



23 August 2024  
EMA/296817/2024

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

26 June 2024, from 10:00 to 12:00 (CEST), Webex

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

Topics	
1.	<p><b>Welcome, declaration of interest and adoption of the agenda</b></p> <p>The Co-Chairs welcomed the new and existing members of the MSSG.</p> <p>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 presented the competing interests identified and applicable restrictions for topics on the agenda. The MSSG secretariat informed the members that the competing interests identified and restrictions applicable will now be published in the minutes of the MSSG meetings for transparency reasons.</p> <p>The agenda was adopted with no additional topics.</p>
2.	<p><b>European Commission (EC) update</b></p> <p>The EC presented a high-level update on the Council discussions on the Regulation's chapter X (availability and security of supply of medicinal products) of the New Pharmaceutical Legislation.</p> <p>In addition, the EC presented an update on the EU guidance on procurement. The development of the guidance is supported by an expert group. Its main objective is to be an informative document on best practices.</p>
3.	<p><b>Joint Action (JA) on Regulatory Flexibilities</b></p> <p>The EC presented the status and details of the JA on regulatory flexibilities. This JA was included in the EC's communication on shortages as one of the short- to mid-term actions to address medicine shortages.</p> <p>The objective of the JA is to promote the effective use of regulatory flexibilities in the application of the Union's legal framework for medicinal products that could be applied at national level to manage and mitigate certain shortages, under specific conditions, without compromising safety and quality standards of medicinal products.</p>



<b>Topics</b>	
	<p>The JA will be designed according to the needs of members, and duplication with ongoing initiatives will be avoided through regular liaison with established groups working on shortages.</p> <p>The objectives of the JA will be to compile knowledge, foster collaboration and best practice sharing between Member States, to promote the effective use of regulatory flexibilities at national level. The JA will also aim at developing proposals for internal guidance for the implementation of such flexibilities at national level, in line with EU legislation.</p> <p>The launch of the JA is expected by the end of 2025 or early 2026.</p>
<b>4.</b>	<p><b>EC update: Update on the Critical Medicines Alliance (CMA) and working groups/forum meeting</b></p> <p>HERA gave an update on the kick-off meeting of the CMA and working groups meetings.</p> <p>HERA presented the composition of the two different working groups (WG), including Co-Chairs' names and affiliation:</p> <ul style="list-style-type: none"> <li>• WG1 - Strengthening EU manufacturing capacities for critical medicines and their active pharmaceutical ingredients;</li> <li>• WG2 - Diversifying international partnerships and cooperation.</li> </ul> <p>HERA also gave feedback on the inaugural meeting of the two working groups that had been held on 17 June 2024 and on the proposal for the next meetings of the WGs, which aim to contribute to the strategic plan by the end of 2024. As a next step, the plan would be finalised by the CMA Steering Board and validated by the Forum.</p> <p>The importance of having members of the MSSG in the WGs was highlighted during the meeting to avoid duplication of work.</p> <p><i>Post-meeting note: HERA confirmed that there are members of the MSSG in both WGs. EMA is also represented on those WGs.</i></p>
<b>5.</b>	<p><b>MSSG solidarity mechanism working group update</b></p> <p>The Co-Chairs of the MSSG solidarity mechanism WG presented the lessons learnt from the experience gained with the three procedures launched so far and the proposals to update the solidarity mechanism procedure.</p> <p>The proposals to change the procedure were adopted by the MSSG and will be published.</p> <p>The Co-Chairs also presented other procedural aspects currently being discussed in the WG, including the potential role of the Union Civil Protection Mechanism in the VSM, identification of barriers at national level delaying the transfer of stocks between countries and need to increase communication on the VSM through e.g., news item or dedicated information in the MSSG webpage.</p> <p>It was concluded that further experience is needed before a thorough review of the procedure can be undertaken.</p> <p>The potential link with the JA on regulatory flexibilities was highlighted.</p>

<b>Topics</b>	
6.	<p><b>MSSG recommendations to strengthen supply chains of critical medicinal products</b></p> <p>EMA presented the proposal for the MSSG to issue recommendations, if required, for some of the products included in the first tranche of medicines for which HERA/DG GROW had finalised the assessment of the vulnerabilities in the supply chain. EMA also highlighted the discussions at the level of the SPOC WP on types of products for which vulnerabilities in the supply chain are known.</p> <p>It was agreed that prioritisation (e.g. criteria) is required to select the products in the Union list for which the MSSG might issue recommendations. This topic will be included for discussion at future meetings of the MSSG.</p>
7.	<p><b>Preparedness activities:</b></p> <ul style="list-style-type: none"> <li>• <b>Shortages of GLP-1 receptor agonists (GLP-1 RA)</b></li> </ul> <p>EMA presented an update on the current supply and availability situation of GLP-1 RAs, the preparation of the multistakeholder workshop on the shortages of GLP-1 RAs taking place on 1 July 2024 both at the EMA premises and virtually. In addition, EMA provided an overview of the <a href="#">MSSG recommendations on shortage of GLP-1 RA</a> which were adopted by the MSSG on 12 June 2024 and published on 26 June, after a press briefing.</p> <p>EMA also presented the scope of the <a href="#">DARWIN EU study on drug utilisation studies on GLP-1 agonist</a>, which aims to provide an overview of the characteristics of patients prescribed with GLP-1 RAs and how they have changed over the past 10 years. This will help contextualise what determinants might be driving the demand for GLP-1 RAs vis-à-vis the observed shortage of medicines, including exploring comparative trends of prescription of other medicinal products used in diabetes and for weight management as well as patterns of off-label use.</p> <ul style="list-style-type: none"> <li>• <b>Cisplatin critical shortage</b></li> </ul> <p>EMA presented an update on the EU critical shortage of cisplatin and alternative sources that could be of help to mitigate the impact of the shortage on patients.</p>
8.	<p><b>AOB</b></p>

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**Next meeting:** *ad hoc* MSSG 1 July 2024

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**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 ongoing 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
<b>Members and observers:</b>		
1.	Emer Cooke	EMA – Co-Chair
2.	Karl Broich	Germany – Co-Chair
3.	Günter Waxenecker	Austria
4.	Hugues Malonne	Belgium
5.	Bogdan Kirilov	Bulgaria
6.	Helena Panayiotopoulou	Cyprus
7.	Jakub Velik	Czechia
8.	Lars Bo Nielsen	Denmark
9.	Susanna Peltoniemi	Finland
10.	Guillaume Renaud	France
11.	Theoni Kousteni	Greece
12.	Zakarias El-Koulali	Hungary
13.	Lorraine Nolan	Ireland
14.	Domenico Di Giorgio	Italy
15.	Sergejs Akulics	Latvia
16.	Linas Mazeika	Lithuania
17.	Aimad Torqui	Netherlands
18.	Tomasz Lisiewski	Poland
19.	Rui Santos Ivo	Portugal
20.	Razvan Mihai Prisada	Romania
21.	Maria Lamas	Spain
22.	Runa Hauksdóttir Hvannberg*	Iceland
*Competing interest declared resulting in no participation in decisions with respect to agenda point 7a		
<b>EC</b>		
23.	Bruno Gautrais	DG SANTE
24.	Laure Geslin	DG SANTE
25.	Carole Rouaud	DG SANTE
26.	Caroline Attard	DG SANTE
27.	Olivier Girard	DG HERA
28.	Corinna Hartung	DG HERA

	Name	Affiliation
<b>Other participants</b>		
1.	Monica Dias	SPOC WP Chair/EMA
2.	Sybille Schotte	SPOC WP Chair/NCA
3.	Mateo Orešić	Croatia
4.	Valerie Denux	France
5.	Wiebke Loebker	Germany - BfArM
6.	Thomas Heberer	Germany - Vet
7.	Stefan Vieths	Germany-PEI
8.	Michael McDonald	Ireland
9.	Ellen McGrath	Ireland
10.	Marcin Wisniewski	Luxembourg
11.	Hanneke Mulder	Netherlands
12.	Kristianne Kok	MINVWS
13.	Katrine Heier	Norway
14.	Dag Jordbru	Norway
15.	Nuno Simoes	Portugal
16.	Lola Vazquez	Spain
17.	Samuel Silkestrand	Sweden
<b>EMA</b>		
1.	Melanie Carr	EMA
2.	Marie-Agnes Heine	EMA
3.	Inga Abed	EMA
4.	Zigmars Sebris	EMA
5.	Mariz Segundo	EMA
6.	Brian Dooley	EMA
7.	Maria Alcaraz	EMA
8.	Joao Ferreira	EMA
9.	Klaus Kruttwig	EMA
10.	Emilija Matelyte	EMA
11.	Pieter-Jan Desiere	EMA
12.	Sandra Dang	EMA
13.	Radu Zaharia	EMA
14.	Benjamin Cid Bourie	EMA
15.	Marta Pennati	EMA
16.	Helene Leon	EMA
17.	Stephanie Marschler	EMA
18.	Magdalena Zuk	EMA
19.	Pia Chambers	EMA