

CHESSMEN Multi-stakeholder Workshop, 27 November 2024 - Report

Work Package 6

JAZMP

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Introduction

The medicines shortages cause disruptions in continued availability of medicines for patients which is an integral part of well-functioning health systems. Shortages have always been present, but the Covid crisis and other recent events, such as lack of antibiotics last two winters, demonstrate that more action is warranted. In the recent years the dynamic of action has increased.

The European Health Union and the Pharmaceutical Strategy for Europe 4 years ago gave a strong boost to different initiatives at EU level. Very important was the establishment of HERA, and the reinforced mandate of the EMA which has already strengthened the coordinated and collaborative EU level management of critical shortages. Furthermore, a “Voluntary Solidarity Mechanism for medicines” that was launched a year ago to support Member States experiencing critical shortages, the first “Union list of critical medicines”, a new “European Shortages Monitoring Platform” and the “Critical Medicines Alliance” are initiatives which are all tackling the important aspects of the drug shortage problem.

The proposed reform of the pharmaceutical legislation introduces structural measures to improve availability of medicines and in addition we expect the Critical Medicines Act to be presented by the European Commission soon.¹

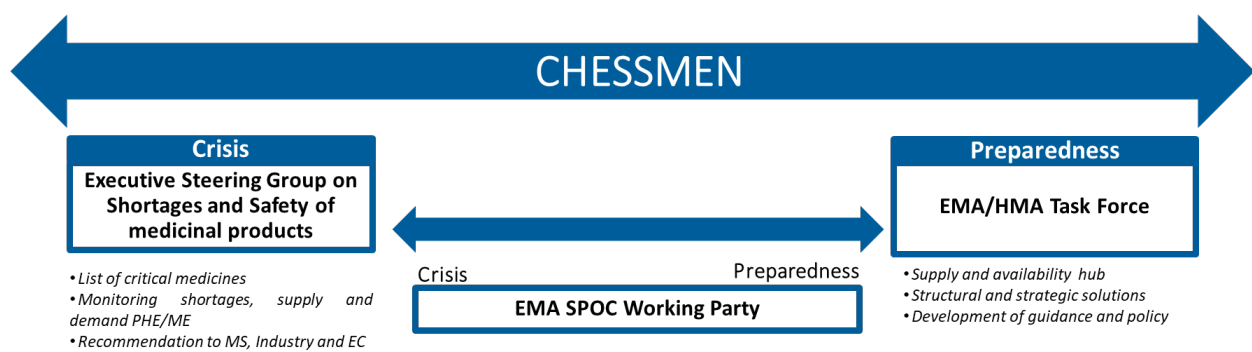
The challenge is complex and there is no single solution. A comprehensive set of measures is therefore appropriate and necessary at EU level which support national measures, in particular as most shortages are managed and resolved at national level. Member States have to manage their medium to high impact shortages on a daily basis. The EU co-funded Joint Action (JA) on Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) helps strengthen national capacities in managing shortages.

CHESSMEN envisages to support Member States to provide a harmonised response to medicine shortages and to promote the use of best preventive practices to reduce shortages of medicinal products, among other measures. JAZMP, lead of the Work Package 6, convened CHESSMEN Multi-stakeholder Workshop bringing together representatives of industry, healthcare professionals, patient and consumer advocates, as well as representatives from national regulatory authorities and other European regulatory bodies.

The virtual workshop was attended by 220 participants and offered key stakeholders in supply chain an opportunity to discuss the current state, key findings, and preliminary conclusions of four technical Work Packages of CHESSMEN JA after almost 2 years of intensive cooperation supporting harmonised response to medicines shortages in EU/EEA.

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Addressing medicine shortages in the EU, 24.10.2023

Domenico di Giorgio (AIFA, CHESSMEN Coordinator) highlighted the collaboration with parallel initiatives on shortages of medicinal products. 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 already present in the field, such as the Executive Steering Group on Shortages and Safety of medicinal products (MSSG), the HMA/EMA Task Force on Availability of authorised medicines of human and veterinary use (TF AAM) and EMA SPOC Working Party.



In collaboration with TF AAM, CHESSMEN has supported the development of the Union list of critical medicines, the definition of the SPMP, the update on guidance on Preventing and Communicating Medicine Shortages.

Session 1: Best practices in reporting and managing medicine shortages

Chair: Melita Tovornik (JAZMP, CHESSMEN WP 6 Lead)

The aim of this session was to present the key findings and recommendations from WP 6 survey *Mapping of best practices in monitoring, reporting and managing medicine shortages* to which followed feedback from main stakeholders in medicine shortages and a general discussion.

The CHESSMEN WP 6, led by JAZMP, is responsible for the identification of established knowledge, procedures and practices to support the process of monitoring, reporting, and managing medicine shortages on national level. The mapping survey collected existing practices and planned measures from 26 EU/EEA Member States.

Jasna Puh (JAZMP, WP 6) highlighted that although only MAHs are obligated to report shortages in the majority of Member States, shortage notifications are also received from pharmacies, wholesalers, patients, and physicians. While reporting timelines vary among Member States, it is important that MAHs notify shortages for all medicinal products as soon as they become aware of it, so the NCA can review the situation and act appropriately. NCAs should foster early reporting through regular and open communication with MAHs and other stakeholders regarding ongoing issues in the supply chain and their possible impact on product availability. In addition, the option to notify unavailability should be available to anyone, including wholesalers, healthcare professionals and patients, which is partially already in place.

To ensure transparency, all shortages confirmed by the MAH should be made publicly available in a shortage catalogue after NCA assessment. Catalogues should include information that provides context and guidance for healthcare professionals and patients, especially therapeutic alternatives, mitigation measures and specific recommendations. Currently, this is included in only a small number of catalogues. Any shortage news in other parts of NCA website should be linked with shortage catalogue for easy access. Additionally, push notifications from catalogues within electronic systems of prescribers and pharmacists when they try to prescribe or dispense a medicine in shortage should be implemented in all Member States. The notification should include information regarding therapeutic alternatives.



After the NCA assessment is complete **all shortages confirmed by the MAH** should be made publicly available.



The shortage catalogue should be **updated** as new information becomes available.



Option for anyone to sign up for **e-mail alerts** for a specific medicinal product.
A notification is sent if the availability of the selected medicinal product(s) changes or there is new information about the shortage.



It is recommended to keep the shortage **records for longer periods** (e.g. 5 years), for transparency purposes.

NCA mostly involve MAHs, wholesalers and pharmacies in coordinating the response to the shortage, while prescribers, insurance funds and patient organisations are included less. The majority of the NCAs set up a taskforce on a case-by-case basis to support the assessment of a particular shortage, considering possible therapeutic alternatives, as well as developing recommendations for improving the supply situation and external communication. However, coordination of stakeholders is currently triggered mainly in case of critical shortages and should be strengthened for the shortages with medium and high impact.

Feedback from invited stakeholders

Catarina Matias (UEMO, European Union of General Practitioners) highlighted that general practitioners are the biggest group of prescribers, and they directly deal with patient concerns and questions. This positions them on the frontline of addressing the medicine shortages.

The challenges that GPs face are ineffective and fragmented communication of shortages, making it difficult for doctors to stay informed, as well as time-consuming administrative burden to find alternative treatments. The need to adapt therapies in real time can generate uncertainty and frustration for both healthcare professionals and patients.

Shortage catalogues should function as an early warning system which flags upcoming shortages. They should also clearly identify therapeutic alternatives, and measures that can be taken by prescribers. Useful feature would be an option to monitor specific medicines, such as antibiotics. The shortage communication to healthcare professionals should also include information about the expected impact on patients, which may be effectively visualized with traffic light system. There should be an option for physicians to report shortage. NCA reporting platform should be user-friendly to increase the engagement. GPs monitor patient outcomes, allowing them to identify the full impact of shortages. Hence, their feedback is invaluable, making it essential for them to be actively involved in policy-making processes.

Ilaria Passarani (PGEU, the European Organisation of Community Pharmacists) highlighted that despite pharmacists' continued efforts to find solutions, we are witnessing a significant negative impact on patient health and a concerning erosion of patient trust in the healthcare system. Shortage of medicines causes distress for patients, leading to treatment discontinuation, in some cases also due to co-payments because therapeutic alternative is more expensive or not reimbursed. Pharmacists spend on average 10 hours per week dealing with medicine shortages. This time has tripled over the last 10 years. Pharmacists are usually the ones who first inform the patient that their medicine is not available. In most cases, they cannot even explain to the patient why the medicine is not available, and this is where the stress and frustration increases. It is therefore crucial to have effective communication channels between MAHs and competent authorities that encourage early notification of expected shortages and timely dissemination of this information to then be disseminated to all healthcare professionals.

The CHESSMEN WP 6 recommendations are aligned with the PGEU Position Paper on Medicines Shortages, namely in terms of transparency, timely reporting by MAHs, enabling community pharmacists to fully utilise their skills, knowledge and experience to find alternative treatments for their patients. Further involvement of pharmacies is needed, namely on information to pharmacists, reporting tools and integration of reporting and monitoring systems with dispensing software.

Several best Practices from PGEU members were also highlighted among them also platforms and systems for reporting medicine shortages and service level reporting e.g. PharmaStatus, DP-Ruptures, Farmaco, CISMED and others.

Nikos Dedes (EPF, European Patients' Forum) highlighted that medicines shortages threaten the patients' right to access safe and quality healthcare. Many patient organisations currently report a lack of information and coordinated communication about shortage from authorities. This leaves patients and their representative organisations unable to plan or respond effectively.

Shortage catalogues are a great tool to provide an informative overview of current and pending shortages. They should be user-tested with patient involvement, as they are a key target population. In addition, to achieve that catalogues are easy to use and find, targeted awareness campaigns and trainings are suggested to ensure patients and their representatives are well-informed. The integration of national shortage catalogues with electronic prescribing systems is important as it can prevent delays in obtaining appropriate treatment and associated stress.

Patients should have the opportunity to contribute to reporting of shortages, and the recommendation for this to be more widely used is welcomed.

Patients may be left feeling worried and confused even when alternatives to their treatment are available. To address this, it is essential to involve patients in the coordination of responses to treatment shortages. NCAs should foster ongoing collaboration and actively engage patient organisations in developing national shortage policy solutions, which should include communication strategy to the general public.

Liana Petrosova (Medicines for Europe) highlighted the challenges that generic industry is facing, namely long lead time for production and related forecast accuracy, especially in the event of case of unexpected increase in demand, safety stock and on the other side increased costs of production and price pressure (restricting price polices and unsustainable tendering practices). The following measures were highlighted to improve the monitoring, reporting and management of medicine shortages: EMVS data could be used for market monitoring and shortage prediction, digitalisation of shortage export through ESMP and system interconnectivity, generation and pre-filling of Shortage Prevention Plans templates by existing data and merging shortage notification with Shortage Mitigation Plans, protecting confidential MAH's information when publishing shortages, active and early engagement with MAHs to move

stock in case of shortages in specific markets, introduction of permanent regulatory flexibilities and financial incentives for critical medicines in case of shortages (with a particular focus on labelling and packaging flexibilities), avoidance of rigid and inflexible stockpiling policies and support for policies that favour European solidarity and stock sharing, such as the Voluntary Solidarity Mechanism.

Finally, Liana Petrosova also highlighted the need for preventive measures, in particular improving price and reimbursement systems to allow for price adjustments to promote sustainable competition and amending public procurement rules to reward criteria other than price that reward the resilience of supply.

Their presentations acknowledged that CHESSMEN WP 6 recommendations for improving shortage management are aligned with the stakeholders who are on the frontlines in addressing the issue of medicine shortages.

The discussion that followed highlighted that reporting shortage way in advance only makes sense when it is already confirmed by MAH to avoid overreporting. Some Member States have financial penalties in place but most of them do not enforce them. The NCAs put more emphasis on communication with MAHs to raise awareness about importance of reporting shortages. Deeper understanding of underlying causes of shortages, especially manufacturing issues, is key to effectively prevent shortages in the future and find appropriate solutions for continuous availability of medicines for patients. It is crucial to collaborate and communicate not only with MAHs, wholesalers, importers and manufacturers but also other decision makers such as payers and public procurement bodies.

Session 2: Main achievements of JA CHESSMEN so far

Chair: Nuno Simões (INFARMED, CHESSMEN WP 2 Lead)

This aim of this session was to present the main achievements of the CHESSMEN technical WPs 5, 7 and 8, dealing with root causes, the digital information concept for the monitoring and reporting medicines shortages and prevention and mitigation measures to combat medicines shortages. The representatives of EMA presented the latest guidance developed by TF AAM, such as shortage prevention and mitigation plans and guidance for regulators, healthcare professionals', and patient organisations on prevention and communication of medicine shortages, in which CHESSMEN actively participated.

The main objective of CHESSMEN WP 5 is identification and analysis of the root causes of medicine shortages in Europe. For this purpose, a review of existing reports and publications that included information related to root causes of medicine shortages was initially conducted. Once the main causes were identified, a series of surveys were conducted to map relevant information from NCAs and Industry associations. **Laura Marrero (AEMPS, WP 5 Lead)** highlighted the main results of analysis:

- Most EU/EEA Member States have in place a template that facilitates shortage root cause data collection and the subsequent analysis on the frequency of the root causes.
- There is a high variability between different shortage notification templates, some collect very detailed information while others are more general.
- The most frequent root causes of shortages during 2022 and 2023 were manufacturing issues, followed by unexpected increases in demand, commercial and distribution issues.
- The comparison of the root causes of shortages among Member States is very complex due to the lack of harmonisation on the root causes recorded by each of them.
- A unique root cause classification system would be necessary, based on the SPOC WP classification.

CHESSMEN WP 7 focuses on the development of a European IT concept model for the monitoring and management of drug shortages, taking into account existing tools and good practices developed at European Member State level, in order to achieve an efficient integration of Member States' existing systems and information sources through an integrative approach. **Gabriele Eibenstein (BfArM, WP 7 Lead)** highlighted the analysis and review of IT solutions at European and Member State level for shortages recording and monitoring and identified best practices in data submission, data analysis and data storage. Based on these key findings, WP 7 will develop an implementation concept for an electronic platform to monitor and manage medicine shortages, which aims to harmonise and standardise processes, procedures and IT tools of existing national systems to converge national approaches towards a unified strategy on how medicine shortages are monitored and managed.

CHESSMEN WP 8 aims to support Member States in the prevention and mitigation of likelihood of medicines shortages. **Johanna Linnolahti (Fimea, WP 8 Lead)** highlighted the recently conducted survey to better understand which preventive and mitigation measures are used or

planned to be implemented in Member States. Responses from 25 Member States were received, including through the SPOC WP. The next step is a plan for the implementation of the most effective preventive and mitigating measures by the NCAs, which can be adapted without change in legislation in collaboration with the SPOC WP. Best practices for stakeholder dialogue platforms for supply chain stakeholders, patients and healthcare providers as part of the prevention and mitigation plan will also be addressed.

With the aim to shift from a reactive (management) to a proactive (prevention) approach to address shortages the TF AAM developed the [Good practice guide for industry on prevention/management of shortages of medicinal products for human use](#) that was published in May 2023. The recommendations from guidance for development of shortage prevention and mitigation plans are now further supported with the templates for [Shortage Prevention Plan](#) and [Shortage Mitigation Plan](#) published on 18 June 2024. **Maria Jesus Alcaraz Tomas (EMA, TFAAM)** highlighted that Shortage Prevention and Mitigation Plans (SPMPs) also support preparedness for the implementation of the new pharma legislation and explained the voluntary pilot project that will facilitate the implementation of SPMPs by collecting feedback from industry on the proposed templates and challenges that could be identified during the process.

Inga Abed (EMA and TF AAM) emphasized importance of prevention and the role of patient and healthcare professional organisations. Participants were reminded of the [published guidance](#) as a useful tool to promote good practice for shortage prevention and fostering interaction and improving information exchange between the different stakeholders. Inga Abed also presented the work on updating the guidance [Good practice guidance for communication to the public on medicines' availability issues](#). The updated guidance, which will be published on 16 December 2024, highlights the need to engage with the media to ensure that information in the media is contextualized and framed in a way that avoids negatively impacting public behaviour when it comes to buying medicines, debunk common misconceptions about shortages and promote understanding of shortage management in the EU. The updated guidance also addresses the role of social media and provide recommendations for communication through social media.

The discussion that followed highlighted the need to further promote the use of already existing guidelines and the current and future findings of the JA CHESSMEN work.

Closing remarks

Improved collaboration between national authorities and effective communication with key stakeholders in the supply chain, healthcare professionals and patients can contribute to a more efficient and effective management of shortages across the EU. This workshop shed light on how this cooperation can be strengthened through concrete examples from current practice.

Many questions from the audience and a lively discussion that followed the presentations show that active involvement and coordination of all stakeholders is a topic that needs to be addressed also going forward.



List of abbreviations

| | |
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| AEMPS | Spanish Agency for Medicines and Medical Devices |
| BfArM | Federal Institute for Drugs and Medical Devices, Germany |
| EEA | The European Economic Area |
| EMA | European Medicines Agency |
| EMVS | European Medicines Verification System |
| EPF | European Patients’ Forum |
| ESMP | European Shortages Monitoring Platform |
| Fimea | Finnish Medicines Agency |
| GP | General practitioner |
| HCP | Health Care Professional |
| HERA | Health Emergency Preparedness and Response |
| HMA | Heads of Medicines Agencies |
| INFARMED | National Authority of Medicines and Health Products, Portugal |
| JA | Joint Action |
| JAZMP | Agency for Medicinal Products and Medical Devices of the Republic of Slovenia |
| MAH | Marketing Authorisation Holder |
| MSSG | The Executive Steering Group on Shortages and Safety of Medicinal Products |
| NCA | National Competent Authority |
| PGEU | European Organisation of Community Pharmacists |
| SPMP | Shortage Prevention and Mitigation Plan |
| SPOC | Medicine Shortages Single Point of Contact |
| TF AAM | HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use |
| UEMO | European Union of General Practitioners |
| WP | Work Package |

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