



Network priorities to 2025: TF AAM workplan

Session 3 – Prevention of shortages Multi-stakeholder workshop on shortages

Presented by Maria Alcaraz on 2 Mach 2023 Co-Chair TWG1 Supply and Availability of Medicines and Devices - EMA







Agenda





Work programme to 2025 – Prevention of shortages



Good practice guidance on prevention on shortages





TF AAM: Activities to 2025



- TF AAM with mandate extended to 2025
- Two working groups of task force:
 - TWG1- Availability and Supply Disruptions
 - TWG2 Communication
- Dedicated activities reflected in work programme
- Adopted:
 - Steering Committee on 28 January 2022
 - HMA on 6 May 2022
 - EMA-MB on 16 June 2022
- Published on <u>EMA/HMA</u> website







TF AAM: Work programme to 2025 - prevention of shortages



Interaction with stakeholders



Communication



Activities in the field of veterinary section

Activities to increase harmonization within the EEA and with international partners





Work programme to 2025 - prevention of shortages



Analysis of recommendations listed on the EC report on the root causes of shortages and identify possible prevention activities

For Vets: analysis of results of the EC study on shortages of human medicines to explore if the root causes of shortages are similar for shortages of veterinary medicines, and if actions for human medicines could be adapted for veterinary medicines



Proposals to change the legislation to improve prevention and management of shortages



Pilot projects



Implementing guide to harmonize criteria to improve the management of shortages and their prevention





Good practice guidance for patients and healthcare professional organisations





13 May 2022

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

1. Introduction

Medicine hortrages as well as availability issues due to revocations or resistance 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 articing furupers countries. This may have a splintactive impact or pagelet care as they affecting furupers countries. This may have a splintactive impact to pagelet care as they are recognised as regiment. The use of literathysters may also detail of a solid pagelet care story the area of the regiment. The use of literathysters may also det to deverse events caused by unexpected drug-drug interactions and to suboptimal treatment controllers, which can lead to additional healthcare costs. Availability issues with softenges in participation are recognised as an angle rare to tacked from developed to the page of the commission's readmay for a Primareculation Servicely. "Timely patient access to affordate in englere at to tacked in the European Medicines Agencies Network Strategy to 2025 is set set as in the European Commission's readmay for a Primareculation Strategy." Timely patient access to affordate in enderine 2 The European for the Participation of the European Commission's readmay for a Primareculation Strategy. Timely patient access to affordate in enderine 2 The European Commission's readmay for a Primareculation Strategy in the Primareculation Strateg

Supply chains are complex and involve many different stakeholders, from patients and healthcare professionals to the pharmacouscial inclusive. The caused of shorteges are multifactivity, and can include manufacturing problems causing delays or interruption in the production, shorteges of raw materials, increased deformed of medicines, distribution problems, labour disruptions and natural distasters. Close involvement of stakeholders is a prerequible for avoiding and handling shortages. In distasters, Close involvement of stakeholders is a prerequible for avoiding and handling shortages. In distasters, Close involvement of stakeholders is a prerequible for avoiding and handling shortages. In distance, the control of the contr

This paper focuses on proactive mechanisms to prevent shortapes 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 shortapes 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 rational use for medicines that are either in short supply or expected to

<u>Intra://www.ema.europa.eu/on/news/faunch-oublic-consultation-loint-natwork-strategy-2025</u>
<u>https://www.ema.europa.eu/info/law/hatter-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines</u>

A/397143/2020

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. Stortages referred to in this guidance are to be understood in the content of the humonised definition agreed by 8AM-84M in the "Colladance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MRS) in the United (ESE)." 3 Abstrages of a medicinal product of human or verterinary use occurs when supply does not meet cleamed at a national level." The definition applies to all shortages that are views uponly does not meet cleamed at a national level." The definition species to all shortages that are to both prescriptions 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 tacked disruptions is supply of human and veterinary medicines and to ensure their continued availability. The document does not address commercial activities such as original off medicines because this is, onlight 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 (PCWP). 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 peneral principles for patient and healthcare prefessional organisations and sould be considered as a

7143/2020

- 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







Actions in work programme until 2025

- Review practices following publication of guidance
- · Initial feedback suggests limited awareness and implementation
- Discuss with patient and HCP representatives how to raise awareness and promote implementation
- Collect feedback on initiatives and use of the prevention guide and how this can be improved
- Link to existing initiatives





Reporting of shortages to EMA by patient and healthcare professional organisations at EU level

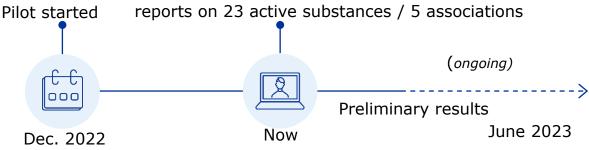
Pilot to explore added value of shortage reports from eligible EU patient and healthcare professional organisations at EU level to EMA



For shortages affecting one or more EU member states and where medicine in question is critical or



In context of public health emergency, any information that could indicate an upcoming shortage







Good practice for industry on prevention of shortages of medicinal products for human use

SCOPE

- Good practices on shortage prevention to the key stakeholders involved in the medicines supply chain to reduce the likelihood of shortages
- Recommendations on how to mitigate a shortage event are also included.
- Describes some of the most common reasons for shortages (not exhaustive)
- NOT: commercial activities (pricing of medicines) and the clinical specifics of patient treatment

in the event of a shortage

• Ongoing discussion for veterinary medicinal products / dedicated session

Key players and roles in the supply chain







Optimisation of current systems

1. Earlier notifications

2. Increased transparency

3. Increase accuracy

10 recommendations

Prevention and mitigation strategies

- 4. Shortage prevention plan
- 8. Improve communication
- 5. Shortage management plan
- 9. Fair & equitable distribution

- 6. Optimisation of PQS
- 7. Increase resilience

10. Steps to minimise the risk of parallel trade or exports exacerbating shortages





Good practice for industry on prevention of shortages of medicinal products for human use



Drafting process

- TWG1
- TWG2
- Steering Committee



Document presented to industry associations



Written consultation



Comments received



Next steps

-)
- mmittee September 2022

· Initial feedback



October 2022

- Affordable Medicines Europe
- EFPIA
- EIGA
- · Europa Bio
- GIRP
- · Medicines for Europe







Good practice for industry on prevention of shortages of medicinal products for human use – Main comments received

Scope

Pricing & reimbursement - Affordability

Commercial reasons

Shortages of raw materials/APIs/excipien ts/other components

Harmonization

Definition of shortage

Harmonization on reporting

SPMP

Critical medicines

Roles / responsibilities

Wholesalers

Parallel traders

Other

Regulatory flexibilities

Digital transformation, ePI





Good practice for industry on prevention of shortages of medicinal products for human use



- Develop best practice guide on prevention / management of shortages of medicinal products for veterinary use
- Joint good practice for HCP/patients organisations and industry on the prevention of shortages
- ➤ SPP → future action





Thank you for listening

Further information

See websites for contact details

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

