

Network priorities to 2025: TF AAM workplan

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

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

Agenda



Introduction



Work programme
to 2025 –
Prevention of
shortages

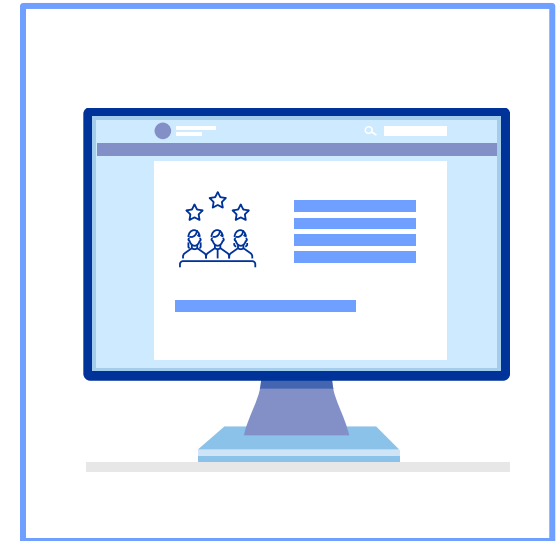


Good practice guidance
on prevention on
shortages

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 [EMA/HMA](#) website



TF AAM: Work programme to 2025 - prevention of shortages



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

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

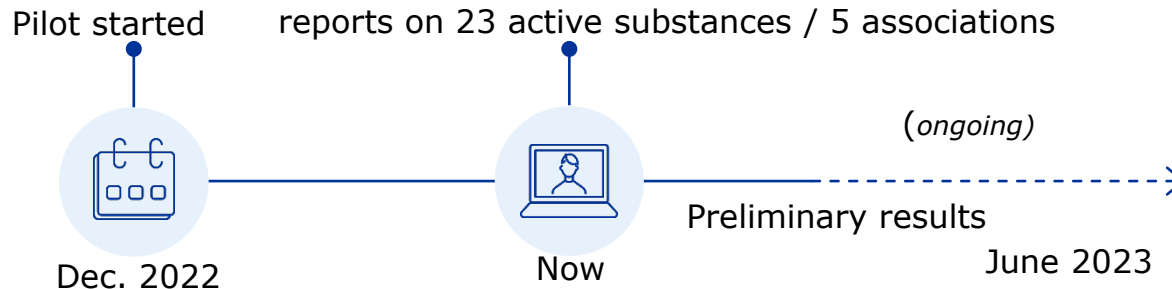
Pilot to explore added value of shortage reports from eligible EU patient and healthcare professional organisations at EU level to EMA



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

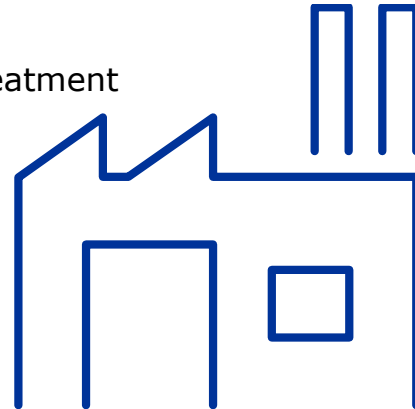


Good practice for industry on prevention of shortages of medicinal products for human use

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



10 recommendations

Optimisation of current systems

1. Earlier notifications

2. Increased transparency

3. Increase accuracy

Prevention and mitigation strategies

4. Shortage prevention plan

5. Shortage management plan

6. Optimisation of PQS

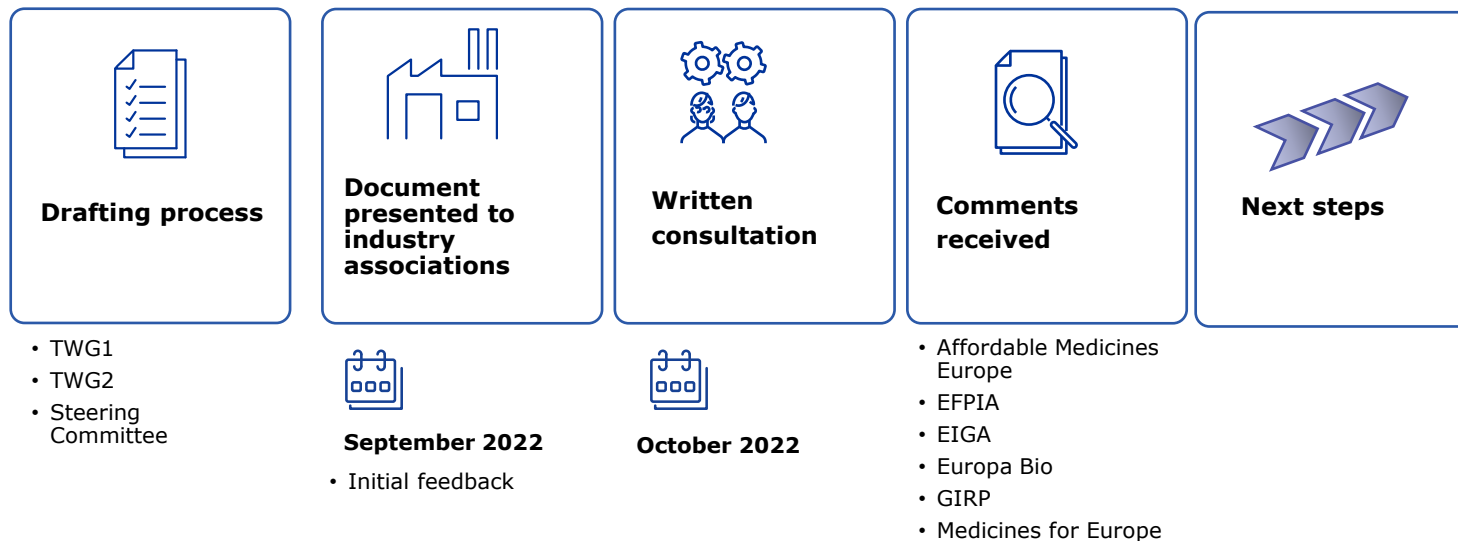
7. Increase resilience

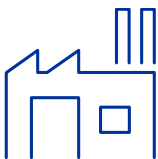
8. Improve communication

9. Fair & equitable distribution

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





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/excipients/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



Next steps

- 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

The European Medicines Agency is
an agency of the European Union

