



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mandate and objectives for the Working Group of the MSSG on the Voluntary Solidarity Mechanism and Policy

1. Background

One of the recommendations included in the Belgian non-paper to improve the security of medicines supply in Europe, signed by 23 Member States (MS), is to set up a European Union (EU) voluntary solidarity mechanism (VSM) for MS where stocks of important medicines are critically low and where all other available options have been exhausted. They can send out a notification through this mechanism, to which other MS may respond to provide some temporary relief.

In this context, the Commission, together with the European Medicines Agency (EMA), decided to establish a joint mechanism with MS to formally enable EU solidarity in the context of medicines shortages. For this purpose, article 6.4 of the [Rules of Procedure of the Medicine shortages and Safety Group \(MSSG\)](#) foresees the setting up of Ad-hoc Drafting Groups (in the form of Working Groups) composed of multidisciplinary experts according to the tasks assigned to support the work of the MSSG. Therefore, a Working Group of the MSSG was created to support the setting up of the solidarity mechanism (the MSSG Working Group on VSM). The creation of the MSSG Working Group on VSM was agreed by the MSSG during its meeting held on 19 June 2023.

The HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use (HMA/EMA TF-AAM) was created in 2016 with the aim to be a hub to monitor availability related activities, provide strategic support, advice for coordination and concerted approach to the Network on the availability of the medicinal products authorised in the EU.

In December 2024, it was agreed that the HMA/EMA TF-AAM could be formally closed, and relevant outstanding tasks could be transferred to the MSSG. The activities would be transferred to the MSSG Working Group on VSM with an extended scope and would be renamed as 'MSSG Working Group on VSM and Policy'.

2. Mandate and objectives

The MSSG Working Group on VSM and Policy (subsequently referred to as the Working Group) will be responsible for the continuous development of VSM, and other policy activities related to the availability and supply of medicines, including the implementation of European medicines agencies network strategy

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2028 (EMANS) (theme 5 Goal 1 activities). Concretely, the Working Group will be responsible for activities related to:

- Shortages response and preparedness: Progress on ongoing activities around mitigation and prevention of shortages of human and veterinary medicines (e.g. VSM, outstanding activities of the TF-AAM and EMANS 2028).
- Supply and Availability Hub: Track progress on ongoing and planned supply and availability activities, to streamline processes, ensure synergies and avoid duplication of work within the network.
- Communication: In collaboration with the Working Group of Communication Professionals (WGCP) enhance communication on supply problems and provide guidance and good practice documents.

3. Composition and rules of participation

The Working Group is composed of MS which are MSSG representatives or delegates, European Commission (DG SANTE, Health Emergency Preparedness and Response Authority (HERA) and Secretariat-General), Medicine Shortages Single Point of Contact (SPOC) Working Party representatives, representatives of the WGCP and Veterinary Strategy Focus Group (VSFG), and EMA Secretariat.

Membership of the Working Group implies a commitment to participate actively in the activities of the group by attending Working Group meetings regularly. The Working Group can invite other experts if needed and confidentiality rules will be enacted.

The Working Group is supported by technical 'focal groups', which may focus on specific activities outlined under 2. Mandate and objectives. Members of the technical focal groups are made up of SPOC WP members and other national experts.

4. Meeting frequency and method of operation

The Working Group meets virtually on a quarterly basis in so called "main MSSG Working Group on VSM and Policy meetings", to discuss and provide strategic direction on the above-mentioned mandate and objectives.

Additional technical meetings on focal group level are taking place in-between the quarterly meetings to progress with the technical work relating to the different respective activities. Participation of Working Group Members in these technical meetings is welcomed as is possible and feasible. Any progress made will be brought to the main MSSG Working Group on VSM and Policy meetings for strategic input or alignment.

Adoption of deliverables will be undertaken by the MSSG. The Working Group will closely interact with the new MSSG Working Group on the Vulnerability Assessment Methodology to ensure alignment and to avoid any potential overlap.

EMA will provide the secretariat to the Working Group, providing technical, scientific and administrative support.