HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

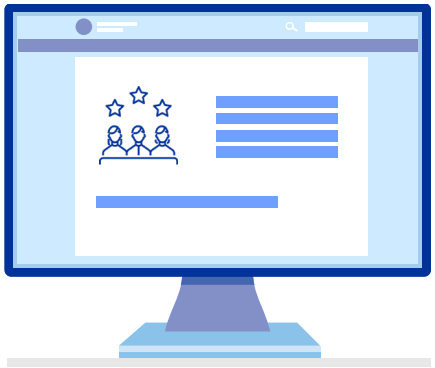
HMA/EMA Task Force on Availability of Authorised Medicines (TF AAM)

Update on EU guidance on shortage prevention and communication to the public

PCWP/HCPWP annual meeting 15th November 2022

Presented by Inga Abed, Stakeholders and Communication Division, European Medicines Agency

Introduction



- What are these guidance documents?
- Why are they relevant for patients and healthcare professionals?
- Results of survey
- Next steps and preparation for the workshop

Good practice guidance for EU authorities on public communication

30 October 2018
EMA/632473/2018

Best practices for communication on medicines' availability issues

Recommendations to EU regulatory authorities 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 to the pharmaceutical industry. In addition to measures to improve reporting and management of problems with availability, measures aimed at improving communication of availability issues 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 consistent information is necessary to ensure good 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 help to maintain and improve trust in the regulatory system.

Most shortages are managed by national agencies or authorities; some are managed at EU level. Processes for communication 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 regulators, promoting best practices and improving EU coordination.

1.1 Purpose of the document

This document provides EU regulatory authorities with key principles and examples of best practices for communication to the public on shortages and availability issues for human medicines[1]. It is intended for guidance only. Implementation should be done taking into account available resources.

It aims to promote best practice by:

[1] At present this guidance applies to human medicines and a similar guidance to address veterinary medicines is currently under preparation.

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- Enhancing current communication practices and ensuring a multidisciplinary approach within regulatory authorities
- Aligning criteria for publication across EU network
- Increasing visibility and accessibility of information on availability on medicines.
- Fostering interaction with stakeholders.

This document is based on the results of a survey of all EU member States carried out by the HMA-EMA task force to collect information on how issues related to shortages and availability of medicines are measured and communicated.

The guidance addresses the following areas:

- *Who* should communicate
- *Who* is the target audience
- *Which* format or tools
- *What* information to be published
- Timing of publication
- *How* to involve stakeholders in the preparation and dissemination of information
- *Internal* collaboration
- *Examples* of communication and interaction with stakeholders

Shortages referred to in this guidance are to be understood in the context of the definition agreed by EMA-HMA.

1.2 Summary of recommendations

Recommendations for best practice	
Public communication practices by regulators	**EU regulatory authorities** should communicate on: • **shortages** of medicines within their territory (nationwide issues rather than local issues). Ideally regulatory authorities should not apply selection criteria for publication and should communicate on any nationwide shortage. In some instances, this communication may complement information issued centrally by EMA. • **revocation** or **suspension** of medicines within their territory • **cessations of marketing authorisations** in their territory

Best practices for communication on medicines' availability issues
EMA/632473/2018 Page 2/10

Key principles and examples of good practices for communication to the public on shortages and availability issues for human medicines

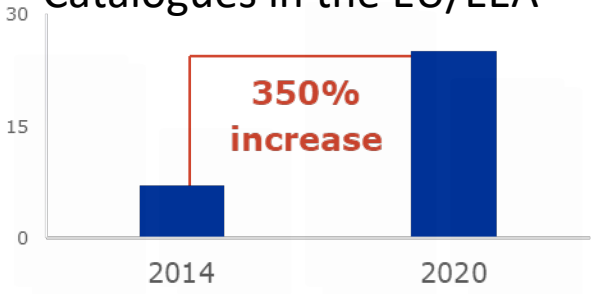
What does the guidance cover?

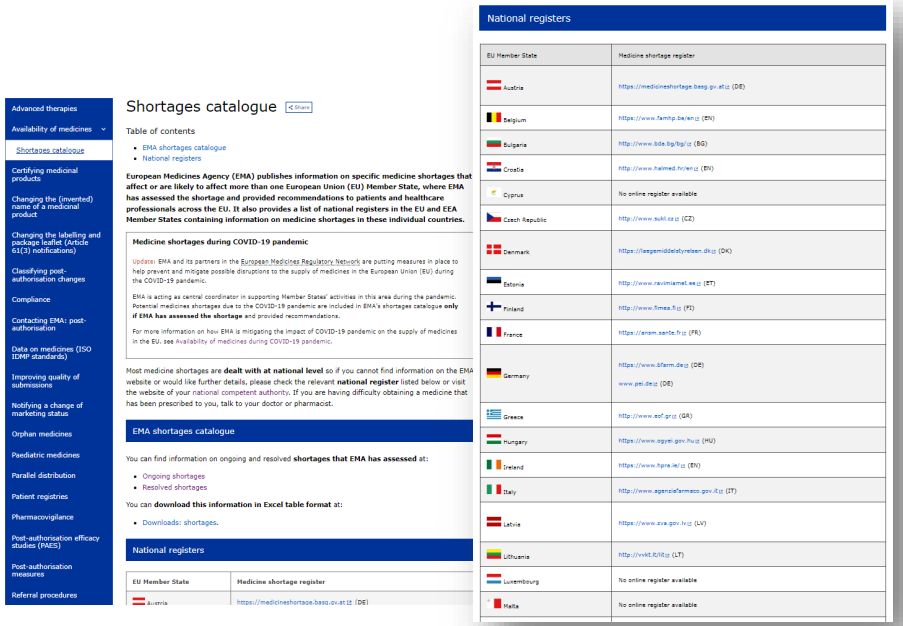
- **Who** should communicate on shortage?
- Who is the **target** audience?
- Which **format** and communication tools?
- **What** information and when to publish?
- **How** to involve stakeholders?

3

Shortage catalogues

- Calls by organisations for timely alerts and allow for efficient planning
- Gradual increase of information on shortages
- Catalogues in the EU/EEA





Good practice guidance on prevention of shortages

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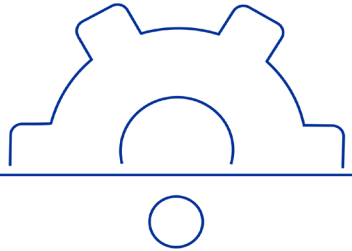
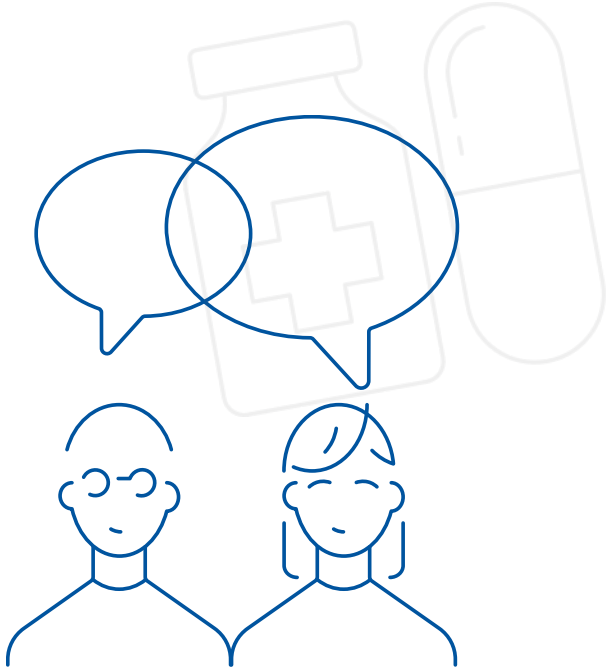
- Enhancing practices for prevention;
- Increasing visibility on existing practices;
- Fostering interaction and improving information exchange between the different stakeholders.



Recommendations for Patient and healthcare professional organisations

- Shortage observatories that **collect and analyse information on shortages**
- Obtain feedback on **risks of replacement/ substitution therapies**
- **Key messages, education campaigns and guidance**

Recommendations for Patient organisations



- **Guidance for patients on:**

  - How to deal with shortages to avoid worsening of the situation
  - Where to find information about specific shortages
  - How to ‘report’ information on shortages

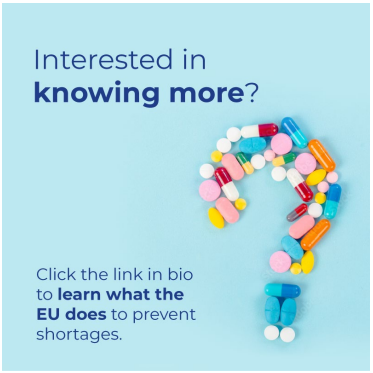
Recommendations for HCP organisations (I)

- Liaise with authorities to ensure **better access to data** and promote awareness on **how to notify shortages**
- Signalling to authorities sudden **unexpected increases in demand of medicines**
- **Risk assessments** for medicines with high clinical impact
- Guidance on **safe compounding** of medicines in short in supply

Recommendations for HCP organisations (II)

- **Guidance on dose sparing measures:**
  - Dose reduction
  - interruption or restrictions in target patient groups

EMA communication campaign



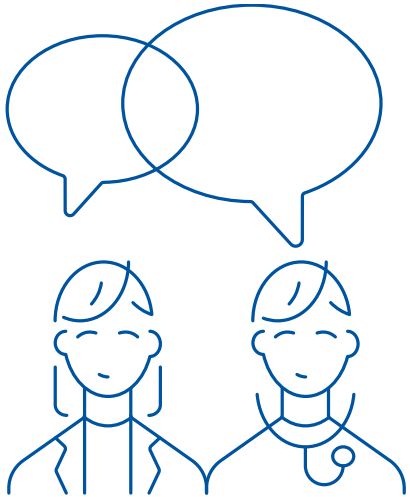
Outcome of awareness survey

Responses from HCPs

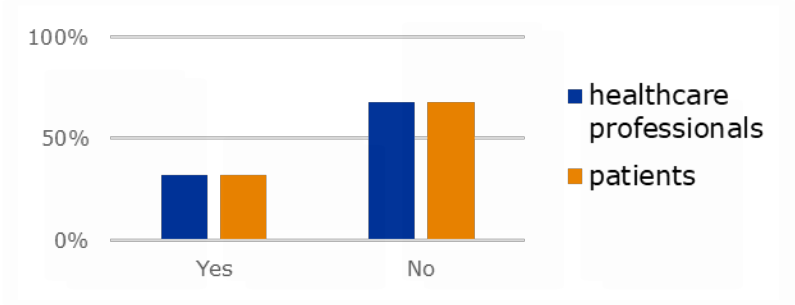
- 114 responses from across the EU
- Main EU member states: IT, Gr,Po, Fr, Es

Responses from patients

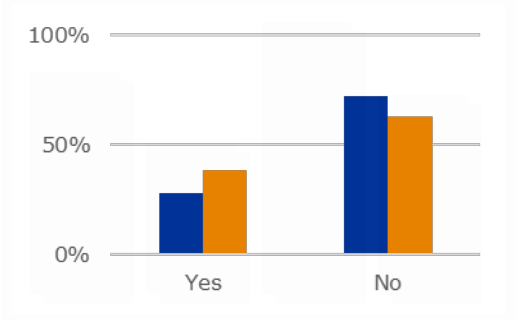
- 32 responses from across the EU
- Main EU member states: Gr, Fr, Ire, It, Es, Ro



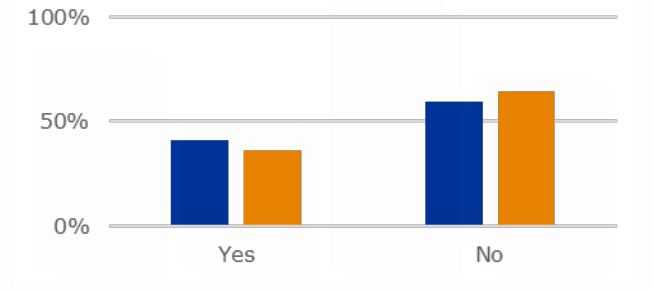
Are you aware of the Good practice guidance for communication to the public on availability issues?



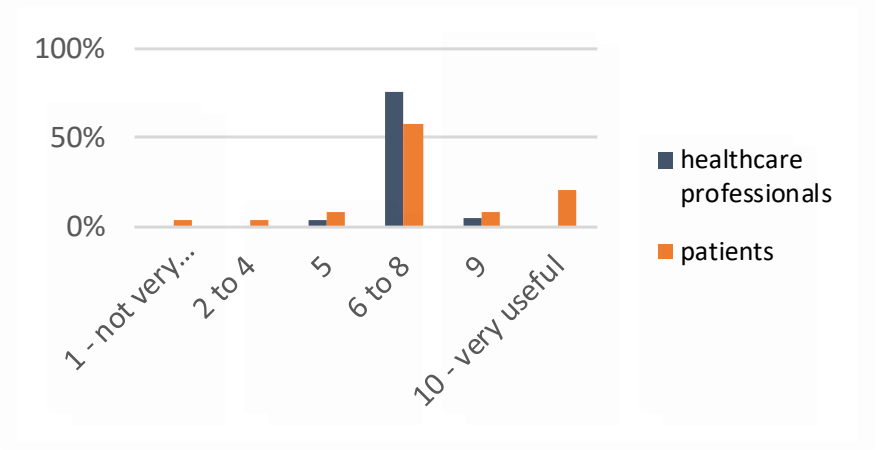
Are you aware of EMA's catalogue of shortages or national shortage catalogues



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 pts and HCPs felt that information was missing (alternatives and cause of shortages)

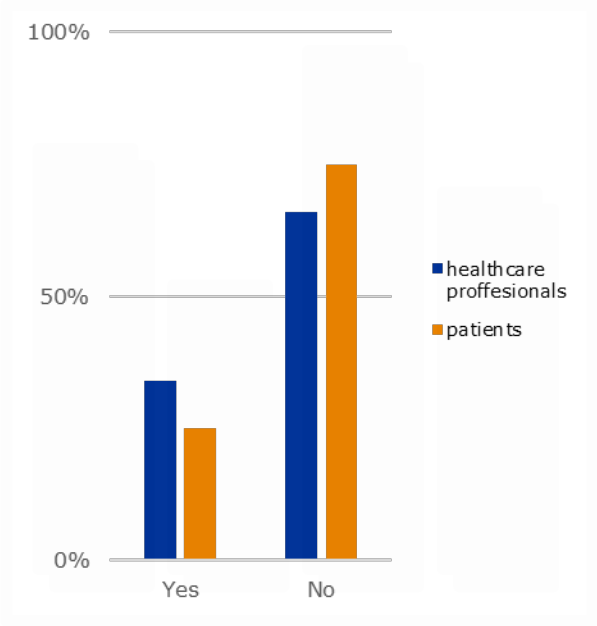
General comments

> Needs to be integrated with prescribing software

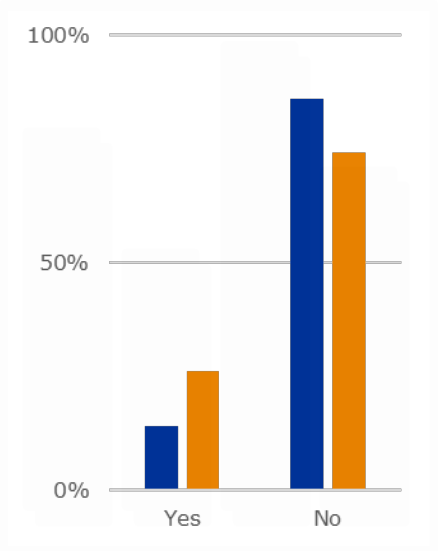
> Difficult to access

> Not known enough

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?



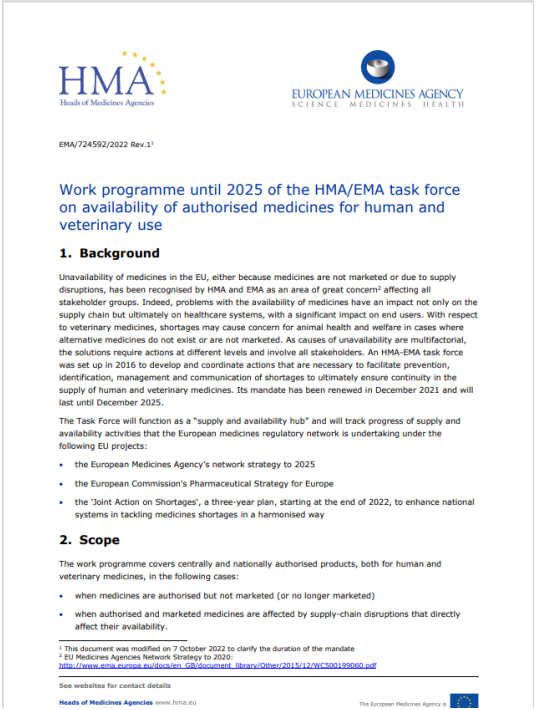
Next steps

Good practice guidance for EU authorities on public communication

- **Work programme of taskforce**: Monitor implementation by surveying national competent authorities

Good practice guidance for on prevention of shortages

- **Work programme of taskforce:** Define metrics and monitor implementation of guidance and review practices



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

Preparation for workshop

- Increase awareness – **we need your help** – promote single point of entry to shortage information
- Monitoring activities

Good practice guidance for EU authorities on public communication

- Prepare survey of national competent authorities
- Use case studies

Good practice guidance for prevention of shortages

- Assess implementation needs from stakeholders
- Get feedback on how practice has changed

Any questions?

See websites for contact details

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