

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

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

27/06/2024





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 harmonised response to medicinal products shortages and promote the use of best preventive practices.

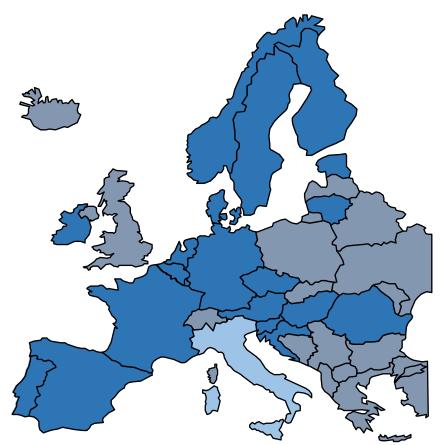
The Joint Action has officially started on 16 January 2023 and will be running for 3 years, bringing together 22 countries. The Italian Medicines Agency (AIFA, Agenzia Italiana del Farmaco), supported by the Italian National Blood and Transplant Centers (ISS-CNS/CNT), is responsible for the coordination of the Joint Action.







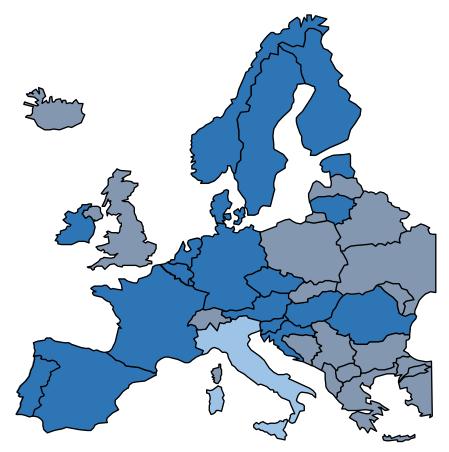
Coordinator



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)

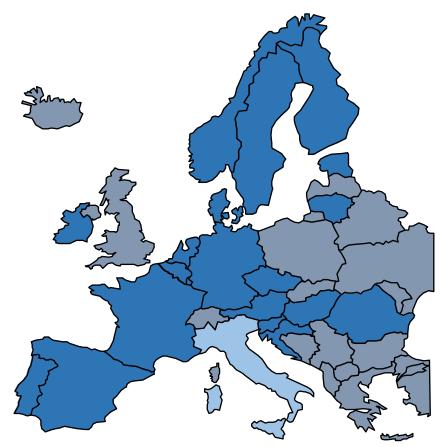
- **PHS** The Pharmaceutical Services of Cyprus (Cyprus)
- **SAM** Estonian State Agency of Medicines (Estonia)

SUKL - Státní Ústav Pro Kontrolu Léčiv (Czech Republic) Classified as public by the European Medicines Agency





Affiliated Entities



AGES/BASG - Osterreichische Agentur fur Gesundheit und Ernahrungssicherheit 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)





Objectives

CHESSMEN aims to support European Member States to provide a harmonized response to manage, prevent and mitigate medicines shortages and to contribute to an appropriate and timely availability of medicinal products, in collaboration with the existing structures working in this area.

Key working areas

- the identification of the root causes of medicines shortages
- the identification and promotion of best practices
- the definition of a common dataset proposal for the notification and management of medicines shortages
- the reduction of shortages via preventive strategies





Work-Packages (WPs)

Horizontal Work-Packages

WP 1

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Coordination and management Leader AIFA, Italy

• WP 2

Communication, dissemination and exploitation Leader INFARMED, I.P., Portugal

• WP 3

Evaluation Leader FAMHP, Belgium

• WP 4

Sustainability Leader HPRA, Ireland

Technical Work-Packages

• WP 5

Identifying the root causes of observed shortages of medicines Leader AEMPS, Spain

• WP 6

Identification of best practices to address medicines shortages Leader JAZMP, Slovenia

• WP 7

Digital information exchange for monitoring and reporting medicine shortages Leader BfArM, Germany

• WP 8

Reducing the likelihood of medicines shortage via preventive and mitigation strategies Leader FIMEA, Finland



Deliverables

Work package 5

- List of Key definitions relating to shortage medicines
- Review on existing documents or information relating to root causes of medicines shortages in the EU
- Analysis report on root causes

Work package 6

- Report on the existing documents on shortages of medicines
- Mapping of best practices in monitoring, reporting, and managing medicine shortages
- Multi-stakeholder workshop, November 2024





Deliverables

Work package 7

- Analysis report on the IT solutions in the EU and Member States
- Report on EU best practice solutions and minimum common datasets
- Concept platform to monitor and manage medicines shortages

Work package 8

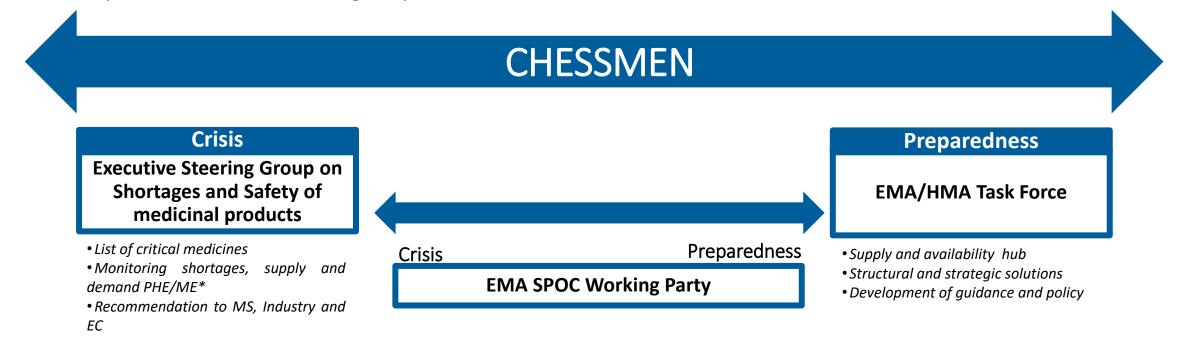
- Analysis report on the existing preventive and mitigation measures at national level
- Prevention and mitigation Plan
- Implementation plan





Collaboration with parallel initiatives

To guarantee the success of CHESSMEN long-standing strategic plan for sustainability it is essential to avoid the duplication of work and redundancies through the cooperation with existing networks and initiatives, such as the Executive Steering Group on Shortages and Safety of medicinal products (MSSG), the HMA Task Force on Availability of authorised medicines of human and veterinary use and EMA SPOC Working Party.





Intermediate meeting – 17 & 18 June 2024, Lisbon







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Other ongoing Joint Actions



CHESSMEN participation in the EU-JAMRAI 2, Joint Action on Antimicrobial Resistance & Healthcare-Associated Infections



CHESSMEN participation in the International Conference 'The Supply of Plasma-Derived Medicinal Products in the Future of Europe'





The Stakeholder Engagement Plan





Objectives

Provide beneficiaries and affiliates an orientation in establishing relations with national stakeholders to promote the projects' key findings.

Each Member State is expected to collaborate with national stakeholders to present and discuss the projects key findings.

National partners play an important role in the dissemination strategy through their own communication and exploitation channels, both at national and European levels.





National Stakeholders

Pharmaceutical Industry Associations, including:

- Marketing Authorisation Holders
- Wholesalers
- Manufacturers

Professional and academic associations:

- Healthcare providers and professionals
- Learned societies
- Academia
- Technical and scientific bodies

Healthcare and patient advocacy associations:

- Hospital
- Pharmacies
- Patient
- Consumers and payers
- Non-Governmental Organisations (NGOs)

Ethical and Legal Oversight:

• Legal and Ethic Experts





Key objectives

- Make the project known to pre-identified target groups.
- Ensure results and deliverables reach all national partners.
- Enhance stakeholders' understanding of the projects' goals and enrich joint action outputs.
- Increase transparency.





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