21 October 2026
EMA/214171/2026
European Medicines Agency

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

23 September 2026, from 10:00 to 12:00 (CEST), TEAMS

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

Item	Topics
1.	**Welcome, declaration of interests and adoption of the agenda** The Co-Chairs welcomed members and experts attending the meeting. The MSSG secretariat reviewed the declarations of interests of MSSG members and experts in accordance with the Agency's applicable policy. The MSSG secretariat announced the competing interests identified for the meeting and the corresponding restrictions applied. The relevant competing interest under agenda item 5.b) and the relevant restriction communicated to the member concerned prior to the meeting will be recorded in the meeting minutes. The agenda was adopted with the addition of an item under AOB concerning the Danish Medicines Agency's request for access to data to support validation of an assessment tool developed in the context of the vulnerability assessment exercise.
2.	**RAMP UP Initiative – Update** DG HERA provided an update on the Rapid Agile Manufacturing Partnership for Union Protection (RAMP UP), a voluntary industry preparedness network intended to map and mobilise EU manufacturing and supply-chain capacity for medical countermeasures during health emergencies. The initiative builds on lessons learned during the COVID-19 pandemic and is intended to facilitate faster mobilisation of production capacity. DG HERA clarified that RAMP UP is not a regulatory or procurement framework and does not provide participating companies preferential access to contracts. It will operate as a dynamic, strategic registry, and participation will be voluntary and free of charge. The pilot phase, running until the end of November 2026, focuses on onboarding a limited number of companies with portfolios covering relevant medical countermeasures. From the first quarter of 2027, participation is expected to be opened to other relevant supply-chain actors,

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	including those involved in medical devices, in vitro diagnostics and personal protective equipment (PPE). DG HERA is liaising with EMA to avoid duplicative requests or overlap with the ongoing vulnerability assessment exercise. It was clarified that the two activities have distinct scopes: EMA's vulnerability assessments focus on critical medicines, whereas RAMP UP addresses crisis preparedness and manufacturing capacity for medical countermeasures. Information already collected by EMA will be used where appropriate, while companies may provide additional information specifically required for RAMP UP. Members discussed the participation of small and local manufacturers and the scope of capacity mapping. DG HERA indicated that the pilot would test the partnership with a limited number of companies, while the full initiative would welcome all relevant actors with a demonstrated role in ensuring access to crisis-relevant medical countermeasures. Members also noted the importance of maintaining manufacturing capacity for influenza vaccines in the EU.
3.	**New pharmaceutical legislation and Critical Medicines Act – Update** DG SANTE provided an update on the new pharmaceutical legislation, focusing on provisions relevant to the MSSG. The text was undergoing legal review, with formal adoption expected in December 2026. Some provisions of chapter X are expected to apply immediately upon entry into force, anticipated for late December 2026 or early January 2027. Work on the necessary implementing and delegated acts has started, with implementation activities being coordinated in preparation for the broader application of the legislation in Q4 2028. An implementing act concerning the Union list of critical medicines is targeted for adoption in early 2027. The discussion also highlighted the relevance of resilient procurement criteria beyond price and the links with vulnerability assessments. DG SANTE also updated the MSSG on the Critical Medicines Act. Adoption is expected by the end of 2026, with entry into force in early 2027. Member States were encouraged to begin preparations, including identifying the designated national authority, preparing national programmes and procurement-related arrangements, and nominating a representative to the Critical Medicines Coordination Group. The Commission informed the MSSG that they are preparing guidance on public procurement and contingency stocks and would carry out several implementation tasks in cooperation with DG HERA. DG SANTE underlined the need for a consistent approach, avoidance of duplication and timely preparation to meet the expected implementation deadlines.
4.	**Preparedness activities:**
	a) Seasonal influenza vaccine supply ECDC opened the presentation by outlining the potential disruptions to seasonal influenza vaccine supply and presenting the results of its survey of EU/EEA countries, together with the latest epidemiological information. The reported delays primarily affected standard-dose, egg-based inactivated influenza vaccines. ECDC reported that the mitigation measures being implemented included optimising distribution, adjusting campaign schedules, prioritising high-risk groups, purchasing

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	additional doses where possible, and enhanced monitoring and preparedness. ECDC confirmed that they continue to monitor influenza activity in EU/EEA primary and secondary care settings to identify when the peak of cases is expected. Data from other regions is also being monitored to inform this work. EMA then provided the latest supply update. EMA contacted all Marketing Authorisation Holders (MAHs) of seasonal influenza vaccines and a survey was circulated in parallel to the SPOC WP for input from National Competent Authorities (NCAs). Delayed deliveries were confirmed by NCAs and a number of MAHs. Although total supply is expected to meet demand, deliveries are expected to arrive significantly later than planned in some markets. Discussions with the companies concerned are ongoing to clarify the extent of the delays and the potential impact on EU/EEA supply. EMA also noted that the complexity of the market and distribution channels at national level makes it difficult to determine precise market shares both at EU and at Member State level. Following coordination between ECDC, the EC and EMA, it was agreed to escalate the topic to the MSSG ahead of a Health Security Committee meeting scheduled for 30 September 2026. MSSG members supported continued coordination between ECDC, the EC and EMA. Several MSSG members indicated that national communication was already under way or being prepared. Members agreed that communications should remain primarily national. Use of the voluntary solidarity mechanism could be considered if needed. MSSG members were invited to provide the requested follow-up information and share relevant national communications with EMA after the meeting to support alignment of messages and continued assessment of the supply situation.
	b) Update on the critical shortages of ifosfamide and cyclophosphamide in the EU EMA provided an update on ongoing mitigation activities for the shortages of ifosfamide and cyclophosphamide. The supply situation appears to have stabilised, as illustrated by the supply plan for the remainder of 2026. This improved outlook has also been confirmed during the SPOC WP meeting on 15 September 2026, however planning for 2027 is still ongoing. EMA will continue to monitor the supply situation and implementation of the MSSG recommendations with the marketing authorisation holders concerned, in coordination with the relevant SPOC WP subgroup and Baxter. In addition, once the proposed supply plan is available for 2027, EMA will ensure that this is communicated to all member states without delay.
5.	**VSM procedures launched in July and August:** **a) Tamoxifen** **b) Calcium levofolinate** Due to time constraints, it was agreed that the MSSG would receive the corresponding presentations, for information, in writing for this point on the agenda after the meeting.
6.	**Major event simulation exercise (2–5 December 2025): survey results and lessons learned** EMA presented the results of the participant survey and the lessons learned from the major event simulation exercise coordinated by EMA, with the support of the MSSG, in December

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	2025. Feedback collected through online surveys had been consolidated into a report. Members noted that the volume of documentation had been challenging and that roles and responsibilities should be clarified further in future exercises. The EMA Co-Chair thanked MSSG members for their contributions to the lessons-learned process. The MSSG was invited to submit comments on the report within two weeks, after which the report would be finalised. *Post-meeting note: As announced during the meeting, a written consultation on the draft report was launched by email on 23 September, inviting MSSG members to provide comments by 7 October.*
7.	**AOB** The MSSG discussed the request to share additional data with Danish Medicines Agency's to test and validate an assessment tool developed to support the rapporteur assessment process in the vulnerability assessment exercise. The tool could subsequently be made available to EMA and NCAs for use in future exercises. The Co-Chairs and members who intervened strongly supported the request. The MSSG agreed that the requested data could be provided to the Danish Medicines Agency for the purpose of refining the tool. EMA and the Danish Medicines Agency confirmed that commercially confidential information will be protected as per the agreed procedure for the vulnerability evaluations. The Danish Medicines Agency will report the outcome of the validation work to the MSSG. The EMA Co-Chair noted that the next MSSG meeting would take place in Dublin and thanked the HPRA for hosting it in the margins of the HMA meeting. Members were asked to arrange their travel and update the attendance table circulated by the MSSG secretariat, indicating whether they would participate in person or remotely.

Next meeting: MSSG 5 October 2026 (F2F meeting in Dublin)

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).

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 23 September 2026 MSSG meeting, which was held virtually.

Name	Role	Member State or affiliation	Interest level of e-DoI
Emer Cooke	Co-Chair	EMA	No interest declared
Karl Broich	Co-Chair	Germany	No interest declared
Anna Chioti	Member	Luxembourg	No interest declared
Nils Falk Bjerregaard	Member	Denmark	No interest declared
Bogdan Yavorov Kirilov	Member	Bulgaria	No interest declared
Theoni Kousteni	Member	Greece	No interest declared
Ott Laius	Member	Estonia	No interest declared
Hugues Malonne	Member	Belgium	No restrictions applicable to this meeting
Agnes Mathieu-Mendes	Member	EC	No interest declared
Timo Mauriala	Member	Finland	No interest declared
Linas Mazeika	Member	Lithuania	No interest declared
Helena Panayiotopoulou	Member	Cyprus	No interest declared
Grainne Mary Power	Member	Ireland	No restrictions applicable to this meeting
Rui Santos Ivo	Member	Portugal	No restrictions applicable to this meeting
Anthony Serracino-Inglott	Member	Malta	No restrictions applicable to this meeting
Günter Waxenecker	Member	Austria	No interest declared
Runa Hauksdottir Hvannberg	Member	Iceland	No interest declared
Fabian Kurzemann	Member	Liechtenstein	No interest declared
Trygve Ottersen	Member	Norway	No restrictions applicable to this meeting
Nikos Dedes	PCWP	European AIDS Treatment Group E.V.	No restrictions applicable to this meeting
Monica Dias	SPOC WP	EMA	No interest declared
Piera Polidori	HCPWP	EAHP	No restrictions applicable to this meeting

Name	Role	Member State or affiliation	Interest level of e-DoI
Charles Denonne	Expert	Belgium	No interest declared
Soňa Fundárková	Expert	Slovakia	No interest declared
Jeanne Majland	Expert	Denmark	No interest declared
Roelie Marinus	Expert	Netherlands	No interest declared
Ellen McGrath	Expert	Ireland	No interest declared
Michael McDonald	Expert	Ireland	No interest declared
Mateo Orešić	Expert	Croatia	No interest declared
Andreas Sundgren	Expert	Sweden	No interest declared
Melita Tovornik	Expert	Slovenia	No interest declared
Ly Tran	Expert	Netherlands	No interest declared
Agoritsa Baka	Invited speaker	ECDC	Confidentiality agreement
Edoardo Colzani	Invited speaker	ECDC	Confidentiality agreement
Kate Olsson	Invited speaker	ECDC	Confidentiality agreement
Representatives from the European Commission attended the meeting.			
Meeting run with the help of EMA staff.			