

CHESSMEN

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



Co-funded by
the European Union

About CHESSMEN

CHESSMEN (Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network) is a co-funded Joint Action that envisages to support European Member States to provide a harmonized response to medicinal products shortages and promote the use of best preventive practices.

The Joint Action has officially started on 16 January 2023 and will be running for 4 years, bringing together 22 countries. The Italian Medicines Agency (AIFA, Agenzia Italiana del Farmaco), supported by the Italian National Blood and Transplant Centers (ISS-CNS/CNT), is responsible for the coordination of the Joint Action.



Starting date
16/01/2023



**7,85 million € co-
funding by EC**



22 Beneficiaries



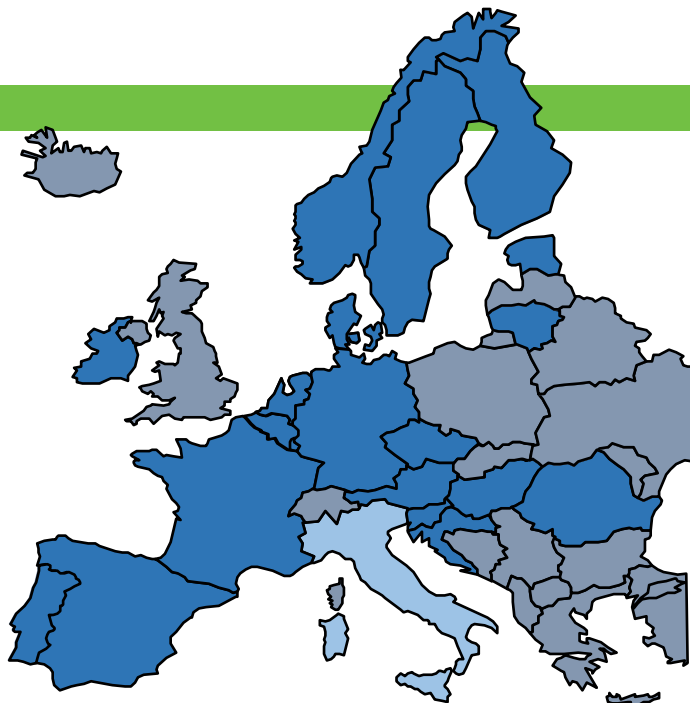
**3 years
+ 1 year extension**



**21 EU Member States
and 1 EEA country**



7 Affiliated Entities



Affiliated Entities

AGES/BASG | Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (Austria)

GÖG | Gesundheit Österreich GmbH (Austria)

ISS – CNS/CNT | Istituto Superiore Di Sanità, Centro Nazionale Sangue, Centro Nazionale Trapianti (Italy)

NAMMDR | Agentia Nationala a Medicamentului Si a Dispozitivelor Medicale din Romania (Romania)

PEI | Paul Ehrlich Institut (Germany)

FCSAI | Fundación Estatal, Salud, Infancia y Bienestar Social (Spain)

STS | Serviciul de Telecomunicații Speciale (Romania)

Coordinator

AIFA | Agenzia Italiana del Farmaco (Italian Medicines Agency), supported by the Italian National Blood and Transplant Centres (ISS-CNS/CNT)

Beneficiaries

AIFA | Agenzia Italiana del Farmaco (Italy)

AEMPS | Agencia Espanola De Medicamentos Y Productos Sanitarios (Spain)

ANSM | The Agence Nationale de Sécurité du Médicament et des Produits de Santé (France)

ATNA | The Austrian Ministry of Social Affairs, Health, Care and Consumer Protection (Austria)

BFARM | Bundesinstitut Für Arzneimittel Und Medizinprodukte (Germany)

DKMA | The Danish Medicines Agency (Denmark)

DPM | The Division of Pharmacy and Medicines within the Luxembourg Health Directorate (Luxembourg)

ESSC | Health Emergency Situation Centre of The Ministry of Health of Lithuania (Lithuania)

FAMHP | Federal Agency for Medicines and Health Products (Belgium)

FIMEA | Lääkealan Turvallisuus- Ja Kehittämiskeskus (Finland)

HALMED | Agencija za Lijekove I Medicinske Proizvode (Croatia)

HPRA | The Health Products Regulatory Authority (Ireland)

INFARMED | The Autoridade Nacional Do Medicamento E Produtos De Saúde I.p. (Portugal)

JAZMP | Javna Agencija Republike Slovenije Za Zdravila in Medicinske Pripomočke / Agency for Medicinal Products and Medical Devices of The Republic Of Slovenia (Slovenia)

LÄKEMEDELSVERKET | The Swedish Medicinal Products Agency (Sweden)

MINISTRY VWS | The Department of Pharmaceutical Affairs and Medical Technology of The Dutch Ministry of Health, Welfare and Sport (Netherlands)

MS/MOH | Ministerul Sănătății România (Romania)

NoMA | Statens Legemiddelverk (Norway)

OGYEI | Országos Gyógyszerészeti És Élelmezés-egészségügyi Intézet (Hungary)

PHS | The Pharmaceutical Services of Cyprus (Cyprus)

SAM | Estonian State Agency of Medicines (Estonia)

SUKL | Státní Ústav Pro Kontrolu Léčiv (Czech Republic)

Objectives

To strengthen the **coordinating structure**, as well as **optimize** the use of the available resources of all Member States, by **both supporting the existing networks and initiatives already active in the field** (such as the Medicines Shortages Single Point of Contact (SPOC) Working Party and the Heads of Medicines Agencies / European Medicines Agency Task Force on Availability of authorised medicines for human and veterinary use) and enhancing Member States cooperation in the:

Identification of the root causes of medicines shortages.

Identification and promotion of best practices in monitoring, reporting and managing medicines shortages.

Definition of a common dataset proposal for the notification and management of medicines shortages.

Reduction of shortages via preventive strategies.

WP SUMMARY

An overview of the **key activities**, **deliverables** and **results** developed across the CHESSMEN Work Packages, supporting a more coordinated and harmonised approach to medicines shortages in Europe.



WP5

Identifying the
root causes of
observed
shortages of
medicines

List of Key Definitions Relating to Medicines Shortages

One of the first challenges identified by WP5 was the lack of a common terminology for medicines shortages and terms related to shortages across EU/EEA countries. Different definitions and interpretations were being used, making it difficult to compare data, analyse shortages and coordinate responses at European level.

To address this issue, WP5 compiled and reviewed 22 key definitions related to medicines shortages. The definitions were collected from existing literature and documents shared within the Consortium and subsequently discussed by experts to ensure consistency and accuracy.

The deliverable established a common terminology framework for the Joint Action and supported greater harmonisation of concepts across Member States. It also included an analysis of national shortage definitions, highlighting that most countries currently use their own definition of medicine shortage.

Examples of terms included in the list of definitions considered for harmonisation:

- **Shortage**
- **Demand**
- **Supply**
- **Medicinal Product**
- **Marketing Authorisation Holder (MAH)**
- **Wholesale Distributor**
- **Healthcare Professional**
- **Manufacturer**

By creating a shared understanding of these key concepts, WP5 laid the foundations for more consistent reporting, analysis and management of medicines shortages across Europe.

WP5

Identifying the root causes of observed shortages of medicines

Analysis of the Root Causes of Medicine Shortages

Why do medicine shortages occur?

Understanding the root causes of medicine shortages is essential to reduce their impact and support more effective prevention strategies. To address this challenge, WP5 analysed shortage notification systems across EU/EEA countries and assessed the root causes of more than 83,000 reported shortages during 2022 and 2023.

The analysis revealed significant differences in how Member States collect and classify shortage data, highlighting the need for greater harmonisation to support meaningful comparisons and coordinated action across Europe.

Key findings

- Manufacturing issues were the leading cause of shortages (**50.6%**)
- Unexpected increased demand accounted for **16.7%**
- Commercial reasons represented **11.2%**
- Distribution issues accounted for **10.6%**
- Quality and regulatory issues represented a smaller share of reported shortages

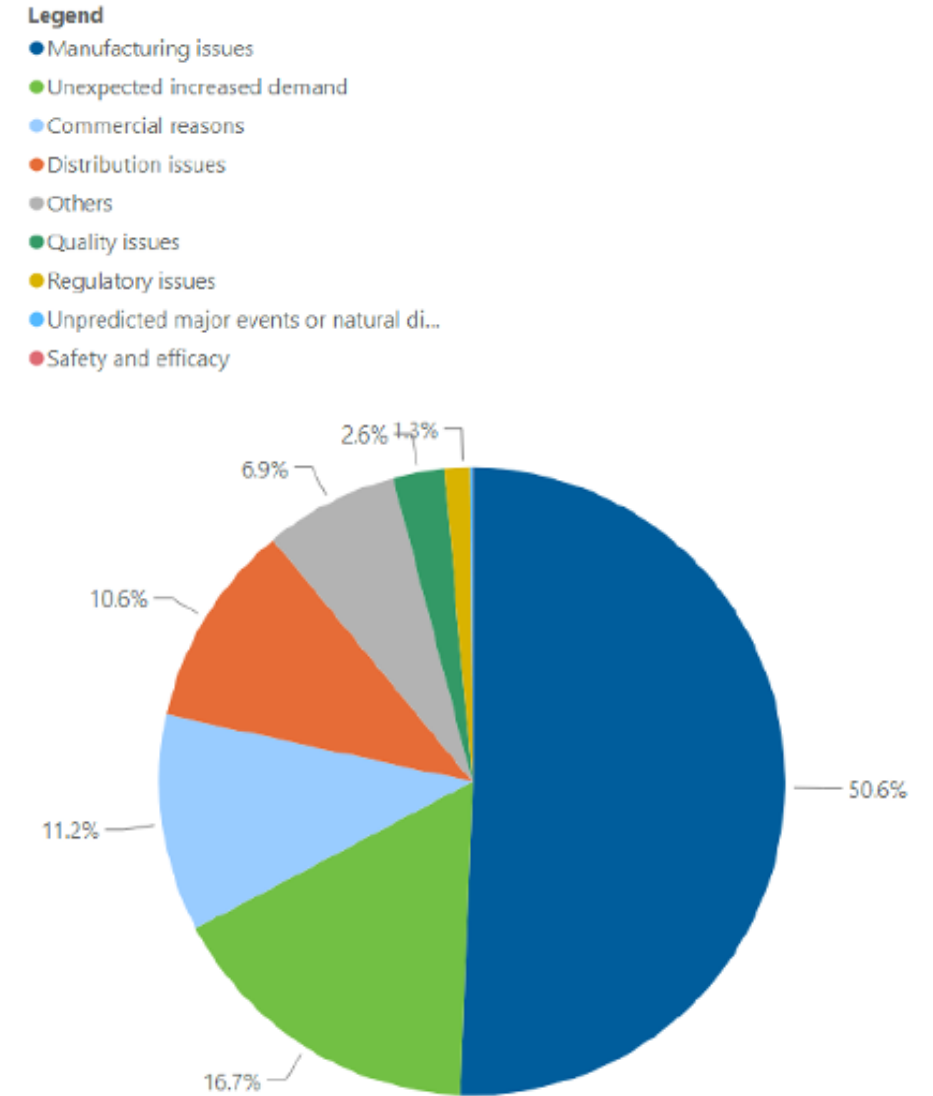


Fig. 1 Root causes of medicine shortages in 2022 and 2023 in EU/EEA countries, grouped according to SPOC working party classification

WP5

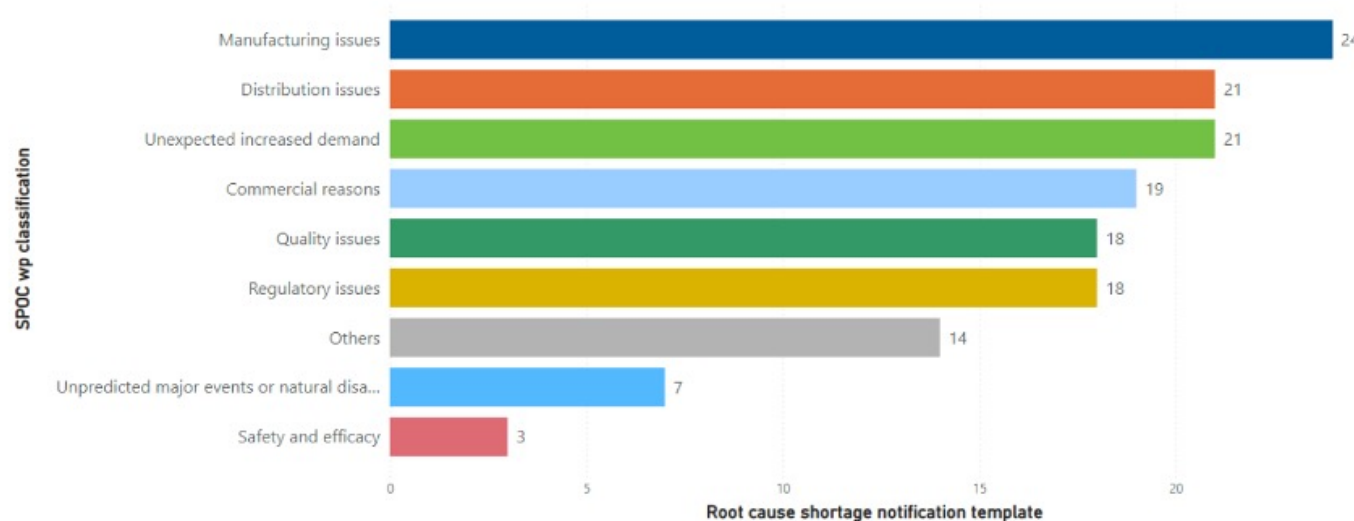
Identifying the
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Key Conclusions

WP5 found that most EU/EEA countries already use structured templates to collect information on the root causes of medicine shortages. However, these systems vary significantly in terms of detail, terminology and classification criteria.

The analysis showed that comparing shortages across Member States remains challenging due to the lack of harmonised reporting practices. To support future EU-wide analyses, WP5 highlighted the importance of developing a common template and a more standardised approach to root cause classification.

Industry organisations also contributed valuable insights, identifying additional factors such as supplier issues, lack of raw materials, reimbursement changes, stockpiling requirements and tender practices.



A common EU approach to collecting and classifying root causes would enable more accurate comparisons, better data quality and stronger coordination between Member States.

Fig. 2 Type of categories of root causes included in the analysed Templates according to SPOC working party classification

Identifying and Consolidating Best Practices

Technical Work Package 6 focused on identifying and consolidating established knowledge, procedures and best practices for addressing medicine shortages, particularly in the areas of monitoring, reporting and management of shortages, as well as the development of national lists of critical medicines.

Stakeholder engagement

The recommendations were discussed during the CHESSMEN Multi-stakeholder Workshop, which gathered **220 participants** from industry, healthcare professionals, patient organisations, national authorities and European regulatory bodies. Stakeholders confirmed the relevance of the recommendations and highlighted the importance of timely reporting, stronger communication and improved understanding of shortage root causes.

Key achievements

Collection of existing documents

WP6 collected and mapped documents addressing medicine shortages at EU, EMA/HMA, national and international levels. By June 2025, the repository contained **189 documents**, providing a valuable knowledge base for all technical Work Packages.

Mapping of best practices

A survey involving 26 Member States analysed good practices in monitoring, reporting and managing medicine shortages. Based on the findings, WP6 developed recommendations covering:

- Regular monitoring of stock levels and demand data
- Reporting of medicine shortages
- Publication of shortage information
- Structured dialogue with stakeholders
- Regulatory measures and financial incentives
- Communication with stakeholders and the public
- Widening pharmacists' professional competences

WP6

Identification
of best
practices to
address
medicines
shortages

Common Protocol for Monitoring, Reporting and Managing Shortages

Based on the insights and best practices collected during mapping survey, WP6 developed recommendations for a common protocol including shortage management decision tree.

The protocol aims to support coordinated approach to shortage management procedures at national level:

- Shortage notification
- Impact assessment
- Implementation of mitigation measures
- External communication

Harmonising the shortage impact assessment, together with corresponding management strategies, is essential for effective mitigation and facilitates collaboration between Member States.

Looking ahead

During the one-year extension of CHESSMEN, WP6 will continue its work through:

- Development of a time-series demand forecasting model
- Mapping pharmacists' competences during medicine shortages across the EU/EEA

Demand Forecasting

The analysis showed that demand forecasting remains largely non-harmonised across Member States. Most authorities rely on historical consumption data, while advanced statistical methods and artificial intelligence tools are still rarely used. The report highlights the need for common modelling principles and harmonised minimum data requirements to support coordinated European forecasting.

National Lists of Critical Medicines

WP6 developed recommendations for establishing and maintaining national lists of critical medicines and aligning them with the Union List of Critical Medicines. The recommendations support a coordinated EU-wide approach to identifying medicines that are critical for healthcare systems and whose continuous supply must be safeguarded.

WP7

Digital
Information
Exchange for
Monitoring and
reporting
medicine
shortages

Understanding the Current Landscape

Work Package 7 focused on improving the digital exchange of information for monitoring and reporting medicine shortages across Europe. Its objective was to support greater harmonisation, interoperability and transparency between Member States.

Analysis of Existing IT Solutions

WP7 analysed existing IT solutions at both EU and Member State level for shortage notification and monitoring. The study assessed:

- Availability of data across Member States
- National shortage reporting systems
- Strengths, weaknesses, opportunities and threats (SWOT)
- Additional data sources beyond National Competent Authorities

Identification of Best Practices

Building on this analysis, WP7 identified best practices in:

- Data submission
- Data analysis
- Data storage
- Shortage monitoring and management

The work resulted in a proposal for **minimum common datasets** to support harmonised data collection and future information exchange across Member States.

WP7

Digital
Information
Exchange for
Monitoring and
reporting
medicine
shortages

Framework for a Concept Platform

WP7 developed a framework providing recommendations and guidance for Member States to ensure:

- Data consistency
- System interoperability
- Seamless information exchange

The framework builds on existing tools, knowledge and best practices to improve shortage management processes at IT level and support more regular and harmonised data exchange across Europe.

Expected Impact

The proposed framework aims to:

- Converge national approaches
- Increase transparency
- Simplify access to relevant information
- Support harmonised monitoring and management of medicine shortages across the EU

Communicating the Results

To make these findings accessible to a wider audience, WP7 is developing a video demonstrator presenting the concept platform, the challenges of medicine shortages and ongoing efforts across Member States to harmonise and standardise shortage management processes.

Current systems → Best practices → Common dataset → Concept platform

From Reactive Responses to Preventive Action

Work Package 8, led by the Finnish Medicines Agency (Fimea), focuses on reducing the likelihood of medicines shortages through preventive and mitigation strategies. Its objective is to support National Competent Authorities (NCAs) in implementing practical measures that prevent shortages from occurring and reduce their impact on patients when they do occur.

Key Objectives

- Identify and analyse effective preventive and mitigation measures already in use in Member States
- Promote harmonisation across the EU/EEA while allowing flexibility for national contexts
- Provide guidance on implementing measures using existing regulatory frameworks
- Support longer-term policy alignment and sustainability

Preventive and Mitigation Measures

Deliverable 8.2 defines a set of best-practice measures that can be implemented without new legislation. Key recommendations include:

- Structured stakeholder dialogue
- Collaboration with healthcare professionals, patient organisations and industry
- Regulatory flexibilities to support medicine availability
- Shortage Prevention Plans (SPPs)
- National lists of critical medicines
- Harmonised shortage impact assessment frameworks

Stakeholder dialogue was identified as one of the most widely used and effective tools for shortage prevention, helping to improve communication, identify early warning signals and coordinate responses.

Implementation Plan

While Deliverable 8.2 defines what measures are recommended, Deliverable 8.3 focuses on how these measures can be implemented in practice. The Implementation Plan provides a structured and adaptable approach that can be tailored to national circumstances.

Key Recommendations

- Establishing national multi-stakeholder advisory forums
- Creating permanent communication groups with key stakeholders
- Strengthening coordination across regulatory, inspection and shortage management functions
- Investing in data-driven tools and automated monitoring systems
- Conducting gap analyses to assess implementation needs and priorities

The Implementation Plan promotes a progressive approach, encouraging Member States to start with measures already widely used and gradually move towards more advanced shortage prevention systems.

Looking Ahead

WP8 is currently preparing a Position Paper (D8.4) that will propose recommendations for minimum standards and further harmonisation of preventive and mitigation measures across Europe. The work will be supported by a survey assessing the implementation of WP8 recommendations and by a study visit focused on shortage mitigation practices and preparedness procedures.

Moving from reactive shortage management towards proactive prevention and preparedness.



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