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
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

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?
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 of medicines for human use

1. Introduction

Medication shortages as well as availability issues due to fluctuations in requirements and capacity of marketing authorizations are recognized as a growing issue across the EU and globally. In the COVID-19 pandemic, this issue has become even more pressing. They affect medicine of all classes and can be transmitted by mechanisms of all kinds. The impact of shortages is not without economic impact, with potential increases in costs, increased costs associated with hospitalization, and increased costs associated with the provision of healthcare services.

2. Enhancing practices for prevention

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

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

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

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

Consult the available catalogue on medicine shortages regularly.

Interested in knowing more?

Click the link in bio to learn what the EU does to prevent shortages.
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?

- Healthcare professionals
- Patients

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

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