CHESSMEN

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

Q&A

KICK-OFF MEETING

10th FEBRUARY

Co-funded by the European Union

Executive Summary

In order to ensure a good and organized dissemination of the Joint Action, this document provides some of the main ideas of the project, so that the message delivered is cohesive and well-articulated.

In support of the dissemination plan there are some **essential key messages**, for example that shortages of medicines are a growing concern for many European Union Member States and Europe is working together to mitigate shortages and to promote best practices in reporting, monitoring and managing shortages.

Each Member State has been implementing its own mitigation measures, which even if successful or with somewhat positive results shows a clear lack of harmonization with the rest European Member States, such as the lack of key common definitions, policies, management procedures and tools. CHESSMEN aims to bring EU Member States closer in terms of shortage monitoring and management.

Q&A

1. What is the Joint Action CHESSMEN?

CHESSMEN is a project that officially started on 16th January 2023, and will run for three years, bringing together a total of 22 participating countries as beneficiaries and 5 participating organizations as affiliated entities, under the coordination of AIFA - Italian Medicines Agency/Agenzia Italiana del Farmaco, with the support of the Italian National Health Institute (CNS and CNT). The project is co-funded by the EU.

Short supply of medicines is an issue of concern to public health and medical care delivery at both national and international levels. CHESSMEN Joint Action envisages to support EU Member States to develop an harmonized structured strategy to drive the process of management of medicine shortages and foresee the implementation of proper structures, measures and tools to tackle potential lack of medicines. The monitoring and prevention of medicine shortages are key factors in sustaining the long-term and timely access of citizens to the respective therapeutics.

This will be done, not only by strengthening the existing coordination network, but also through capitalizing and building on existing knowledge, such as the development of model initiatives/practices based on the European Commission studies and the existing Good Practices already in place in EU Member States.

2. Why did the creation of this project become necessary?

Shortages of medicines are a longstanding concern in the EU, and the COVID-19 pandemic has placed significant pressure on the medicines supply chain. Since 2020, all EU Member States had to face the problem of short supply of medicines, such as the ones for Intensive Care Units.

The scarcity of medicines leads to the postponement or cancellation of treatments, medicine adverse reactions or higher treatment costs for citizens and health systems. The reasons behind shortages are multifactorial and englobe different stakeholders.

EU Member States and EU institutions were forced to set up ad-hoc units and/or initiatives, highlighting the need for stronger coordination of concurrent activities, and a harmonisation of the approaches between and among Member States.

Additionally, the 2021 European Commission study on medicine shortages highlighted the need for greater coordination in the case of shortages prevention and mitigation across the EU. Moreover, the regulation EU 2022/123 reinforced the role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

In this context, the European Commission deemed strategically important to elaborate a Work Program specifically focused on “Supporting action to mitigate shortages of medicines and improve the security of supply including of COVID-19 therapeutics”.

3. What are the main objectives of the project?

CHESSMEN Joint Action envisages strengthening the coordination and harmonisation between different Member States, supporting the existing networks and initiatives already present in the field, and therefore enhancing Member States cooperation in identifying the root causes of observed shortages of medicines, monitoring and reporting medicine shortages, including a common dataset proposal, and reducing the impact of shortages on patients. In addition, it also foresees the definition of preventive strategies for shortages and the capitalization and expansion of previous knowledge, such as through the creation of model initiatives and practices based on studies conducted by the European Commission and Good Practices already in use in EU member states.

The strategy for making this coordination structure a concrete tool, rather than a mere formal reactive network, is to set up practical objectives that will allow reinforce the collaboration within the different Member States improve the current modus operandi both:

- **Directly** by building a collection of "Good Practices" gathered from the Member States experiences that could be fully or partially adapted and adopted by all the other interested Member States.

- **Indirectly** by working together to build the collection of models and Good Practices, and the tools that will be designed within the Joint Action program.

The partnership will develop a mechanism to gather practical models for Member States while considering the findings of the Future-proofing Pharmaceutical Legislation Study on Medicine Shortages: Final Report and the Structured Dialogue on Security of Medicine Supply.

4. What are the expected results?

- Establish 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 harmonization strategy.

- Agreement on common definitions, concepts and procedures towards the implementation of a harmonized structured strategy to drive the process of management of medicine shortages

- Identification and categorization of the root causes of shortages.

- Identification of best practices to address medicine shortages.

- Provide 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 the likelihood of medicine shortages considering the respective root causes.

5. Who are the project's partners, stakeholders, and target groups?

Different types of partners are involved in the project with different roles and responsibilities towards the project and respective content management. There are 3 types of partners in the Joint Action:

1) The main partner of the Joint Action is AIFA, represented by the Programme coordinator Domenico Di Giorgio.

2) There are 22 associated partners (AIFA included as the coordinator role) participating on the Joint Action at the moment.

3) There are 5 affiliated entities. Collaborating partners play an important part in the development of the Joint Action as their valuable inputs increase the scientific knowledge and help in the dissemination of the results within EU Member States.

To achieve the goals of the Joint Action CHESSMEN, key stakeholders at both institutional and professional levels will be involved in the discussions. National and European institutional and professional stakeholders act as key elements to take the knowledge, conclusions and results from the project into practice at EU level.

The main target groups of the project are EU Regulators and national policy makers, Industry associations, professional associations, patients' associations, academia, and the general public.

6. How is the CHESSMEN Joint Action organized?

The CHESSMEN project is organized into 8 work packages, important subdivisions of the project, consisting of **four horizontal packages**, that support the whole Joint Action, and **four technical work packages**, that are directly aligned with the project's specific objectives.

Horizontal Work-packages:

Work Package 1 - Led by AIFA, who is responsible for the management and coordination of the project, horizontally and vertically, ensuring that it is implemented as planned, and managed following the EU rules and procedures.

Work Package 2 - Led by INFARMED, I.P., who is responsible for the identification of the target groups, both internal and external, the respective dissemination and communication strategy, as well as the development of the project visual identity and for setting up the intermediate and final meetings.

Work Packages 3 - Led by FAMHP, who is responsible for the evaluation of the Joint Action, namely the evaluation of the effectiveness of the project.

Work Package 4 - Led by HPRA, who is responsible for ensuing the sustainability of the identified policy measures, including good practices, in line with the overall objectives of the JA. This Work-package is in close collaboration with the other Work-packages to support the technical WP, in

order to assure the timely development of the deliverables and to analyze the transferability between Member States and networks.

Technical Work-packages:

Work Package 5 - Led by AEMPS, who is responsible for the identification of the root causes of shortages of medicines, on the basis of available published and unpublished information, knowledge and experience of the participants and known practices.

Work Package 6 - Led by JAZMP, who is responsible for the identification of established knowledge, procedures and practices in order to support the process of monitoring, reporting, and managing medicine shortages.

Work Package 7 - Lead by BFARM, who is responsible for the development of an European IT concept model to monitor and manage medicines shortages, taking into consideration the already existing tools/good practices developed at EU MS level, in order to achieve an efficient merging of the available systems and information sources of MS, with an inclusive approach.

Work Package 8 - Led by FIMEA, who is responsible for the elaboration of an operating concept platform to monitor and report medicines shortages on the basis of standardized common minimum datasets.

7. What will be the work methodology?

This Joint Action will foster this harmonisation through an operative, collaborative, bottom-up approach: the coordination structure between the Member States experts that will become the reference contacts in the field will be working together for the 3-year timeframe of the Joint Action, and this cooperation will build the ground for future initiatives.

In order to better cope with the needs of Member States in this field, the methodology will be articulated on three pillars:

I) A shared scientific approach.
II) An operational approach.
III) An implementation approach.

In particular, the methodology will include the gathering, the evaluation and the dissemination/promotion of the good practices already applied in the different Member States.