



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

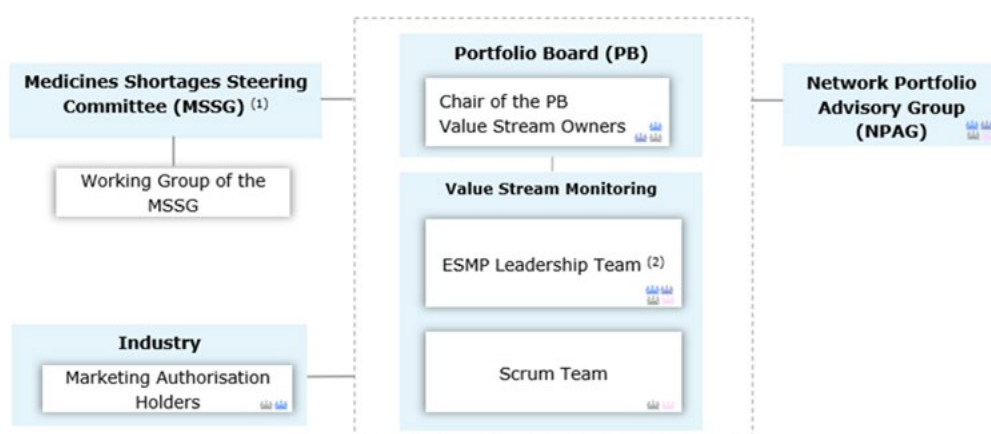
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Mandate and objectives for the Working Group of the MSSG on the ESMP

1. Background

Within the provisions of Regulation (EU) 2022/123 (Article 13) the Agency is tasked with setting up, maintaining, and managing an IT platform to be known as the European shortages monitoring platform ('ESMP'). Article 13 also states that the Agency will develop the technical and functional specifications of the ESMP, including the data exchange mechanism for exchanging with the existing national systems and the format for electronic submissions, in collaboration with the MSSG.

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 composed of multidisciplinary experts according to the tasks assigned to support the work of the MSSG. Therefore, a working group of the MSSG is created to support the development of the ESMP. The ESMP governance model foresees the interaction between different groups, including the MSSG (below is a schematic representation of the governance model for the ESMP).



2. Mandate and objectives

The working group will develop the technical and functional specifications of the ESMP, including the data exchange mechanism for exchanging with the existing national systems and the format for electronic submissions. The Working group will be tasked to strengthen the cooperation with the Network and, in particular with the Joint action on Shortages, to ensure that there is no duplication of efforts in the Network.

The Working Group will be responsible for:

- Development of key requirements and the Roadmap
 - Identify key requirements for the MVP (i.e. interoperability)
 - Enable the consolidation of the ESMP Roadmap
 - Develop guidance on features
- Strengthen the cooperation with the Network
 - Facilitate the interaction between the Product Owners and SMEs with the Network
 - Resolve Network (cross border) risks/impediments
 - Provide solutions for the MVP, when necessary
- Ensure alignment with the activities under the Joint Action (JA) on Shortages
 - Select and bridge to relevant activities of the JA on shortages
 - Ensure that the ESMP development is fully aligned with the activities under the JA on Shortages
- Update the MSSG
 - Provide regular updates to the MSSG on the progress made in the development of the ESMP

3. Composition and rules of participation

The working group is composed of MSSG representatives, Product Manager, Product Owners (EMA and network), representatives from the JA on Shortages and the Value stream Owner and Manager.

Membership of the working group implies a commitment to participate actively in the activities of the group by participating regularly to meetings and workshops.

4. Meeting frequency and method of operation

Members will meet via teleconference 2 to 3 times every quarter before each PI planning. In addition, a F-2-F meeting per year will also be scheduled, preferably in close proximity with the meeting of the EMA Management Board.

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