CHESSMEN

Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network

# A plan for National Competent Authorities' Preventive and Mitigation Measures against Medicines Shortages, based on the information collected from the National Shortage Experts

## Work Package 8

Deliverable 8.2

15.5.2025

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# 1 Executive Summary

This document provides a comprehensive plan for National Competent Authorities (NCAs) to implement preventive and mitigation measures against medicine shortages. The plan is based on information collected from national shortage experts and aims to harmonize strategies across EU/EEA Member States. It also considers communications from the European Commission, the Heads of Medicines Agency and the European Medicines Agency.

Key preventive and mitigation measures that do not require legislative changes were recognized, e.g., stakeholder dialogue and simplified regulatory procedures. This plan proposes recommendations at a general level.

Deliverable 8.2 defines these best practice proposals, while Deliverable 8.3 outlines a structured implementation plan to support NCAs in applying the measures at national level in a harmonised and practical manner.

# 2 Introduction

Emerging medicine shortage situations have made it necessary for NCAs and other representatives of EU/EEA Member States (MS) and the European Commission (EC) to consider new measures and develop existing means of managing, preventing and mitigating the effects of medicine shortages, especially during and after the Covid-19 pandemic. These prevention and mitigation solutions vary between EU/EEA Member States and harmonisation at national level would be beneficial.

The Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) initiative aims to address the challenges posed by medicine shortages through collaborative efforts and harmonised strategies across Member States.

## 2.1 Definitions

Preventive and mitigation measures are defined here as follows:

**Preventive measures:** Actions taken to prevent shortages of a medicinal product, and implemented before the actual shortage occurs (e.g. regulatory flexibilities or increased local production of medicines).

**Mitigation measures:** Actions taken to reduce the impact of a shortage on patients and the healthcare system. Mitigation measures may be implemented when a shortage has already begun or before a shortage starts (e.g. procedures for an export ban).

## 2.2 Objective and Scope

One of the primary objectives of Work Package 8 (WP8) within CHESSMEN is the development of a comprehensive plan—Deliverable 8.2—detailing the preventive and mitigation measures employed by National Competent Authorities (NCAs) to address medicine shortages and minimize their effect on patient care. Deliverable 8.2 is grounded in empirical data collected from national shortage experts, including members of the Medicine Shortages Single Point of Contact Working Party (SPOC WP). It synthesizes best practice proposals derived from a literature review conducted under Work Package 6 (Deliverable 6.1), which involved the collection and dissemination of relevant documents across participating work packages. These proposals were further analysed by WP8 and consolidated in Deliverable 8.1, which provides an analytical overview of existing national-level measures. The overarching aim is to enhance the **harmonisation and applicability** of shortage prevention and mitigation strategies across Member States. Notably, the proposed measures are designed for **autonomous implementation by NCAs, without necessitating legislative amendments or prior authorization from higher regulatory bodies**. Measures that require legislative changes fall outside the scope of Deliverable 8.2.

# 3 Methodology

To support the CHESSMEN Joint Action's objective of identifying common strategies for harmonising preventative and mitigation measures, those found to be the most effective and broadly applicable across Member States have been included in the set of National Prevention and Mitigation Measures of WP 8 (Deliverable 8.2) and in the corresponding implementation plan (Deliverable 8.3):

- Stakeholder dialogue
- Collaboration and consultation with external stakeholders
- Simplified/flexible regulatory procedures
- Shortage prevention plan
- List of critical or strategic products
- Assessing the impact of shortage

Certain measures identified in the analysis of WP 8, cannot be developed without changes in legislation and/or decisions by the Member States. Therefore, they may not be applicable or harmonised across all Member States and were left out of the scope of WP 8's plans (Deliverables 8.2 and 8.3.). These measures include:

- Stockpiling and stockholding obligations
- Optimal management and distribution of stocks and rationed use of medicines
- Widened professional competence use - extending the scope of pharmacy practice when medicines are in short supply
- Export bans and restrictions

However, it is important to acknowledge these measures, as they can also contribute to the prevention and mitigation of shortages across Member States.

WP 8 conducted a survey among SPOC WP members to gather information preventive and mitigation measures currently in use or planned for implementation. Responses were received from 25 EU Member States (25 out of 30), including 12 countries participating in CHESSMEN WP 8 (AT, CY, EE, FI, DE, IE, IT, LU, PT, RO, SI, NL) and 9 additional Member States (BE, BG, DK, FR, GR, NO, PL, SK, ES). For four Member States (HR, CZ, HU, LT), questionnaires were pre-populated from earlier surveys, documentation, and other literature collected by WP 6 (Deliverable 6.1). The

results are presented in Figures 1 and 2. This plan is based on those findings and earlier information collected by national shortage experts, including SPOC WP members, regarding national measures.

In addition, during 2024 and 2025, WP 8 consulted other relevant stakeholders, such as the EMA/HMA Task Force on Availability of medicines (TFAAM) and SPOC WP, supply chain stakeholders, healthcare professionals, and patient advocacy groups. Their insights and feedback were incorporated into the finalisation of the plan as Deliverable 8.2.

# 4 Survey Results

The results of the survey on preventive and mitigation measures currently in use or planned for implementation are shown below in Figures 1 and 2. According to the survey, "stakeholder dialogue" emerged as one of the primary measures employed by Member States to prevent and mitigate shortages, along with "assessing the impact of shortage ", "collaboration and consultation with external stakeholders" and "regulatory procedures". In contrast, the "list of critical medicines" and the "Shortage Prevention Plan (SPP)" are not yet widely adopted, although many Member States intend to implement or further develop them further in the future.

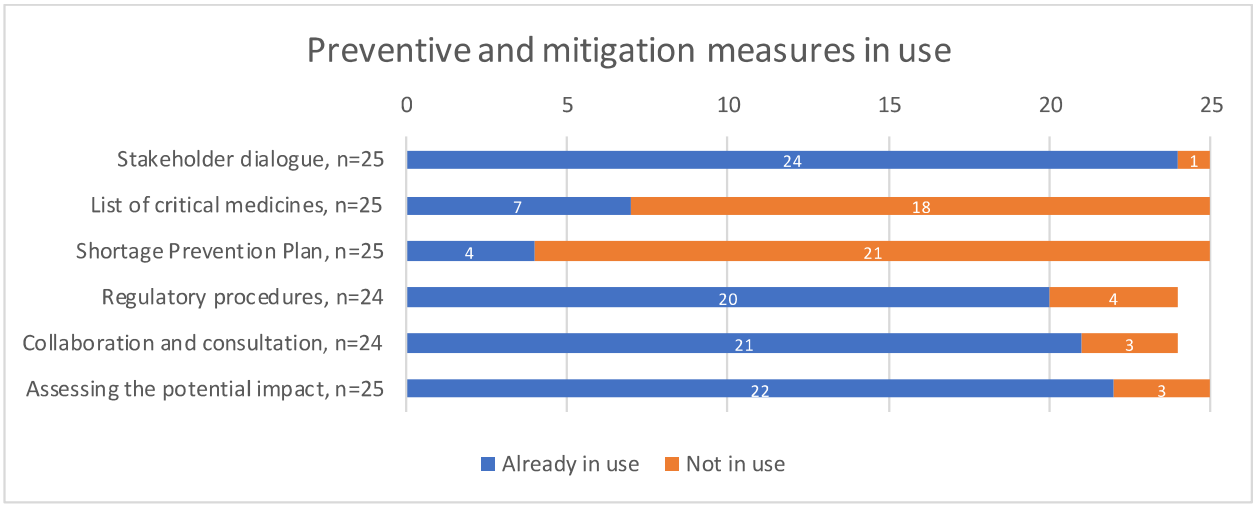


Figure 1. Collection of preventive and mitigation measures used in the Member States.

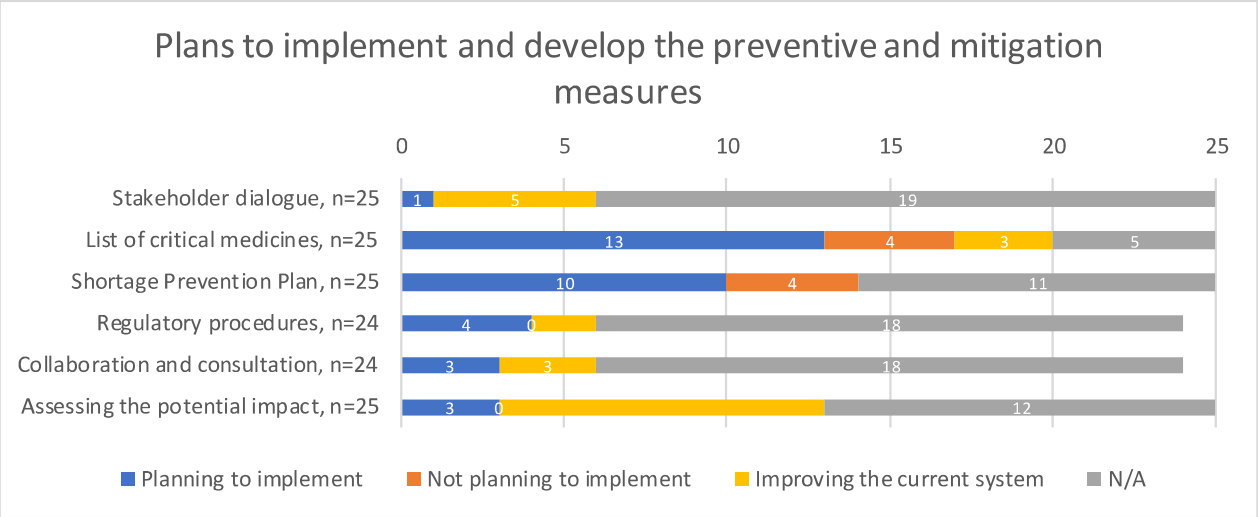


Figure 2. Measures that are planned to be implemented or further developed in the Member States.

The following chapters outline the key actions identified by WP 8 for targeted implementation within the CHESSMEN initiative. These actions are intended to be applicable across all National Competent Authorities (NCAs).

## 4.1 Key Preventive and Mitigation Measures

### 4.1.1 Stakeholder Dialogue

Stakeholder dialogue on policy actions and new legislation concerning shortages and availability of medicinal products – engaging key actors across the supply chain, healthcare professionals, patients and general public, particularly through media - has been regarded as highly valuable by the NCA's shortage experts. Such dialogue is in use in almost all Member States involving different stakeholders. The results of the survey are presented in Figure 3. Notably, there have also been significant developments related to this measure in recent years.

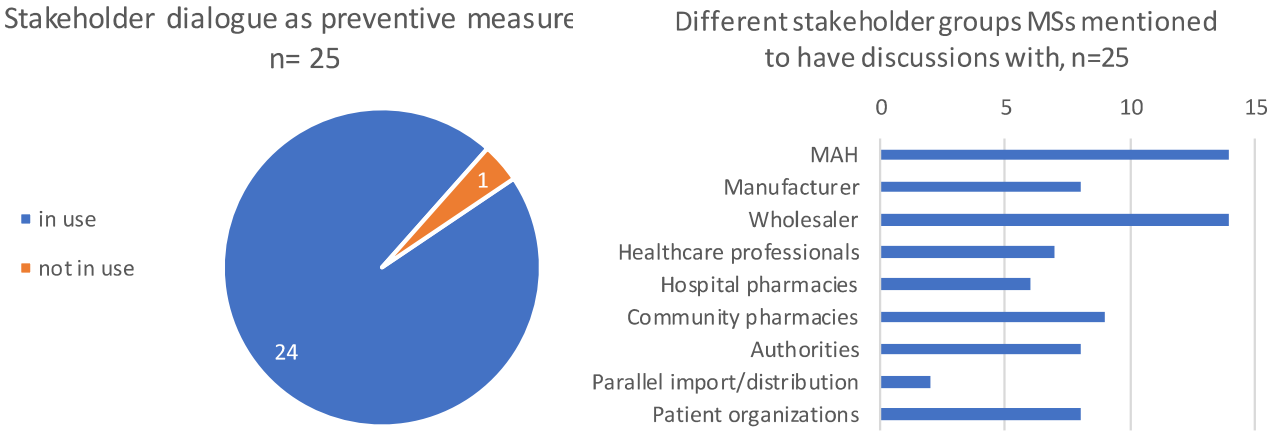


Figure 3. Stakeholder dialogue used as a preventive measure and different stakeholder groups in Member States.

While medicine shortage data are published by most NCAs, awareness remains limited. (Abed, 2023) (EMA TFAAM WG2, 2023) **Targeted awareness campaigns** to inform healthcare professionals and pharmacists about national and EMA shortage catalogues are strongly recommended. In addition, **an open-access shortage data environment** that interfaces seamlessly with the prescriber and pharmacy systems would be highly beneficial. (EMA/HMA, 2022)

The NCAs should consider developing new guidelines or revising existing ones on effective communication of medicines shortages. It is crucial to prioritise the timely publication of shortages that may compromise treatment continuity. Furthermore, **communication should be strategically directed** to the relevant stakeholders at appropriate times to serve as a preventive or mitigating measure, thereby minimizing potential adverse impacts on patient care. (EMA/HMA Workshop, 2023)

It is also recommended to **establish cooperation structures** at the national level, in alignment with guidelines and existing frameworks like the SPOC WP and Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). **The development of platforms enabling manufacturers, wholesalers, and pharmacies/healthcare providers** to discuss and report shortages should be coordinated at the national level and integrated to the EMA SPOC WP and European Shortages Monitoring Platform (ESMP), using common datasets. Furthermore, healthcare professionals and pharmacists should be regularly informed about shortage catalogues at the national level. To support these national efforts, it is advisable to apply the most recent communication guidelines. (German Medicines Act section 52 b, 2021) (Infarmed, 2022) (Di Giorgio D, et al., 2019)

NCAs should **collaborate closely and regularly with agencies responsible for pricing, reimbursement, and procurement of medicines**. Although the role of medicines NCAs does not encompass procurement and pricing issues, their shortage analysis can provide valuable insights at the national level. Establishing formal cooperation mechanisms between medicines NCAs and national reimbursement and procurement authorities could be advantageous. It is recommended that national and regional procurement agencies revise their practices to encourage more operators to enter the market for critical medicinal products. This can be achieved by including various criteria (e.g., Most Economically Advantageous Tender, MEAT) in tenders, facilitating multiple tender winners. Lead times should be set to allow manufacturers to build up stock levels, especially for generic medicines. (European industry associations: AESGP, EAEPC, EFPIA, GIRP, EIPG, Medicines for Europe, Vaccines for Europe, 2019)

**Expected Impact:**

**Timeframe:** Short to medium term

**Targeted root cause:** Lack of coordination and communication among supply chain actors, leading to delayed responses to emerging shortages

**Impact measurement:**

- Frequency of stakeholder meetings
- Diversity of stakeholder groups engaged
- Documented outcomes (e.g. joint action plans, early warnings issued)
- Surveys or feedback from participants to evaluate perceived usefulness and responsiveness

### 4.1.2 Collaboration with External Stakeholders

**Agile procedures** for informing stakeholders and relevant authorities about shortages of critical medicines should be developed. For example, establishing **permanent cooperation with healthcare professional and patient associations** is essential to educate stakeholders, disseminate information on the root causes of shortages, and influence demand-side factors. (Miranda-Garcia M. et al, 2022) (Fimea, 2023)

**Arranging "master classes"** on medicine shortage communication for media representatives and other interest groups, such as physicians and pharmacists, should also be considered to help mitigate disruptions originating from the demand side. (EMA/HMA, 2024)

**Expected impact:**

**Timeframe:** Short to medium term

**Targeted root cause:** Limited awareness and preparedness among external actors regarding the causes and consequences of medicine shortages, which can exacerbate demand-side disruptions

**Impact measurement:**

- Evidence of improved public and professional awareness (e.g., fewer panic-induced demand spikes, more timely reporting on shortages)
- Number and regularity of cooperative initiatives with external stakeholders
- Diversity of stakeholder groups engaged

### 4.1.3 Accelerating Regulatory Procedures

National competent authorities should consider mechanisms to **accelerate regulatory processes** when these processes pose a risk to the availability of critical medicinal products. **MSSG Toolkit recommendations** should serve as a framework for informing Marketing Authorisation Holders (MAHs) about prevention and mitigation tools. For example, regulatory flexibilities that enable prompt implementation of changes to alternative sources of raw materials, manufacturing sites, equipment, packaging, and batch sizes can help increase production capacity and support sparing use of the product. Other examples include flexibilities to support agile product distribution between markets and shelf-life extension (EMA, 2023). Additionally, clear national guidance should be established for collaboration with EMA and European Commission regarding centrally authorized products, including structured outreach to stakeholders.

**Expected impact:**

**Timeframe:** Short to medium term

**Targeted root cause:** Delays in regulatory processes affecting medicine availability

**Impact measurement:**

- Number of accelerated procedures
- Stakeholder feedback
- Evidence indicating potential shortages that could be prevented

### 4.1.4 Shortage Prevention Plan

Shortage prevention plans (SPPs) have been introduced in the current revision proposal of the pharmaceutical legislation by the European Commission (European Commission, 2023) and their implementation is pending the adoption of this legislation. (European Commission, 2023)

The now completed HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TFAAM) has developed a template for SPPs for MAHs, together with guidance for industry on implementing SPPs (EMA/HMA, 2023). A SPP pilot began in December 2024, and includes the participation of various NCAs. (EMA, 2024)

In addition to the EMA/HMA template, NCAs should consider developing supervisory frameworks to assess the quality and completeness of submitted SPPs. These frameworks could include criteria for evaluating risk identification, mitigation strategies, and communication protocols, ensuring that SPPs are not only formal requirements but also effective tools for early intervention.

Additionally, NCAs could develop IT systems for requesting SPPs and early warnings, as has been done in some countries.

**Expected impact:**

**Timeframe:** Medium to long term

**Targeted root cause:** Lack of proactive planning by MAHs and NCAs

**Impact measurement:**

- Number of SPPs submitted
- Quality of plans
- Early warnings issued

### 4.1.5 Lists of Critical Medicinal Products

The development and publication of lists of critical or strategic medicinal products have been identified by several shortage experts in the WP 8 survey as valuable tools for managing the availability of medicinal products. These lists can help focus the preventive and mitigation efforts of NCAs, which may be time-consuming and require continuous oversight, in the most effective way. Various Member States and the EMA have already adopted or are currently developing such lists, as reflected in the results of the survey (Fig. 4). NCAs are encouraged to **participate in the preparation and revision of an EU-wide list of critical medicines, as well as potential national lists**, especially from the shortage prevention perspective, while engaging with national clinical and scientific bodies. (Lehtinen J. et al., 2022) (German Medicines Act section 52 b, 2021) (30th Ordinance: Ensuring the supply of medicines, 2020) (Government Ordidance, 2023) (EMA, 2022) (EMA, 2023)

WP 6 is currently reviewing existing national-level lists in detail and preparing recommendations for development of national lists of critical medicines (Deliverable 6.4).

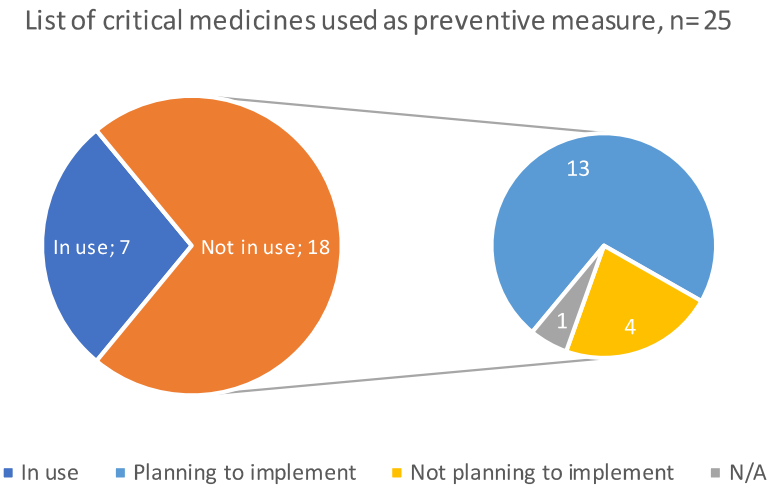


Figure 4. List of critical medicines used as preventive measure in Member States

**Expected impact:**

**Timeframe:** Medium term

**Targeted root cause:** Lack of prioritisations and focus in shortage mitigation efforts

**Impact measurement:**

- Number of critical medicines listed
- Updates to the list
- Use of the list in decision-making

### 4.1.6 Assessing the Impact of Potential Shortages

NCAs play a crucial role in identifying the most critical medicines following the analysis of a shortage situation. Most EU/EEA Member States have established procedures for assessing the impact of shortages, as this has been a prerequisite for cooperation on preparedness activities within the EMA/HMA network since Regulation 123/2022 extended the EMA's mandate. Approaches vary from country to country, and the need for more automated systems has increased. (Regulation (EU) 2022/123)

NCAs are encouraged to implement automated, computerised systems to assist with analysis. These systems should be **designed to monitor and analyse incoming data about potential shortages**. NCAs are advised to use decision trees and checklists to assess the criticality of a potential shortages. Clear processes and guidance should also be established to support consistent assessments. Additionally, re-examining the readiness of NCAs to monitor and analyse shortages from a prevention perspective would be beneficial, in collaboration with WPs 6 and 7. (Musazzi UM, 2020)

**A common, harmonised approach to reporting uniformly categorised shortages** among Member States would help establish a common understanding of the root causes that require EU level action. The aim is to shift from reactive

shortage management to preventive measures to avoid shortage situations before they occur. WP 5 has recommended the development of uniform root cause categorisation to the SPOC WP. Additionally, steps to establish minimum common datasets are being prepared as part of WP 7.

**To improve their expertise on available alternatives,** NCAs should use tools such as medicine and shortage catalogues, Pharmacy and Therapeutics Commissions and lists of mutually interchangeable products. This will help inform healthcare professionals and the public when applicable. Best practices should be reviewed and published as guidance where appropriate. (EMA/HMA, 2024) As part of routine monitoring of stock and demand data for either all or critical medicinal products, flagging of potential shortages is recommended. This would allow time to mitigate the actual shortages or lessen their impact on healthcare and patients.

**Expected impact:**

**Timeframe:** Ongoing/Short term

**Targeted root cause:** Insufficient analysis of shortage severity and consequences

**Impact measurement:**

- Consistency in categorization
- Evidence indicating potential shortages that could be prevented

# 5 Next Steps

An implementation plan (Deliverable 8.3), including a detailed action plan on how to accomplish the measures within the NCAs is being developed. The level of harmonisation at national level will be discussed in position paper (Deliverable 8.4).

# 6 Conclusions

This deliverable presents a structured and evidence-informed framework for national competent authorities to enhance the prevention and mitigation of medicinal product shortages. Drawing on empirical data, stakeholder consultation, and best practices across Member States, the proposed measures address both systemic and operational root causes of shortages. By introducing targeted actions—ranging from stakeholder dialogue and regulatory flexibility to strategic planning and impact assessment—this plan supports a harmonised yet adaptable approach across the EU. The inclusion of expected impacts, timeframes, and measurable indicators for each measure ensures that implementation can be monitored and refined over time. Ultimately, this plan contributes to strengthening the resilience of national medicines supply systems and safeguarding public health through proactive and coordinated action.

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