HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

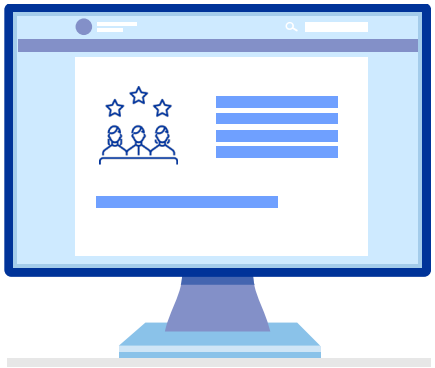
Session 5: Communication and transparency

TFAAM workplan

HMA/EMA Multi-stakeholder workshop on shortages, 1st and 2nd March 2023

Presented by Inga Abed and Juan Garcia Burgos
Stakeholders and Communication Division - European Medicines Agency

Introduction



- What has been done so far?
- Good practice guidance on communication for EU/EEA authorities
- Improving communication and transparency at EU level: EMA shortage catalogue
- Actions in work programme until 2025

Setting the scene

Compared to 2016, environment has changed:

Communication key aspect of work of taskforce:

- improving access to information on shortages
- enhancing interaction and communication with stakeholders

New opportunities with EMA's extended mandate which brought new tools to deal with shortages, revision of pharmaceutical legislation

New challenges with increase in shortages since COVID-19

Shortages are on everyone's mind – communication and transparency are more important than ever.

Timely information essential to:

- avoid treatment interruption
- ensure switch to alternative in time
- give necessary training

Information should be appropriately framed to avoid undue alarm

Open and **transparent** communication between regulators, healthcare professionals and patients to:

- improve preparedness
- lessen impact of shortages
- help to maintain and improve trust in the regulatory system.

What has happened since 2016?

- Collaboration and exchange of practices led to guidance defining good practice for communication and transparency
- The guidance laid foundation for increased transparency across EU/EEA
- We have come a long way since over the last 7 years but more work needs to be done

4 July 2019
EMA/619472/2018

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

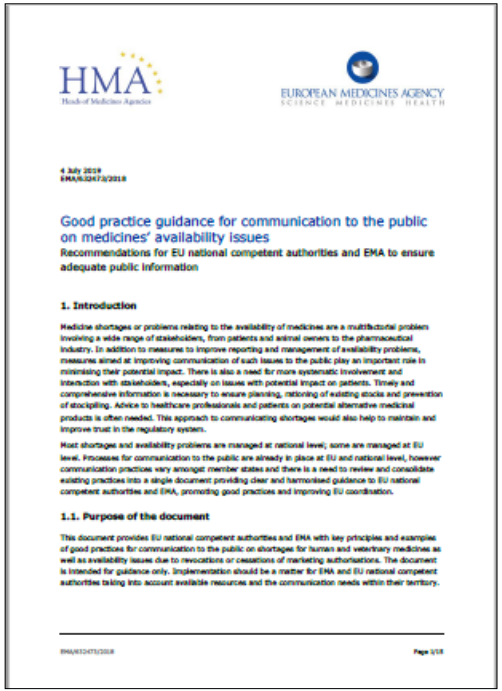
This document provides EU national competent authorities and EMA with key principles and examples of good practices for communication to the public on shortages for human and veterinary medicines as well as availability issues due to revocations or cessations of marketing authorisations. The document 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.

EMA/619472/2018 Page 1/18

Good practice guidance on public communication

Increase visibility and accessibility of information on availability on medicines

More interaction with stakeholders



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Allow timely access to up-to-date information

Multi-disciplinary approach within regulatory body

Align criteria for publication across EU network

Good practice guidance on public communication

Target audience

- Primarily HCPs, veterinarians, patients and animal owners (general public)
- Public friendly language

Tools

- Systematic listing for shortages
- For high profile issues consider tools with more visibility (i.e press releases)
- Similar information for withdrawals and suspensions but in separate listing

Timing of publication

- Important to allow for planning and continuity of care

Involvement of stakeholders

- Early involvement is key

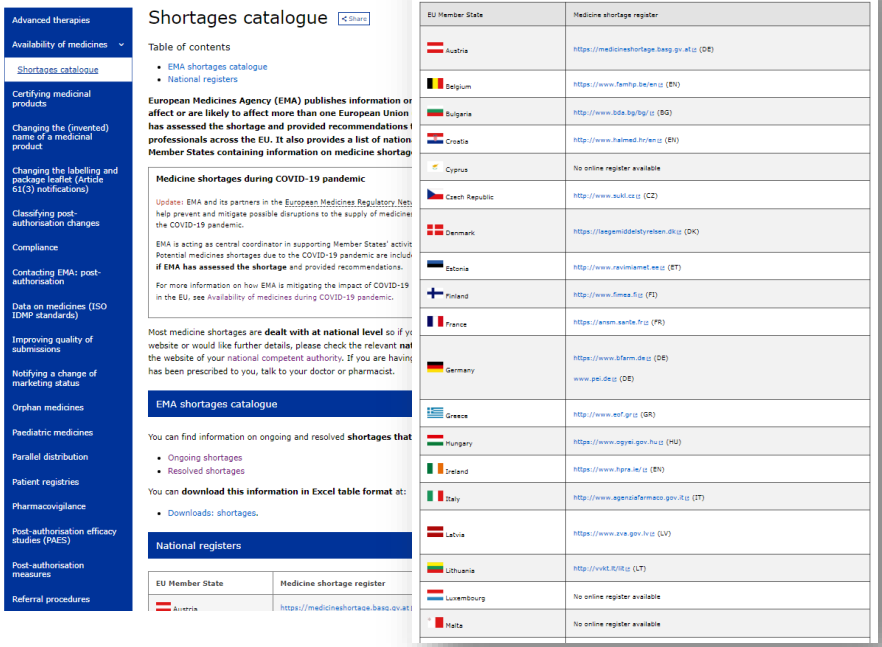
Guidance based on existing practice

Dissemination

- Organisations' channels
- Professional/medical journals
- Media (incl. social media)
- Newsletters
- Electronic prescribing systems

EMA shortages catalogue

- Set up in 2016
- Linked to catalogues in the EU/EEA
- EU/EEA coverage of catalogues gradually increased over the years



Actions in work programme until 2025

Provide analysis of communication practices by national competent authorities on shortages

Surveys in 2018 and 2020

Analysis shows increase in transparency across EU/EEA

Catalogues for **human** medicines:
74% (2018) and 81% (2020)

For **veterinary** medicines:
27% (2018) and 40% (2020)

Human medicines:

Around 50% of regulatory agencies have implemented or plan changes.

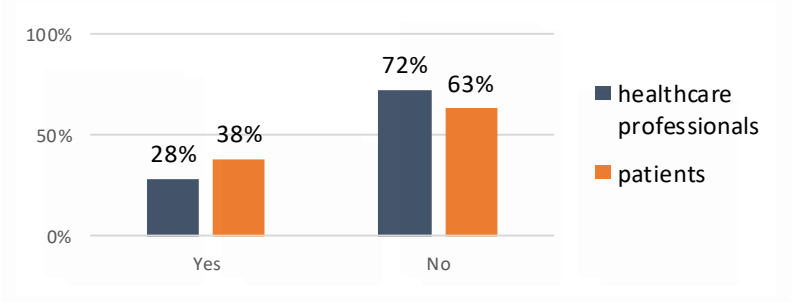
For **veterinary** medicines:

Around 41% of regulatory agencies have implemented or plan changes.

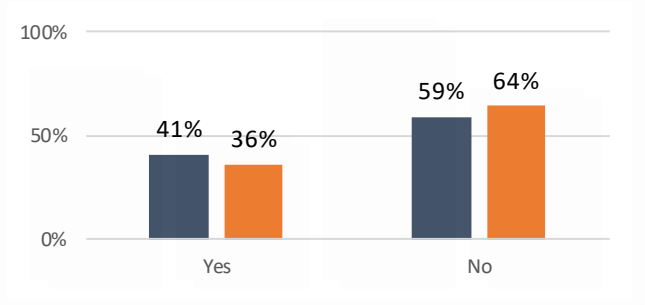
Further changes possible to provide more information (e.g. on alternatives and causes)

Results of 2022 survey with eligible patients and healthcare professionals

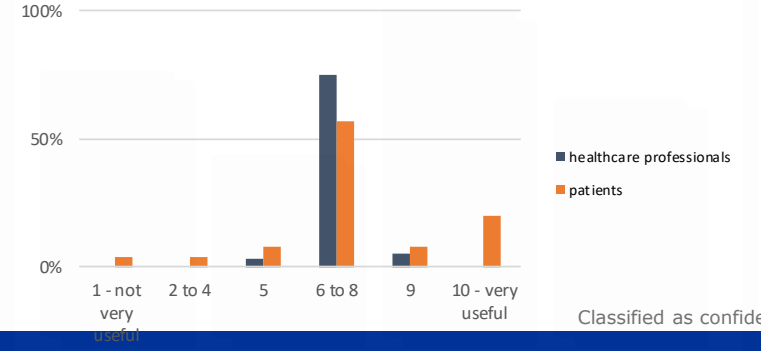
Are you aware of EMA's catalogue of shortages or national shortage catalogues



Do you feel that information on shortages provided from regulatory authorities has improved in the last 2-3 years?



How useful do you find EMA's catalogue of shortages and your national shortage catalogue?



35%

of patients and healthcare professionals felt that information was missing (alternatives and cause of shortages)

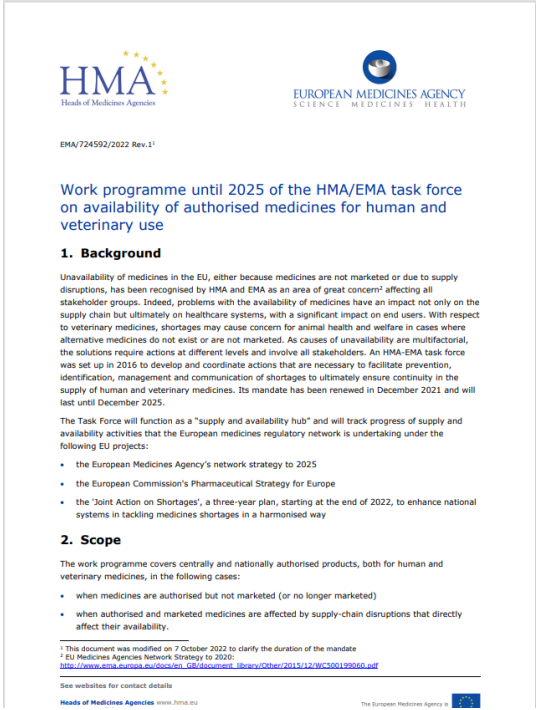
Actions based on work programme until 2025

Promote and monitor implementation of guidance

Enhance communication of supply problems

Intensify stakeholder interaction

Collaborate with Joint Action on shortages



EMA/724592/2022 Rev.1[1]

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[2] 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.

[1] This document was modified on 7 October 2022 to clarify the duration of the mandate
[2] EU Medicines Agencies Network Strategy to 2020:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf

See websites for contact details

Heads of Medicines Agencies www.hma.eu

The European Medicines Agency is

Enhance transparency and communication at EU level

Need to communicate better on the work done at EU level to prevent and manage shortages

Transparency: earlier publication of minutes and highlights at EMA level

Communication: more information on key shortages (extend scope of EU shortages catalogue)

Need for honest, open communication to foster trust

Need to frame information appropriately to avoid stockpiling (stockpiling not an argument for limiting transparency)

Good practice guidance for patient and healthcare professional organisations on the prevention of shortages

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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[1] 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 crisis.

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-ema-network-strategy-2025

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13452-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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Many important aspects of communication are addressed in guidance.

Importance of campaigns to raise awareness

How to avoid worsening of shortages

Where to find info on specific shortages

How organisations and individuals can 'report' information on shortages

Conclusion

- Information on shortages has become more accessible across the EU/EEA over the years (e.g. catalogues of shortages are routinely published).
- However, more needs to be done.
- Enhance information on EMA's catalogue and overall transparency (e.g. minutes, highlights).
- Continue promoting and monitoring good practice and assessing information needs of patients and healthcare professionals.

Any questions?

See websites for contact details

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

The European Medicines Agency is an agency of the European Union