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

Subgroup on implementation of the Good practice guide on prevention of shortages

PCWP/HCPWP meeting 3 July 2024

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Prevention of shortages - Good practice guidance for patients and healthcare professional organisations

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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 20251 as well as in the European Commission's roadmap for its Pharmaceutical Strategy - Timely patient access to affordable medicines.2 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

[1] https://www.ema.europa.eu/en/news/launch-public-consultation-joint-network-strategy-2025
[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines

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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 (EEA)": "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

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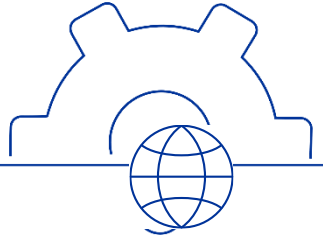
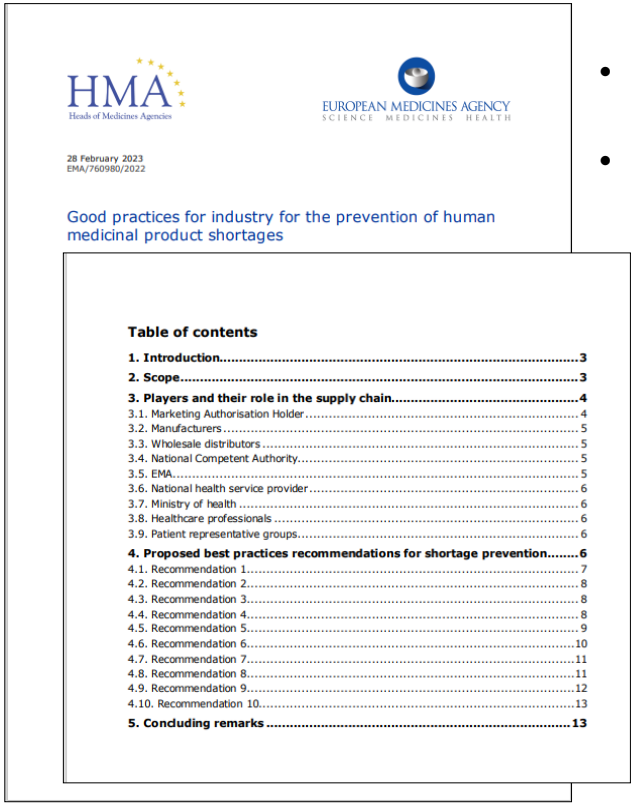
- Enhancing practices for prevention;
- Increasing visibility on existing practices;
- Fostering interaction and improving information exchange between the different stakeholders.



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

Table of contents

- Published in May 2023
- 10 recommendations for marketing authorisation holders, wholesalers, distributors and manufacturers:
  - Early notification to national competent authorities;
  - Shortage Prevention Plans and Shortage Management Plans;
  - Optimising pharmaceutical quality systems and increasing resilience of complex supply chains;
  - Timely communication between stakeholders in medicine supply chain;
  - Promotion of fair and equitable distribution of medicines

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

Subgroup discussion

Subgroup with patients and healthcare professionals (EAP, ERS, PGEU, EPF, Thalassaemia Association, European Heart Association, EAHP)

Aim: Discuss implementation of guidance and review practices

Meeting on 7 March with discussion on:

- Ongoing new initiatives
- How to increase awareness
- Needs of organisations

Outcome of subgroup discussion

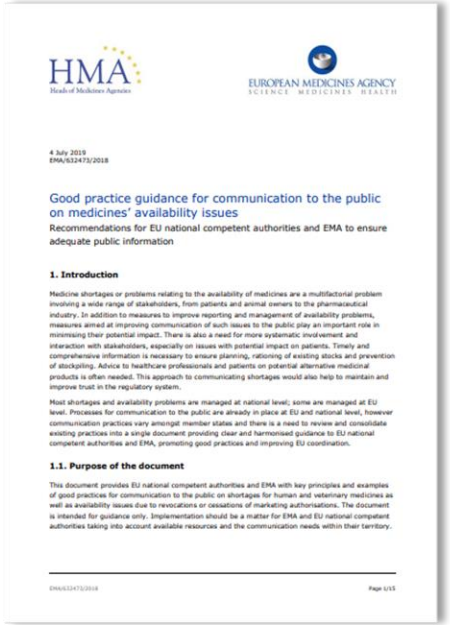
- Update of initiatives and recommendations
- Translation of factsheet
- Webinar as opportunity to illustrate real-life examples and to inform about shortages management and promote new initiatives

Webinar and other inititaives

- Planned EMA campaign on shortages:
  - General narratives on shortages
  - Infographics/webpage/EMA corporate video
  - Media seminar
  - Co-created social media campaign with eligible organisations
- Webinar could take place in Q4 2024 together with co-created campaign Q4 2024
- Questions: do you support the idea of a webinar?
- Would you like to be involved? Please provide real-life examples from you and your members?

Communication to the public on shortages - good practice guidance

- Reflection on role of media following recent experiences.
- Review reflects role of media in influencing people's behaviour. Need to engage to ensure information in media is appropriately framed.
- Key facts to highlight to journalists about shortage management.
- Role of social media and need for social media listening to pick up concerns and false narratives.
- Consider collaboration with carefully selected influencers to raise awareness and educate citizens.



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EUROPEAN MEDICINES AGENCY
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EMA/632473/2018

Good practice guidance for communication to the public on medicines' availability issues

Recommendations for EU national competent authorities and EMA to ensure adequate public information

1. Introduction

Medicine shortages or problems relating to the availability of medicines are a multifactorial problem involving a wide range of stakeholders, from patients and animal owners to the pharmaceutical industry. In addition to measures to improve reporting and management of availability problems, measures aimed at improving communication of such issues to the public play an important role in minimising their potential impact. There is also a need for more systematic involvement and interaction with stakeholders, especially on issues with potential impact on patients. Timely and comprehensive information is necessary to ensure planning, rationing of existing stocks and prevention of stockpiling. Advice to healthcare professionals and patients on potential alternative medicinal products is often needed. This approach to communicating shortages would also help to maintain and improve trust in the regulatory system.

Most shortages and availability problems are managed at national level; some are managed at EU level. Processes for communication to the public are already in place at EU and national level, however communication practices vary amongst member states and there is a need to review and consolidate existing practices into a single document providing clear and harmonised guidance to EU national competent authorities and EMA, promoting good practices and improving EU coordination.

1.1. Purpose of the document

This document provides EU national competent authorities and EMA with key principles and examples of good practices for communication to the public on shortages for human and veterinary medicines as well as availability issues due to revocations or cessations of marketing authorisations. The document is intended for guidance only. Implementation should be a matter for EMA and EU national competent authorities taking into account available resources and the communication needs within their territory.

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Next steps in ongoing consultation

- Consultation with EMA/HMA taskforce on availability of medicines for human and veterinary use
- Consultation with PCWP/HCWP

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

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