



23 August 2024
EMA/307188/2024

Minutes – ad hoc Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

1 July 2024, from 09:30 to 11:45 (CEST), EMA Meeting room 1A/Webex

Co-Chairs: Emer Cooke (EMA) and Karl Broich (HMA)

Topics

- 1. Welcome, declaration of interest and adoption of the agenda**

The Co-Chairs welcomed the members of the MSSG.

The MSSG secretariat reviewed members' and experts' declared interests in accordance with the Agency's policy on handling of declarations of interests (DoI) of Scientific Committees' members and experts, applicable to members and experts of the MSSG. The MSSG secretariat announced the competing interests identified and applicable restrictions for topics in the agenda.

The agenda was adopted with no additional topics.
- 2. a) Supply and availability of GLP-1 Receptor Agonists (GLP-1 RAs) from the Marketing Authorisation holder (MAH) Novo Nordisk:**
 - *Update on the supply and availability situation by EMA*
 - *Presentation from Novo Nordisk and Q&A*
 - *Closed discussion*

EMA presented an update on the supply situation of medicinal products marketed by Novo Nordisk as well as the shortage mitigation measures. This presentation was followed by a presentation from Novo Nordisk explaining the root causes for the shortage, the availability of medicinal products in the EU/EEA and proposals/timelines for the implementation of further shortage mitigation measures.
- b) Supply and availability of GLP-1 Receptor Agonists from the MAH Sanofi:**
 - *Update on the supply and availability situation by EMA*
 - *Presentation from Sanofi and Q&A*
 - *Closed discussion*

EMA presented an update on the supply situation of the GLP-1 RA product marketed by the MAH, which was followed by a presentation from the MAH.



Topics

c) Overview of the supply and availability of GLP-1 Receptor Agonists from the MAH Astra Zeneca:

- *Update on the supply and availability situation by EMA*

The topic was cancelled due to time constraints.

d) Supply and availability of GLP-1 Receptor Agonists from the MAH Eli Lilly:

- *Update on the supply and availability situation by EMA*
- *Presentations from Eli Lilly and Q&A*
- *Closed discussion*

EMA presented an update on the supply situation of the GLP-1 RA medicinal products marketed by Eli Lilly, including an overview of shortage mitigation measures.

This presentation was followed by a presentation from Eli Lilly on short, medium and long-term mitigation measures.

3. AOB

Next meeting: 18 September 2024

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

	Name	Affiliation
Members and observers:		
1.	Emer Cooke	EMA – Co-Chair
2.	Karl Broich	Germany – Co-Chair
3.	Günter Waxenecker	Austria
4.	Hugues Malonne	Belgium
5.	Helena Panayiotopoulou	Cyprus
6.	Jakub Velik	Czechia
7.	Lars Bo Nielsen	Denmark
8.	Ott Laius	Estonia
9.	Eija Pelkonen	Finland
10.	Theoni Kousteni	Greece
11.	Lorraine Nolan	Ireland
12.	Domenico Di Giorgio	Italy
13.	Sergejs Akulics	Latvia
14.	Linas Mazeika	Lithuania
15.	Aimad Torqui	Netherlands
16.	Tomasz Lisiewski	Poland
17.	Roman Dorčík	Slovakia
18.	Momir Radulovic	Slovenia
19.	Maria Lamas	Spain
20.	Bjorn Eriksson*	Sweden
21.	Olof Thorhallsdottir	Iceland
*Competing interest declared resulting in no participation in decisions with respect to agenda point 2.c		
EC		
22.	Bruno Gautrais	DG SANTE
23.	Kristof Bonnarens	Secretariat General
24.	Sara Ashall	DG COMP
25.	Daniel Irisarri Lolin	DG COMP
Other participants		
1.	Monica Dias	SPOC WP Chair/EMA
2.	Sybille Schotte	SPOC WP Chair/NCA
3.	Nikos Dedes	PCWP

	Name	Affiliation
4.	Piera Polidori	HCPWP
5.	Olga Rögelsperger	Austria
6.	Mateo Orešić	Croatia
7.	Johanna Linnolahti	Finland
8.	Camille Ramahefarivony	France
9.	Wiebke Loebker	Germany - BfArM
10.	Martina Weise	Germany - BfArM
11.	Gabriele Eibenstein	Germany - BfArM
12.	Thomas Heberer	Germany - Vet
13.	Constance McDaniel	Germany - Vet
14.	Stefan Vieths	Germany-PEI
15.	Michael McDonald	Ireland
16.	Ellen McGrath	Ireland
17.	Oscar Cruciani	Italy
18.	Hanneke Mulder	Netherlands
19.	Patrick Vrijlandt	Netherlands
20.	Dag Jordbru	Norway
21.	Guri Wilhelmsen	Norway
22.	Yngvil Knudsen	Norway
23.	Nuno Simoes	Portugal
24.	Helena Ponte	Portugal
25.	Melita Tovornik*	Slovenia
26.	Barbara Razinger	Slovenia
27.	Lola Vazquez	Spain
28.	Maria Esplugues	Spain
29.	Kristina Dunder	Sweden
Industry		
1.	Eli Lilly	
2.	NovoNordisk	
3.	Sanofi	
EMA		
1.	Emmanuel Cormier	EMA
2.	Marie-Agnes Heine	EMA
3.	Inga Abed	EMA
4.	Luisa Costa	EMA
5.	Mariz Segundo	EMA
6.	Sofia Zastavnik	EMA
7.	Anne-Charlotte Fer	EMA

	Name	Affiliation
8.	Claudia Vincenzi	EMA
9.	Maria Alcaraz	EMA
10.	Joao Ferreira	EMA
11.	Klaus Kruttwig	EMA
12.	Emilija Matelyte	EMA
13.	Pieter-Jan Desiere	EMA
14.	Sandra Dang	EMA
15.	Radu Zaharia	EMA
16.	Inga Valionyte	EMA
17.	Marta Pennati	EMA
18.	Helene Leon	EMA
19.	Efstratia Vatzaki	EMA
20.	Andrei Spinei	EMA
21.	Stephanie Marschler	EMA
22.	Magdalena Zuk	EMA
23.	Pia Chambers	EMA
24.	Benjamin Pelle	EMA
25.	Heidi Janssen	EMA