20 November 2025
EMA/337800/2025
European Medicines Agency

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

20 October 2025, from 10:00 to 12:00 (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 MSSG Co-Chairs welcomed Agnès Mathieu-Mendes as a new member representing the European Commission. The MSSG Co-Chairs welcomed all members and experts attending the meeting. 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 EMA Co-Chair announced that no competing interests were identified for this meeting. The agenda was adopted with no additional items.
2.	**Adoption of the minutes of the MSSG meeting held on 24 September 2025** The EMA Co-Chair announced that the draft minutes of the meeting held on 24 September were distributed via email prior to the meeting. No comments were received before or during the meeting. Minutes were adopted and will be published on the EMA website.
3.	**ESMP/EMVS (European Medicines Verification System) Gap analysis final report** EMA presented the outcomes of the ESMP/EMVS Gap analysis report, outlining its objectives, methodology, and conclusions. Input to the report was provided by EFPIA, Medicines for Europe, and the European Medicines Verification Organization (EMVO). EMA informed the MSSG that while supply data from EMVS cannot replace industry reporting to ESMP, it can complement it, provided that both EMVS supply data and dispensation data are included. It was concluded that EMVS supply data alone offers limited value and requires product/package information to be mapped to product management service (PMS) identifiers. A 3-step approach was recommended to include (1) the mapping of EMVS

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	product data to PMS, (2) the consumption of EMVS supply data by ESMP, and (3) the subsequent consumption of EMVS dispensation data. It was acknowledged that to be of value dispensation data would be needed and this would require agreement from EMVO governance. A joint statement from EFPIA and MfE with reflections on the conclusions and recommendations of the report was also presented. As next steps, the report will be presented to the Directors General of participating industry associations and EMVO Board for further discussion and agreements. The EC acknowledged the work done to explore the integration of EMVS data into the ESMP, emphasising the need to present the findings to the EMVO Board and to streamline available information to avoid duplication of information and enhance its utility across IT systems.
4.	**Vulnerability Assessment Methodology** **a) Presentation of the draft methodology from the Working Group of the MSSG on the Vulnerability Assessment Methodology** **b) Feedback from and Q&A with Industry Associations representatives** **c) Closed discussion** EMA Secretariat and a member of the Working Group presented the proposed methodology to identify vulnerabilities in the supply chains of critical medicines included on the Union list, to inform policy measures set out in the proposed pharmaceutical legislation and the proposed Critical Medicines Act. The presentation described the two-phased approach, taking into account work already carried out by the European Commission and the Critical Medicines Alliance. They noted that the methodology may need to be further refined following further testing, in light of the data driven approach and ongoing co-legislative processes. Aspects related to implementation, including deliverables and confidentiality considerations will need to be considered in a next phase. The results of a survey conducted with industry associations and how this feedback was integrated were also shared. Industry associations representatives participated in this presentation and provided input. Overall, they expressed support for the methodology with the need to consider specificities of certain types of products (e.g. patented medicines, generics, and plasma derived medicinal products). During the meeting, MSSG members expressed support for the methodology and agreed to proceed with a written procedure to formally adopt the methodology. The MSSG acknowledged the immense work conducted by the working group in such a short period of time. The EC called for further development of the ESMP to automate data collection and analysis, where possible, to support the implementation of the proposed legislation. It was noted that industry collaboration will remain voluntary until legal obligations become applicable. The MSSG highlighted the need to progress testing, with the involvement of industry stakeholders, in advance of final agreement on the two legislative proposals. To support this, a request will be sent to industry associations to identify volunteers. MSSG also asked for further clarity on potential confidentiality constraints.

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	Post-meeting note: The written procedure was launched on 28 October with a deadline for comments until 14 November 2025.
5.	**European Court of Auditors (ECA) audit report on critical shortages of medicines** EMA presented the ECA special report 19/2025 on critical shortages of medicines published on 17 September 2025 after the audit conducted by ECA. The presentation focused on main findings, recommendations, EMA replies to the report and next steps. EMA will finalise the improvement action plan, ensuring alignment with the EU medicines agencies network strategy (EMANS) and keep the MSSG informed. The MSSG acknowledged that the system functions effectively and we are now better prepared than in 2019 due to the activities conducted by the SPOC WP and MSSG. The upcoming new pharmaceutical legislation, which builds upon the established systems and processes, will further improve the situation. The EC also presented ongoing discussions regarding the implementation of the ECA recommendations addressed to the Commission. Some MSSG members raised concerns about issuing and publishing clinical recommendations on appropriate alternative medicines because the national competence is not always with the NCA. The MSSG agreed to launch a survey to gather information on national practices.
6.	**AOB**

Next meeting: MSSG 20 November 2025

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 20 October 2025 MSSG meeting, which was held remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI
Karl Broich	Co-Chair	Germany	No interest declared
Emer Cooke	Co-Chair	EMA	No interest declared
Anna Chioti	Member	Luxembourg	No interest declared
Domenico Di Giorgio	Member	Italy	No interest declared
Zakariás El Koulali	Member	Hungary	No restrictions applicable to this meeting
Theoni Kousteni	Member	Greece	No interest declared
Ott Laius	Member	Estonia	No interest declared
María Jesús Lamas Díaz	Member	Spain	No interest declared
Ann Lindberg	Member	Sweden	No restrictions applicable to this meeting
Agnès Mathieu-Mendes	Member	European Commission	No interest declared
Linas Mazeika	Member	Lithuania	No interest declared
Helena Panayiotopoulou	Member	Cyprus	No interest declared
Eija Pelkonen	Member	Finland	No interest declared
Magdalena Rychter	Member	Poland	No restrictions applicable to this meeting
Anthony Serracino-Inglott	Member	Malta	No interest declared
Aimad Torqui	Member	Netherlands	No interest declared
Jakub Velik	Member	Czechia	No interest declared
Günter Waxenecker	Member	Austria	No interest declared
Nikos Dedes	PCWP	European AIDS Treatment Group E.V.	No restrictions applicable to this meeting
Monica Dias	SPOC WP	EMA	No interest declared
Benedicte Bertholom	Expert	France	No interest declared
Sophie Bruneel	Expert	Belgium	No interest declared
Thomas Heberer	Expert	Germany (Vet)	No restrictions applicable to this meeting

Dag Jordbru	Expert	Norway	No interest declared
Asa Kumlin Howell	Expert	Sweden	No restrictions applicable to this meeting
Jeanne Majland	Expert	Denmark	No interest declared
Roelie Marinus	Expert	Netherlands	No restrictions applicable to this meeting
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
Patricia Rodriguez Molla	Expert	Spain	No restrictions applicable to this meeting
Samuel Silkestrand	Expert	Sweden	No interest declared
Emilia Stoyanova	Expert	Bulgaria	No interest declared
Melita Tovornik	Expert	Slovenia	No interest declared
Jacob Brogren	Member MSSG-WG on VAM	Sweden	No interests declared
Martin Créton	Member MSSG-WG on VAM	France	No restrictions applicable to this meeting
Gabriele Eibenstein	Member MSSG-WG on VAM	Germany	No restrictions applicable to this meeting
Ellen Mc Grath	Member MSSG-WG on VAM	Ireland	No interest declared
João Simões	Member MSSG-WG on VAM	Portugal	No interest declared
Representatives from the European Commission attended the meeting.			
Representatives of Industry Associations attended topic 4.b).			
Meeting run with the help of EMA staff.			