



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MSSG recommendations to strengthen supply chains of critical medicinal products

Industry Standing Group (ISG) meeting, 28 June 2024

Presented by Maria Alcaraz

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

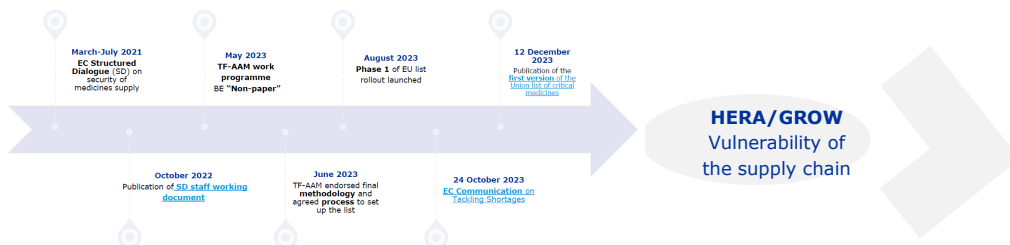
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MSSG recommendations to address vulnerabilities in the supply chain

MSSG: regulatory measures / CMA: industrial policy measures



MSSG

- Recommendations to address vulnerabilities short-medium term solutions
- *Product specific recommendations*

Critical Medicines Alliance (CMA)

- Relevant stakeholders to identify key challenges and propose solutions to address vulnerabilities
- To develop recommendations on industrial policy
→ long term solutions
- *Not product specific recommendations*



MSSG recommendations to address vulnerabilities in the supply chain

MSSG: regulatory measures / CMA: industrial policy measures

- MSSG may propose measures to address vulnerabilities and strengthen the security of supply of medicines included in the Union list
- Recommendations will be considered by the MSSG on a case-by-case basis, taking into account their proportionality, and will be tailored according to the identified vulnerabilities of the supply chain and the specific intrinsic characteristics of the product(s) in question
- Possibility to issue recommendations to the CMA
- Living document [published](#) on 23 April 2024



**Increase of the
manufacturing
capacity**



**Diversification of
the suppliers in
the supply chain**



**Inventory
management:
monitoring of
available stock,
supply and demand**



Safety stocks



**EU joint
procurements**



- **Regulatory obligations (SPP)**
- **Regulatory support**



**Incentives for
investment**



Next steps

- Evaluation of the results of HERA/DG GROW exercise on the vulnerability assessment to progress with the MSSG recommendations, if needed
- Ongoing discussion at the SPOC WP and MSSG



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Shortage Prevention and Mitigation Plans (SPMP)

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SPMP

- Recommendations of the “Good practices for industry for the prevention of human medicinal product shortages” published in May 2023
- Included in the proposal of the new pharmaceutical legislation
- The development of SPP is one of the elements of the upcoming revised pharmaceutical legislation that could be anticipated according to the Communication on addressing medicine shortages in the EU published by the European Commission on 24 October 2023



SPMP

- **Scope** (human medicinal products):
 - Mandatory in case of a crisis for medicines included in the list of crisis list of critical medicines according to Regulation 2022/123
 - Recommended for all medicinal products according to the good practice guidance
- **Objective:**
 - The SPP identifies possible risks in the supply chain (vulnerabilities in the supply chain) and includes proposals to manage those risks → preventive document
 - The SMP is produced to address potential or actual shortages and includes proposals to mitigate the impact of that specific shortage on patients → reactive document



- Deliverable of the HMA/EMA Task Force on Availability of Authorised Medicinal Products

First draft adopted by the Steering Committee on 27 November 2023



- SPOC WP consultation



- Industry consultation: written comments received and assessed



- Final adoption on 13 June 2024



- Publication on 18 June 2024



- Implementing guide under development



- Pilot
 - Scope under discussion (selection of molecules)
 - NAPs and CAPs
 - EMA and NCA involvement (SPOC WP, WP6/WP8 of CHESSMEN)
 - SPMPs will be requested actively during the pilot



Any questions?

Further information

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