



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Iniciativas europeias (CE/EMA): atividades em curso e nova legislação

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Reunião Anual do Conselho do Colégio de Especialidade de Assuntos Regulamentares da Ordem dos Farmacêuticos, 9 Novembro 2023

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Supply and Availability of Medicines and Devices, EMA



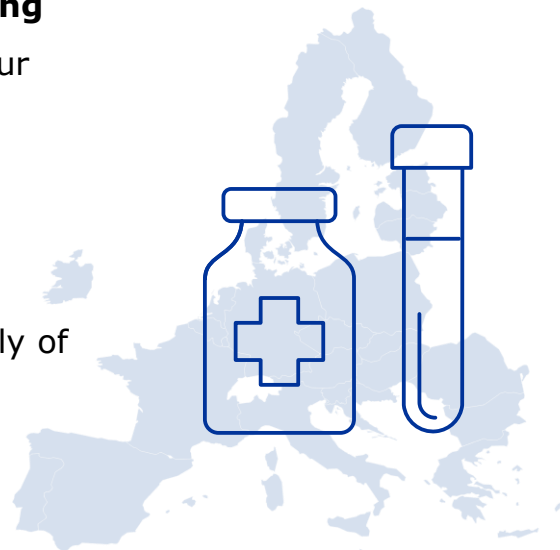


# Outline

- 1 Management of shortages in the EU
- 2 Availability of medicines: EU level coordination
- 3 EMA Extended Mandate: Monitoring and mitigating shortages of critical medicines
- 4 Preparedness activities: “toolkit”, case studies, and development of Union list
- 5 Reform of the EU’s Pharma Legislation
- 6 EC Communication on shortages (October 2023)
- 7 Conclusions

## Shortage management context

1. Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Agencies**
2. Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur
3. In December 2016, a joint **HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM)** was established to:
  - provide **strategic support** and advice to tackle disruptions in the supply of human and veterinary medicines and ensure their continued availability



## Key deliverables since 2016



- **Proposals to change the legislation** to improve shortage prevention and management



- Good practice for industry on **prevention of shortages** of medicines for human use



- Activities in the field of the **veterinary** sector

- Activities to increase **harmonization** within the EEA and with **international** partners



- Commitment to **transparency**



- Good Practice Guidance for **patient and healthcare professional organisations** on the **prevention of shortages**



- **Communication** to the **public** on medicines' availability issues

- Multi-Stakeholder Workshop (March 2023)

## Monitoring and mitigating **shortages of medicines** and management of public health emergencies/major events



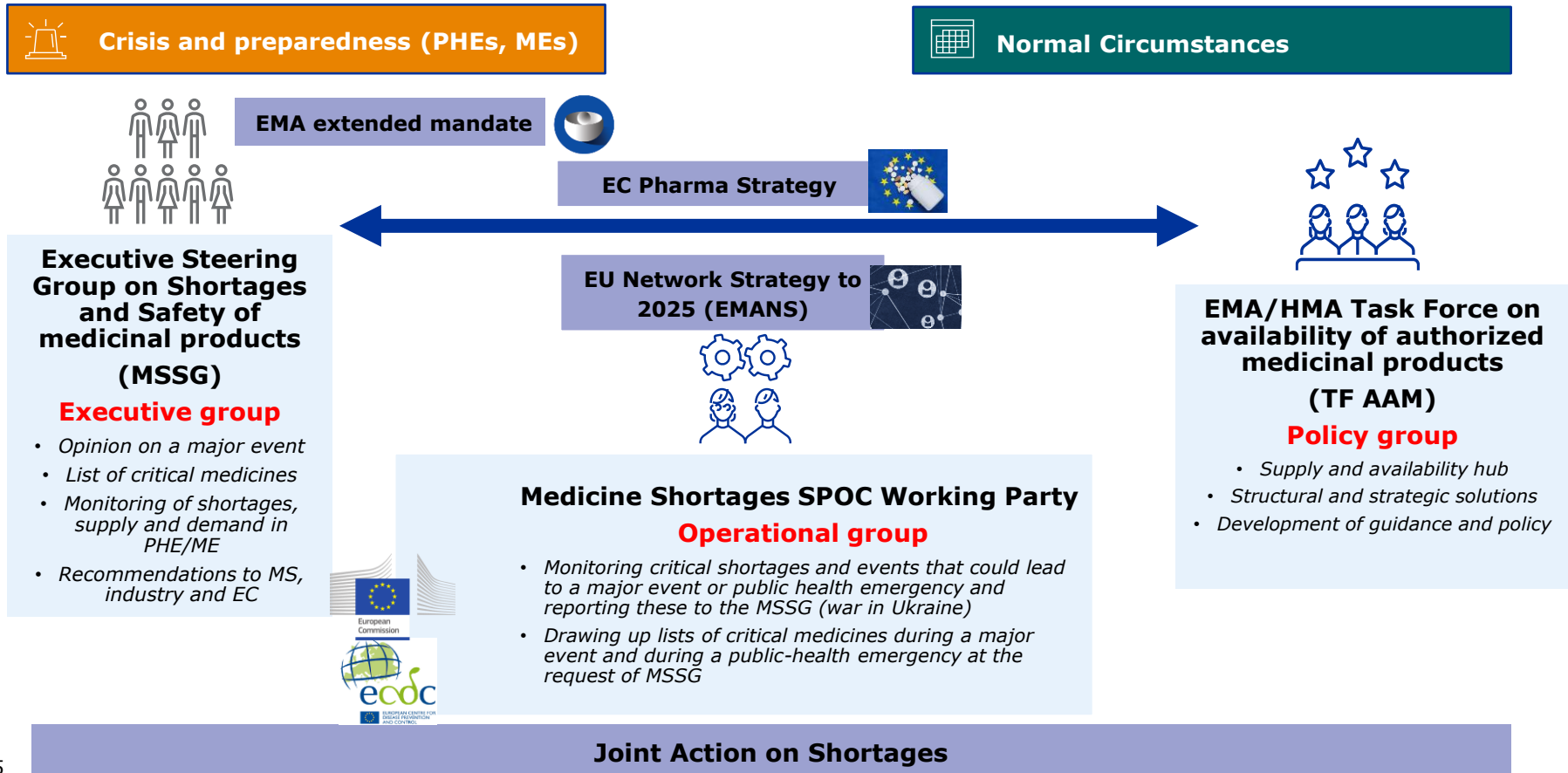
Regulation (EU) 2022/123 applicable **from 1 March 2022**

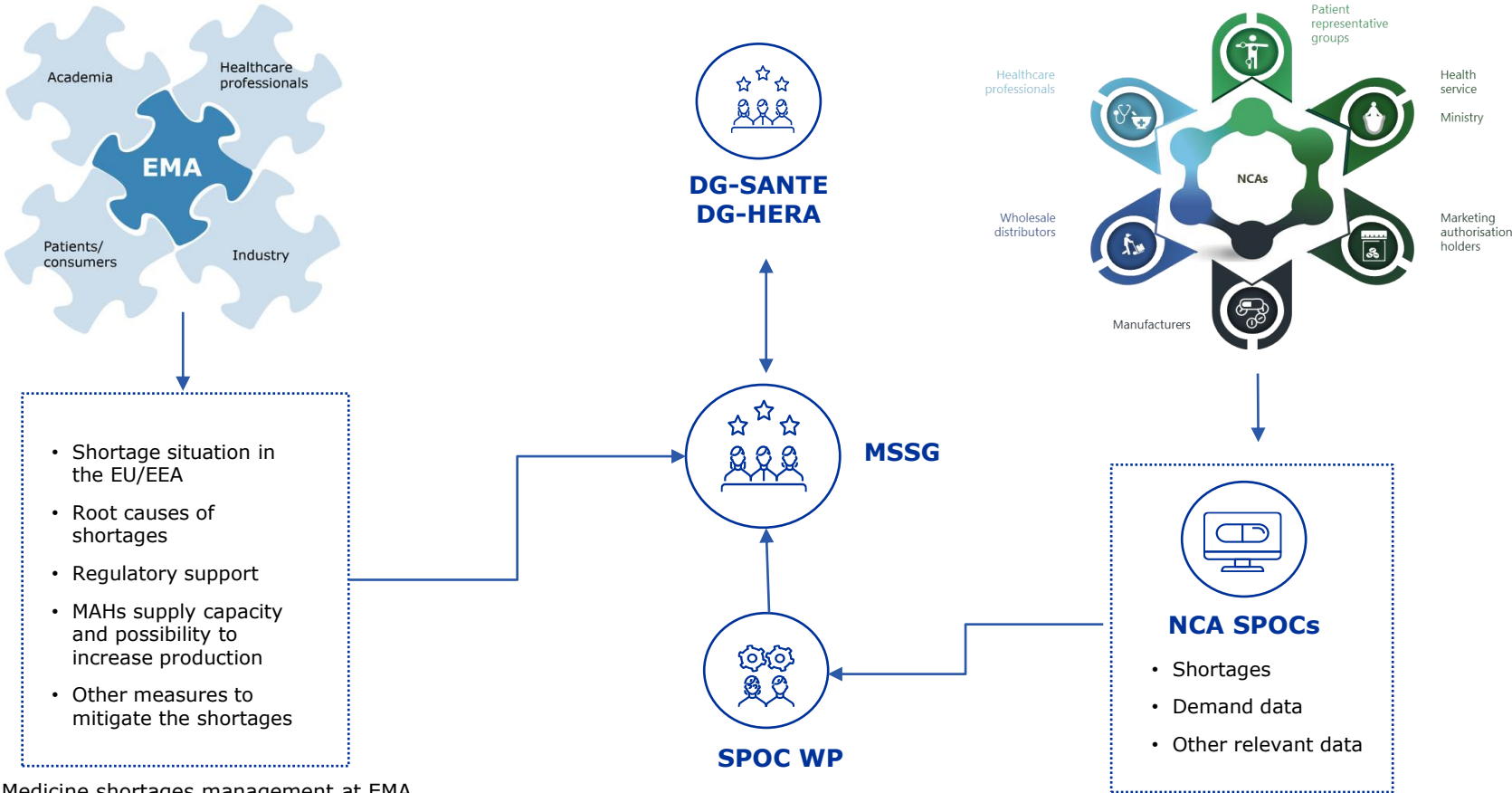
1. Provides a framework for activities established by the European Medicines Agency to monitor and **mitigate potential and actual shortages of medicines**
1. Sets processes/tools for shortages reporting and coordinates responses of EU countries to shortages of critical medicines (during a crisis) and for monitoring of events, including medicine shortages, which might lead to a crisis (public health emergencies or major events)
2. Establishes "**Medicines Shortages Steering Group**" (MSSG) supported by the SPOC **Working Party** and a Network of contact points from pharmaceutical companies (i-SPOCs)
3. Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by February 2025



### KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU



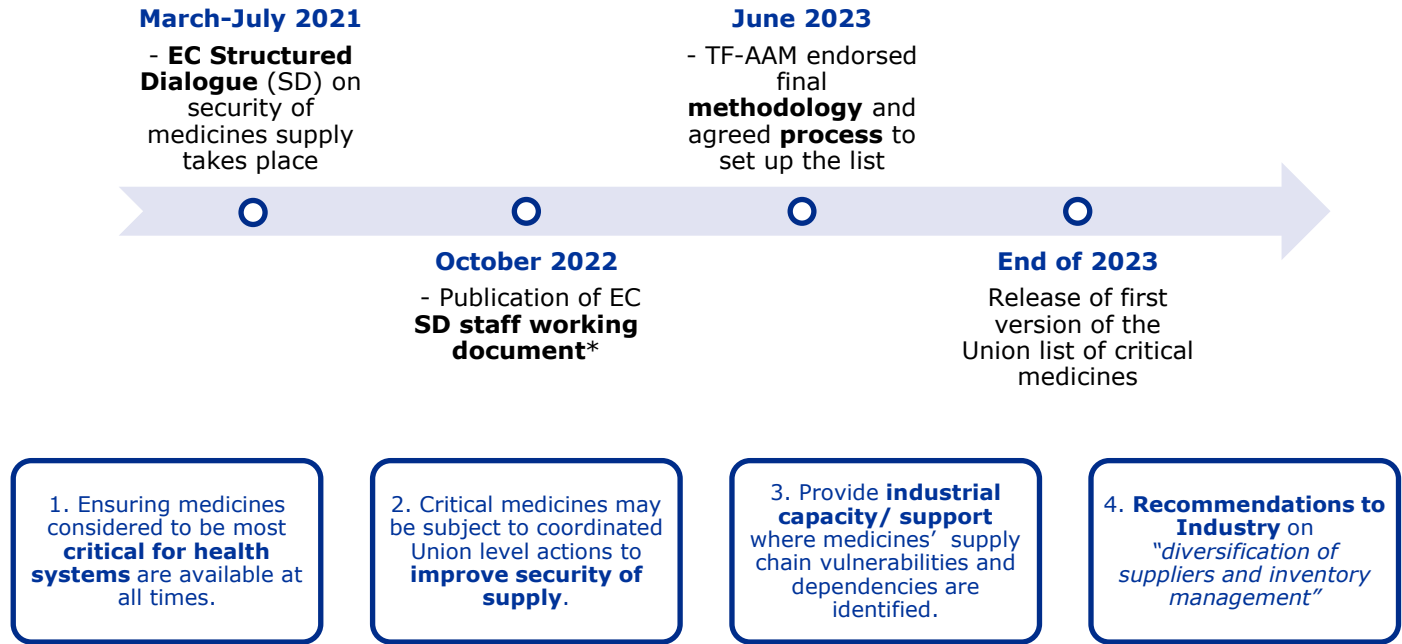


## Shortages of antibiotics & thrombolytics: measures undertaken

- **Engagement with MAH/manufacturers to agree possible mitigating measures**, incl. communication, increase manufacturing and supply, regulatory flexibilities, controlled distribution
- Central role of MSSG in **sharing best practices** (incl. **Toolkit** on mitigating measures)
- **Interaction** with other **stakeholders** in supply chain (wholesaler industry associations, HCP/PCs organisations) at EU and national level
- **Oral explanations** at SPOC WP and MSSG to highlight criticality of situation and for MSs to discuss directly with MAHs
- **Interaction with MAHs in 3<sup>rd</sup> countries** to secure extra products from those markets for the EU
- **Communication** to reassure the public & promote rational use of medicines in shortage e.g. [Joint EMA/EC/HMA public statement on shortages of antibiotic medicines](#)
- [EMA's shortages catalogue](#) updated with information to healthcare professionals and patients (e.g. amoxicillin/clavulanic acid, tenecteplase)



## Background, objectives and timelines





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Today we present once in a generation proposals to ensure medicines are accessible, available and affordable at all times for 🇪🇺 citizens no matter where they live. A Single Market for medicines delivering for citizens and keeps our industry as a 🌍 leader. #EUPharmaStrategy  
[pic.twitter.com/u5I5xRTtmT](https://pic.twitter.com/u5I5xRTtmT)



**Margaritis Schinas**

@MargSchinas

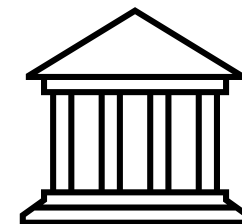


#EUPharmaStrategy is a Single Market for Medicines. Triple A: Access, Affordability, Availability. Triple C: Competitiveness, Compliance, Combatting antimicrobial resistance. An EU #HealthUnion with no 1st and 2nd class citizens, no MS left behind. [ec.europa.eu/commission/pre...](https://ec.europa.eu/commission/pre...)  
[pic.twitter.com/BJKV7yqPk3](https://pic.twitter.com/BJKV7yqPk3)



## **New EU pharmaceutical legislation proposal**

1. New requirements for monitoring of shortages of medicines by national authorities and EMA and a stronger coordination role for EMA.
2. Strengthened obligations on companies, earlier reporting of shortages and withdrawals of medicines and development of shortage prevention plans.
3. Establishment of an EU-wide list of critical medicines, assessment of supply chain vulnerabilities, mitigating measures taken by supply chain stakeholders.
4. Commission can adopt legally binding measures to strengthen the security of the supply of specific critical medicines.





## EC Communication (dated 24 October 2023): Securing medicines supply and preventing critical shortages

The Key actions from the non-legislative measures described include:

1. *Identifying and securing key antibiotics.*
2. *Launching a European Voluntary Solidarity Mechanism for medicines.*
3. *Establishing a Union list of critical medicines.*
4. *Providing regulatory flexibilities to allow medicines to reach patients timely.*
5. *Issuing EU guidance on medicines procurement.*

The screenshot shows the European Commission's press release page. At the top, there is the European Commission logo and the text 'European Commission'. To the right, there is a search bar and the text 'English EN'. Below the header, there is a navigation bar with 'Home > Press corner > Addressing critical shortages of medicines in the EU'. A language selector shows 'Available languages: English'. The main heading of the press release is 'Commission steps up actions to address critical shortages of medicines and strengthen security of supply in the EU'. Below the heading, there is a 'Page contents' section with links for 'Top', 'Quote(s)', 'Related media', 'Print friendly pdf', and 'Contacts for media'. The main text of the press release begins with 'The Commission has adopted today a set of actions to better prevent and mitigate critical medicine shortages in the EU, this winter, next winter and beyond. Recent critical shortages, including of certain antibiotics last winter, show that continued coordinated action is needed to address supply challenges and to make Europe's medicine supply chains more resilient in the long run. The key goals of today's Communication are to prevent and mitigate critical shortages at EU level. It puts a particular focus on the most critical medicines, for which security of supply in the EU must be ensured at all times.'

**23 October 2023:** [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_23\\_5190](https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190)

- EMA continues coordinating/managing shortages of centrally authorised medicinal products and **critical** shortages of nationally authorised medicinal products outside public health emergencies/major events (e.g. amoxicillin) under **preparedness activities**;
- Under the HMA/EMA TF AAM, EMA is developing a **Union list of critical medicinal products**
- IT development work on **ESMP** is underway to ensure delivery by early **2025**
- Shift from a reactive (management) approach to a **proactive (prevention) approach** to address shortages
- The European Commission's proposals for revising **the general EU pharmaceutical legislation** will also tackle the complexities of shortages.



# Thank you for your attention

## Further information:

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