato (EUDF)

Mary McCarthy (UEMO)

Jorge Batista (PGEU)

Elspeth Kay (TGA)

Questions and Answers 20'

14:10 Session 2: Mitigation measures

Chair: Hugues Malonne (HMA)

Mitigation measures recommended by EMA/MSSG 5'

Klaus Kruttwig (EMA)

Sharing of good practice – examples from EU/EEA countries 20'

Sybille Schotte (FAGG-AMPS, BE)

Jakub Velik (SUKL, CZ)

Domenico di Giorgio (AIFA, IT)

Guri Wilhelmsen (NOMA, NO)

	Sharing of good practice – examples from a non-EU regulator	5'
	<i>Robert Kosko (FDA)</i>	
	Prevention and mitigation measures taken by companies	20'
	<i>Emily Pegg (Eli Lilly)</i>	
	<i>Emel Mashaki Ceyhan (Novo Nordisk)</i>	
	<i>Jukka Westerbacka (Sanofi)</i>	
	Questions and Answers	40'
15:50	Coffee break	
		30'
16:20	Session 3: communication and engagement	
	<i>Chair: Björn Eriksson (HMA)</i>	
	Communication activities by EMA/MSSG on shortages of GLP-1 receptor agonists	10'
	<i>Juan Garcia Burgos (EMA)</i>	
	Role of Patients and Consumers'/Healthcare Professional organisations in supporting communication activities	15'
	<i>Elisabeth Dupont (IDF Europe)</i>	
	<i>Jaqueline Bowman (PA-AP)</i>	
	<i>Francesco Giorgino (EASD)</i>	
	<i>Euan Woodward (EASO)</i>	
	Sharing of good practice – examples on communication from Member States	15'
	<i>Diego Cabo Pernas (AEMPS, ES)</i>	
	<i>Yngvil Knudsen (NOMA, NO)</i>	
	Sharing of good practice – examples on communication from a non-EU regulator	10'
	<i>Anthony Lostracco (Health Canada)</i>	
	The role of social media in shortages of GLP-1 receptor agonists	10'
	<i>Ancel.la Santos (BEUC)</i>	
	Questions and Answers	30'
18:00	Final discussion and conclusion	
	<i>Chair: María Lamas (HMA) and Monica Dias (EMA)</i>	
		25'
18:25	Closing remarks	
	Wrap up	5'
	<i>Emer Cooke (EMA)</i>	
18:30	End of meeting	