



## HMA/EMA Task Force on Availability of Authorised Medicines (TF AAM)

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### **Implementation of the Good practice guide on prevention of shortages**

PCWP/HCPWP annual meeting 28 June 2023

EMA/724592/2022 Rev.1<sup>1</sup>

## Work programme until 2025 of the HMA/EMA task force on availability of authorised medicines for human and veterinary use

### 1. Background

Unavailability of medicines in the EU, either because medicines are not marketed or due to supply disruptions, has been recognised by HMA and EMA as an area of great concern<sup>2</sup> affecting all stakeholder groups. Indeed, problems with the availability of medicines have an impact not only on the supply chain but ultimately on healthcare systems, with a significant impact on end users. With respect to veterinary medicines, shortages may cause concern for animal health and welfare in cases where alternative medicines do not exist or are not marketed. As causes of unavailability are multifactorial, the solutions require actions at different levels and involve all stakeholders. An HMA-EMA task force was set up in 2016 to develop and coordinate actions that are necessary to facilitate prevention, identification, management and communication of shortages to ultimately ensure continuity in the supply of human and veterinary medicines. Its mandate has been renewed in December 2021 and will last until December 2025.

The Task Force will function as a "supply and availability hub" and will track progress of supply and availability activities that the European medicines regulatory network is undertaking under the following EU projects:

- the European Medicines Agency's network strategy to 2025
- the European Commission's Pharmaceutical Strategy for Europe
- the 'Joint Action on Shortages', a three-year plan, starting at the end of 2022, to enhance national systems in tackling medicines shortages in a harmonised way

### 2. Scope

The work programme covers centrally and nationally authorised products, both for human and veterinary medicines, in the following cases:

- when medicines are authorised but not marketed (or no longer marketed)
- when authorised and marketed medicines are affected by supply-chain disruptions that directly affect their availability.

<sup>1</sup> This document was modified on 7 October 2022 to clarify the duration of the mandate  
<sup>2</sup> EU Medicines Agencies Network Strategy to 2020  
[https://www.ema.europa.eu/en/documents/other/ema-network-strategy\\_08-november-2019\\_en.pdf](https://www.ema.europa.eu/en/documents/other/ema-network-strategy_08-november-2019_en.pdf)

See websites for contact details

Heads of Medicines Agencies [www.hma.eu](http://www.hma.eu)

The European Medicines Agency is



## Thematic working group 2: Communication

Actions	Timelines
<b>Improve coordination of information and actions for EU regulatory authorities, stakeholders and international partners</b>	
Finalise good practice guide for patient and healthcare professional organisations on the prevention of shortages	Q1 2022 – Completed and <a href="#">published</a>
Provide analysis of communication practices by national competent authorities on shortages	Q1 2022 - Completed
Enhance communication of supply problems to EU citizens, their representatives and HCPs	Q4 2022
Review of practices following publication of good practice guide	Q4 2024
In collaboration with thematic working group 1, explore good practice guide on prevention / management of shortages of medicinal products for veterinary use	Q4 2025
Monitor implementation of <a href="#">good practice guidance for communication to the public on medicines' availability issues</a> to the public by surveying national competent authorities	Continuous
<b>Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners</b>	
Organise a second multi-stakeholder workshop on stakeholders' perspectives and follow-up on the outcome of the first workshop	Q1 2023

# Good practice guidance for patients and healthcare professional organisations

13 May 2022  
EMA/397143/2020

## Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use

### 1. Introduction

Medicine shortages as well as availability issues due to revocations or cessations of marketing authorisations are recognised as a growing issue across the EU and globally, and the COVID-19 pandemic has further increased their impact. They affect medicines of all classes and are increasingly affecting European countries. This may have a significant impact on patient care as they can lead to medicine rationing and delay of critical treatments and can require patients to use alternatives which may be less efficacious or may increase the risk of medication errors due to unfamiliarity with the new regimen. The use of alternatives may also lead to adverse events caused by unexpected drug-drug interactions and to suboptimal treatment outcomes, which can lead to additional healthcare costs. Availability issues with shortages in particular are recognised as a major area to tackle in the European Medicines Agencies Network Strategy to 2025<sup>1</sup> as well as in the European Commission's roadmap for its Pharmaceutical Strategy – 'Timely patient access to affordable medicines.'<sup>2</sup> The European Commission's roadmap for its Pharmaceutical Strategy and the legal mandate to reinforce the role of EMA in supply shortages in times of crisis will also provide further opportunities to pursue full transparency for shortage information, especially during times of crises.

Supply chains are complex and involve many different stakeholders, from patients and healthcare professionals to the pharmaceutical industry. The causes of shortages are multifactorial, and can include manufacturing problems causing delays or interruption in the production, shortages of raw materials, increased demand of medicines, distribution problems, labour disruptions and natural disasters. Close involvement of stakeholders is a prerequisite for avoiding and handling shortages. In addition, a successful response to medicine shortages requires a multi-layered approach that includes detection, prevention and response strategies.

This paper focuses on proactive mechanisms to prevent shortages of medicines for human use. As patients and healthcare professionals are the main actors at the end of the supply chain, their activities in preventing shortages are usually limited to demand management strategies. This paper goes beyond standard demand management strategies and also looks at measures that help to improve preparedness, planning and rationed use for medicines that are either in short supply or expected to

<sup>1</sup> <https://www.ema.europa.eu/en/medicines/health-public-consultation-joint-network-strategy-2025>  
<sup>2</sup> [https://ec.europa.eu/health/ph\\_strategy/strategy/14224\\_pharmaceutical\\_strategy\\_timely\\_patient\\_access\\_to\\_essential\\_medicines\\_en](https://ec.europa.eu/health/ph_strategy/strategy/14224_pharmaceutical_strategy_timely_patient_access_to_essential_medicines_en)

be so in the near future. Such actions may not prevent a shortage at hand but may help to manage the impact of future shortages. Measures include improved communication and information flow, as well as measures to better handle the use of alternative medicines.

This guidance refers to medicines for human use only. Shortages referred to in this guidance are to be understood in the context of the harmonised definition agreed by EMA-HMA in the 'Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EUA)': 'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level'. The definition applies to all shortages that are already affecting or that are expected to affect one or more EU member states in the future. It applies to both prescription and non-prescription medicines.

Availability issues are wider than shortages and concern supply issues linked to revocations or cessations of marketing authorisations.

Most shortages and availability issues are managed at national level; some are managed at EU level. Processes for prevention of shortages and availability issues vary among member states and this document intends to review and consolidate existing practices into a single document, providing clear and harmonised guidance to stakeholders, promoting good practices and improving EU coordination.

#### 1.1. Purpose of the document

This document provides patients and healthcare professionals with key principles and examples of good practices (included as an annex) for shortage prevention and management. It is intended for guidance only. Implementation needs to consider national healthcare settings and regulatory frameworks in place at national level.

This document has been developed in the context of the HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use, which was set up in December 2016 to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and to ensure their continued availability. The document does not address commercial activities such as pricing of medicines because this is outside the remit of the Task Force.

The recommendations given in this document have been developed following a review of current practices across the EU, in consultation with representatives of 'healthcare professionals' and 'patients' organisations, taking into account other published frameworks for the management and prevention of medicine shortages. These practices are presented in more detail in the annex (section 2).

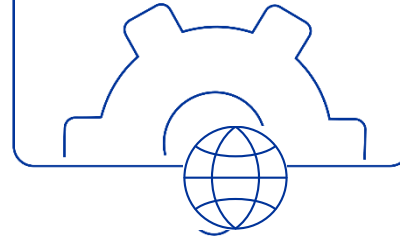
The document aims to promote good practice by:

- Enhancing and exploring current practices for prevention;
- Increasing visibility and accessibility of information on existing practices for prevention;
- Fostering interaction and improving information exchange between the different stakeholders.

#### 1.2. Key recommendations for good practice for patient and healthcare professional organisations

The recommendations below have been drawn up based on consultation with member organisations of the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP). They are based on existing practices and initiatives in individual countries or organisations where the recommendations have been implemented often in isolation. The recommendations include general principles for patient and healthcare professional organisations and should be considered as a

- Enhancing practices for prevention;
- Increasing visibility on existing practices;
- Fostering interaction and improving information exchange between the different stakeholders.



# Recommendations

- **Shortage observatories**
- Key messages, **education** campaigns and guidance
- **better access** to data and promote **awareness**
- **Risk assessments** for medicines with high clinical impact
- Guidance on **safe compounding** of medicines in short in supply
- Improving **communication** tools within the supply chain
- Guidance on **dose sparing measures**



# Good Practice guidance for industry



28 February 2023  
EMA/760980/2022

Good practices for industry for the prevention of human medicinal product shortages



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- Published in May 2023
- Gives ten recommendations for marketing authorisation holders, wholesalers, distributors and manufacturers including:
  - early notification to [national competent authorities](#);
  - establishing robust shortage prevention and shortage management plans;
  - optimising pharmaceutical quality systems and increasing resilience of complex, multinational supply chains;
  - timely communication between stakeholders in medicine supply chain;
  - general principles to promote fair and equitable distribution of medicines

# EMA campaign

What can you do when it comes to **shortages of medicines?**



Ask your doctor for **information** about any **medicine** you may receive as an **alternative**



**Don't ask** your doctor or pharmacist for **more medicines than you need.**



Consult the available **catalogue** on medicine shortages regularly



# Factsheet

Infosheet:

## Towards better prevention of medicine shortages

EMA has published key principles and examples of good practices to support patients' and healthcare professionals' organisations in preventing and managing shortages of human medicines.



What **patients' organisations** can do to prevent shortages of medicines

Develop **observatories** in collaboration with national authorities to **collect and analyse information** from patients on shortages and their early signs.

Work with national authorities to develop criteria and a methodology for **registries of essential and critical medicines**.

**Communication and awareness raising** among members on causes of shortages, the safe use of alternative medicines, risks of stockpiling and where to find information on ongoing shortages.

What **healthcare professionals' organisations** can do to prevent shortages of medicines

Develop **observatories** in collaboration with national authorities to **collect and analyse information** from healthcare professionals on shortages and their early signs.

Work with national authorities to develop criteria and a methodology for **registries of essential and critical medicines**.

**Communication and awareness raising** among members on causes of shortages, the safe use of alternative medicines, risks of stockpiling and where to find information on ongoing shortages.

Work with national authorities to ensure **reporting, electronic prescribing and alert systems are linked up** to minimise workload and optimise information flows.

Promote **transparency in the supply chain** so pharmacists can identify alternative suppliers more easily.

Collaborate with health authorities to put in place measures to **avoid stockpiling of medicines**, when needed.

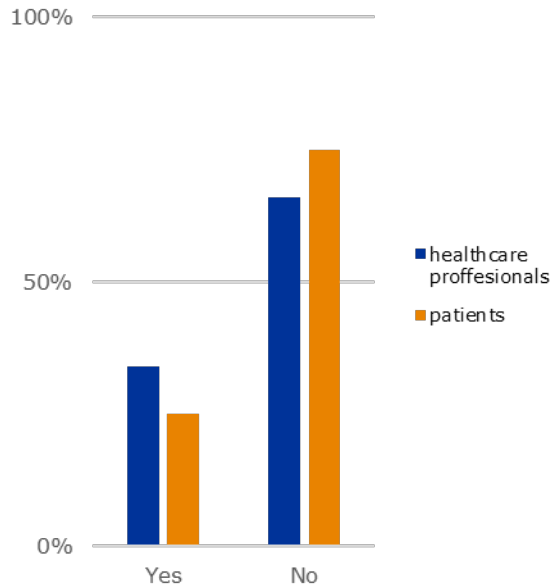
Liaise with health authorities to issue guidance on **dose-sparing measures**.

Encourage healthcare professionals to carry out shortage **risk assessments** for medicines with high clinical impact.

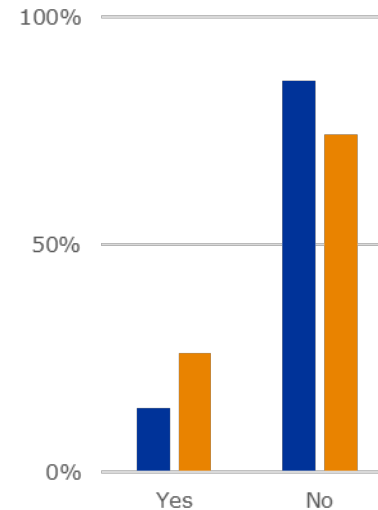


# Awareness of guidance amongst eligible patients and HCPs

**Are you aware of the Good practice guidance on the prevention of shortages of medicines?**



**Have you implemented or are you planning to implement any actions of the guidance?**





# Actions in work programme until 2025

## Review of practices following publication



Raise awareness and promote



Collect feedback on initiatives  
and use



Need for update/ improvements

## CHESSMEN – Joint Action

Coordination and Harmonisation of the Existing Systems against Shortages of Medicines, European Network

- Brings together 22 EU Member States
  - Several work packages including best practices on communication and prevention
  - To give support for a harmonized response to mitigate shortages
  - Collaboration to increase implementation and increasing awareness of guidance
- Important for reach and implementation at national level. Collaboration between taskforce and Joint Action
  - More information: <https://www.ja-chessmen.eu/>



## Follow-up questions

- Have you used the recommendations of the guidance?
- Have you promoted the guidance amongst your members?
- What specific initiatives would you welcome from EMA to help with implementing it further (i.e. factsheets and support material to support campaigns for example)?
- Would you welcome a discussion in a small group with regular follow-up at WP?



# Any questions?

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See websites for contact details

**Heads of Medicines Agencies** [www.hma.eu](http://www.hma.eu)  
**European Medicines Agency** [www.ema.europa.eu](http://www.ema.europa.eu)

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