

*CHESSMEN*

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

Rome, April 24<sup>th</sup>, 2024



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 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.



Starting date  
**16/01/2023**



**7,85 million €** co-  
funding by EC



**22** Beneficiaries



**3** years



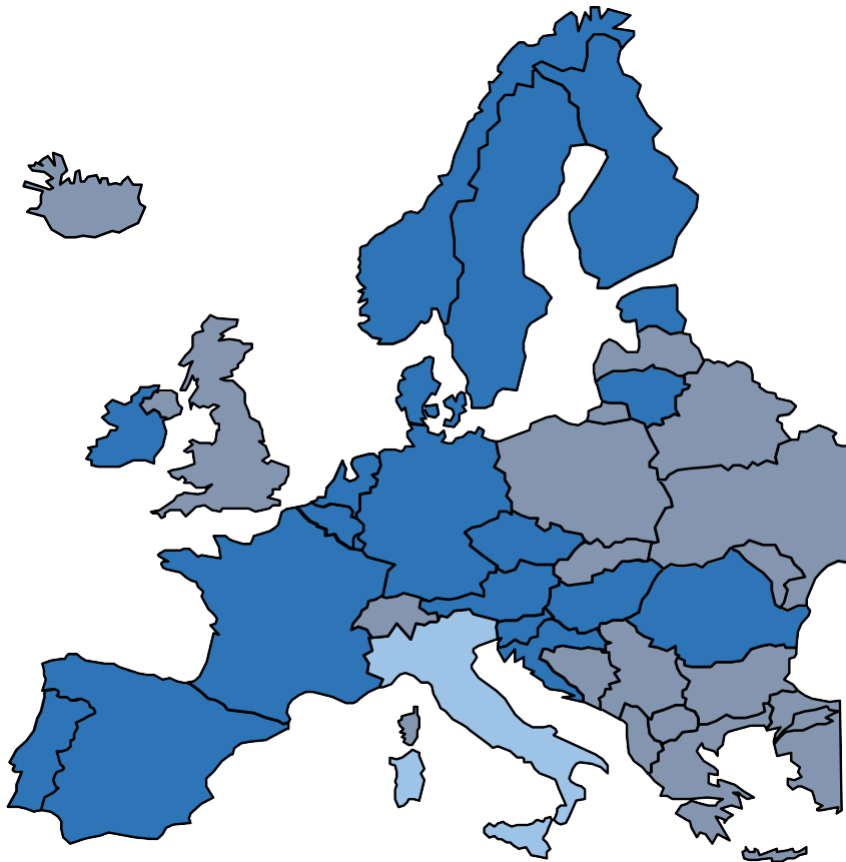
**21** EU Member States  
and **1** EEA country



**5** Affiliated Entities

# 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)

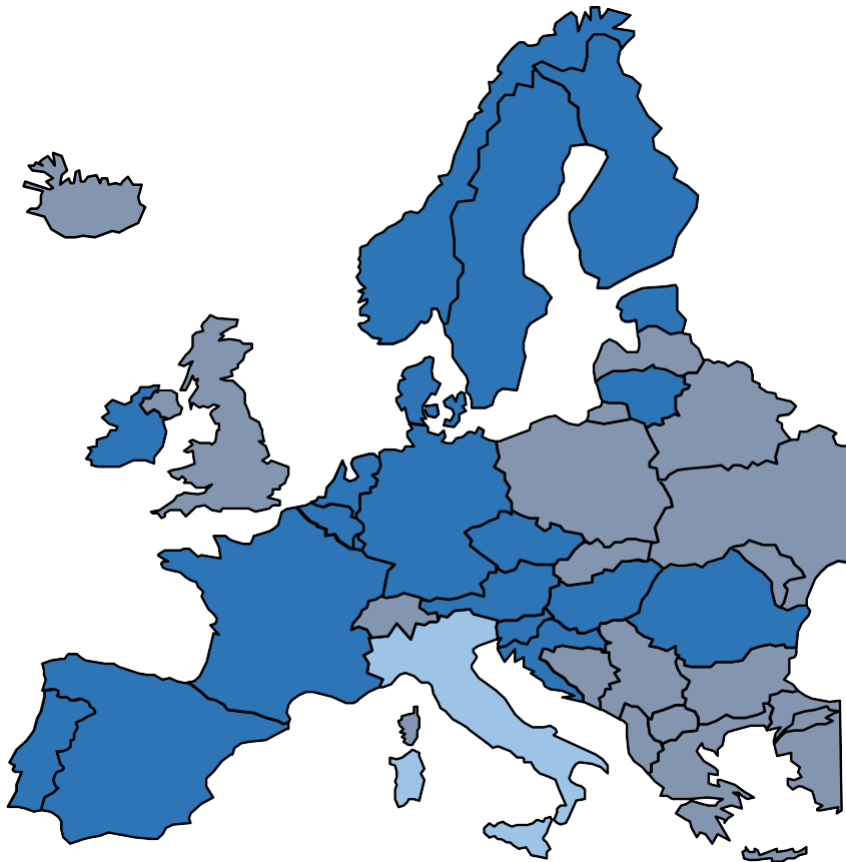
**OGYEI** - Országos Gyógyszerészeti És Élelmezés-egészségügyi Intézet (Hungary)

**PHS** - The Pharmaceutical Services of Cyprus (Cyprus)

**SAM** - Estonian State Agency of Medicines (Estonia)

**SUKL** - Státní Ústav Pro Kontrolu Léčiv (Czech Republic)

# Affiliated Entities



**AGES/BASG** - Osterreichische Agentur fur 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)

# Objectives

# Focus

To strengthen the **coordinating structure**, as well as **optimizing** the use of the available resources of all Member States, by **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), 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.

## Aims of the Action

- Establishment of a coordinating structure between the Member States experts and the European Competent Authorities.
- Collection and consolidation of country specific data, statistics, definitions, concepts and procedures to support the bottom-up harmonisation strategy.
- Agreement on common definitions, concepts and procedures towards the harmonisation of the *modus operandi*.
- Identification and categorisation of the root causes of shortages.
- Identification of best practices to address medicine shortages.
- Provision of common grounds for a harmonised IT concept model for the management of medicine shortages, monitoring supply and implementation of mitigation measures.
- Definition of preventive and mitigation strategies to reduce medicine shortages considering the root causes.



# Work-Packages

# Work-Packages (WPs)

## Horizontal Work-Packages

- **WP 1**  
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

# Sustainability

# Engagement of stakeholders

The sustainability of the JA depends on the engagement of key stakeholders at both national and European institutional and professional levels, whose input is essential for:

- **Promoting the JA and its results:** active dissemination of results and deliverables produced by the JA with the Member States through the available channels, including, but not limited, to in-country or professional networks.
- **Providing key information to the JA:** stakeholders as important sources of information and key players in the success of the JA.
- **Supporting the development of national and professional platforms for the dissemination of information related to shortage management and notification:** cooperation on the establishment of the minimum criteria and the maintenance of the sustainability of dedicated platforms.

# Strengthening of CHESSMEN network

CHESSMEN is strongly focused on growing and strengthening the network in order to broaden the scope of the discussions, as well as to increase the feedback and valuable information received from the stakeholders and all partners taking part in the Joint Action.

The network should cover a wide geographical area and facilitate the sharing of information among all parts.

CHESSMEN envisages the involvement of countries that are not directly participating in the Joint Action. The respective entities will be approached and inquired about their interest in contributing to the work in progress. For example, EU candidate countries, Non-EU and EEA (European Economic Area) States.

Thus, CHESSMEN has already started discussions with other National Authorities (e.g. Malta) and institutions (e.g. EDQM).

# Case study: antibiotics

# Scenario



The screenshot shows the European Medicines Agency (EMA) website. At the top left is the EMA logo and the text "EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH". To the right is a search bar. Below this is a dark blue navigation bar with links: "Medicines", "Human regulatory", "Veterinary regulatory", "Committees", "News & events", "Partners & networks", and "About us". Below the navigation bar is a breadcrumb trail: "Home > News > European Health Union: EU steps up action to prevent shortages of antibiotics for next winter". The main content area has a light blue background with the title "European Health Union: EU steps up action to prevent shortages of antibiotics for next winter" in large blue font. Below the title is the date "17 July 2023" and three category tags: "News" (highlighted in dark blue), "Human", and "Medicine shortages". The main text paragraph reads: "The European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency are today issuing recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the next winter season. These recommendations, which have been developed through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), complement the process to develop an EU list of critical medicines. In close cooperation with the EU Member States, the Commission will take operational follow-up actions, including, if necessary, possible joint procurements." Below this is a grey box with the heading "Recommendations to ensure sufficient supply for EU patients". The text below the heading reads: "If the demand in the coming winter season is similar to an average level of consumption in previous years, the data collected suggest that supply to the EU of oral formulations of key first and second-line antibiotics for respiratory infections will match demand in the coming winter season. EMA and the European Health Emergency Preparedness and Response Authority (HERA) will continue to work with".

# Possible counteracting measures

- Optimization of the use of antibiotics **(data gathering via HP/pharmacies, guidelines)**
- Increase of the availability **(reshoring, import via Joint Procurement Agreement)**
- Promotion of the information on the available alternatives **(information to HP, awareness campaigns)**
- Monitoring of available stock **(data gathering via MAH/distributors)**
- Stockpiling **(MS procurement, import, extraordinary manufacturing)**
- (...)



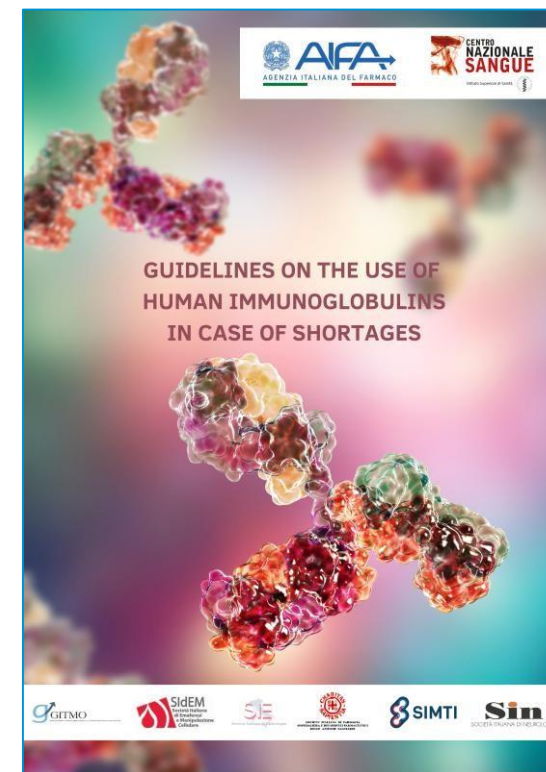
## A similar scenario: plasma products in 2020

Scenario: possible shortage due to the reduced plasma gathering during pandemic.

Possible mitigation initiatives:

- Optimization of the use (**guidelines**)
- Increase of the availability of the source product (plasma) (**promotion of donation**)
- Increase of the availability of the finished product (**increase of the manufacturing efficiency**)
- Increase of the availability of plasma from commercial sources (**increase of the budget**)

# Building on existing experiences for the network



## Work Package 6 approach: identification of best practices

- Collection of the existing documents in the EU, EMA/HMA and national contexts related to shortages of medicines to support harmonized approach to the topics of the JA and facilitate all the next steps in all technical work packages.
- Identification and mapping of the best practices in monitoring, reporting, and managing medicine shortages.
- Based on the outcomes of mapping activity, development of comprehensive protocol for monitoring, reporting and managing medicine shortages to support harmonisation of the approaches within Member States.
- Contribute to the work of TWG1 of the TF AAM on the development of EU list of critical medicines, and based on the outcomes prepare the recommendations for development of National lists of critical medicines. (new objective).
- Performing pilot on demand forecasting at national level for selected medicines.
- Development of training material on the WP6 outputs and workshop for the NCAs.



# Conclusions

22 January 2024  
European Medicines Agency



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Meeting Summary - Medicine Shortages (SPOC) Working Party

| Item | Topic  |
|------|--|
| 4.   | <p><b>Potential impact of the international situation (e.g. War in Ukraine) and energy crisis on the supply of medicinal products for human and veterinary use to the European market:</b></p> <p><b>a) Antibiotic shortages: Update on preparedness activities</b></p> <p>EMA provided an update on the shortages reported by the SPOC WP, and the feedback that in several MSs the situation is considered to be better than last year. Moreover, EMA presented the feedback from Sandoz oral explanation during the MSSG meeting in November 2023 and the feedback from alternative antibiotic suppliers.</p> <p><u>Comments raised</u></p> <p>A number of SPOC WP members informed that the situation is manageable, and no additional support is required at this stage. Nevertheless, SPOC WP members noted that the situation may change quickly depending on the epidemiological situation and ability to increase supplies if necessary, therefore potential future need for additional actions cannot be excluded.</p> <p><b>Agreed action:</b></p> <ul style="list-style-type: none"> <li>SPOC WP members to continue reporting critical and non-critical shortages to EMA for the set of antibiotics.</li> </ul> |

*Thank you!*

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