

# Shortage prevention and mitigation measures - Implementation Plan

## Work Package 8

Deliverable 8.3

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## 1 Introduction

The implementation plan aims to provide a structured approach for National Competent Authorities (NCAs) to harmonise and implement preventive and mitigation measures against medicine shortages at the national level. This plan is based on the Analysis Report on Existing Preventive and Mitigation Measures of Medicines Shortages at National Level (Deliverable 8.1) and insights from national shortage experts and SPOC WP Members.

The measures found most effective according to the survey conducted among NCAs, and which are recommended to be implemented independently by the Member States without requiring legislative changes, are included in this implementation plan.

Deliverable 8.2, A Plan for National Competent Authorities' Preventive and Mitigation Measures Against Medicines Shortages, defined best practice proposals for preventive and mitigation measures to better address and tackle medicines shortages at the national level. These have been discussed in detail in deliverable 8.2.

EMA MSSG Toolkit recommendations and other EMA/HMA guidance (e.g., on communication) were considered in the plan. The reference documents are listed in Deliverable 8.2., and EMA documents are available at EMA website for further reference.

As Member States have already implemented various measures to differing extents, each NCA is encouraged to conduct a gap analysis to assess how existing national practices align with the measures outlined in this plan.

## 2 Objective

This implementation plan aims to facilitate harmonisation of preventive and mitigating measures across the EU. It emphasises dialogue and collaboration with stakeholders, acceleration of regulatory procedures, the Shortage Prevention Plan (SPP), list of critical medicines and assessment of impact of shortages. The plan has been developed in cooperation with the SPOC Network to ensure consistency and alignment with existing similar initiatives.

These actions are intended to be initiated progressively, depending on the extent to which they have already been implemented in each Member State, as illustrated in Figure 1. The position paper will formulate recommendations for minimum standards in November 2025 and provide an overview of the main considerations in harmonising the measures throughout the Member states.

## 3 Stakeholder Dialogue and Collaboration

By establishing a robust stakeholder dialogue framework, NCAs can ensure effective communication and collaboration among all relevant parties, leading to better prevention and mitigation of medicinal product shortages.

Based on Deliverable 8.1, stakeholder dialogue is the measure most widely implemented across Member States and has been evaluated by them as most effective. Stakeholder dialogue may occur at various levels and in different formats. The following recommendations aim to improve stakeholder dialogue and collaboration.

### 3.1 Multi-stakeholder Advisory Forum

Establish a framework for national stakeholders to address potential medicine shortages and develop preventive strategies at the national level. The forum should also serve to discuss strategic measures and review the effectiveness of implemented actions. It should include representatives from various sectors, including authorities,



supply chain operators, including retailers, healthcare professionals, and patient organisations. These advisory forum meetings should be held periodically, such as biannually or annually.

Recommended participants include:

- National competent authority
- Ministry of Health
- Other relevant authorities
- Pharmaceutical industry (possibly represented by trade organisations)
- Wholesalers
- Pharmacists (associations of pharmacies/retailers)
- Hospital pharmacists
- Medical professionals or healthcare professional organisations
- Patient organisations
- Health insurers

## 3.2 Permanent Communication Groups

Establish permanent groups for regular communication and cooperation with Marketing Authorization Holders (MAHs), healthcare professionals, and patient groups to discuss and manage shortages. These separate groups should report and discuss emerging situations, share information, and develop mitigation strategies. Regular stakeholder dialogues will ensure continuous engagement. This can be supported by maintaining up-to-date national contact information for stakeholders within NCAs.

### 3.2.1 Healthcare Professionals

- Form a group/commission comprising hospital specialists and hospital pharmacists to meet regularly (e.g. biannually) to discuss shortages.
- Create smaller focus groups for specific needs (e.g. paediatric medicines, antibiotics consumption, other critical categories), meeting biannually or ad hoc.
- Where applicable, monitor hospital procurement decisions and their impact on medicine availability after contracts are finalised. These processes vary between Member States.
- Engage professional associations of doctors, pharmacists, and other healthcare professionals to gather insights and feedback.  
Involve hospital pharmacists and healthcare institutions in annual conferences or platforms to share information on anticipated needs (e.g., epidemics, antibiotics or vaccines).

### 3.2.2 Marketing Authorization Holders (MAHs)

- Maintain continuous communication with MAHs and local representatives to ensure adequate market supply and address any emerging issues promptly.
- Organise periodic meetings (e.g., quarterly or more frequently if needed) to discuss the future prospects of specific topics such as the availability of antibiotics.

### 3.2.3 Patient Group Representatives and Associations

- Include patient associations in dialogues to ensure the needs and concerns of patients are addressed.



- Organise meetings (e.g., biannually) with patient group representatives and relevant authorities (e.g., pricing and reimbursement bodies).
- Distribute newsletters to patient associations to facilitate rapid dissemination of information.

#### **3.2.4 Pricing, Reimbursement and Procurement Agencies**

- Establish regular collaboration between NCAs and the national agencies responsible for pricing, reimbursement, and procurement to encourage more operators of critical medicinal products to enter and stay on the market.

### **3.3 Agile Procedures for Communicating Shortages**

Develop agile procedures and best practice guidance for informing stakeholders and other authorities about shortages of critical medicines and those affecting treatment continuity. Communication to pharmacists and hospital pharmacists should also address responsible procurement of medicinal products during shortages to ensure equitable availability across the country. Additionally, wholesalers should be informed about responsible distribution practices.

- Establish agreements with other national authorities on how to notify them about acute critical shortages and potential crisis situations, and ensure that contact information is regularly updated.
- Implement Medicines Shortages Communication (MSC) as part of each Member State's operational procedures.
- Develop procedures to inform the general public and the media about broader availability issues, for example via the NCA's website.

#### **3.4 Master Classes for Media Representatives**

Organise "master classes" on shortage information for media representatives to enhance their understanding and communication skills regarding medicine shortages.

- Host seminars or communication events for journalists, drawing on the experience of the EMA's event arranged in November 2024. The objective is to explain how shortages are managed nationally, the role of NCAs in shortage management, and where to access reliable information.
- This initiative aims to improve public understanding, foster relationships with the media, and promote responsible communication to prevent unnecessary hoarding.
- Maintain ongoing communication with media representatives, for example, through annual follow-up sessions.

### **3.5 Awareness Campaigns on Shortage Catalogues and EU-level Actions on Shortages**

Enhance awareness of shortage catalogues and EU-level actions on shortages. There have been significant developments in shortage management at the European level in recent years. These developments include the extended EMA mandate (EU Regulation 2022/123), the resulting increased role of the EMA SPOC-WP and MSSG, initiatives such as CHESSMEN and the launch of the European Shortage Monitoring Platform. Most of these developments already have or are expected to have an impact on national stakeholders. Examples include the

shortage prevention and mitigation plans that MAHs must comply with, or the national and EMA's shortage catalogues that healthcare professionals and pharmacists can use.

However, most national stakeholders are not aware of many of these European initiatives. To enhance awareness of these developments, NCAs are recommended to include information on EU-level developments in their communication channels. This can take the form of specific information days, presentations, awareness campaigns and digital communication through national websites.

## 4 Accelerating Regulatory Procedures

### 4.1 Cross-Organisational Communication on Medicine Availability

Within the NCA, establish cross-organisational communication among experts to address issues related to medicine availability, including those related to shortages, product defects, special permits, and exemptions. Ensure that the following topics are included in the communication:

- Current shortages
- Granted exemptions and special permits
- Changes in clinical practices, new medicines, etc.
- Quality defects and GMP non-compliances and their impact on shortages
- Other concerning signals (e.g. pricing and reimbursement) and possible solutions

This communication can be arranged through regular meetings, such as weekly or bi-weekly, or by creating a collaboration network or a formalised notification system.

### 4.2 Speed up Regulatory Processes for Critical Medicinal Products

Arrange regular communication and status updates between the team handling shortages and the regulatory department. Particular focus should be placed on nationally authorised critical medicines and their regulatory status and ongoing variations affecting availability. Changes in the regulatory environment (e.g. nitrosamines, new regulations potentially affecting availability) to be raised to the team handling shortages.

- Frequency of the communication/meetings: Every two months, or ad hoc when necessary
- As recommended in the MSSG toolkit, use available flexibilities to facilitate prompt implementation of changes in raw materials, manufacturing sites, equipment, packaging, and batch sizes to enable the MAH to increase production.
- Explore the feasibility of a “zero-day” procedure in the marketing authorisation process.

### 4.3 National Guidance for Centrally Authorised Medicines

In exceptional circumstances, for centrally authorised medicines, accelerated timelines for adoption of the Commission decision on the required variations might be needed, considering the context and the justification provided for the specific urgency of the request.

- Develop and disseminate clear national guidance on collaboration with EMA/EC for centrally authorised products, including outreach of national stakeholders where necessary (MSSG toolkit).

#### 4.4 Flexibilities to Support Agile Redistribution of Medicines

Seek possibilities to support redistribution of critical medicinal products between EU/EEA countries:

- Explore the possibility of importing foreign packs of authorised or unauthorised medicines within the framework of national legislation (MSSG toolkit).
- Where feasible, expedite the processing of export/import licences for narcotic products.
- Support the use of the Voluntary Solidarity Mechanism (VSM) when other measures have been exhausted.

### 5 Shortage Prevention Plan (SPP)

The European Commission's current revision proposal of pharmaceutical legislation includes the introduction of Shortage Prevention Plans (SPPs) for MAHs. The implementation of SPPs is pending the adoption of the legislation.

A template for SPPs has been published by EMA and included in the guidance, along with a common guidance document for NCAs to review the template. The pilot for SPPs began in 2025, and NCAs are encouraged to participate and contribute to the development of SPPs to prepare for potential changes in pharmaceutical legislation.

- Organise awareness campaigns on SPPs (e.g., through the NCA's website or targeted presentations to MAHs) and encourage relevant MAHs to engage in the ongoing pilot.
- Participate in the EMA/HMA TFAAM pilot to review SPP templates.

### 6 Lists of Critical Medicines

The development and publication of lists of critical or strategic products has been identified as one of the most effective measures to prevent shortages. The TF AAM (HMA/EMA Joint Task Force on Availability of authorised medicines for human and veterinary use) adopted the first version of the Union's list of critical medicines in 2023, and many Member States maintain national lists of critical medicines. The existence of multiple lists can lead to confusion among national stakeholders and reduce the impact of these lists.

WP 6 of CHESSMEN has been drafting recommendations for developing national lists of critical medicines. NCAs are recommended to inform national key stakeholders about these recommendations when national lists of critical medicines are being formed.

- Assess the differences between the national lists of critical medicines and the Union List of Critical Medicines

### 7 Assessing the Impact of Potential Shortages

Most EU/EEA Member States have a procedure to guide the assessment of shortage impacts, since this has been a prerequisite for cooperation on preparedness activities within the EMA/HMA network since Regulation (EU) 2022/123 extended the EMA's mandate. Approaches vary from country to country, and NCAs should work towards harmonising their methodologies.

## 7.1 Harmonised Reporting

Implementing a harmonised shortage reporting system with common data fields and terminology across all Member States ensures that data is consistent and comparable. This approach allows for better data evaluation, risk assessment, and identification of mitigation measures, thereby preventing or mitigating many potential shortages.

A harmonised reporting system among Member States also helps to create a common understanding of the root causes that need to be addressed at the EU level. This shift from reactive shortage management to preventive actions can prevent shortage situations before they occur.

This development of uniform categorisation was recommended by WP 5 to the SPOC WP. Recommendations regarding shortage reporting were developed by WP 6. Additionally, steps to establish minimum common datasets are being prepared as part of WP 7.

## 7.2 Decision Trees and Checklists

Using decision trees and checklists to assess the criticality of a potential shortage is recommended. These tools can support manual work until automated systems are fully implemented.

Processes and guidance within NCAs' assessment frameworks should be established if not yet in place. Variables from EMA/HMA methodology for criticality, as recommended by WP 6, should be considered when creating the decision tree.

A common protocol for managing medicine shortages – including a common decision tree and detailed impact assessment methodology – is a WP 6 deliverable D6.2. This report presents a unified protocol for effective monitoring, reporting, and managing medicine shortages.

The aim of the protocol is to facilitate the prevention of potential shortages or to reduce their impact on patients and the healthcare system through coordinated shortage management. The document focuses primarily on improving procedures for notifying shortages, assessing their impact, implementing mitigation measures, and enhancing external communication based on identified good practices.

This method supports preventive mitigation of medicine shortages by addressing managed shortages of similar products.

## 7.3 Tools for Determining Alternative Treatments

Recommended risk management tools for determining alternative treatments and for monitoring new medicines entering or leaving the market include:

- Develop lists of interchangeable products and integrate them into the shortage reporting system.
- Collaborate with specialists to create lists of therapeutic alternatives for critical products to proactively mitigate potential shortages.
- Establish a method to monitor the entry of new medicines and generics, and assess their availability and impact on existing products (e.g., due to parallel trade).
- Develop a method to track medicines exiting the market, including a decision tree for risk evaluation. Where necessary, negotiate with MAHs to maintain market presence or apply alternative mitigation strategies.



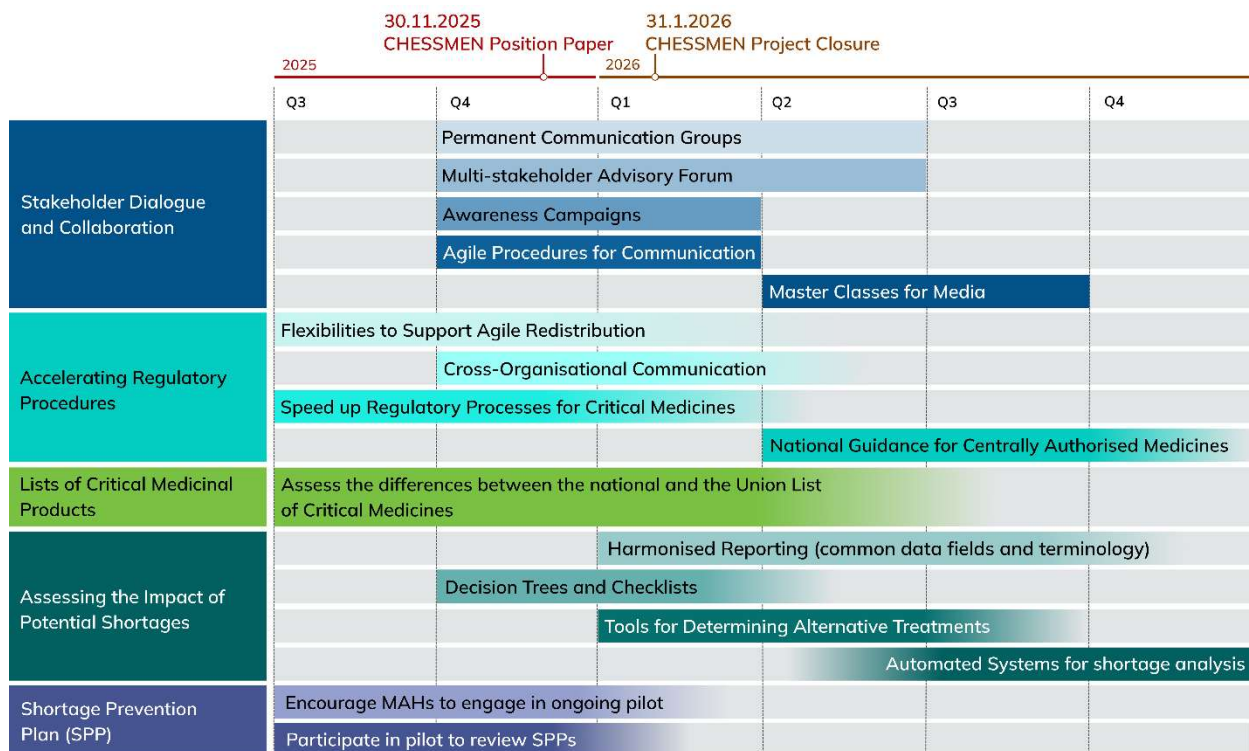
## 7.4 Automated Systems

NCA's are recommended to implement automated computerised systems for monitoring and analysing incoming data on potential shortages. An automated system helps distinguish actual shortages that affect treatment availability and supply disruptions that do not impact patient care.

Re-examining the readiness of NCA's for monitoring and analysis – particularly on the prevention side of mitigation – would be beneficial and should be conducted in cooperation with WPs 6 and 7.

In parallel, the potential application of artificial intelligence (AI) in shortage monitoring should be further explored. While current AI technologies are not yet sufficiently mature to support real-time shortage detection and analysis, ongoing evaluation of their capabilities is recommended to inform future integration into national monitoring systems.

## 8 Summary and Next Steps



**Figure 1. Roadmap of Planned Measures.** This figure presents a timeline of proposed actions, organized by increasing implementation effort and resource intensity. The five primary measures (listed in the left column) are broken down into individual actions, each with its own proposed initiation point. Darker shades indicate actions associated with higher workloads. The timelines represent suggested starting points for communication or setup; actual implementation schedules may vary across Member States. Several actions are already underway in some countries. Where not yet initiated, this roadmap may serve as a planning aid for national authorities.

Although common principles regarding medicines availability exist across Member States, the specific circumstances and implementation practices vary significantly. Each National Competent Authority (NCA) should review this plan in light of its national context and expertise, and prioritise measures according to its specific needs and available resources. Figure 1 (Roadmap of planned measures) may assist planning efforts by illustrating the relative workload associated with each action and suggesting logical starting points for implementation.

While the establishment of automated systems requires an initial investment of resources, such systems can ultimately streamline operations and improve efficiency. Artificial intelligence is also emerging as a valuable tool for NCAs, offering new opportunities for data analysis and decision support.

The ultimate objective of harmonisation is to reduce duplication of efforts across Member States.

Although the adoption of new measures entails resource commitments, this implementation plan enables Member States to adopt proven solutions rather than developing new ones independently. This approach may be particularly beneficial for smaller or resource-constrained NCAs, supporting more efficient use of limited resources.

Work Package 2 (Communication, led by Portugal) will support the next steps of WP8 by coordinating the publication and promotion of the prevention and mitigation plan, organizing stakeholder engagement activities, and facilitating the final scientific conference where WP8 outcomes will be presented and discussed.

Work Package 4 (Sustainability, led by Ireland) is responsible for ensuring the long-term impact and transferability of WP8's outputs. The next steps for WP4 include integrating the WP8 implementation plan into the broader CHESSMEN sustainability strategy, evaluating the feasibility of national adoption, and identifying policy levers and stakeholder partnerships that can support continued implementation.

Together, WP2 and WP4 will ensure that the preventive and mitigation strategies developed in WP8 are not only communicated effectively but also sustained and scaled across Member States.