5 August 2026
EMA/166542/2026
European Medicines Agency

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

17 July 2026, from 10:00 to 11:30 (CEST), TEAMS

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

Item	Topics
1.	**Welcome, declaration of interest and adoption of the agenda** The Co-Chairs welcomed members and experts attending the meeting. The MSSG secretariat reviewed the declaration of interests (DoI) of members and experts in accordance with the Agency's policy on handling of declarations of interests of Scientific Committees' members and experts, as applicable to MSSG members and experts. The MSSG secretariat announced that no competing interests had been identified for this meeting. The agenda was adopted without amendments.
2.	**Adoption of minutes** The minutes of the ad-hoc MSSG meeting held on 17 July 2026 were adopted without comments.
3.	**New Pharmaceutical Legislation and Critical Medicines Act - Update** DG SANTE provided a status update on the new pharmaceutical legislation, with a particular focus on the Regulation and the provisions relevant to the MSSG. DG SANTE informed the MSSG that the lawyer-linguist review had been finalised ahead of translation into all EU languages and formal adoption later in 2026. DG SANTE noted that publication is expected in December 2026 and that most provisions are expected to apply 24 months after publication. Provisions relating to shortage prevention plans are expected to apply six months after publication, while provisions concerning the Union list of critical medicines and vulnerability assessment are expected to apply immediately after publication. DG SANTE also provided an update on the Implementing Act for Commission adoption of the Union list of critical medicinal products. DG SANTE further updated the MSSG on the Critical Medicines Act, including the provisional political agreement reached under the Cypriot Presidency. The Commission highlighted provisions of relevance to Member States, EMA and the MSSG, including tasks related to contingency stocks,

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	the voluntary solidarity mechanism and MSSG recommendations on collaborative procurement and stock allocation where needed. DG SANTE noted that the obligation on the Agency to establish and maintain a digital overview of contingency stock requirements could be implemented using a spreadsheet format such as Excel.
4.	**Working Group on the Vulnerability Assessment Methodology Updates**
	a. Vulnerability Assessment Methodology - Update EMA provided an update from the MSSG Working Group on Vulnerability Assessment on the ongoing 2026 Vulnerability Assessment exercise, including the number of responses received from marketing authorisation holders and initial feedback from Member State Rapporteurs. EMA informed the MSSG that 197 marketing authorisation holders had been contacted and that follow-up would focus on companies with a significant market share where responses remained outstanding. The European Commission offered support in following up with outstanding responses, where needed. EMA noted that technical discussions with Rapporteurs are ongoing, with technical drop-in sessions on specific topics. Members discussed the challenges linked to insufficient data and poor-quality data, including cases where companies with a high market share had not yet provided information. It was agreed that the exercise should continue using the data gathered and that the Working Group would present the outcome to the MSSG for consideration in December, providing clear justification and description of challenges, where relevant. Members also discussed the need to better understand the main challenges faced by companies in providing data, including reasons for non-response and opportunities to simplify data requirements over time while maintaining the necessary level of information for the assessment. The Co-Chairs thanked the EMA and Rapporteurs for their continued support and contributions to the exercise.
	b. SPP template and guidance – Update EMA presented the updated Shortage Prevention Plan template and corresponding guidance for industry for adoption by the MSSG. EMA noted that feedback received from industry associations through the written consultation and a dedicated workshop had been considered in the revision of both documents. The European Commission acknowledged the work undertaken by EMA and the Working Group and noted the importance of ensuring that the template and guidance remain aligned with the requirements of the new pharmaceutical legislation. The Commission also noted that companies may use the period before application of the relevant provisions to prepare for implementation. The MSSG adopted the updated SPP template and guidance, with no additional comments.
5.	**Preparedness activities:**
	a. Update on Visudyne critical shortage in the EU

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	EMA provided an update on the ongoing critical shortage of Visudyne, including developments related to the new supply chain and planned next steps. EMA noted that supply from the new manufacturing supply chain will increase in Q3/Q4 2026, with a more stable supply situation expected from Q1 2027. EMA referred to the latest bi-monthly report submitted by the marketing authorisation holder on 2 July 2026, which had been circulated in the pre-mailing. Although the marketing authorisation holder proposed discontinuing regular reporting, the SPOC WP subgroup recommended continuing periodic updates on critical shortages and targeted medicines identified for follow-up, for shortage prevention purposes. The MSSG agreed that the bi-monthly reporting should continue. EMA will inform the marketing authorisation holder accordingly.
	b. Update on ifosfamide and cyclophosphamide critical shortage in the EU EMA provided an update on the ongoing critical shortage of ifosfamide and cyclophosphamide, including revised supply projections indicating lower forecast deliveries than previously reported. EMA explained that the revised projections reflect updated assumptions regarding batch yields and ongoing manufacturing deviations at the manufacturing site. EMA noted that supply remains unpredictable and insufficient due to lower-than-expected yields for multiple batches and fewer batches than planned. Several countries are experiencing very low stock levels or stock-outs, and the global supply situation is worsening, which may affect the availability of both authorised and unauthorised alternative products. EMA presented ongoing mitigation measures, including contacts with alternative manufacturers of both ifosfamide and cyclophosphamide to explore possibilities to increase manufacturing capacity of the authorised products, or to source unauthorised products from international sources. In addition, the potential to facilitate collaborative procurement for non-authorised products was mentioned. EMA also presented the updated MSSG recommendations and provided an update on Baxter's implementation status. Members discussed the importance of continued engagement with the supervisory authority and the manufacturing site, including on root-cause analysis, oversight and implementation of any additional regulatory flexibilities measures. Members noted that alternatives are limited or unavailable for certain indications, in particular for paediatric sarcoma, and discussed whether clinical prioritisation considerations could be reflected at Union level while recognising that detailed clinical recommendations are generally implemented at national level. The MSSG considered that Union-level recommendations may support consistent implementation where no suitable alternatives are available. Members also noted difficulties in securing importation options and the significant work required at national level to identify alternatives for specific indications. Member States were encouraged to share information with EMA if additional sources are identified. The shortage is expected to remain critical at least until the end of 2026.
6.	**AOB** The MSSG noted that DG HERA will provide an update on RAMP UP in a future meeting. The MSSG EMA Co-Chair made some announcements.

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	The MSSG EMA Co-Chair noted that a placeholder meeting is scheduled in August and may be cancelled if there are no urgencies.

Next meeting: MSSG 23 September 2026

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 17 July 2026 MSSG meeting, which was held virtually.

Name	Role	Member State or affiliation	Interest level of e-DoI
Karl Broich	Co-Chair	Germany	No interest declared
Emer Cooke	Co-Chair	EMA	No interest declared
Anna Chioti	Member	Luxembourg	No interest declared
Bogdan Yavorov Kirilov	Member	Bulgaria	No interest declared
María Jesús Lamas Díaz	Member	Spain	No interest declared
Katrina Luksa	Member	Latvia	No interest declared
Hugues Malonne	Member	Belgium	No restrictions applicable to this meeting
Agnes Mathieu-Mendes	Member	EC	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
Razvan Mihai Prisada	Member	Romania	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
Aimad Torqui	Member	Netherlands	No interest declared
Jakub Velik	Member	Czechia	No interest declared
Günter Waxenecker	Member	Austria	No interest declared
EEA			
Runa Hauksdottir Hvannberg	Member	Iceland	No interest declared
Permanent observers			
Nikos Dedes	PCWP	European AIDS Treatment Group E.V.	No restrictions applicable to this meeting

Experts			
Sophie Bruneel	Expert	Belgium	No interest declared
Soňa Fundárková	Expert	Slovakia	No interest declared
Ingeborg Gerngross	Expert	Austria	No interest declared
Thomas Heberer	Expert	Germany (Vet)	No restrictions applicable to this meeting
Katrine Heier	Expert	Norway	No interest declared
Asa Kumlin Howell	Expert	Sweden	No restrictions applicable to this meeting
Roelie Marinus	Expert	Netherlands	No interest declared
Ellen McGrath	Expert	Ireland	No interest declared
Michael McDonald	Expert	Ireland	No interest declared
Hanneke Mulder	Expert	Netherlands	No interest declared
Mateo Orešić	Expert	Croatia	No interest declared
Guillaume Renaud	Expert	France	No restrictions applicable to this meeting
Patricia Rodriguez Molla	Expert	Spain	No restrictions applicable to this meeting
Nuno Simões	Expert	Portugal	No interest declared
Melita Tovornik	Expert	Slovenia	No interest declared
Stefan Vieths	Expert	Germany (PEI)	No restrictions applicable to this meeting
Representatives from the European Commission attended the meeting.			
Meeting run with the help of EMA staff.			