EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mandate and objectives for the Working Group of the MSSG on the Vulnerability Analysis Methodology

1. Background

Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment. The root causes of shortages are multifactorial, with challenges identified along the pharmaceutical supply chain, including quality and manufacturing problems. Shortages of medicinal products can also result from supply chain disruptions and vulnerabilities affecting the supply of active pharmaceutical ingredients and starting materials.

In efforts to shift towards preventative approaches to ensure continuity and security of supply for health systems and patients, there has been extensive discussion at Union level in recent years, in particular with respect to the identification of critical medicines and vulnerabilities in their supply chains[1].

Concretely, the proposed pharmaceutical legislation includes a provision obliging the Agency, in collaboration with the SPOC working party, to develop a common methodology to identify critical medicines, including the evaluation of vulnerabilities with respect to the supply chains of those medicines.

As a first step towards that objective, in anticipation of the legislation, the EC, HMA and EMA published a document[2] on 29 June 2023, outlining the methodology, governance and matrix for identifying medicines to be included in the Union list of critical medicines. The methodology was implemented, with the second version of the Union list of critical medicines[3] published in December 2024. That document acknowledged that final Union list of critical medicines will have to factor in assessment of the vulnerabilities of the supply chain at a later stage.

Therefore, this Working Group will now progress work towards delivering the second part of that objective, to develop a methodology to evaluate vulnerabilities in the supply chain of those medicines.

The methodologies will inform the MSSG proposal for an updated Union list of critical medicines, for adoption by the Commission. Subsequently, the MSSG may provide recommendations on appropriate

[1] Structured dialogue on security of medicines supply — European Commission; EC SWD Vulnerabilities of the global supply; Strategic Report of the Critical Medicines Alliance; Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report — European Commission
[2] https://www.ema.europa.eu/en/documents/other/methodology-identify-critical-medicines-union-list-critical-medicines_en.pdf
[3] union-list-critical-medicines-en.xlsx

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security of supply measures to marketing authorisation holders, the Member States, the Commission or other entities. The proposed Critical Medicines Act also includes provisions that rely on the vulnerability evaluation set out in the proposed pharmaceutical legislation, at an aggregate level.

Finally, the proposed legislation also requires marketing authorisation holders to have shortage prevention plans in place, to prevent shortages. It also proposes that the Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans. This work is progressing under the MSSG Working Group on VSM and Policy and is complementary to the work of the Working Group of the MSSG on the Vulnerability Analysis Methodology.

2. Mandate and objectives

The working group will develop a proposal for the vulnerability analysis methodology taking into account previous experience, as well as the work of the European Commission and the Critical Medicines Alliance, in order to leverage knowledge already available in the European medicines regulatory network and beyond.

The Working Group will be responsible for:

- development of the vulnerability analysis methodology:
  - Agreement on indicators and thresholds.
  - Identification of data sources and data interoperability needs.
  - Organisation of the planning for implementation of the methodology, including but not limited to:
    - prioritisation of INNs/medicinal products
    - workflow (tools for analysis, coordination of evaluations, agreement on outcomes, review)
    - process towards adoption by MSSG,
- scope of interactions with industry and other stakeholders;
- provision of updates to the MSSG on the progress made by the WG;
- testing of methodology, including consideration of the information gathered through the Shortage Prevention Plan pilot, and update of the methodology where necessary;
- monitoring of the effectiveness and efficiency of the methodology after implementation.

3. Composition and rules of participation

The working group is composed of MS which are MSSG representatives or delegates, European Commission, Medicine Shortages SPOC WP representatives and EMA Secretariat.

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 for technical meetings via teleconference at regular intervals until the proposal for the vulnerability analysis methodology is finalised. High level meetings will be arranged in preparation for updates to MSSG, where necessary.

When the proposal is fully implemented the WG will evaluate the effectiveness of this methodology in identifying vulnerabilities and informing MSSG recommendations and evaluate the need to further fine tune any operational aspects.

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