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CHESSMEN

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

Report on the Common Protocol for Monitoring, Reporting and Managing Medicine Shortages

Work Package 6

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List of Abbreviations

BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte, Germany
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
HMA	Heads of Medicines Agencies
HPRA	Ireland's Health Products Regulatory Authority
JAZMP	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
MAH	Marketing Authorisation Holder
MAT	Moving Annual Total
MSC	Medicine Shortage Communication
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
NCA	National Competent Authority
SAM	Supply and Availability of Medicines and Devices
SMP	Shortage Mitigation Plan
SPOC WP	Medicine Shortages Single Point of Contact Working Party
SPP	Shortage Prevention Plan
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization
WP	Work Package

1 Introduction

The European Union (EU) co-funded Joint Action on Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) is an initiative designed to support EU Member States by strengthening a more harmonised response to medicine shortages across Europe. Among other measures, it promotes the use of established and effective preventive practices to reduce the incidence of shortages of medicinal products.

Technical Work Package 6 (WP 6) aims to identify and promote best practices in monitoring, reporting and managing medicinal product shortages.

This report (D6.2) presents a recommendation of a common protocol for the effective monitoring, reporting and managing of medicine shortages for NCAs based on best practices collected from CHESSMEN partners. Figure 1 illustrates the context of D6.2 within the WP 6. The aim of the protocol is to support the prevention of notified shortages or reduce their impact on patients and the healthcare system through coordinated shortage management. The document focuses primarily on improving procedures for notifying shortages, assessing their impact, implementing potential measures and enhancing external communication, based on identified good practices. The steps of the protocol and the corresponding decision-making process are visualised in the Shortage Management Decision Tree (Shortage Management Decision Tree).

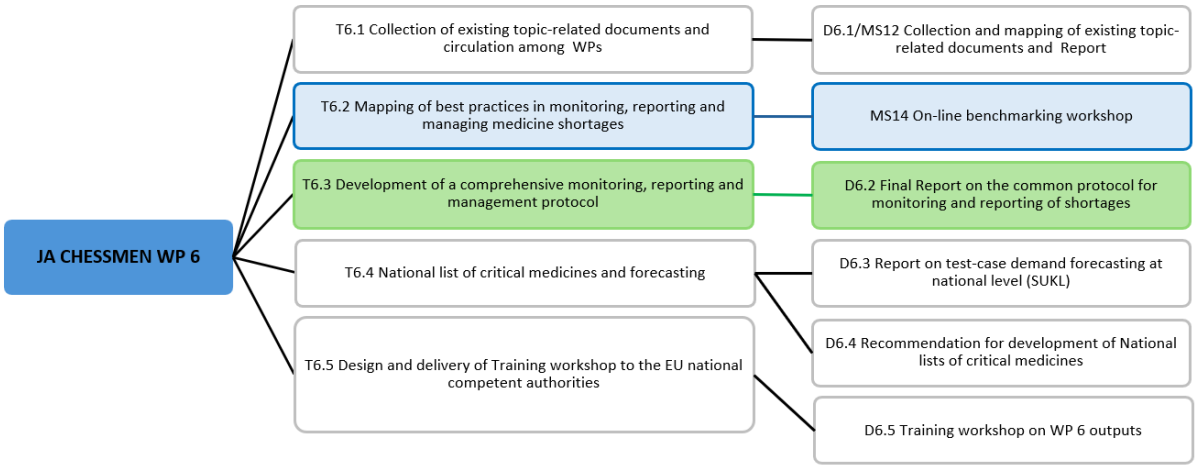


Figure 1. D6.2 Report within the context of WP 6 tasks

The report was built on the insights and best practices in monitoring, reporting and managing medicine shortages collected during the implementation of Task 6.2. A mapping survey was conducted in September 2023 to gather information on the current practices and planned measures of Member States in monitoring, reporting, and managing medicinal product shortages. The findings of this survey are summarized in the *WP 6 T6.2 Report on Mapping of*

Practices in Monitoring, Reporting and Managing Medicine Shortages[1] (hereinafter referred to as the T6.2 Report), public version can be found in Annex 2: WP 6 T6.2 Report on Mapping of Practices in Monitoring, Reporting, and Managing Medicine Shortages. October 2024. This report served as the basis for discussions with various stakeholders at a workshop organised by WP 6 in November 2024. The stakeholder feedback gathered during the workshop is summarised in the *Report on the CHESSMEN Multi-stakeholder Workshop*[2] (see Annex 3: WP 6 T6.2 Report on the CHESSMEN Multi-stakeholder Workshop, 27 November 2024. December 2024.).

The report was sent for final review to the Medicine Shortages Single Point of Contact Working Party (SPOC WP). No feedback was received from the SPOCs. Additional input was provided by the EMA's Supply and Availability of Medicines and Devices (SAM) team, primarily concerning the shortage impact assessment methodology. The team suggested some additional elements for inclusion in the methodology. These proposals require further discussion at the SPOC WP level to ensure alignment and harmonisation as outlined in the Section *Next Steps*.

[1] WP 6. *T6.2 Report on Mapping of Practices in Monitoring, Reporting and Managing Medicine Shortages*. October 2024.
[2] WP 6. *T6.2 Report on the CHESSMEN Multi-stakeholder Workshop*, 27 November 2024. December 2024.

2 Methodology

2.1 Data Collection

Current practices and planned measures of Member States in monitoring, reporting, and managing medicinal product shortages were collected within Task 6.2 activities.

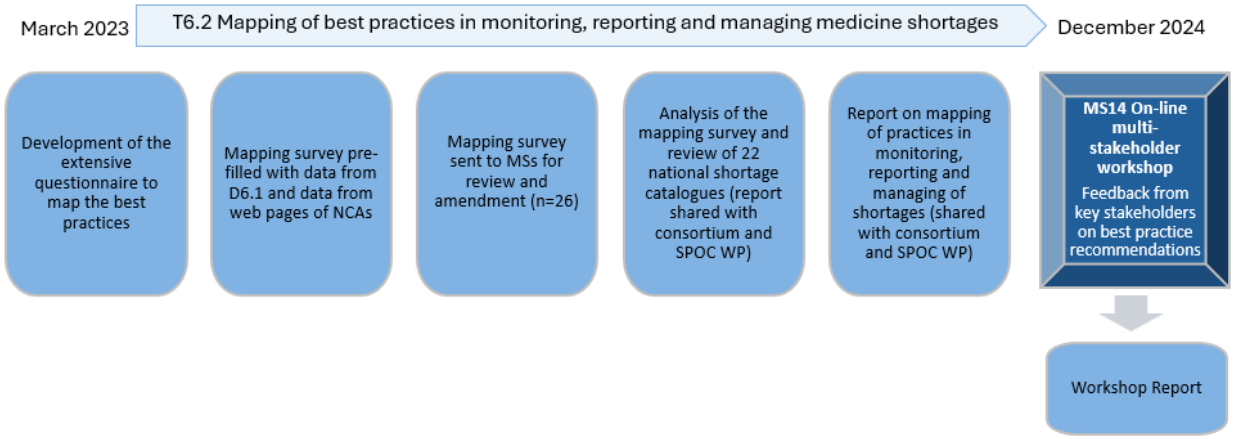


Figure 2. Steps of the T6.2 process to collect information for the preparation of the D6.2 Report on the common protocol for monitoring and reporting of shortages

A literature review was also conducted, drawing on relevant, primarily national documents related to medicinal product shortages. These documents were collected by WP 6 as part of the *D6.1 Report on Existing Documents on Shortages of Medicines.*[3] The review aimed to examine existing shortage management frameworks and methodologies for assessing the impact of medicine shortages. The following documents have been identified and served as the basis for the preparation of this report:

- HPRA. *Medicines Shortages Framework – A Multi-stakeholder Approach*. January 2023.
- Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe. International Journal of Pharmaceutics,* 2020; 579.
- Dutch Working Party Drug Shortages. *Roadmap for Handling of Notifications of Medicinal Product Shortages*. March 2017.
- BfArM. *Toolbox – Actions to Avert and Mitigate Supply-Relevant Shortages*. (National document from the CHESSMEN Library.)

[3] WP 6. *D6.1 Report on the Existing Documents on Shortages of Medicines*. June 2023.

In addition, detailed guidelines for assessing the impact of medicine shortage on patients and for identifying appropriate therapeutic alternatives were adopted from the methodology used to establish the Union List of Critical Medicines.[4]

2.2 Adaptation of Existing Methodologies for Impact Assessment

For shortage impact risk assessment at the EU level, the use of the Union List of Critical Medicines methodology is recommended in the *Shortage Prevention Plan*[5] and in the *European Shortages Monitoring Platform (ESMP) Implementation Guide for Marketing Authorisation Holders.*[6] However, no matrix is provided to define the overall impact level of a shortage as high, medium or low.

For shortage impact assessment at the national level, Ireland's Health Products Regulatory Authority (HPRA) methodology, as outlined in the *Medicines Shortages Framework – A Multi-stakeholder Approach,*[7] was used as a basis to determine the expected impact on patients and the availability of therapeutic alternatives.

In our view, the HPRA's methodology for determining the availability of appropriate therapeutic alternatives – based on the approved indication of the alternative treatment, the feasibility of switching in terms of patient safety, and the size of the patient population, while also considering the effort required from healthcare professionals and the burden on the healthcare system – effectively reflects national needs in the event of a medicine shortage. This methodology, combined with the assessment of the market share of therapeutic alternatives, is better suited for national assessment of appropriate therapeutic alternatives availability than the methodology used for the Union List of Critical Medicines, where this criterion is based solely on the number of appropriate alternatives. The same applies for Criterion II described in Musazzi et al. (2020), therefore the original levels for determining therapeutic alternatives were modified to reflect the HPRA's assessment of the availability of therapeutic alternatives, as shown in Table 1 below.

The HPRA's impact matrix was also used to determine the overall impact level of a shortage.
To incorporate the market share of the medicine in shortage into the HPRA's matrix, the methodology described by Musazzi et al. (2020) was applied. To align both methodologies, slight adaptations were made to each matrix.

[4] HMA/EMA. *Methodology to Identify Critical Medicines for the Union List of Critical Medicines*. June 2023.
[5] HMA/EMA. *Shortage Prevention Plan (SPP).* June 2024.
[6] EMA. *European Shortages Monitoring Platform (ESMP) Implementation Guide for Marketing Authorisation Holders*. March 2025.
[7] HPRA. *Medicines Shortages Framework – A Multi-stakeholder Approach*. January 2023.

Score	Original Musazzi's Criterion II	Adapted Criterion II
a	Not more than two medicinal products containing drug substances in the same ATC level III (same therapeutic/pharmacological subgroup) or IV (same chemical/ therapeutic/pharmacological subgroup)	**Possible** (ATC 3) Different active substance from the same pharmacological or therapeutic subgroup
b	More than two medicinal products for the same ATC level III, but not for the same ATC level IV	**Acceptable** (ATC 4) Different active substance from the same chemical subgroup
c	More than two medicinal products containing drug substances in the same ATC level IV, but no generic products are available for the same ATC level V (same chemical substance or therapeutic moiety)	**Similar** (ATC 5) Same active substance but different strength or pharmaceutical form or route of administration, A fixed-combination product replaced by medicines containing the same active substances at the same strength
d	More than two generic products for the same ATC level V	**Exact** (ATC 5) Same active substance, strength and pharmaceutical form

Table 1 Adaptation of Musazzi's Criterion II - Determination of the Availability of Therapeutic Alternatives.

2.3 Selection of Mitigation Measures

This report considers national measures commonly used by Member States to mitigate the impact of shortages, as identified in the *T6.2 Report*, as well as measures described in the *Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) Toolkit*, using its terminology.

The mapping survey also captured national-specific measures that were not included in this protocol. They are listed in the Table 2 below.

Question: Do you have in place a system to permit the importation of equivalent or alternative locally unauthorised medicines from other Member States/third countries?
• Yes, for hospital needs and on a named-patient basis.
• Yes, in the event of shortage of reimbursed medicines wholesalers are allowed to import equivalent medicines and they are dispensed on a named-patient basis.
• Yes, a specialist or GP activates the import procedure with a "Shortage form", managed by the hospital pharmacy or competent authority - if the medicine is on a shortage list with no alternative on the market.
• Yes, compassionate use for a named patient.

Table 2. National-specific measures

Throughout this report, the term *National Competent Authority (NCA)* refers to the authority responsible for implementing mitigation measures. However, it should be noted that in certain Member States, some of these measures may fall under the jurisdiction of other authorities, such as the Ministry of Health.

3 Protocol

3.1 Notification of a Medicine Shortage

The MAH or their representative should notify the NCA of any medicine shortage in accordance with Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA) and in line with the final compromise text of the Regulation, as published by the Council of the European Union on 24 February 2026.[8,9] Any other suspected unavailability in the supply chain may be reported by other stakeholders, such as wholesalers, pharmacies or patients. However, if the medicinal product is listed as available, stakeholders should first exclude other potential causes of supply delays not related to actual shortages (e.g. uneven regional distribution or logistical issues) before reporting to the NCA.

Based on findings from WP 6 T6.2, the following recommendations apply:

- MAHs should be required to notify shortages for all medicinal products, irrespective of prescription status, clinical importance or shortage duration.
    - The SPOC WP subgroup proposes that the duration of 2 weeks could be set as a benchmark for shortage notifications for marketing authorisation holders (MAHs) in line with the final compromise text of the Regulation, as published by the Council of the European Union on 24 February 2026 and reflecting current practices in certain Member States.
- MAHs should notify shortages as soon as possible and in any event no less than six months before the start of the temporary disruption of supply.[9] NCAs should encourage early MAH notification through regular open communication with MAHs and other stakeholders about any relevant issues in the supply chain and their possible impact on medicinal product availability.
- MAHs should be explicitly advised to include as much information as possible in shortage notifications. However, where limited information is available initially, a preliminary notification with minimal details should still be submitted, followed by updates as more information becomes available.[8]

[8] HMA/EMA. *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA).* July 2019.
[9] NPL: *The final compromise text of the Regulation/Directive, as published by the Council of the European Union on 24 February 2026. Links: REG: https://data.consilium.europa.eu/doc/document/ST-6366-2026-INIT/en/pdf; DIR: https://data.consilium.europa.eu/doc/document/ST-6367-2026-INIT/en/pdf*

The level of current harmonisation of the data elements in the shortage notification across the Member States has been reported and extensively discussed in the two reports from CHESSMEN WP 7.[10,11]

The minimum common dataset needed for a reliable shortage impact and criticality assessment was discussed in the deliverable 7.2 by WP 7[11] and is not part of this report.

- Identifying the root causes of a medicine shortage is essential for implementing mitigation measures and help preventing future occurrences. Therefore, the information on the cause of the shortage should be a mandatory field in the shortage notification.[12]

- MAH shortage notifications should be accompanied by an impact assessment. Although MAHs are not obliged to use the method outlined in this document to assess the impact of a shortage, the principles regarding low, medium or high impact should be applied to ensure a harmonised understanding of the shortage's impact. The impact assessment of the shortage helps guide a timely and proportionate mitigation response from the MAH.

- For medium- and high-impact shortages, a proposal for mitigation measures with a proportionate response to reduce the impact on patients should be part of the notification.
    - A template for mitigation measure proposals should be part of the shortage notification instructions provided to MAHs.
    - When preparing a national template, NCAs should use the SMP template[13] published by the HMA/EMA Task Force on Availability of Authorised Medicines for human and veterinary use (TF AAM).

- The MAH notification should also include information on other affected countries (if known) and other authorities that have been notified (e.g. other NCAs, EMA).[12]

3.2 Data Quality Check

Upon the receiving a shortage notification from the MAH:

- The NCA should conduct a data quality check to ensure the notification is complete. If any data is missing, the NCA should promptly request the MAH to provide the required information without delay.

- The data needed for performing impact assessment of shortage should be available to NCA and/or included in the MAH's notification. Based on EMA guidance,[12] the MAH should provide at least the following information:

[10] WP7. *D7.1 Report on SWOT analysis of the IT solutions at EU and MS*. August 2023.
[11] WP7. *D7.2 Report on EU best practice solutions and minimum common dataset*. January 2024.
[12] HMA/EMA. *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA).* July 2019.
[13] HMA/EMA TF AAM. *Shortage Mitigation Plan (SMP).* June 2024.

- Market sales volume and historical demand data (monthly/twelve months)
- Market share of the medicine in shortage (for hospital and outpatient markets)
- Proportion market sales affected by the shortage (It refers to how much of the market (by sales volume) is impacted due to the unavailability of a particular medicinal product.)
- Estimated stock in the current supply chain
- Supply that will be made available at the expected end date of the shortage and in subsequent deliveries.

- Based on the *T6.2 Report* (Annex 2), the above-mentioned data (sales, market share, demand data and stocks) should also be available to NCA from other sources. By having such data, the NCA is less reliant on the data provided by the MAH. The NCA should maintain an overview of all stocks of medicines in shortage and therapeutic alternatives available nationally.

- The NCA should verify the shortage duration notified by the MAH by performing a demand and stock analysis, also considering the root cause. This ensures appropriate measures are taken to minimise the duration and impact of the shortage.

3.3 NCA Impact Assessment

Impact assessment is performed to determine the impact of a shortage on patients and, consequently, on the healthcare system. The method described below is an adaptation of the methodology used by the HPRA[14] and Musazzi et al., 2020.[15]

The impact assessment combines three main considerations (see Figure 3):

- The expected impact on patients (Criterion I)
- The availability of therapeutic alternatives (Criterion II)
- The market share of the medicine in shortage (Criterion III)

[14] HPRA. *Medicines Shortages Framework – A Multi-stakeholder Approach*. January 2023.
[15] Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe. International Journal of Pharmaceutics,* 2020; 579.

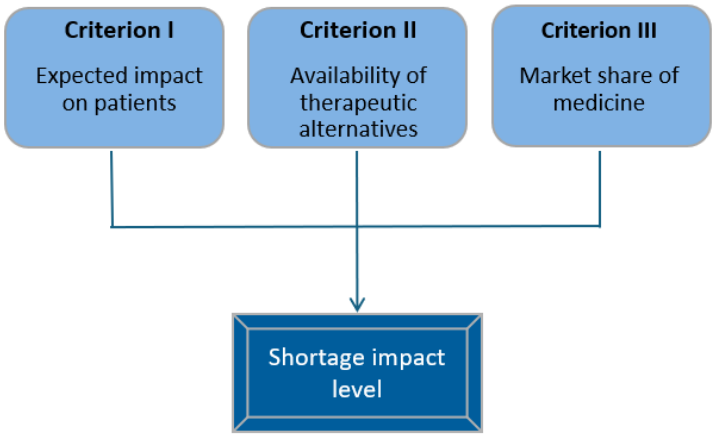


Figure 3. Impact assessment process

The **duration of the shortage** should also be taken into account when assessing its impact on patients and the availability of therapeutic alternatives. Shortage duration should be evaluated in relation to the root causes, the estimated current stock within the supply chain, and the stock expected to become available at the anticipated end date of the shortage, as well as in subsequent deliveries.

When assessing the availability of therapeutic alternatives, the **proportion of market sales affected** by the shortage should also be taken into account. This refers to the share of total market sales (by volume) of a specific medicinal product (or a group of medicinal products) that is impacted by the shortage. Accordingly, shortage notifications concerning alternative therapies should also be considered and monitored.

3.3.1 Impact on Patients (Criterion I)

The impact on patients is determined by taking into account:

- The therapeutic indication
- The specific needs of the patient population
- The consequences of the shortage on the risk of disease progression if left untreated

The categories and associated examples in relation to the impact of a shortage on patients are described in Table 3 and are illustrative.

Criterion I: Impact on Patients	
Categories	**Examples**
Severe	Oncology patients, mid-cycle of a regimen
Moderate	Vulnerable patient populations where some pharmaceutical forms may not be appropriate
Mild	Simple dermatological conditions

Table 3. Description of Criterion I categories

Further detail on assessing the impact on patients is provided below, which have been taken from the methodology used to establish the Union List of Critical Medicines.[16] Where a medicinal product has multiple therapeutic indications, the indication with the most serious implications for patients should determine the impact level.

Severe Impact:
Indications with **very serious implications** for the health of **individual patient or public health**: medicines or classes of medicines used to treat patients with **general life-threatening acute conditions, specific life-threatening acute conditions or irreversibly progressive conditions***

- The disease to be treated is potentially fatal, irreversibly progressive or, if left untreated, would pose an immediate threat, or cause severe impairment to the patient. This applies similarly to acute situations (emergencies), chronic situations or situations with a potentially fatal outcome.
- If the treatment is unavailable or interrupted, it will jeopardise the vital prognosis of patients in the short or medium term or represents a significant loss of opportunity for patients regarding the severity or potential evolution of the disease.
- The treatment must be administered immediately or within regular dosing intervals.**
- The medicinal product is a part of a national disease control program (e.g. vaccination campaign).***

Moderate Impact:
Indications with **serious implications** for the health of **individual patient or public health:**

- Medicines indicated for the treatment of chronic, severely debilitating diseases.
- Medicines for the treatment of vulnerable patient groups (such as paediatric medicines).
- Medicines for the treatment of patient groups or diseases where switching to a therapeutic alternative presents particular challenges.
- Medicines indicated for prevention or treatment of notifiable disease.

[16] HMA/EMA. *Methodology to Identify Critical Medicines for the Union List of Critical Medicines.* June 2023.

- If the disease is left untreated, it may induce potentially irreversible disease progression, or hospitalisation or intensified treatment, but no fatality is expected.
- A medicine which prevents relapses of a condition, but, if suspended, would not immediately expose relapses; the relapse may only occur weeks or months after treatment interruption (e.g. multiple sclerosis), or the disease progression is slow (Duchenne muscular dystrophy or cystic fibrosis).

Mild Impact: Other indications. A medicinal product is classified to the mild impact level if it does not meet the abovementioned criteria for severe- or moderate-impact.

* For the purpose of this sub-criteria "to treat" should be interpreted as to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, in line with the EU definition of medicinal product.
** This requirement originates from the recommendations of the *Jour Fixe on Delivery and Supply Shortages.* The opinion of the WS2 is, that the requirement is appropriately defined without a specific time limit. However, if during the risk assessment for medicines, the need to define a specific time period is identified, it should be defined but should not exceed 24 hours.
*** The "national disease control programme" does not refer to lists of essential or critical medicines established by the WHO or available at national level.

3.3.2 Therapeutic Alternatives (Criterion II)

The categories of therapeutic alternatives and associated descriptions are provided in Table 3. These are illustrative and provide guidance when categorising the nature of the therapeutic alternative.

An alternative is appropriate if it meets all the following criteria:

- The alternative medicine is authorised for the same therapeutic indication in the respective Member State (i.e. no off-label use);
- The alternative treatment is clinically feasible, i.e. switching to the alternative treatment does not require extensive clinical consultations and organisation of healthcare services enables the transition to alternative treatment;
- The use of the alternative treatment does not have a negative impact on the patient's health and provides the same standard of care.
- The alternative medicine is currently available on the market without notified shortage.
    - Medicines with very low market share (lower than 2% of the total demand of reference for the medicine in shortage) should not be considered alternative therapies, as their impact on maintaining patient access to therapies is negligible.[17]

[17] Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe*. *International Journal of Pharmaceutics,* 2020; 579.

Criterion II: Therapeutic Alternatives		
Categories	**Description**	**Examples**
Exact (ATC 5)	Same active substance, strength and pharmaceutical form	• Available generic
Similar (ATC 5)	Same active substance but different strength or pharmaceutical form or route of administration A fixed-combination product replaced by medicines containing the same active substances at the same strength	• Different strength tablet • Tablet for syrup substitution • Tablet for suppositories substitution
Acceptable (ATC 4)	Different active substance from the same chemical subgroup	• Proton pump inhibitors • Statins
Possible (ATC 3)	Different active substance from the same pharmacological or therapeutic subgroup	• Management of chronic diseases (e.g. diabetes, hypertension)
None	Unique pharmacology, no alternative treatment option exists	• Certain vaccines

Table 4. Description of therapeutic alternative categories

The following detailed guidelines, adapted from the methodology used to establish the *Union List of Critical Medicines*[18] and aligned with the HPRA's methodology, should be followed when assessing the availability of therapeutic alternatives.

Appropriate alternatives should be evaluated in line with the following clinical considerations:

a. Therapeutic alternative is clinically possible and requires little or no input from medical personnel (*Exact*):

- The therapeutic alternative is possible by using the same active substance, the same strength in the same pharmaceutical form (e.g. generic substitution).
- Substitution with a therapeutic alternative can be performed by pharmacists, without attending physician's involvement, if permitted in the respective Member State.
- The therapeutic alternative does not affect patient safety.

b. Therapeutic alternative is clinically possible but requires little input from medical personnel (*Similar*):

[18] HMA/EMA. *Methodology to Identify Critical Medicines for the Union List of Critical Medicines.* June 2023.

- The therapeutic alternative is possible by using the same active substance, but in a different strength or pharmaceutical form or route of administration.
- Substitution with a therapeutic alternative can be performed by pharmacists in certain cases (e.g. switch to lower strength tablets), if permitted in the respective Member State.
- Substitution with a therapeutic alternative usually requires the involvement of the attending physician and cannot be performed solely by pharmacists.
- The therapeutic alternative may include pharmaceutical preparations (e.g. magistral or officinal formulas), or modified dosing regimens.
- Using the alternative pharmaceutical form does not require switching from self-administration to administration by a healthcare professional.

c. Therapeutic alternative is clinically possible but requires input from medical personnel (*Acceptable*):

- The therapeutic alternative is possible by using a different active substance from the same pharmacological group (ATC Level 4).
- Substitution with a therapeutic alternative cannot be performed by pharmacists without the attending physician's involvement.

d. Therapeutic alternative would require extensive clinical consultations (*Possible*):

- Therapeutic alternative is possible by using a different active substance from a comparable pharmacological group (ATC Level 3).
- Substitution with a therapeutic alternative can be performed only by the attending physician.

e. Therapeutic alternative is not clinically possible (*None*):

- No appropriate therapeutic alternative option is available. The active substance or combination of active substances (e.g. combination of ethambutol, rifampicin and isoniazid used to treat tuberculosis, combination treatment for HIV) has a unique pharmacology.
- Switching to the therapeutic alternative would require extensive clinical consultations not applicable for specific indications.
- Substitution of treatment is expected to affect patient safety or disease prognosis:
    - The therapeutic alternative has a lower therapeutic index than the initial treatment.
    - The therapeutic alternative has additional serious, irreversible or incurable adverse effects compared to the initial treatment. Due to the use of the therapeutic alternative, the target patient population may experience life-threatening complications (e.g. due to greater toxicity).
- Switching to therapeutic alternatives cannot be achieved in a timely manner due to clinical factors such as delayed treatment initiation, compromised disease control (e.g. psychiatric medicines), reduced efficacy (e.g. due to antibiotic resistance) or the need for additional monitoring (e.g. renal or hepatic parameters), which may result in poor clinical outcomes or therapeutic failures.

- Switching to therapeutic alternatives cannot be achieved quickly due to the organisation of healthcare services (e.g. the patient may require a different specialist to receive the alternative treatment), or because it requires a transition from self-administration to in-patient or hospital administration (e.g. from subcutaneous to intravenous administration).
- The therapeutic alternative does not fully meet the clinical needs of the entire target patient population, for example a subset of patients may be unable to use the therapeutic alternative (including patients with specific needs, geriatric, paediatric patients, or individuals with disabilities), or it may be contraindicated.

To find the most appropriate alternative among a range of available medicinal products with the same active substance the algorithm developed by Caviglioli G et al., 2025[19] may be considered.

3.3.3 Market Share of a Medicine (Criterion III)

The existence of therapeutic alternatives alone may not be sufficient to mitigate the negative effects of a medicine shortage. If the therapeutic alternatives have low market shares, their supply capacity may be inadequate to meet demand during the shortage. The risk of shortage for low-market-share alternatives is further increased due to a ripple effect. The more dominant the market share of a medicinal product in shortage is, the higher the probability that alternatives are not able to meet the patients' demands during a shortage. Therefore, the higher the market share of a medicine (calculated from moving annual total (MAT) volumes) in comparison to the existing therapeutic alternatives, the higher the potential risks for the public health in the event of a shortage. To capture fluctuations in market share, e.g. due to seasonal changes, the timeframe could be adapted by replacing MAT volumes with the volumes over a different relevant period of time (e.g. monthly volumes).

Market share is determined by taking into account the medicine market share in comparison to the available alternatives on the entire national market (outpatient and hospital).

The following ranges of market shares were empirically defined (Table 5):[20]

[19] Caviglioli G, Drava G, Pivetta L et al. *Medicine Shortages: An Algorithm for Evaluating the Substitution with Equivalent or Alternative Products. Healthcare,* 2025; 13, 1139.
[20] Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe. International Journal of Pharmaceutics,* 2020; 579.

Criterion III: Market Share	
Category	**Description**
>50%	Market share calculated from MAT volumes or volumes over a relevant period
25%–50%	
<25%	

Table 5. Medicine Market Share by Musazzi et al., 2020 (adapted)

For “Acceptable” and “Possible” alternatives, the medicine market shares should be estimated with reference to the ATC Level 4 or 3 in which the medicine is included. For “Exact” and “Similar” alternatives the medicine market shares should be estimated based on the relevant medicinal forms and strengths in the same ATC Level 5.

3.3.4 Determination of a Shortage Impact Level

Once the availability of therapeutic alternatives and expected impact on patients are determined, the impact level of the shortage should be identified using the matrix described in Table 6.

	Therapeutic Alternative				
Impact on Patients	**Exact**	**Similar**	**Acceptable**	**Possible**	**None**
Mild	**Low**	**Low**	**Low**	**Medium**	**High**
Moderate	**Low**	**Medium**	**Medium**	**High**	**High**
Severe	**Medium**	**Medium**	**High**	**High**	**High**

Table 6. Impact levels matrix

The differences in scores are based on the feasibility of switching patients to alternative treatments and the extent to which this can be achieved, considering the involvement of healthcare professionals and the organisation of healthcare services.

A shortage is expected to be easily mitigated if therapeutically equivalent medicines (i.e. generic medicines) are available, as these can be substituted in a pharmacy setting in most Member States[21] without compromising patient safety. However, as the severity of the disease increases, so does the risk of treatment discontinuation, even when switching to a generic medicine.

Conversely, the unavailability of generic medicines means that, in the best-case scenario, the benefit-risk balance of the therapeutic alternative should be assessed by a physician. This applies to medicinal products where alternatives exist within the same ATC Level 4 (e.g. amoxicillin vs. ampicillin) or ATC Level 3 (e.g. penicillins vs. tetracyclines). In both cases, the efficacy and safety profiles of the alternatives may not be identical, meaning that substitution cannot be automatically performed by community pharmacists. As a result, the impact of the shortage is potentially greater, as patients face a higher risk of treatment discontinuation if their attending physician is not readily accessible or if switching to an alternative treatment requires extensive clinical consultation and/or cannot be accomplished in short time due to the organisational structure of the healthcare system.[22]

The impact assessment classifies medicine shortages into three types: low, medium and high impact shortages.

[21] WP 6. *T6.2 Report on Mapping of Practices in Monitoring, Reporting and Managing Medicine Shortages*. October 2024.
[22] Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe*. *International Journal of Pharmaceutics.* 2020; 579.

Low Impact Shortages

The potential response to a low impact shortage is based on the assumption that healthcare professionals can manage the situation if they have timely access to information about the supply of the medicine in shortage and the supply of therapeutic alternatives.
Example: A shortage of atorvastatin 20mg film-coated tablet where another generic medicine is readily available and can be substituted with minimal disruption to the attending physician, pharmacist and patient.

Medium Impact Shortages

The required response to a medium impact shortage is based on the assumption that healthcare professionals can manage the situation if they have timely access to information about the supply of the medicine in shortage and the supply of therapeutic alternatives, and, in some cases, advice on alternative clinical protocols or dose-sparing measures to ensure continuity of care.
Example: A shortage of a proton pump inhibitor where the attending physician would need to prescribe another proton pump inhibitor.

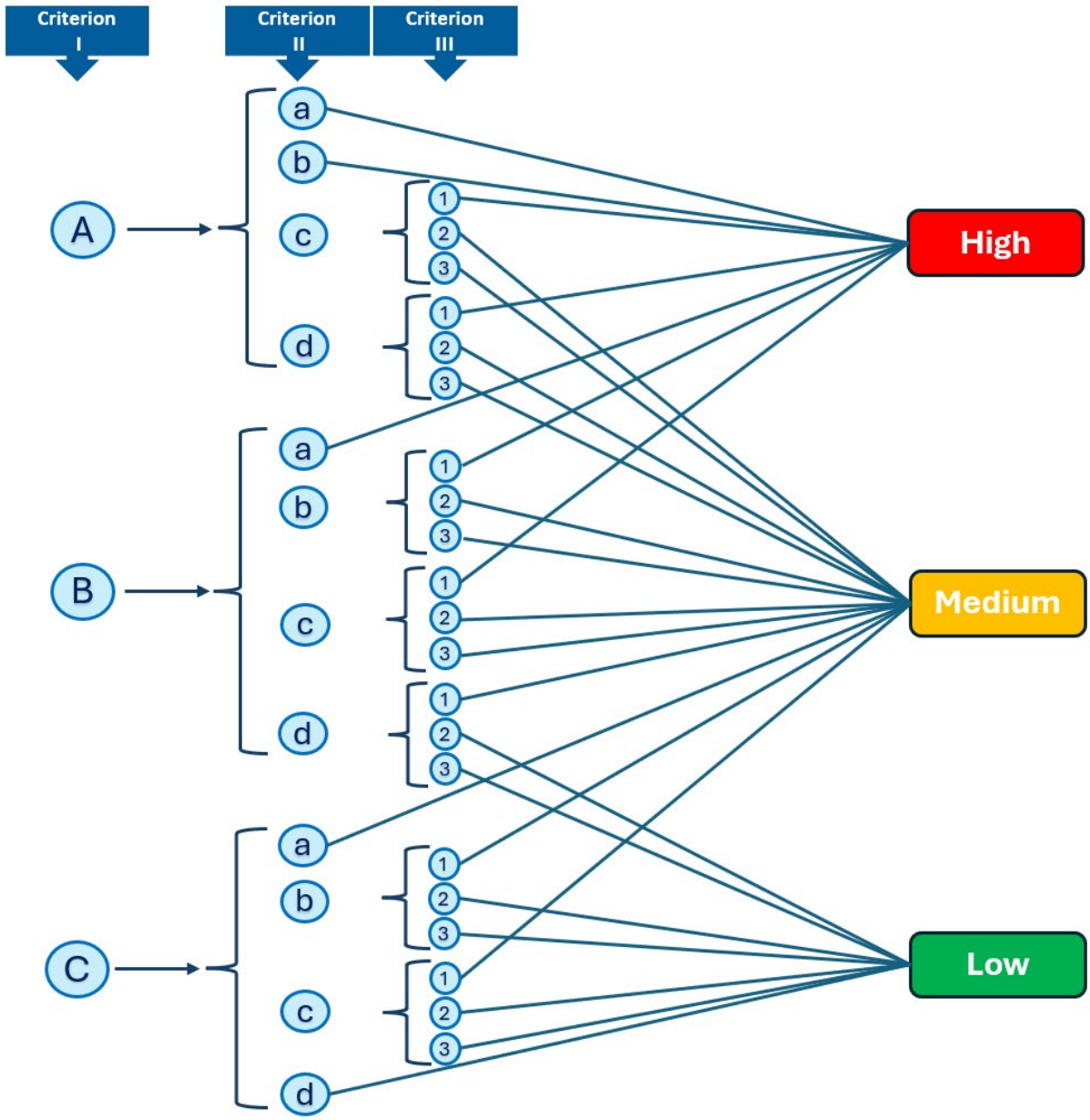
High Impact Shortage

The required response is based on the assumption that healthcare professionals require highly specific and urgent information regarding the nature and expected duration of the shortage, along with details on supply arrangements and advice on alternative clinical protocols or dose-sparing measures to ensure continuity of care.
Example: A batch failure of a heparin-based medicines. This switch to a therapeutic alternative is complex and post-surgical patients could potentially experience life-threatening consequences if this medicine was not available.

3.3.4.1 Impact Level Considering the Market Share

If the market share of the medicine is incorporated into the matrix described above, which consists of the availability of therapeutic alternatives and the anticipated impact on patients, the impact levels may change, as illustrated in Figure 3. This is based on the adapted methodology of Musazzi et al., 2020.

A market share of a medicine in shortage about 50% results in an immediate escalation of the impact to a higher level, whereas a market share between 25% and 50% does not automatically trigger such escalation but does require close monitoring.



Criterion I: Impact on Patients		Criterion II: Therapeutic Alternative*		Criterion III: Market Share	
A	Severe	a	Possible	1	>50%
B	Moderate	b	Acceptable	2	25–50%
C	Mild	c	Similar	3	<25%
		d	Exact		

**The "None" category is not included in the market share assessment, as no therapeutic alternatives are available in such cases. Consequently, market share cannot be calculated, and the impact level is considered high by default.*

Figure 3. Impact levels matrix considering the market share of a medicine

3.4 Measures to Mitigate the Adverse Impact of Medicine Shortages on Patients

Mitigation measures aim to minimise or prevent any possible impact of notified shortages on patients in a timely and proportionate manner.[23]

The decision tree in Annex 1 can be used as a guide and assist NCAs in making effective decisions.

The measures outlined below are already implemented in Member States and are presented in the order in which they may be applied. However, multiple measures may sometimes be explored and carried out simultaneously, depending on the nature of the shortage, the number of stakeholders involved, and the national shortage management framework.

NCAs may add additional situations to the protocol and also indicate reimbursement per situation. The principle is that both the health risk and financial burden for the patient must be minimised.

A record of the mitigation measures taken should be maintained after the resolution of shortages.[24]

3.4.1 Consultation with the MAH of the Medicine in Shortage

- The impact assessment and proposal for mitigation measures with a proportionate response to reduce the impact on patients should be part of the shortage notification by the MAH, including what preventive and corrective actions the MAH has already taken to avoid or resolve the shortage.
- If the medicine is available elsewhere, the MAH can apply for exemptions from labelling, package leaflet or packaging obligations which may be already proposed in the notification. If this is a suitable solution, the NCA grants an exemption to the applicable obligation.
- The NCA may apply further regulatory flexibilities facilitating prompt implementation of changes to alternative (sources of) raw materials, manufacturing site(s), manufacturing equipment, packaging, batch size and other changes to enable increased production and support sparing use of the product.[25] Regulatory flexibilities are listed in Section 3.4.4.

[23] HMA/EMA. *Shortage Mitigation Plan (SMP)*. June 2024
[24] HMA/EMA. *Guidance for industry on implementing Shortage Mitigation Plans (SMP)*. September 2024
[25] EMA. *MSSG Toolkit on recommendations on tackling shortages of medicinal products*. October 2023.

3.4.2 Availability of Therapeutic Alternatives

If an *Exact* therapeutic alternative with the same active ingredient, strength and pharmaceutical form is authorised and marketed in the Member State/EU:

- The market share of the medicine in shortage and the alternatives is considered: Can these alternatives compensate for the shortage? How many alternatives are available?

  The smaller the market share of the medicine in shortage, the greater the likelihood other suppliers will be able to compensate for the shortage.

- The medicine is substituted in a pharmacy if such substitution is legally permitted in the Member State.

- Notifying existing suppliers of alternatives to increase production to fill the gap between supply and demand: The NCA may inform MAHs or parallel distributors of alternatives about the imminent supply gap so they can anticipate increased demand. The NCA may consult MAHs on the possibilities of increasing production, duly accounting for available stock levels, the supply plan and average lead production time.

- Redistribution of available stock among Member States: If the alternative medicine is authorised via a centralised procedure, a mutual recognition procedure or a decentralised procedure (an identical product exists in another Member State), the MAH should investigate the possibility for the redistribution of supplies at the European level.

  If this is possible, the NCA may grant full or partial exemption from certain labelling and packaging requirements for authorised products. These may include local language labelling exemptions, reduced information on the packaging, alternative ways of providing certain labelling information and other exemptions.

  Exemptions from labelling requirements are determined on a case-by-case basis, mostly taking into account dispensing (hospital/community), relevant label information and the original language of the label.

If a *Similar* therapeutic alternative with the same active ingredient, but different strength or pharmaceutical form or route of administration is authorised and marketed in the Member State:

- Based on the number of available alternatives, how comparable they are to the medicine in shortage and the ease of switching to the alternative, the NCA or taskforce (see Section 3.4.6) issues a recommendation regarding the substitution, as well as dose-sparing measures to ensure continuity of care.

- The viability and limitations of switching patients to the alternative is evaluated by the attending physician.

- In certain cases, pharmacist can perform the substitution, e.g. lower strength, different pharmaceutical form with the same route of administration. This solution requires the pharmacist or prescriber to provide the patient with additional support and education, so pharmacists and prescribers must be well-informed. The substitution must be documented in the patient's medical record.

If an *Acceptable* or *Possible* alternative is authorised and marketed in the Member State:

- The viability and limitations of switching the patients to such alternative is investigated and evaluated by the taskforce comprised of healthcare professionals and other stakeholders (see Section 3.4.6).
- Based on the therapeutic group (ATC level 4 or 3) of available alternatives, NCA or taskforce issue recommendation regarding substitution and alternative clinical protocols.
- The viability and limitations of switching the patient to the alternative is evaluated by the attending physician.

3.4.3 Authorising the Importation or Granting Marketing Authorisation for Non-Authorised Medicinal Products

In case where limited or no therapeutic alternatives are available on the market, the NCA may authorise the importation of non-authorised medicinal products from other countries. For this purpose, it is recommended to issue a public appeal on the NCA website calling for additional suppliers of the medicine in shortage or more alternatives on their market due to a notified shortage. The appeal should also encourage applications for marketing authorisation of alternatives. The announcement should be targeted at products considered critical to public health.

From a transparency perspective, all potential importers and MAHs should be informed simultaneously of the need for alternative medicinal products. Possible simplified or accelerated regulatory procedures and financial incentives that may apply for such import or market authorisation may be published together with the appeal.

MAHs or distributors that may be able to market or import the products listed are encouraged to contact the NCA.

3.4.4 Regulatory Flexibilities

To prevent or mitigate shortages of medicinal products the NCA may apply the following flexibilities:

- Flexibilities facilitating the prompt implementation of changes to alternative (sources of) raw materials, manufacturing site(s), manufacturing equipment, packaging, batch size and other changes to enable increased production and promote sparing use.

- Full or partial exemption from certain labelling and packaging requirements for authorised products. These may include, among others, local language exemptions, reduced information on the packaging, alternative ways of providing certain labelling information and other exemptions. Exemptions from labelling requirements are determined on a case-by-case basis, mostly taking into account dispensing setting (hospital/community), relevant label information and original language.
- Allowing importation of non-authorised products – EU pharmaceutical legislation contains certain provisions that allow Member States to authorise, in accordance with their national legislation, the supply of medicines without a marketing authorisation. In particular, the use of exceptions foreseen in Articles 5(1), 5(2) and 126a of Directive 2001/83/EC should be considered, where relevant.[26]
- Shelf-life extension for individual batches already released.

Additionally, the MSSG Toolkit outlines further measures that may be applied to address any medicine shortages including those that have not been escalated to MSSG. However, some measures marked as *"Exceptional"* are reserved for exceptional situations and should only be applied based on a recommendation from MSSG (i.e. their application cannot be proposed by manufacturers and MAHs, but rather initiated only by regulatory authorities), and only in cases where other measures have been exhausted.

3.4.5 Fair Distribution of Medicines

To ensure the fair distribution of remaining or limited medicine supplies, the following measures may be considered:[27]

3.4.5.1 Controlled Distribution

Controlled distribution involves optimising the sales and dispensing of medicines in community pharmacies and healthcare institutions to ration existing stocks and prioritise treatment for patients with the greatest need. This may include restricting the number of units dispensed or limiting dispensing to specific indications or patient groups (e.g. the most vulnerable patients).

Controlled distribution also involves restricting distribution within the supply chain, for example, by focusing on a single distribution channel (retail or hospital).

[26] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*. *Official Journal* November 2001;311:67-128.
[27] EMA. *MSSG Toolkit on recommendations on tackling shortages of medicinal products*. October 2023.

3.4.5.2 Dose-Sparing Measures

Dose-sparing measures include reducing the daily dose, delaying the initiation of treatment, or providing guidance on alternative clinical protocols, including non-pharmacological alternatives, to ensure continuity of care.

3.4.6 Ad-hoc Taskforce

In the event of medium and high impact shortages, the NCA may establish and coordinate an ad-hoc taskforce to support the assessment and implementation of mitigation measures. The taskforce may contribute to: assessing the relevance of a particular supply shortage, taking into account possible therapeutic alternatives, as well as developing treatment recommendations or alternative clinical protocols for improving the supply situation and outward communication. Taskforce members may include: MAHs, wholesalers, pharmacies and pharmacists' associations, affected medical societies, insurance fund and patient representative groups. The composition of the taskforce should reflect the specific nature of the shortage.

The taskforce may also issue guidance on the measures outlined in Section 3.4.5, such as restricting dispensing to specific indications, reducing the daily dose and delaying the initiation of treatment.

3.4.7 Export Restrictions

In the event of a shortage with high impact on public health and/or repeated shortages of a medicine, and if the medicine is on the export restriction list, the NCA may issue an order prohibiting the export of the medicine in shortage as well as alternative medicines that can fill the therapeutic gap for a defined time period/duration of the shortage. These restrictions must be in compliance with Article 36 of the Treaty on the Functioning of the European Union (TFEU), which allow NCAs to establish prohibitions or restrictions on parallel exports on the grounds of the protection of health and life of humans.[28]

3.4.8 Use of Pharmaceutical Preparations

Pharmaceutical preparations (e.g. magistral or officinal formulas) may be used to replace unavailable medicines. The European Directorate for the Quality of Medicines & HealthCare (EDQM) is drafting a methodological guide for selecting medicines at risk of shortage during public health emergencies that can be prepared as standardised stock preparations, and a European Shortages Formulary consisting of texts (monographs) for the temporary preparation

[28] Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe*. *International Journal of Pharmaceutics,* 2020; 579.

and quality control of unauthorised medicines in case authorised medicinal products are unavailable.

3.4.9 National Reserves

The established national stockpile reserves enable the country to meet the basic supply needs of its population and maintain an adequate supply level during emergencies. Medicinal products from national reserves may be released to the market to help mitigate public health emergencies. The use of medicinal products from the national stockpile reserves falls under the exclusive jurisdiction of each Member State and is treated as confidential.

3.4.10 Voluntary Solidarity Mechanism (VSM)

Once other measures and possibilities have been exhausted, the Member State may request assistance through the Voluntary Solidarity Mechanism (VSM), a voluntary system that allows a Member State to request support from other Member States or the MSSG in securing stocks of medicines during critical shortages. This mechanism should be used as a last resort.[29]

3.5 Shortage Communication

Following the completion of the NCA assessment, all shortages confirmed by the MAH should be made publicly available in a shortage catalogue. Having established a systematic listing of shortages in the form of a catalogue is one of the key recommendations of the HMA/EMA Communication Guidance.[30]

- The shortage catalogue should be linked to external electronic systems that allow notifications to prescribers and pharmacists when they attempt to prescribe or dispense a medicinal product in shortage.
- Additionally, the NCA website should provide information targeted at different audiences. Recommended sections include: advice on therapeutic alternatives, advice for prescribers, advice for pharmacists, advice for patients, and also a chapter on reimbursement and price differences between therapeutic alternatives and the medicinal product in shortage.
- Comprehensive information is essential to prevent stockpiling, promote the rational use of existing stocks, and also allow time for safe, effective and affordable therapeutic alternatives to be sourced and introduced, thereby minimising the impact on patients and healthcare systems.

[29] MSSG. Solidarity Mechanism. October 2023.
[30] HMA/EMA. *Good practice guidance for communication to the public on medicines' availability issues*. December 2024.

- Timely notification to prescribers is particularly important to avoid any new initiation of a treatment that will be in short supply for an extended period. Informing community pharmacists can also help mitigate the impact allowing them to dispense therapeutic alternatives, potentially eliminating the need to refer patients back to attending physicians in all cases.
  Where applicable, the advice for prescribers and pharmacists should also contain recommendations on controlled distribution, as well as dose-sparing measures to ensure continuity of care.

- Advice for pharmacies should include resources such as a link to the package leaflet in national language that can be printed for the patient when a foreign package is dispensed, or guidance on crushing/splitting or otherwise manipulating tablets for children when an oral solution is not available.

- The MAH may send medicine shortage communications (MSCs), which are approved by NCA, to healthcare professionals to inform them of certain medicine shortages. The MAH is asked to draft an MSC using EMA template.[31] The NCA should also publish these communications on its website.

- Additional channels of communication with healthcare professionals and patient organisations should be used to improve the dissemination of information, as outlined in the HMA/EMA Communication Guidance, for shortages with medium and high impact that may involve a range of stakeholders collaborating on mitigating the impact.

- In the event of critical shortages for which coordinated Union–level action is considered necessary to resolve the shortage,[32] the NCA may bring the shortage to the attention of the SPOC WP.

3.6 Ongoing Monitoring

Even after mitigation measures are no longer necessary, the NCA should continue to closely monitor the supply situation on the market and engage with MAHs to follow up on outcomes of the implemented measures, until the supply shortage has ended.

[31] *Medicine shortage communications (MSC) https://www.ema.europa.eu/.* Accessed: February 2025.
[32] EMA. *MSSG Toolkit on recommendations on tackling shortages of medicinal products*. October 2023.

4 Conclusions

The work of WP 6 aims to promote the established national best practices in shortage management to support the harmonisation of monitoring, reporting and managing medicine shortages across the EU/EEA. A summary of the measures and key recommendations is provided in the *T6.2 Report*.

Cooperation between Member States is essential in developing practical and rational responses to the challenges associated with medicine shortages. To effectively mitigate and manage shortages at both national and EU levels, it is both desirable and necessary to harmonise the assessment of the impact of medicine shortages on patients, as well as the corresponding management strategies. The approach proposed in this document is intended to enhance information exchange and collaboration among Member States. Indeed, mitigation and management strategies can be streamlined and harmonised on the basis of a harmonised assessment of the impact of medicine shortages carried out by the NCA.

We expect that the common protocol presented in this document will assist Member States in developing, refining or updating their national protocols, while still allowing each Member State to tailor their strategies to align with their national legislation, regulations and operational procedures. Furthermore, the protocol and decision tree can be adapted and used as a model for developing management strategies tailored to regional needs and individual healthcare organisations (e.g. hospitals).

The management of medicine shortages can also be made more efficient by widening the professional competences of community pharmacists, enabling them to apply their expertise during shortages, as outlined in the *T6.2 Report*.

Although prevention and mitigation strategies and measures were not addressed in this document or in the work of WP 6 in general, the same decision tree methodology could be applied to prevention and mitigation measures. In particular, a harmonised decision tree and standardised restriction criteria for the export of medicines affected by shortages should be established, as also proposed by Musazzi et al., 2020. Uncontrolled export restrictions may exacerbate shortages in other European countries.

In the event of a critical supply shortage and/or recurrent supply shortages, additional national measures should be considered to prevent future shortages. Some of the preventive measures already in place in some Member States are:

- Mandatory regular reporting of supply, sales and stock data,
- Requirement to prepare shortage prevention plans,
- Imposed stockholding obligations,
- Export restrictions.

5 Next Steps

Based on this document the WP 6 will develop training material to support NCAs in developing their own national protocol in collaboration with key stakeholders, enabling them to manage national shortages more effectively and contribute to a harmonised response at the EU/EEA level.

Once developed, national protocols should be published on the NCA website and shared with relevant national stakeholders.

This document reflects the current state of play in the work and discussions undertaken within the JA CHESSMEN. It incorporates, as far as possible, the reflections and input provided by the EMA's SAM team. Its purpose is to provide a solid foundation for further development within the SPOC WP, in the context of the EU's medicine shortage prevention policy, where all EU/EEA Member States are represented.

Future updates to shortage management elements presented in this document are anticipated, and their continued use by relevant EU-level groups may ensure that the impact of this deliverable extends beyond the duration of the Joint Action.

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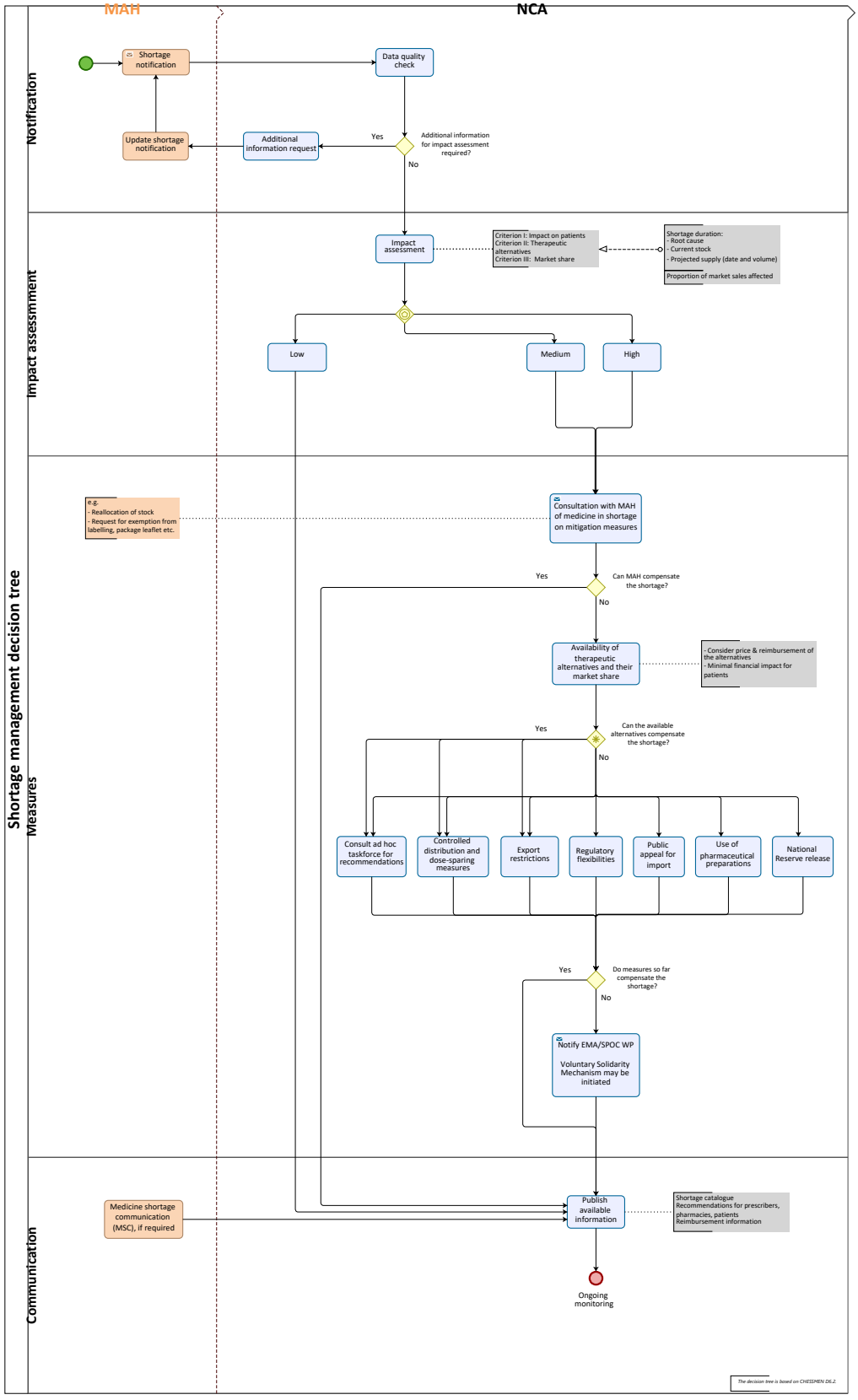
6 Annex 1: Shortage Management Decision Tree



7 Annex 2: *WP 6 T6.2 Report on Mapping of Practices in Monitoring, Reporting, and Managing Medicine Shortages*. October 2024.

Report on Mapping of Practices in Monitoring, Reporting and Managing Medicine Shortages

Work Package: WP 6

Task 6.2

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

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List of abbreviations

DHPC	Direct Healthcare Professional Communication
EEA	The European Economic Area
EMA	European Medicines Agency
EMVS	European Medicines Verification System
ESMP	European Shortages Monitoring Platform
GIRP	The European Healthcare Distribution Association
HaDEA	European Health and Digital Executive Agency
HCP	Health Care Professional
HMA	Heads of Medicines Agencies
JA	Joint Action
JAZMP	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
MAH	Marketing Authorisation Holder
MoH	Ministry of Health
MRP	Mutual Recognition Procedure
MS	Member State of the European Union
NCA	National Competent Authority
SMP	Shortage Mitigation Plan
SPP	Shortage Prevention Plan
RUP	Repeat Use Procedure
SPOC	Medicine Shortages Single Point of Contact
TF AAM	HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use
WP	Work Package

1 Introduction

The European Union (EU) co-funded Joint Action (JA) on Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) is a defined action intended to support European Member States through strengthening a more harmonised response to medicine shortages in Europe and promoting the use of established and effective preventive practices in order to reduce the incidence of shortages of medicinal products, amongst other measures.

Technical work package 6 (WP 6) aims to identify and promote best practices in monitoring, reporting, and managing medicinal product shortages. For this purpose, a mapping survey was performed to collate current practices and planned measures of Member States in monitoring, reporting, and managing medicinal product shortages.

All relevant Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) guidance that is already in place have been considered and taken into account. Conclusions and recommendations of this report aim to avoid repeating already agreed-upon and harmonised approaches.

Furthermore, as the mapping survey began in September 2023 and the report was completed in October 2024, it is based on the EU legislative framework applicable at that time. To a very limited extent, it also considers the European Commission proposal for its revision (in particular Chapter X in its Proposal for the Pharmaceutical Regulation[1]). It does not reflect any subsequent developments in the legislative process.

To avoid duplication with activities of other CHESSMEN technical work packages and ongoing projects at different levels regarding medicine shortages (e.g. by European Commission and European Medicines Agency), the survey focused specifically on regular monitoring of demand and stock data, legal and voluntary framework of reporting, impact assessment frameworks in -situ, information contained within national shortage catalogues and national measures applied when the shortage is already established.

This report summarises the findings of the mapping survey and will serve as a basis for discussion with various stakeholders at a workshop in November 2024 organised by WP 6. Based on the stakeholder feedback, WP 6 will develop a protocol for monitoring, reporting, and managing medicinal product shortages (T6.3)[2].

The report was sent for final review to the Medicine Shortages Single Point of Contact (SPOC) Working Party and HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF AAM).

[1] Available at: Reform of EU pharmaceutical legislation - Public Health.
[2] WP 6. T6.3 Development of comprehensive monitoring, reporting, and managing protocol

2 Methodology

2.1 Data collection

In September 2023, WP 6 carried out a survey to map the best practices in monitoring, reporting, and managing shortages of human medicinal products. The purpose was to assess, qualitatively and quantitatively, how shortages are managed in EU/EEA countries.

The questionnaire (Annex 1) was developed using the solutions to address medicinal shortages, as described in the European Commission's study on medicinal product shortages[3] and input from TF AAM Thematic Working Group 2 on communication of shortages to media.

The survey comprised an extensive questionnaire with 92 questions divided into 3 sections: (1) Monitoring, (2) Reporting and (3) Managing shortages. Questions were a mix of closed (e.g. Yes/No) and open-ended. For all questions Member States were able to provide additional comments for further context in a free text format. In addition, each section of the questionnaire had a designated space for any additional comments and another designated space for sharing of examples of good practices related to either monitoring, reporting and/or managing shortages.

To avoid duplication with WP 7 activities (Digital Information Exchange for Monitoring and Reporting Medicine Shortages) and other ongoing projects at different levels on monitoring shortages (e.g. the development of European Shortages Monitoring Platform of the European Medicines Agency), questions in the Monitoring section were focused on regular monitoring of demand and stock data, which can help identify or better predict shortages.

The Reporting section covers legal frameworks, and the actual activities covered under national shortage reporting. This included which shortages are reported, when and by whom, what information is published and details about the impact assessment methodology utilised. Questions related to the specific shortage related data collected (e.g. MAH details) in the shortage notification were excluded to avoid duplication with WP 7 activities described in D7.1 Report on SWOT analysis of the IT solutions at EU and MS.[4]

Once the questionnaire was designed, where applicable was pre-filled with data from the relevant mostly national documents related to medicinal product shortages, collected by WP 6 in D6.1 Report on the existing documents on shortages of medicines[5], and data from web pages of National Competent Authorities (NCA) including shortage catalogues.

The finalised survey was circulated to all Member States participating in the JA for completion. To collect more comprehensive data on existing practices across the EU, the survey was also sent

[3] European Commission. Future-proofing pharmaceutical legislation – study on medicine shortages. Final report. November 2021.
[4] WP 7. D7.1 Report on SWOT analysis of the IT solutions at EU and MS. August 2023.
[5] WP 6. D6.1 Report on the existing documents on shortages of medicines. June 2023.

to NCAs not participating in the JA through the Medicine Shortages SPOC Working Party for completion. WP 6 also sought additional information from Member States directly where more clarity was needed on any of the responses received.

In addition to the survey, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) reviewed 22 national shortage catalogues in January 2024 in order to complete an overview of best practices in publishing shortage information.

2.2 Analysis

The questionnaire was designed to elicit both quantitative and qualitative data. All closed questions were evaluated using quantitative methods (e.g. response rates, expressed as percentages). Qualitative data has been grouped into categories/themes where possible.

2.3 Limitations

Because most of the questions in the survey were open-ended, the level of details provided in the responses was at the discretion of each Member State.

Not all Member States provided an answer to all survey questions. Percentages provided in the Results are always related to the number of responses and not to the total number of participating Member States.

3 Results

Completed surveys were received from all 22 Member States participating in JA: Austria (AGES, GÖG), Belgium (FAMHP), Croatia (HALMED), Cyprus (PHS - MOH - CY), Czechia (SÚKL), Denmark (DKMA), Estonia (SAM), Finland (FIMEA), France (ANSM), Germany (BfArM, PEI), Hungary (OGYEI), Ireland (HPRA), Italy (AIFA), Lithuania (ESSC), Luxembourg (MOHLUX), Netherlands (NLNA), Norway (NoMA), Portugal (INFARMED), Romania (MS - MoH RO, NAMMDR), Slovenia (JAZMP), Spain (AEMPS), Sweden (MPA).
Additionally, 4 Member States (NCAs) outside the JA also participated: Bulgaria (BDA), Greece (EOF), Latvia (ZVA), Poland (GIF).

A total of 26 responses were received.

3.1 Monitoring

There are two identified HMA/EMA documents on key information for shortage management and monitoring[6,7], which propose a list of key data elements to be extracted from shortage notifications that can be recorded by NCAs and EMA to manage and monitor shortages across the EU in a harmonised manner. Authorities have been encouraged to align with this list, however the adoption of all, or part, of the defined metrics is left at the discretion of the NCA. The level of current harmonisation of the data elements in the shortage notification across the Member States has been reported and extensively discussed in the two reports from CHESSMEN WP 7[8,9]. Further harmonisation is expected to result from the reform of the EU pharmaceutical legislation.

To avoid duplication with WP 7 activities and other ongoing projects at different levels on monitoring shortages (e.g. the development of European Shortages Monitoring Platform of the European Medicines Agency), questions in the Monitoring section of the questionnaire were focused on regular monitoring of demand and stock data, which can help identify prospective shortages. Reliable and timely information on supply and demand data from relevant supply chain stakeholders can be effective in the monitoring of shortages.

The main results are explained below.

[6] HMA/EMA. Key information for shortage management and monitoring by EU regulators. November 2022.
[7] HMA/EMA. Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA). July 2019.
[8] WP7. D7.1 Report on SWOT analysis of the IT solutions at EU and MS. August 2023.
[9] WP7. D7.2 Report on EU best practice solutions and minimum common dataset. January 2024.

3.1.1 Regular monitoring of stock data

In the survey, 10/26 (38%) Member States indicated that they regularly monitor stock data. The other 16 Member States monitor stock data, if necessary, when they receive shortage notification.

All 10 Member States that indicated that they carried out regular monitoring of stock data, receive the data from wholesalers. In addition, 7 Member States also receive data from pharmacies (6 of them from both community and hospital pharmacies, one from hospital pharmacies only) and 3 Member States receive also data from Marketing Authorisation Holders (MAHs).

In 9/10 (90%) Member States that have established regular monitoring of stock data, providing data on stock levels is mandatory, i.e. in national legislation. In 4 Member States the provision of stock data is mandatory only for wholesalers. Stock data is mostly reported directly to NCAs.

Regarding the obligation of wholesalers, there were noted differences in the application between Member States. For example, in two Member States only so-called 'full-liners' have a reporting obligation, whereas in other jurisdictions obligations have been set based on wholesalers' market share (thresholds of at least 10% were reported).

7/10 (70%) Member States regularly receive stock data for all medicinal products. The remaining 3 Member States collect data for selected medicinal products, which were selected on the basis of reimbursement status (1/10) or on the basis of their criticality (2/10).

6/10 Member States receive stock data daily, 3 Member States weekly and 1 every 2 months. 6/9 Member States who receive stock data daily or weekly also analyse the data daily or weekly. Analysis and reporting are focused on reimbursed medicinal products, or critical and hospital products and on active shortage cases. Others only analyse the data when assessing the shortage notification and monitoring active cases of shortages.

4 Member States have an early warning system that, to some extent, flags potential shortages in advance. One such system is considered fully operational for monitoring specific antibiotics, and flags potential shortages 5 weeks in advance.

To detect supply shortages early, one Member State has also established reporting on Service level (Order fulfilment). Service level information captures the level of fulfilment of wholesalers' orders by MAHs. Such information involves comparing the quantity ordered with the quantity actually received at product level. The resulting difference describes the service level. Pharmaceutical 'full-line' wholesalers weekly report on the service level of selected medicinal products. The NCA is currently finalising an alerting algorithm for when the service level is below 50% or 75% for a specified period of time.[10]

[10] Presentation by GIRP, the European Healthcare Distribution Association, at the Medicine Shortages (SPOC) Working Party meeting, 15–16 April 2024, Amsterdam.

Since 2020, one Member State has also been publishing the availability of medicinal products at wholesalers in a very transparent way through the National register of medicinal products. The total amount of stocks at the national level is published and the wholesalers who hold these quantities are listed.

Two Member States have stated that they intend to introduce an obligation for certain stakeholders to report the size of medicinal product stocks to the NCA on a continuous basis.

One Member State indicated that regular monitoring of stock data is not their regular practice. To more effectively reduce the risks of stock-outs, they established a safety stock requirement for medicinal products of major therapeutic interest in September 2021. MAHs are required by the regulation to hold 2-4 months of security stock of their products if they fall under the category of medicine of major therapeutic interest. The stocks may be established outside the Member State in question.

Two Member States plan to use the data from the European Medicines Verification System (EMVS) and in 4 Member States its usage is under evaluation. Other Member States do not plan to use the EMVS and stated that its data are not always reliable and do not represent actual stocks, that the EMVS has not been established for this function, nor has the capability to do so, nor it is possible to use it in terms of existing legislation.

3.1.2 Regular monitoring of demand data

In the survey, 8/26 (31%) Member States indicated that they have regular monitoring of demand data in place. The other 18 Member States monitor demand data, if necessary, depending on the criticality of the shortage notification.

Sources of demand data vary widely. However commonly used sources and data are detailed as follows:

- sales data from wholesalers to pharmacies (community and hospital), that can be provided either by wholesalers, IQVIA or MAH,
- national prescription data (volumes of medicinal product dispensed from community pharmacies),
- reports on consumption from hospitals.

5 Member States receive the demand data from wholesalers and/or IQVIA, 4 Member States receive national prescription data, one Member State also receives data from MAHs and another from hospitals.

In 4 Member States, which have established regular monitoring of demand data that is based on national prescription data, providing this data is mandatory, i.e. in national legislation. Demand data are mainly reported directly to NCAs.

6 Member States regularly receive demand data for all medicinal products. Other 2 Member States retrieve data for selected medicinal products, e.g. reimbursed medicinal products, and selected supply relevant/critical medicinal products.

3 Member States receive demand data daily, 4 Member States monthly and one Member State receives data every 2 months.

All 3 Member States who receive demand data daily also analyse the data daily. Analysis and reporting are focused on reimbursed medicinal products, or active shortage cases.

One Member State stated the importance of national prescribing/dispensing data: "*It is very useful to have prescribing/dispensing data from e-prescription system. We can analyse, for example, out of pocket consumption of Ozempic, weekly trends of antibiotic consumption, etc. We also have approximately 10-year data from wholesalers, pharmacies about trading of medicinal products, including non-authorised medicinal products.*"

3.1.3 Examples of combining stock and demand data

One Member State described an example of regular monitoring of medicinal products with one critical active substance. Following a shortage of paediatric medicinal antibiotic products containing amoxicillin and amoxicillin/clavulanic acid, a monitoring system using Excel files that were shared with relevant MAHs was implemented. Each MAH inputs the required data weekly (stocks, supply forecasts) or monthly (sales data) into a file that is not visible to other MAHs. Entries are automatically collected in a summary file used by NCA for processing and evaluation.

Another Member State has in place a specific organisation that initially played a role in monitoring stocks and demand in crisis situations (during COVID-19) since 2019 and since then has also been utilised for critical shortages. This organisation also recommends where stocks should go (controlled distribution in accordance with local demand) and/or plan for prioritising remaining stocks, which is based on forecasts and availability.

Two Member States stated that they have a system currently in development, to collect data on supply and stock for nationally identified selected essential and/or critical medicinal products.

One Member State is planning to develop an early warning system to further improve the provision of the patients with medicines and strengthen the security of supply. This plan is underpinned by a legislative framework and a requirement to implement such a system. The development of this system is focused on its ability to reliably analyse existing data on medicines supply, availability and demand in order to calculate a valid supply prognosis and highlight potential risks factors. Furthermore, the aim of system is to specifically perform the assessment of the potential shortage automatically, which will remove the burden associated with manually analysing large amounts of data.

3.2 Reporting

The reporting section of the questionnaire surveyed the obligations of stakeholders to report shortages to NCAs, any penalties in place as well as assessing the current application of shortage reporting in the Member States. Separate subsections were designed to investigate the impact assessment applied as a component of shortage notifications to NCAs and the publication of shortage data in shortage catalogues.

3.2.1 Legal and voluntary framework

The HMA/EMA Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)[11] outlines all shortages should be reported, irrespective of the root cause and whether the shortage is currently taking place or anticipated. Furthermore, Article 23a, 2nd paragraph of Directive 2001/83/EC states that MAH shall notify NCAs when the product ceases to be placed on the market of a Member State, either temporarily or permanently. The MAH shall inform the competent authority of the reasons for cessation.

It is recommended that MAHs notify the relevant authorities as soon as possible when the impending/anticipated shortage is confirmed. The notification should be sent as early as possible even if information is limited. This can be supplemented at a later stage as further details become available. The resumption of supply of medicinal product should also be notified.[12,13] EU legislation requires the notification to be made no less than 2 months before the supply interruption. In the reform of EU pharmaceutical legislation revision of the timeline for MAHs to notify NCAs has been proposed.

Only one Member State in our survey did not have a legal obligation for MAHs to notify shortages. Within this Member State the MAHs have made a voluntary commitment to report shortages. In 4 Member States other stakeholders also have a reporting obligation, such as wholesalers and pharmacies.

One Member State described that wholesalers and pharmacies have the obligation to notify the temporary unavailabilities of medicinal products to NCA within 24 hours of experiencing supply difficulties. Wholesalers must notify the NCA of all occasions when the supply request was not fulfilled by the MAH. In these cases, the wholesaler must submit additional information regarding the quantities requested, quantities actually supplied by the MAH, as well as the quantities of the same presentation exported in the last two months. Pharmacies must notify the NCA when

[11] HMA/EMA. Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA). July 2019.
[12] HMA/EMA Good practices for industry for the prevention of medicine shortages. 2023.
[13] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019 (in revision).

a prescription/request from a patient cannot be met (within 12 hours of receipt) due to lack of product availability.

WP 5 (Identifying the root causes of observed shortages of medicines) has already described in D5.1 List of key definitions relating to shortages of medicines[14], Member States do not apply the same definition of a shortage. In some Member States it is based on duration of unavailability of a medicinal product. Examples of such different definitions are: 1) a non-availability that lasts at least two weeks or a limited availability that lasts at least four weeks, 2) interruption that is expected to last longer than 2-3 weeks, 3) disruption in the supply that expected to last longer than 12 calendar days and 4) interruption of supply for more than 3 working days.
In these cases, only product unavailability over the specified periods is considered to be shortages, which limits reporting obligations to those shortages meeting such criteria.

In 21/24 (87%) Member States shortages of any medicinal product must be reported. In the 3 remaining Member States the reporting obligation is only for selected medicinal products, either based on reimbursement status or the criticality status of the product.

Figure 1 below shows different reporting timelines in the 26 Member States surveyed. The majority of Member States (n=17) require shortages to be reported at least 2 months in advance, 5 (19%) Member States have reporting timeline requirements of 3-6 months in advance. 4 (15%) Member States have the obligation to report set as 'as soon as possible' have no other timeline provided. In addition, one of the Member States applies reporting timeline requirements that are based on the shortage impact assessment. For low impact shortages the timeline requirement is no less than 1 month in advance and 'as soon as possible' is the requirement for medium and high impact shortages.

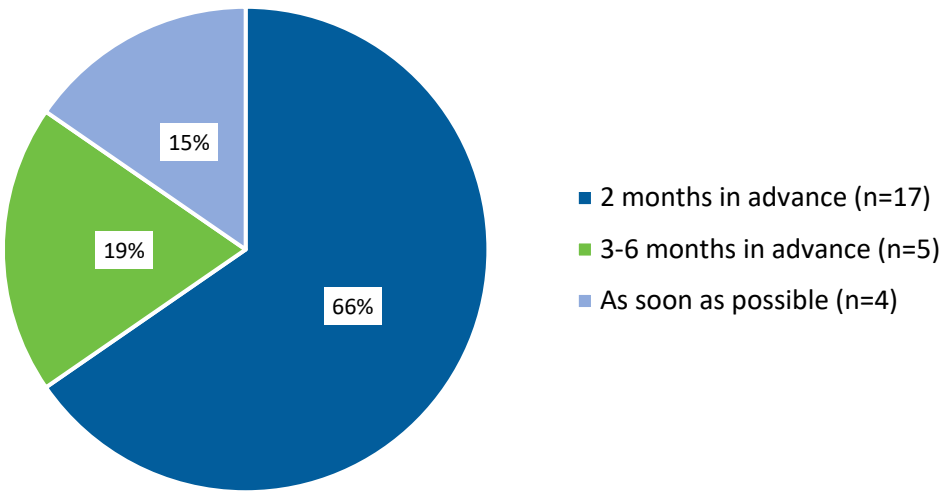

Figure 2. Required shortage reporting timelines in 26 participating Member States

[14] WP 5. D5.1 List of key definitions relating to shortages of medicines. December 2023.

All Member States require where it is not possible to report shortage by the specified time frame for reporting, the MAH should report the shortage as soon as they become aware of it.

In all 26 Member States the shortages are to be reported to NCA or Ministry of health (MoH), in 2 Member States they must be reported additionally to a Public Health authority and in 2 Member States to insurance funds.

19/24 (89%) Member States indicated having financial penalties in place for not reporting or late reporting. These are enforced in only 8/24 (33%) Member States.

In one Member State MAHs receive a warning first. Several Member States described that the fine can depend on various aspects, such as the size of the company, justification for late notification, the shortage impact, duration and recurrence. For example, in one Member State the fine cannot be more than 30% of the turnover for the past year for the affected product or group of products (within a limit of 1 million EUR). Another Member State stated that the fine is higher for failure to report, compared with late reporting.

No incentives, financial or otherwise, are in place for early or timely reporting in any of the Member States.

Survey also examined the stakeholders involved in the reporting shortages, regardless of their legal obligations (Table 1). MAHs report shortages in all 26 Member States. In more than half of Member States pharmacies and wholesalers are reporting as well, follow prescribers, patients, and manufacturers.

Reporting stakeholder	No. of Member States	Percentage
MAH	26	**100%**
Community pharmacies	16	**62%**
Hospital pharmacies	15	**58%**
Wholesalers	15	**58%**
Patients	9	**35%**
Physicians	9	**35%**
Manufacturers	7	**27%**

Table 1. Stakeholders who notify shortages (mandatorily and voluntarily)

One Member State described that community pharmacists, hospital pharmacists and wholesalers can notify the MAH of any suspected unavailability of medicinal product directly through the NCA's shortage reporting platform. They are facilitated in contacting the MAH in case of a suspected unavailability of a medicinal product, a delivery/logistical problem or continued product unavailability that extends beyond the notified resolution date. The MAH answers to questions from pharmacists and wholesalers through the reporting platform. The NCA monitors the communication and reacts if necessary.

Another NCA has a tool which allows pharmacies, physicians and patients to report shortages. In the past this proved valuable to assess if there are regional shortages and to have feedback reflecting the impact of shortages on the public.

3.2.2 Impact assessment

The HMA/EMA Guidance on detection and notification[15] advises that the information provided in the shortage notification is used by the competent authority for triaging and assessing the situation which helps prioritisation and organisation of work. Member States were surveyed on the extent they perform the impact assessment of notified shortages, which stakeholders are involved and what are MAH obligations. The minimum common dataset needed for a reliable shortage impact and criticality assessment was discussed in the deliverable 7.2 by WP 7[16] and is not part of this report.

18/26 (69%) Member States have an impact assessment framework for shortages in place. 6 Member States provided details about their assessment. Criteria used includes indication, availability of therapeutic alternatives and the expected impact on patients (e.g. size of the patient group, duration of shortage).
The assessment methods include grading systems, decision trees and flowcharts that determine the impact and define further actions. Gradings in different Member States classify the shortage into three (low, medium, high) or four (low to high, and critical/very high) types of shortages.

In 15/26 (58%) Member States, MAHs are expected to provide their impact assessment as part of the shortage notification. It varies among Member States whether this is obligatory or voluntary. One Member State requires that MAHs use the NCA's impact assessment methodology. 14 Member States also advise that MAHs include a proposal of mitigation measures for addressing the issue in case of medium or high impact shortage as part of the notification. In many of these Member States this is a voluntary ask/request.

In 7 Member States the proposal of mitigation measures should include details about therapeutic alternatives, marketed within the country or available in other Member States. Other provisions include Direct Healthcare Professional Communication (DHPC), request for permission to import

[15] HMA/EMA. Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA). July 2019.
[16] WP7. D7.2 Report on EU best practice solutions and minimum common dataset. January 2024.

foreign packages and identified measures to prevent a shortage and minimise the impact on public health.

3.2.3 Shortage catalogue

The HMA/EMA Good practice guidance for communication to the public on medicines' availability issues[17] provides EU national competent authorities and the EMA with key principles and examples of good practices for communication to the public on medicinal product shortages. The guidance addresses what information should be published, when to publish it and which format or tools to use. Annex 2 of this guidance includes "Information currently provided in shortage catalogues" for 22 Member States and the EMA. This was compared with the information in the catalogues at the time of this report. Of note many Member States have updated and expanded their catalogues since 2019.

22/26 (85%) Member States that participated in the survey have a public national shortage catalogue in place. 1 Member State has a shortage catalogue, but it is not public. Almost two thirds of Member States with a public catalogue (68%, n=15) publish all notified shortages. One third of Member States (32%, n=7) publish selected shortages only. These Member States use different criteria to determine whether a shortage is published. The criteria include impact assessment, therapeutic indication, criticality or duration of a shortage. The Member States that publish shortages anticipated to last longer than a specified period (e.g. 3 weeks) explained that this period was determined based on the average duration of existing stocks of the medicinal products in the Member State.

One of the Member States without shortage catalogue does publish news items about shortages with medium to very high impact, accompanied with related recommendations that is disseminated to pharmacies, hospitals and healthcare providers.

In 17/22 (77%) Member States with public shortage catalogue, the catalogue is updated daily, in 4 of those it is updated after each shortage notification. Two Member States update it weekly, the remaining 3 Member States twice a week, twice a month and once a month.

Figure 2 details when Member States publish shortage notifications in their shortage catalogues. 9/22 (41%) Member States publish the information about a shortage immediately, which can take from real time up to 24 hours after receiving the notification. 4 Member States publish the information about a shortage as soon as the NCA assessment is complete. 3 Member States publish them on the start date of shortage. Two Member States publish the information 2 weeks before the shortage begins (and not earlier), and the rationale provided is to mitigate the risk of stockpiling in certain notified shortage cases. 3 Member States publish shortages weekly and 1 twice a month. We did not explore when does the NCA assessment take place.

[17] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019. (under revision)

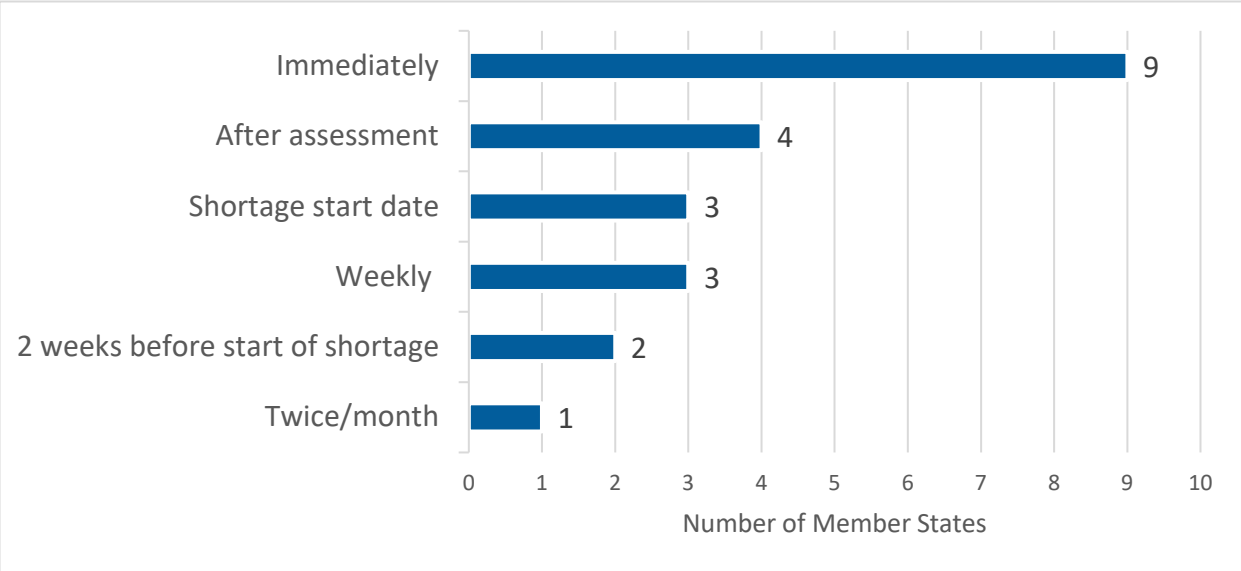

Figure 2. Responses to question "When do you publish notification in the shortage catalogue?"

9/20 (45%) Member States store the shortage records in the catalogues indefinitely, 2 Member States maintain them for a period of 5–10 years, 3 Member States for 4–6 months and 1 Member State for 3 weeks. 5 Member States keep the records in their catalogue until the shortage is resolved.

Table 2 shows information currently included in the shortage catalogues for 22 Member States for 19 selected data points. Listed are also 4 Member States that took part in the survey but do not have a (public) shortage catalogue. Data points are presented in the descending order according to the number of Member States that publish them in the catalogue. Member States are shown in the descending order from the one with the most to the one with the least data points in their catalogue.

'Product name', 'strength' and 'pharmaceutical form' are published in all 22 Member States, 'active substance' and 'expected end date of shortage' are each not published in only 1 Member State. 'MAH name' and 'pack size' follow with being published in 20 and 19 Member States, respectively.

14/22 (64%) Member States publish the root cause of shortages. The root causes are provided in categories, with the number of categories ranging from 4-5 up to 15. Few of the Member States use the category "Other root cause". One of the Member States has a field with further explanation of the shortage in the catalogue where the root cause may be elaborated. One of

the Member States publishes the root cause of shortage only if MAH gives consent for the publication. If no consent is given, that is indicated in the root cause field of the catalogue.[18]

At the bottom end of the published information are 'Shortage status' (e.g. anticipated, ongoing, ongoing with alternatives, resolved or not available, limited availability, available), 'Actual end date of the shortage' and 'Mitigation measures' which are published in only 5 (23%) Member States. 'Therapeutic alternatives listed' and 'Information to HCPs' are published in 6 and 7 Member States, respectively.

When reviewing the shortage catalogues, it was noted that catalogues of some Member States include links to the relevant part of the NCA website with the information about therapeutic alternatives, information to HCPs and patients, or mitigation measures. A few catalogues have only a summary of this information without links. A catalogue of one Member State only indicates whether the information for HCPs is available but no link or note where this information could be obtained is given in the catalogue.

The content of communication to HCPs and patients is detailed in chapter 3.3.4.

[18] "The MAH has not approved that the NCA publishes the reason for the shortage situation."

Data point	SE	NO	DE	BE	PT	AT	CZ	FI	FR	HR	EE	ES	HU	IE	IT	GR	DK	LV	LT	RO	SI	BG	CY	LU	NL	PL	26
Product name	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■					22
Strength	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■					22
Pharmaceutical form	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■					22
Active substance/INN	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■					21
Expected end date of shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						21
MAH	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■						20
Pack size	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■		■	■		■	■					19
Actual start date of shortage	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■		■			■						17
Root cause of shortage	■	■	■	■	■	■	■			■			■	■	■	■	■			■							14
Availability of alternatives	■	■	■	■	■		■				■	■	■	■	■	■		■	■								13
Date of notification	■	■	■			■		■	■	■									■	■	■						11
ATC code	■	■	■	■			■	■			■	■	■				■	■									11
Date of notification update	■	■	■	■	■	■	■	■	■					■			■										10
Expected start date of shortage	■	■	■	■			■	■		■		■					■										9
Information to HCPs	■	■	■		■	■			■					■													7
Therapeutic alternatives listed	■		■		■		■				■							■									6
Shortage status*	■	■		■		■			■																		5
Actual end date of the shortage	■			■	■	■				■																	5
Mitigation measures	■	■			■							■			■												5
Total: 19	19	17	16	15	15	14	14	12	12	12	11	11	11	11	11	10	10	10	9	8	8	5					

Table 2. Selected data points published in shortage catalogues by individual Member States, reviewed by JAZMP in January 2024.

Data categories: Medicinal product Shortage details Information for the HCPs, therapeutic alternatives, mitigation measures

**e.g. Anticipated, Ongoing, Resolved*

3.2.3.1 Linking catalogues to other electronic systems

11/25 (44%) Member States have a system with push notifications to prescribers for shortages. The system then notifies prescribers when they try to prescribe a medicinal product not available, and in some cases prohibits prescription of such medicinal products. In 9 out of these 11 Member States the notification includes information about available therapeutic alternatives, in 2 of them only whether any alternative is available. In some Member States the content of the shortage catalogue is made available in a machine-readable XML format which can be uploaded into prescribers' software daily. However, several Member States stated that because data must be first uploaded into prescribers' IT systems not all prescribers are availing of this service. Additionally, different regions or prescriber offices may use different software programs leading to implementation challenges related to automatic integration and time delays.

In 8 Member States with push notifications, the system will also alert pharmacies at the time of dispensing the medicinal product. In 7 out of those systems, the notification includes information about available therapeutic alternatives.

Another example of shortage notifications emanating directly from shortage catalogues, applied in some Member States, is the possibility for anyone to sign up for a weekly shortage alert or to stay informed about the availability of a specific medicinal product. Additional strategies that Member States use to inform stakeholders are discussed in chapter 3.4.4.

One Member State which does not have a push notification system link their shortage catalogue with the national medicinal product compendium and publishes the most important shortages on the NCA website.

WP 7 provided detailed description of connection of shortage systems with other internal or external systems/databases in deliverable 7.2[19].

[19] WP7. D7.2 Report on EU best practice solutions and minimum common dataset. January 2024.

3.3 Managing

The NCA's role in medicinal product shortage is to co-ordinate the response to a potential or actual shortage across stakeholders so that the impact is mitigated as much as possible. The NCA has a number of regulatory tools and strategies available to assist stakeholders in preventing or minimising the impact of a medicinal product shortage on patients.

The management of a shortage starts after the evaluation of the shortage notification. It is important to establish the nature of the shortage, the potential impact on patients and to identify mitigation measures, including for cases of potential shortages. WP 8 (Reducing the likelihood of medicines shortages via preventive and mitigation strategies) will provide details on these measures. To avoid duplication with the work of WP 8, WP 6 has focused on measures that can be applied when the shortage is already established.

The purpose of this chapter is therefore to outline a set of measures taken by NCAs to address the issue of actual medicinal product shortages. In addition to managing shortages, it is equally important to communicate externally and provide timely information on all shortages of authorised medicinal products through national shortage catalogues (as described in previous chapter) and through other media where appropriate.

4/26 (15%) Member States have indicated that they have a roadmap in place to address medicinal product shortages and have also submitted the supporting documents available that detail those plans. These documents will be used for the execution of the next WP 6 task i.e. T6.3 Development of comprehensive monitoring, reporting, and managing protocol that will combine above mentioned work of WP 8 on impact assessment of shortage notification and all the available measures at national level into one comprehensive protocol.

The measures analysed in the survey are described below.

3.3.1 Stakeholder dialogue – coordination of response to shortages

According to European Commission's study on medicinal product shortages[20] one of the most important measures is a dialogue with stakeholders. All NCAs take an active role in coordinating the response to the shortage across stakeholders. Mainly with MAHs, wholesalers, pharmacies, and prescribers (see Figure 3).

[20] European Commission. Future-proofing pharmaceutical legislation – study on medicine shortages. Final report. November 2021.

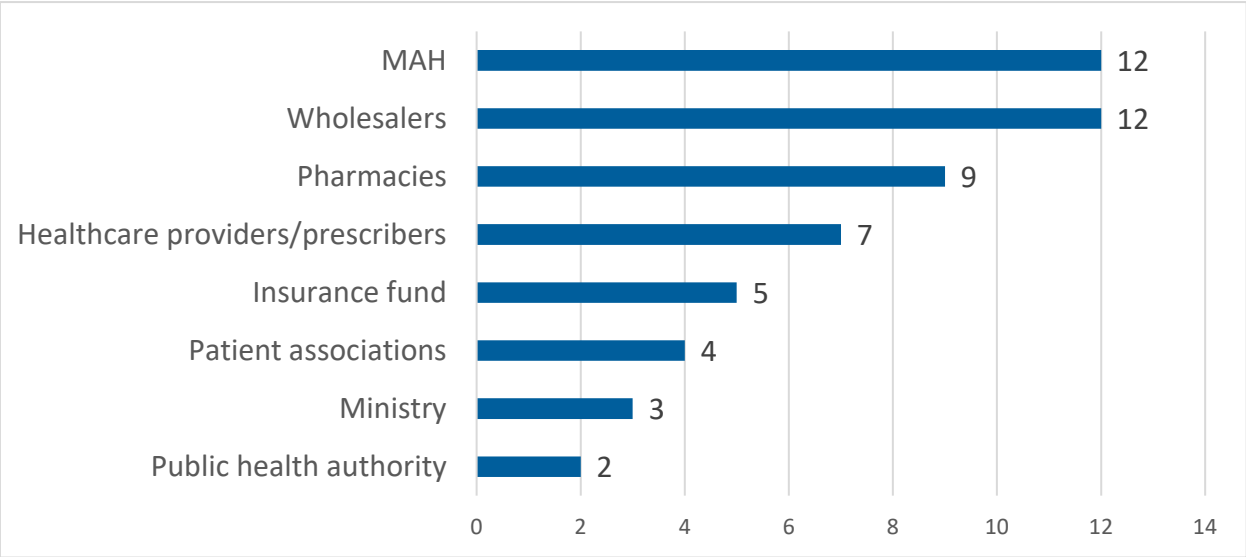

Figure 3. Stakeholders that NCAs involve in co-ordination of response to shortages. Answers from 14 Member States.

Several NCAs have established working groups with 6–7 different stakeholders. Only one NCA has established a multi-stakeholder advisory council to deal with shortages, which has been provided a formal footing via national legislation. This advisory council supports the health authorities in assessing the relevance of supply shortage, considers possible therapeutic alternatives, and develops recommendations for improving the supply situation. Other NCAs have the facility to set up a multi-stakeholder taskforce on a case-by-case basis.

Measures that NCAs proactively take:

- **Notifying existing suppliers of alternative medicinal products to increase production to fill the gap between supply and demand**

In the case of shortages with a medium and high impact, the responsible authority of the Member State (e.g. MoH or NCA) informs MAHs or parallel distributors of alternative medicinal products about the supply gap so that they can anticipate a possible increase in orders. The authority may consult MAHs on the possibilities of increasing production, duly accounting for available stock and average lead production time.

One NCA stated that where there is more than one alternative supplier, it can get complicated as each supplier can assume that 100% of the demand will go to them. There is a potential risk of exposure to claims for loss of profits by the industry.

One NCA, has applied a system whereby the notifier of the shortage may authorise the following regarding submitted information on current demand (monthly sales volume): "*In case of a limited number of alternatives, I authorise the NCA to share this data with other companies offering comparable alternatives to determine whether they can meet any increase in demand.*"

The Member State explained that this authorisation is not specifically required. If the NCA demonstrates that the public interest to give access to the information outweighs a requirement to withhold any commercially sensitive data, then the information can be shared. However, by obtaining consent from the MAH, this scenario can be avoided. If the MAH authorisation is not given via the notification in the online system and the NCA deems this information is necessary for another MAH to assess if they can meet the uplift in demand, they ask for MAH for authorisation via e-mail. It is only shortages considered critical, where this information is shared without this consent when it is deemed to be in the interest of public health. That occurs very rarely.

- **Coordination of stakeholders on import of the alternative medicinal products (authorised/unauthorised)**

In case of the limited or no therapeutic alternatives available on the market, almost all NCAs (92%; n=24) proactively coordinate wholesalers to support temporary importation of alternative medicinal products from other Member States or third countries. 3/24 NCAs do that only in case of critical shortages.

To implement this measure there is an established regulatory procedure in all Member States for approval of import and exemptions to the labelling and package leaflet obligations in national language for authorised medicinal products as well as procedures to approve import of unauthorised medicinal products.

As MAHs of medicinal product in shortage have a commercial interest in maintaining patients on their medicinal product, they take proactive steps and assess availability of their medicinal products marketed in other Member States. If the product is available elsewhere, the MAH can apply for exemptions from labelling and package leaflet obligations in national language. This action is frequently proposed as part of the shortage notification.

In the event that the import of an authorised medicinal product in foreign packaging is not an option, the NCAs approach wholesalers and parallel importers/exporters to import alternative unauthorised medicinal products.

From a transparency perspective, all potential importers must be informed at the same time of the need for alternative medicinal products. Three NCAs do this in a very transparent way. Two of them by publishing on their website the need for more suppliers or alternatives in their markets if a potential or actual shortage is identified due to withdrawal, marketing cessation or vulnerable supply. The third NCA sends a notice to all wholesalers via e-mail. The notice applies to products that are critical to the market, with respect to public health. MAHs or wholesalers who may be able to market or import product listed are encouraged to contact the relevant agency.

- **Coordination of stakeholders on issuing treatment recommendations during shortages of medicinal products**

71% (n=17) of NCAs coordinate stakeholders on issuing treatment recommendations during shortages of medicinal products, however, mainly in case of critical shortages.

Treatment recommendations are mainly issued by NCAs, after the consultation with affected medical societies, pharmacists associations and even patient representative groups.

Distribution channels for treatment recommendations are discussed in chapter 3.4.4 of this report.

- **Coordination of stakeholders on communication to public/patients**

74% (n=17) of NCAs co-ordinate stakeholders on communication to patients and public. More information is available in chapter 3.4.4 of this report.

3.3.2 Regulatory measures – simplified regulatory procedures

As already mentioned, all Member States have established regulatory procedures for approval of import and exemptions to the labelling and package leaflet obligations in national language for authorised medicinal products and procedures to approve import of unauthorised medicinal products.

Exemptions from labelling requirements are determined on a case-by-case basis, mostly taking into account dispensing (hospital/community), relevant label information, and original language.

In some Member States, in addition to wholesalers, hospital pharmacies can also import unauthorised medicinal products.

The majority of Member States (73%; n=16) have also established fast-track regulatory procedures for approval of variations, e.g. to permit MAHs to quickly source starting materials, reagents, intermediates, or active substances from alternative suppliers, in case of medicinal products authorised under national procedures. As another example, a type-II variation procedure is shortened from 90 days to 30 days.

In two Member States, NCAs will prioritise the assessment of a variation if it is needed to resolve a critical or medium/high impact shortage.

In order to solve a particular shortage situation and, more importantly, the long-term availability of a given medicinal product, almost all Member States (95%; n=21) have established procedures for granting national marketing authorisation within a shortened time schedule for medicinal products authorised in another EU/EEA Member State, e.g. Day Zero Mutual Recognition Procedure/Repeat Use Procedure.

The NCA, which publishes on its website the need for more suppliers or alternatives in its market if a potential shortage is to arise due to a market withdrawal, marketing cessation or vulnerability in supply is identified, also publishes possible simplified regulatory procedures and financial incentives that may apply on a case-by-case basis:

- reduced or waived application fee,
- shortened application procedure,
- reduced or waived fees for future renewals and variations,
- reduced or waived supplier tax,
- reduced documentation requirements,
- exemptions from requirements on labelling and serialisation,
- for products intended for hospital use, exemption from the linguistic requirement to have a national package leaflet,
- it is possible to set a higher maximum price for prescription-only medicinal products than what the main rules state.

3.3.3 Financial incentives

Limited financial incentives are possible for imported therapeutic alternatives, mainly higher prices, as stated by 10 Member States, and full reimbursement in certain cases (2 Member States).

The price difference of the therapeutic alternative versus the referenced medicinal product in shortage is mainly covered by insurance funds, if the therapeutic alternatives is reimbursed, or by hospital (n=14) and/or the patient (n=10). In 3 Member States, the MAH covers the pricing difference, but only when MAH is contractually bound to do so.

There are also financial incentives in place for MA applications that address availability issues e.g. MA application fee reduced or waived (n=4), variation fee reduced (n=3), yearly MA fee reduced (n=2), Zero Day RUP fee reduced (n=1). In the 2 mentioned Member States, only those medicinal products that are included in the list of essential medicines are entitled to a fee reduction.

3.3.4 Communication of shortages to stakeholders

Stakeholders, especially healthcare professionals (HCP) and patients, can contribute more to addressing shortages if there is adequate communication. For example, timely notification to prescribers is very important, especially to avoid any new initiation of a treatment that will be in short supply for an extended period. Informing community pharmacists can also help mitigate the impact through the dispensing of therapeutic alternatives, which can mean that patients are not required to be referred back to attending physicians in all cases.

Timely and informative notification of actual or potential shortages to HCPs can facilitate changes in prescribing and dispensing, preventing stockpiling and promote rational use of existing stocks,

and also allow time for safe, effective and affordable therapeutic alternatives to be sourced and introduced, thereby reducing the impact on patients and healthcare systems.

The majority of NCAs (n=22) use shortage catalogues as a communication tool for all stakeholders. Shortage catalogues are an important tool, but they only target stakeholders who are affected by the shortage and are actively seeking information. Less than 50% of Member States (n=11) have established a link between the shortage catalogue and the electronic prescribing system and only 8 Member States have established a link between the shortage catalogue and pharmacy dispensing systems (see chapter 3.2.2.1), which allows alerts (pop-ups) on shortage at the point of prescribing or dispensing the medicinal product in question.

Another example of shortage notification directly from the shortage catalogues, which is only used in a few Member States, is the possibility for anyone to sign up for a weekly shortage alert or to stay informed about the availability of a specific medicinal product.

Shortages with medium and high impact may involve a range of stakeholders collaborating on mitigating the impact, in which case additional communication channels should also be used.

The timing of the communication through additional channels was not explored. It is considered to depend on the dynamics and criticality of the specific shortage.

- **Other channels of communication to prescribers:**

The most frequently used channel is DHPC (n=10), then communication through representative organisations (n=6) and NCA's websites (n=5), less through an e-mail (n=3) and (news)letter (n=2).

E-mail notifications are sent with weekly updates or when news about shortages is published or updated.

One NCA sends a notification of shortage in parallel with the publication of the shortage in the national shortage catalogue to the national regions to inform their prescribers.

- **Other channels of communication to pharmacists:**

The same channels as for prescribers are used also for pharmacists: DHPC (n=6), communication through representative organisations (n=5), e-mail (n=5), NCA's websites (n=4), and (news)letter (n=2).

E-mail notifications are sent with weekly updates (mainly to hospital pharmacies) or when news about shortages is published or updated.

One NCA sends a notification of a shortage in parallel with the publication of the shortage in the national shortage catalogue to the national regions to inform their pharmacists.

One NCA holds weekly meetings on potential critical shortages with representatives of pharmacy association and pharmacy chains.

- **Other channels of communication to patients' organisations:**

Only 2 Member States stated that they have in place regular notification to patients' organisations: one through weekly e-mail to patient representative groups and the other through DHPC (sent by MAH also to affected patients' organisations).

In case of critical shortages: patients' organisations are notified through patient's representatives in the multi-stakeholder meeting organised by NCAs (n=2), two NCAs publish press-release on their websites, another two NCAs inform affected association by phone or e-mail. In such cases information about therapeutic alternatives is also provided.

- **Review of the NCA's websites**

In addition to the survey, JAZMP reviewed news of supply issues and specific product updates posted on NCAs' websites and noted the following good practices:

- There is a link from the published information about the shortage of a particular medicinal product in the shortage catalogue to additional information about the supply issue published on the website.
- Additional information consists of the following chapters: advice on therapeutic alternatives, advice for prescribers, advice for pharmacists, advice for patients and a chapter on reimbursement/information on price differences.
- The measures implemented to mitigate the impact of the shortage are also indicated (e.g. restricted use for remaining medicinal product stocks in the supply chain, export bans).
- If necessary, the advice for prescribers and pharmacists also contains recommendations on controlled distribution, limiting the initiation to certain indications or populations, changing doses, etc., so that remaining supply of the medicinal product will last as long as possible.
- Advice for pharmacies includes, for example, a link to package leaflet in national language that can be printed for the patient when a foreign package is dispensed, or a link to advice on crushing/dividing and manipulating tablets for children in the absence of oral solution.

3.3.5 Information to media/general public

Only 23% (n=5) of Member States proactively provide information to the media on shortages and shortage situations and 27% (n=6) only in specific cases.

3/5 NCAs that proactively provide information to the media stated that they provide information through press releases, through press conferences (organised by the MoH) and send items about shortages published on the NCA's website in parallel to media.

NCAs handle media inquiries mainly by answering questions by e-mail (n=17) or by phone (n=13) and by giving interviews (n=10) (Figure 4).

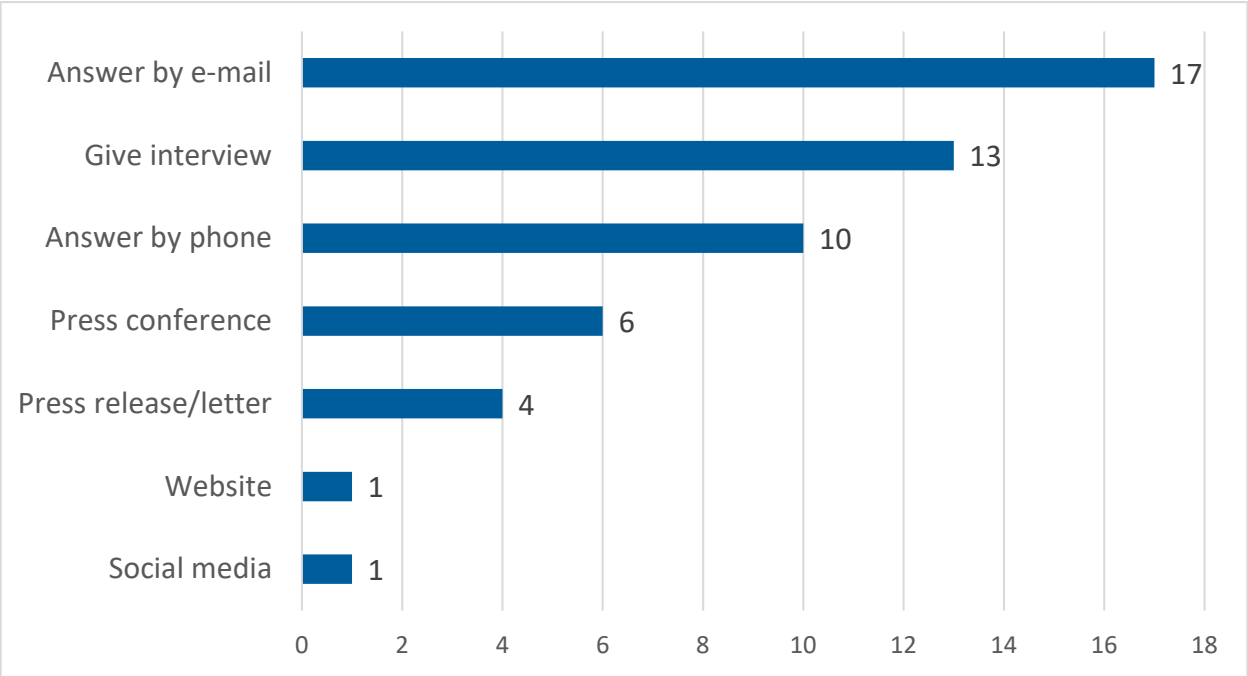

Figure 4. How NCAs handle media inquiries. Answers from 20 Member States.

80% (n=16) of Member States agreed that media reporting has increased stockpiling. One NCA has found evidence of a direct relationship between media reports and an increased stockpile at pharmacy, hospital and patient level.

3.3.6 Widening professional competences of pharmacists

An opportunity was also identified for more efficient management of medicinal product shortages by widening professional competences of community pharmacists during shortages. Community pharmacists can mitigate the impact of shortage by dispensing therapeutic alternatives so that not all patients are referred back to attending physicians.

Currently generic substitution (at the ATC5 level) is still not allowed in 25% (n=6) of Member States, and therapeutic substitution at ATC4 is not allowed in any Member State.

During a shortage, switching to the same medicinal product with a different strength is allowed only in 23% (n=5) of Member States. In this case, the total amount of active ingredient dispensed must not be greater than that prescribed.

The majority of Member States (n=13) do not agree with the possibility of switching to the same medicinal product with the different administration route without consultation with the attending physician. Only 6 Member States support this option, subject to no safety concerns being identified.

Almost all Member States (95%; n=19) agree that it could be useful and endorse having shared electronic communication tools between pharmacists and prescribers (e.g. shared electronic health records) to enable effective and safe substitution of the therapy during the shortage.

11 Member States agree that shortages could also be managed with magistral or galenic production of certain medicinal products, however mainly in hospital pharmacies, and in case of a shortage of paediatric formulations. Member States are concerned about the availability of active substances and pharmacopeial monographs and that this type of production can only be carried out on a small scale.

It is acknowledged that proposals to widen professional competences of pharmacists require changes in national legislation.

3.3.7 National production

9 Member States indicated that they have national, state-owned production sites – mainly galenic manufacturing and hospital pharmacies. Only 5 Member States have a national military production site. As part of a pandemic preparedness initiative, the government of one Member State has a contract with vaccine manufacturers to ensure the continued availability of production capacity for pandemic vaccines.

4 Discussion

4.1 Best practices on regular monitoring of stock and demand data

Continuous information on stock levels and demand data can be used for early detection of a potential supply issue as well as to forecast demand to inform preventive or mitigation measures. Early detection of potential supply issues at the medicinal product and active substance level can support effective mitigation measures for imminent shortages and even prevent shortages from occurring or at least prevent escalation to these being critical shortages. Continuous information on demand data can help forecast the demand of specific medicinal products and therapeutic alternatives in the event of expected shortage, thereby enabling more effective impact assessment and more effective preventive or mitigation measures. By having such data, the NCAs are less reliant on the data provided by MAHs, including predictions of the impact and the necessary supply.

The survey shows that only 6 Member States (23%) have a system in place to collect information on stock levels of medicinal products and demand data.

Currently only one Member State receives stock data from all major actors in the supply chain i.e. MAHs, wholesalers, and pharmacies (community and hospital). In general, the main source of information on stock levels are wholesalers (full-liners) and pharmacies (community and hospital).

On the other hand, sources of demand data vary widely. The main sources used were identified as: sales data from wholesalers to pharmacies (community and hospital), that can be provided either by wholesalers, IQVIA or MAH, national prescription data (volumes of medicinal products dispensed from community pharmacies) and reports on consumption from hospitals. It should be considered that the sales data to pharmacies and hospitals from wholesalers (e.g. IQVIA) does not include direct sales to pharmacies. On the other hand, national prescription data may be available with a time delay and not on a monthly level. The usefulness of different data should be assessed by each Member State.

In 9/10 Member States that have established regular monitoring of stock data, providing data on stock levels is mandatory. In 4 Member States that have established regular monitoring of demand data based on national prescription data, providing national prescription data is mandatory, i.e. in national legislation.

The majority of Member States regularly receive stock and demand data for all medicinal products. The majority of those who receive data on stock and demand on a daily or weekly basis also analyse it on a daily or weekly basis. They focus on reimbursed medicinal products, or critical and hospital products and on active shortage cases. Only one Member State has an early warning system that flags potential shortages in advance. It is a fully operational system that flags the potential shortages for specific antibiotics 5 weeks in advance.

Even if the data is not regularly analysed, it is important that reliable and timely information from relevant stakeholders in supply chain is available at the time of shortage notification, as this is also a prerequisite for effective monitoring of potential shortage. It also enables forecasting of the demand for the medicinal product and the therapeutic alternatives, thereby enabling more effective impact assessments and more effective preventive or mitigation measures.

Based on the WP 7 D7.2 report, systems for stock and demand data and systems to make forecasts for shortage preventive or mitigative measures are not linked. There would be benefits to having these systems linked and also linked to other internal systems, such as the shortage catalogue system. Ideally the analysis of the data could be automated without much manual effort.[21]

When establishing regular data transfer, NCAs should consider the future requirements of the European Shortages Monitoring Platform (ESMP) for the submission of data by NCAs in case of monitoring shortages that could lead to a Public Health Emergency/Major Event (Preparedness) or in case of monitoring and management of critical medicinal products.[22] In both cases NCAs will be required to report demand data i.e. volume of sales and prescriptions (so called historical consumption and historical volume of prescriptions) and Member State available stock. Available stocks at Member State level consist of hospital stocks, community pharmacy stocks, wholesaler stocks and any strategic reserve. Member States' current stock collecting practices are largely in line with the ESMP requirements and our recommendations (see chapter 5.1).

With the implementation of the ESMP, harmonisation of the requirements for stock and demand data is expected to occur over time.

Further recommendations on best practice solutions from an IT tools perspective can be found in the WP 7 D7.2 report.

4.2 Best practices on reporting medicine shortages

Obligation for MAH to report shortages is present in almost all Member States. However, requirements for reporting vary between Member States. In some, the shortages of all medicinal products should be reported, while in others only shortage notifications concerning prescription-only medicinal products or products of major therapeutic interest are required. In some Member States MAHs have the reporting obligation only for the shortages lasting longer than a specified period. This is contrary to the HMA/EMA Guidance on detection and notification of shortages[23] which advises that all shortages of all medicinal products, irrespective of the clinical importance and duration, should be reported. The shortages for all medicinal products regardless of their prescription status, therapeutic importance and shortage duration should be reported as lack of availability of medicinal products could negatively impact public health.

[21] WP7. D7.2 Report on EU best practice solutions and minimum common dataset. January 2024.
[22] Regulation (EU) 2022/123.
[23] HMA/EMA. Guidance on detection and notification of shortages of medicinal products for MAHs. July 2019.

In 4 Member States other stakeholders than the MAH also have reporting obligations to be met, for example wholesalers and pharmacies. In practice, these stakeholders report shortages in more than half of the Member States. Additional notifications are received also by prescribers and patients. Two Member States shared that they have a website and reporting system specifically in place so that anyone, including patients and HCPs can inform the NCA of a risk of shortage or if they are unable to obtain a certain medication. This way NCA may receive warning signals of potential medicinal product unavailability or regional unavailability as well as develop relevant insights on how much the shortage impacts the public.

We identified a very simple and efficient system for reporting by pharmacies and wholesalers which does not present a burden arising from false signals to the NCA. The Member State described that community pharmacists, hospital pharmacists and wholesalers notify the MAH of suspected unavailability of medicinal product directly through the NCA's shortage reporting platform. MAH answers to questions from pharmacists and wholesalers directly, through this reporting platform. The NCA monitors the communication and reacts if necessary.

Member States have the same or stricter timeline for reporting than that set in Directive 2001/83/EC, of notification no less than 2 months before the supply interruption. In any case it is important that MAHs notify shortages as soon as they become aware of it, so the NCA can review the situation and act appropriately. In the European Commission study on medicine shortages[24], it was highlighted that for shortages caused by unforeseen supply disruptions, MAHs frequently only notify the NCA at, or even after, the actual time the shortage occurs. NCAs generally recognise the challenge of providing early notification in such situations, and recognise it being outside the control of the MAH providing the late notification. Many different stakeholders emphasised the importance of regular open communications between national authorities, MAHs, distributors and pharmacists to discuss any relevant issues in the supply chain and their possible impact on product availability.

Financial penalties for no or late notification are in place in 89% of the Member States but enforced in only 33% (n=8). This may indicate that the penalties are not effective and NCAs give more emphasis on resolving shortages and promote the importance of notifying of shortages through other means such as regular communication with stakeholders as mentioned above.

Complete shortage information facilitates effective prioritisation and work planning. In the event that the MAH does not provide a detailed enough reason and circumstances, it is difficult to fully ascertain the extent of the shortage and the viability of possible solutions. This increases the frequency of follow-up requests from the NCA to the MAH seeking additional information and prolongs the time it takes to determine the best solutions or mitigation measures for the shortage. However, to avoid delays in reporting due to collecting all information, the notification should be sent to the relevant authorities even if information is limited at first. Initial notification can be supplemented at a later stage when further details become available [25]

[24] EC. Future-proofing pharmaceutical legislation — study on medicine shortages. November 2021.
[25] HPRA. Medicinal Product Shortages. Two-Year Review. November 2022.

As mentioned in previous chapters, the minimum common dataset to be provided in the initial notification to the competent authority was proposed by WP 7 in D7.2[26]. Amongst this is a risk assessment of the impact of the shortage. The MAH providing such an assessment enables the responsible NCA to plan a proportionate and timely response to reduce the impact on patients. Furthermore, if NCA and MAH used the same impact assessment methodology it would facilitate a more effective response. However, currently NCAs use many different methodologies, and some do not have any methodology in place at all. WP 8 plans to work on common impact assessment methodology.

Similarly, it would be preferential if MAHs include proposals for mitigation measures to address the shortage issue as part of the notification procedure, in particular for shortages assessed as having a medium or high impact. Just over half of the Member States advised that MAHs should provide such proposals, but in many this is voluntary. According to our survey, the most important piece of information in the proposal are details about therapeutic alternatives, marketed within the country or available in other Member States. Other items include Direct Healthcare Professional Communication (DHPC), request for permission to import foreign packages and identified measures to prevent shortage and minimise the impact on public health.

When issuing national guidance for MAHs on impact assessment and Shortage Mitigation plans NCAs should also consider recently developed guidance by TF AAM.

TF AAM developed and published the SPP and SMP templates[27,28] in June 2024. The TF AAM has also developed an implementing guide for MAHs to facilitate a harmonised implementation of the SPP and SMP, which also includes impact assessment methodology.

SMPs will be submitted to the Competent Authorities concerned (Competent Authority of the Member State where the medicinal product is marketed and, in addition, the EMA for a medicinal product covered by a centralised marketing authorisation) upon request according to timelines laid down in the pharmaceutical legislation and national regulations. SMPs may also be submitted to Competent Authorities when MAHs become aware of a shortage, in such case the shortage notification and SMP might be merged in a single document.

For any product for human use marketed in the EU/EEA, outside of a crisis, the development of SPP and/or SMP remains voluntary, which is expected to change with the EU pharmaceutical legislation reform.

[26] WP7. D7.2 Report on EU best practice solutions and minimum common dataset. January 2024.
[27] EMA/HMA TF AAM. Shortage Prevention Plan (SPP). June 2024
[28] EMA/HMA TF AAM. Shortage Mitigation Plan (SMP). June 2024

4.3 Best practices on publishing of shortages

One of the key recommendations of the HMA/EMA Communication guidance[29] is to have established a systematic listing of shortages in the form of a catalogue. A catalogue should provide in one place relevant information for a wide audience, from healthcare professionals and patients to other regulators and economic operators. Since the guidance was published, more Member States have established catalogues, or they have updated and/or expanded them. This shows that the awareness of the importance of transparent communication about medicine shortages has increased.

While a third of Member States publish only selected shortages, the majority publish all shortage notifications. Different Member States employ different criteria when determining whether to publish, some of which include impact assessment, criticality, therapeutic indication and duration of the shortage. The Member States that publish only shortages lasting longer than certain period (e.g. 3 weeks) explained that this period was determined based on the average duration of existing stocks of the medicinal products in the Member State. Due to different stock sizes in Member States, this approach may be hard to harmonise.

The shortage catalogues are mostly updated daily which means the intended audience, including prescribers and pharmacists, receive information about upcoming and ongoing shortages promptly.

Time of publication of notified shortages is also an important consideration in communicating shortages. 4 Member States publish the shortage after the NCA assessment. In 2 Member States the information is published only 2 weeks before the shortage begins and in 3 Member States on the shortage date. However, most of the Member States publish the shortage immediately and we did not explore when does the NCA assessment take place.
It is important that shortages are published once they are confirmed by the MAH and the NCA assessment is completed, so any recommendations for mitigation or management of the shortage are already included. Even if the shortage is published immediately, updates should be issued to reflect any relevant change in the situation[30].

The shortage catalogues should be easily accessible to the public and it should be easy to search whether a certain medicine is unavailable. Member States document very well the details about the medicinal products for which the shortage is reported. Since one of the main audiences of the catalogues are HCPs and patients, there needs to be an emphasis on, having information that is practical and relevant and to ensure the context of the shortage is provided, including its anticipated duration, whether therapeutic alternatives are available and any other relevant recommendations or guidance. This information is included in only a small number of catalogues (see Table 2). Publishing this information on other parts of the NCA website disperses

[29] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019. (under revision)
[30] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019. (under revision)

information and may decrease the effectiveness of shortage communication. A good practice employed by some of the Member States is to include links to any such supplementary sites in the shortage catalogue.

The root causes in shortage catalogues are typically listed under several different categories. The number of categories range from 4 to 15. Categories should be unified across Member States to facilitate harmonised reporting and enable NCAs to receive complete information about shortages. This would enable a quick and comparable overview of reported shortages across EU/EEA.

The most effective use of a shortage catalogue is to have it linked to external electronic systems such as prescribing or dispensing systems. The system then notifies prescribers and pharmacists when they try to prescribe or dispense a medicinal product in shortage. The push notification should include information about available therapeutic alternatives.

Less than half of the Member States with the catalogue enable such connection. In 9 out of these Member States the notification includes information about available therapeutic alternatives, in 2 of them only whether the alternative is available or not. It was also pointed out that while there may be option to link the catalogue with the electronic systems in a Member State, not all regions, prescribers and pharmacists decide to use this function. Existing shortage catalogues should be updated so they may be linked to other systems. Once in place, the NCAs should promote the usefulness of this feature to HCPs.

Another example of communicating shortages directly from shortage catalogues is the option for anyone to sign up either for a weekly shortage alert, or to keep being informed about the availability of a specific medicinal product.

Member States store the shortage records in catalogues from only several weeks to up to 10 years, or indefinitely. It is considered good practice to keep these records for longer periods (e.g. 5 years), for transparency purposes.

4.4 Best practices on managing shortages

The NCA's role in managing shortages of medicinal products is to coordinate the response to a potential or actual shortage across stakeholders so that the impact is mitigated as much as possible. The NCA has several regulatory tools and strategies available to assist stakeholders in preventing or minimising the impact of a medicinal product shortage on patients.

The cause and impact of a shortage is varied and therefore responses to medicinal product shortages are on a case-by-case basis and may require flexibility in approach. We have collected best practices on the most important and common measures that can be applied when the shortage is already established.

Coordination of response to shortages:

The most important measure is dialogue with stakeholders and all NCAs take an active role in coordinating the response to the shortage across the stakeholders. Active dialogues are mainly with MAHs, wholesalers, and pharmacies. The majority of the NCAs set up a taskforce on a case-by-case basis to support the assessment of the relevance of particular supply shortages, taking into account possible therapeutic alternatives, as well as developing recommendations for improving the supply situation and outward communication.

The establishment of a multi-stakeholder advisory council, which is also formally established in the legislation, is more of a preventive measure and represents a holistic approach to managing shortages. Such an advisory council meets regularly to establish a framework for all national stakeholders to effectively address potential or actual medicinal product shortages at the national level, to develop preventative strategies and propose changes to national legislation.

Once a shortage has already occurred, measures are limited. In the case of shortages with a medium and high impact, all Member States first notify the MAHs of alternative medicinal products of the imminent supply gap, so that they can anticipate a possible increase in orders. NCAs may consult with MAHs on the possibilities of increasing production based on information on available stocks and production capacity. In case of limited or no therapeutic alternatives available on the market, almost all NCAs rely on the temporary importation of therapeutic alternative from other Member States or third countries.

The differences between NCAs are mainly in how proactive they are in their engagement with the stakeholders on import of alternative medicinal products. In some cases, this action is only taken for critical shortages.
Regarding transparency in communication, two very good practices were identified:

- The shortage notifier may authorise the NCA to disclose submitted information on current demand (e.g. monthly sales volume) to third parties involved in the shortage notification, which eliminates the need to seek explicit permission for this. This can be done by including statements such as: "*In the event of a limited number of alternatives, I authorise the NCA to share this information with other companies offering comparable alternatives to determine whether they can meet any increase in demand.*"

- Two NCAs publish on their website the need for more suppliers or alternatives in their markets, where a potential or actual shortage is identified due to withdrawal, marketing cessation or established vulnerability in supply. The notice applies to products that are critical to the market, with regards to public health. MA holders or distributers who may be able to market or import products listed are encouraged to contact the agency. Another NCA sends a notice to all wholesalers via e-mail.

Coordination of stakeholders in issuing treatment recommendations and informing patients and the public during the shortages with medium and high impact should be improved upon, as it is currently only triggered in cases of critical shortages.

Regulatory measures:

All Member States have established regulatory procedures for approval of import and exemptions to the labelling and package leaflet obligations in national language for authorised medicinal products and procedures to approve import of unauthorised medicinal products. More exemptions are allowed for medicinal products dispensed in hospitals.

The majority of Member States have also established fast-track regulatory procedures for the approval of variations or they prioritise the assessment of a variation where it is needed to resolve a critical or medium/high impact shortage.

In order to solve a particular shortage situation and, more importantly, the long-term availability of a given medicinal product, almost all member States have established procedures for granting national marketing authorisation with a shortened time schedule for medicinal products authorised in another EU/EEA Member State, e.g. Day Zero Mutual Recognition Procedure/Repeat Use Procedure.

As a good practice was identified that one NCA, which is referred to already, publishes on its website the need for more suppliers or alternatives in its market where a potential shortage due to withdrawal, marketing cessation or vulnerability in supply is identified. That NCA also publishes the possible simplified regulatory procedures and financial incentives that may apply on a case-by-case basis.

Financial incentives:

Limited financial incentives are possible for imported unauthorised alternative medicinal products: this is mainly higher price, but only in 10 Member States. The price difference of alternative medicinal product vs. reimbursed referenced medicinal product that is in shortage should be covered by insurance fund or hospital and not by patient. This practice is still observed in ten Member States.

There are also financial incentives in place for MA applications that solve availability issues e.g. MA application fee reduced or waived, variation fee reduced, yearly MA fee reduced, Zero Day RUP fee reduced, but only in limited number of Member States (36%, n=8).

Financial incentives should be enforced at least for those medicinal products that are included in the list of essential medicinal products, strategic or critical medicinal products.

Communication of additional information about shortages to stakeholders and media/general public:

Stakeholders, especially HCPs and patients, can contribute more to addressing shortages if there is adequate communication. For example, timely notification to prescribers is very important, especially to avoid new initiations of therapies that will be in short supply for an extended period. Informed community pharmacists can also mitigate the impact by dispensing therapeutic alternatives, which may mean that patients do not need to be referred back to attending physicians.

Timely and informative notification of actual or potential shortage to HCPs can facilitate changes in prescribing and dispensing, preventing stockpiling and promote rational use of existing stocks, and allow time for safe, effective and affordable therapeutic alternatives to be sourced and introduced, thereby reducing the impact on patients and healthcare systems.

In 2019 the EMA published extensive guidance for communication to the public on medicinal products availability issues.[31] Although the use of shortage catalogues as a communication tool by regulatory authorities has increased since the publication of this guidance, further improvements in communication and transparency are needed, as set out in chapter 4.2.

For shortages with medium and high impact involving a range of stakeholders collaborating on mitigating the impact, additional communication channels should also be used. However, the most frequently used channel for informing prescribers and pharmacists is DHPC (prepared by MAH), then communication through representative organisations, NCA's websites and an e-mail, less so a (news)letter. Patient organisations are rarely notified even in the case of critical shortage.

News of supply issues or specific product updates posted on NCA's websites were reviewed and some good practices were identified regarding advice to different stakeholders. This includes the provision of a link from the published information about the shortage of a particular medicinal product in the shortage catalogue to where additional information about this supply issue was published on the website (see chapter 3.3.4).

The HMA/EMA Communication Guidance in revision highlights the importance of regulators proactively engaging with the media and supporting reporting to promote understanding of shortage management in the EU. This is particularly important for critical shortages of medicinal products with a significant impact on clinical practice. Currently only 50% of Member States proactively provide information to the media on shortages and shortage situation and half of them only in specific cases. At the same time 80% (n=16) of Member States agree that media reporting has increased stockpiling. Media reporting can only be improved through regular

[31] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019. (under revision)

communication and cooperation, such as continuous education of key journalists who cover healthcare related news. The Communication Guidance is currently under revision and will provide additional guidance on communication with the media.

The timing of the communication through additional channels was not explored. It is considered to depend on the dynamics and criticality of the specific shortage.

Widening professional competences of pharmacists and national production

An opportunity was also identified for more efficient management of medicinal product shortages by widening professional competences of community pharmacists during shortages. Community pharmacists can mitigate the impact of shortage by dispensing therapeutic alternatives where appropriate, to avoid the scenario of patients being referred back to attending physicians.

Generic substitution (at the ATC5 level) should be allowed in all Member States. Therapeutic substitution at ATC4 is not allowed in any Member State, but it could be allowed for certain therapeutic groups in agreement with defined authorities, e.g. with the Chamber of Physicians and Pharmacists. Also switching to the same medicinal product with a different strength should be allowed. Only 6 Member States (27%) support the possibility of switching to the same medicinal product with a different administration route in cases where there are no safety concerns.

Almost all Member States agree that it could be useful and endorsed to have a shared electronic communication tool between pharmacists and prescribers (e.g. shared electronic health records) to enable effective and safe substation of the therapy during the shortage.

The majority of Member States agree that shortages could also be managed with magistral or galenic production of certain medicinal products, however mainly in hospital pharmacies.

Magistral and galenic production will be a topic of the new JA on Regulatory flexibility.

All proposals for widening the professional competences of pharmacists require changes in national legislation.

5 Recommendations

The following recommendations are based on the identified good practices above. Implementing them is advisable to improve and harmonise the response to medicine shortages at EU level. However, implementation is optional and at the discretion of the responsible national authority based on available resources.

5.1 Recommendation on regular monitoring of stock and demand data

To establish a regular exchange of stock levels and demand data that NCAs can use for early detection of a potential supply issue and to forecast demand to establish better preventive or mitigation measures, the following recommendations should be implemented:

- Stock levels and demand data should be submitted to NCAs on a regular basis (daily or weekly), using legislation to underpin this as a requirement.
- Regular data transmission can be required for all medicinal products or only selected (e.g. essential/critical medicinal products, supply relevant/critical medicinal product). In case of selected medicinal products, the relevant lists should be established.
- Data on stock levels should be requested from wholesalers (full-liners) and pharmacies (community and hospitals).
- For the evaluation of the national demand the following sources are recommended:
    - The most reliable demand data are volumes dispensed from community pharmacies and consumption data from hospitals.
    - Reliable are also sales data from wholesalers (all) to pharmacies (community and hospital) from e.g. IQVIA.
- To avoid overburdening NCA staff, it is also necessary to establish a system that analyses the data from various sources and flags potential shortages, as well as enables reliable forecasting.

When establishing regular data transfers, NCAs should consider the latest requirements of the ESMP for the submission of data by NCAs in case of monitoring shortages that can lead to a Public Health Emergency/Major Event (Preparedness) or in case of monitoring and management of critical medicinal products during a Public Health Emergency/Major Event (Crisis). This will ensure harmonisation of the data structures.

5.2 Recommendations on reporting medicine shortages

- MAHs should have the obligation to report shortages for all medicinal products, irrespective of the prescription status, clinical importance and shortage duration.
- MAHs should notify shortages as soon as they become aware of it. NCAs should foster early MAH reporting through regular open communication with MAHs and other stakeholders to discuss any relevant issues in the supply chain and their possible impact on product availability.
- MAHs should be explicitly advised that shortage notifications should contain as much information as possible. However, they should be made aware that the initial notification of a potential shortage may contain only minimum details in the event that information is limited at first. Additional information should be provided as a follow-up.
- The option to notify NCAs of an unavailability of a medicinal product should be available to anyone, including wholesalers, healthcare professionals and patients.
    - The NCA notification platform may allow wholesalers and pharmacists to notify the MAH of suspected unavailability through the notification platform. MAHs could answer to the questions from wholesalers and pharmacists through the reporting platform. That way the NCA could monitor the communication and react if necessary, which also lessens the burden on the NCA in case of false signals.
    - The shortage notification templates/platforms for different stakeholders should be available on the NCA shortage webpage.
- MAH shortage notifications should be supported by their impact assessment.
    - MAHs should use the NCA impact assessment methodology.
    - The NCA impact assessment methodology should be publicly available. The methodology should be part of the shortage notification instructions for MAHs.
    - The NCA impact assessment methodology should be harmonised as much as possible across the EU.
    - The TF AAM has also developed an implementing guide for MAHs to facilitate a harmonised implementation of the SPP and SMP, which also include impact assessment methodology.
- In case of medium and high impact shortages, proposal for mitigation measures with proportionate response to reduce the impact on patients should be part of the notification.

- NCAs should consider applying the SMP template[32] that has been already published by TF AAM when developing a national template.
- The template for proposal for mitigation measures should be part of the shortage notification instructions provided to MAHs.

5.3 Recommendations on publishing of shortages

- After the NCA assessment is complete all shortages confirmed by the MAH should be made publicly available.
  - To protect MAH confidential information not all shortage information is to be published. Fields for completion with information that will not be published should be clearly marked in the notification template/platform.
  - A unified list of root cause categories should be implemented on EU level.
- Shortage catalogues should be easy to use, searchable and provide quick overview of ongoing, as well as resolved and potential shortages.
  - As described in the HMA/EMA Communication guidance[33] this includes the use of colour-coding and symbols, as well as options to sort, filter, and export data.
  - The shortage catalogue should be updated as new information becomes available.
  - Each shortage entry in the catalogue should include links to parts of the NCA website with relevant information and news regarding the shortage. This applies especially to recommendations by NCA, list of therapeutic alternatives and other important information for HCP and patients.
  - If there are various categories of therapeutic alternatives available for the product in shortage (e.g. alternative packaging, alternative with the same active substance) they should be clearly identified.
- Shortage catalogues should be linked to external electronic systems in the way that it notifies prescribers and pharmacists when they try to prescribe or dispense a medicinal product in shortage.
  - Additionally, the catalogue may include an option to sign up for e-mail alerts for a specific medicinal product or group of medicinal products. A notification is sent if the availability of the selected medicinal product(s) changes or there is new information about the shortage.

[32] EMA/HMA TF AAM. Shortage Mitigation Plan (SMP). June 2024
[33] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019 (in revision).

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

5.4 Recommendations on managing shortages

5.4.1 Dialogue with stakeholders

A dialogue with stakeholders is the most important measure and the following recommendations should be implemented:

- Establishment of a multi-stakeholder advisory council, which is also formally enshrined in the legislation, to establish a framework for all national stakeholders to effectively address potential or actual medicinal product shortages at the national level, to develop prevention strategies and propose changes to national legislation.
- Setting up a (multi-stakeholder) taskforce on a case-by-case basis to support the assessment of the relevance of supply shortage, considering possible therapeutic alternatives, as well as developing recommendations for improving the supply situation and external communications.
- Proactive engagement with the stakeholders on mitigating shortages with medium and high impact.
- When notifying MAHs of alternative medicinal products about supply gaps so that they can anticipate increased orders, the NCA could request information on available stocks, supply plan and production capacity. This information is then used as part of the consultation with MAHs about the possibilities of increasing production.
- To improve transparency in finding alternatives, the following two actions are recommended:
    - To prevent the NCA from spending time assessing what information about the shortage gap may be shared with MAHs of therapeutic alternatives, the shortage notifier may authorise the disclosure of submitted information on current demand (e.g. monthly sales volume) to relevant third parties identified by the NCA. This can be done by including the statement within the notification such as: *"In the event of a limited number of alternatives, I authorise the NCA to share this information with other companies offering comparable alternatives to determine whether they can meet any increase in demand."*
    - NCAs should make public on their website or via e-mail the need for more suppliers or alternatives in their markets if a potential or actual shortage due to withdrawal, marketing cessation or vulnerability in supply is identified. The notice applies to products that are critical to the market with respect to public health.

MAHs or distributors who may be able to market or import the listed products are encouraged to contact the respective agency.

- Coordination of stakeholders in issuing treatment recommendations and informing patients and the public during the shortages with medium and high impact should be improved, as it is currently triggered mainly in case of critical shortages.

5.4.2 Regulatory measures and financial incentives

- Financial incentives should be implemented for MA applications that address availability issues. As a minimum this measure should be applied to medicinal products that are included in the list of essential medicinal products, strategic or critical medicinal products.

- It is recommended that stakeholders are informed that financial incentives and any simplified regulatory procedures are available in exceptional situations of shortages. These procedures may apply on a case-by-case basis. Some examples include:
    - reduced or waived application fee,
    - shortened application procedure,
    - reduced or waived fees for future renewals and variations,
    - reduced or waived supplier tax,
    - reduced documentation requirements,
    - exemptions from requirements on labelling and serialisation,
    - for products intended for hospital use, exemption from the requirement to have a national package leaflet,
    - it is possible to set a higher maximum price for prescription-only medicinal products.

- The difference in the price of the alternative medicinal product compared to the reimbursed referenced medicinal product in shortage should be covered by insurance fund or hospital and should not be imposed on the patient.

5.4.3 Communication of additional information about shortages to stakeholders and media/general public

- Recommendations for the publication of news on supply issues published on NCA websites and their content regarding advice to various stakeholders:

    - There should be link from the published information about the shortage of a particular medicinal product in the shortage catalogue to additional information about this supply issue published on the website.

    - Additional information should consist of the following chapters: advice on therapeutic alternatives, advice for prescribers, advice for pharmacists, advice for patients and also a chapter on reimbursement and price difference of therapeutic

alternatives. The latter explains who covers eventual price difference between the therapeutic alternative and the referenced medicinal product in shortage.

- It is also recommended to provide information on the measures implemented to mitigate the impact of the shortage (e.g. restriction of use of remaining medicine stocks, ban on export).
- If necessary, the advice for prescribers and pharmacists should also contain recommendations on controlled distribution, limiting the initiation to certain indications or populations, changing doses, etc., so that remaining or constrained supply of the medicine will last as long as possible.
- Advice for pharmacies should include, for example, a link to package leaflet in national language that can be printed for the patient when a foreign package is dispensed, or a link to advice on crushing/splitting or otherwise manipulating tablets for children in the absence of oral solution.

- As also the HMA/EMA Communication Guidance[34] highlights, for shortages with medium and high impact that may involve a range of stakeholders collaborating on mitigating the impact, additional communication channels to HCPs and patient organisations should be used to improve dissemination of information.
- The proactive communication of NCAs with the media should be improved, especially in the case of critical shortages of medicines that have a significant impact on clinical practice. Regulators' proactive cooperation with the media also needs to be improved, as also emphasised in the HMA/EMA Communication Guidance.

5.4.4 Widening professional competences of pharmacists and national production

- Management of medicine shortages can be more efficient by widening professional competences of community pharmacists that can then be applied during the shortages. Currently identified opportunities are:
  - Generic substitution (at the ATC5 level) should be allowed in all Member States.
  - Therapeutic substitution at ATC4 is not allowed in any Member State, but it could be allowed for certain therapeutic groups, in agreement with the relevant authorities, e.g. with the Chamber of Physicians and Pharmacists.
  - Switching to the same medicinal products with a different strength should be allowed. In this case, the total amount of active ingredient dispensed must not be greater than that prescribed.

[34] HMA/EMA. Good practice guidance for communication to the public on medicines' availability issues. July 2019. (under revision)

- Switching to the same medicinal product with the different route of administration in cases where there is no safety concerns could be allowed, in agreement with the relevant authorities, e.g. with the Chamber of Physicians and Pharmacists.
- Shortages could also be managed with magistral or galenic production of certain medicinal products.
- All proposals for widening the professional competences of pharmacists require changes in national legislation.

6 Next steps

The next step is to organise a multi-stakeholder online workshop in November 2024. We look forward to feedback on our recommendations particularly from the community pharmacists, general practitioners, patients and the industry.

The next WP 6 task after the workshop is T6.3 Development of comprehensive monitoring, reporting, and managing protocol and will combine work of WP 8 on impact assessment of shortage notifications and all the available measures at national level into one comprehensive protocol. This protocol should be followed if a notification could result in a shortage. A few Member States have indicated that they have a roadmap or decision tree in place to address medicinal product shortages and have also submitted their national documents on this topic.[35] These documents will be used for the execution of this task.

As the objective of this task was to collect the practices in monitoring, reporting and managing medicine shortages, we expect this report to support Member States in improving their current practices, as most of the recommended good practices do not require changes in national legislation.

[35] WP 6. D6.1 Report on the existing documents on shortages of medicines. June 2023.

7 Annex 1: Survey questionnaire

Part I: MONITORING	
Parameter	**Question**
Regular monitoring of demand data	Do you have in place regular monitoring of demand data?
	What is the source of demand data?
	How frequently you get the data?
	Do you have a data system that flags potential shortages weeks or months in advance? How much in advance?
	Do you monitor all medicinal products or only selected?
	Are demand data analysed by NCA regularly (daily, weekly, monthly)?
	Is providing data on volumes dispensed from pharmacies obligatory i.e. in the legislation?
	Responsible institution to report demand data
	Are the national prescription data published? How frequently?
Regular monitoring of stock data	Do you have in place regular monitoring of stock data?
	From whom you get the data?
	How frequently you get the data?
	Do you have a data system that flags potential shortages weeks or months in advance? How much in advance?
	Do you monitor all medicinal products or only selected?
	Are stock data analysed by NCA regularly (daily, weekly, monthly)?
	Is providing regular data on stock levels obligatory e.g. in the legislation?
	Who is obliged to report data on stock level?
	Are they obliged to report data on all (authorised) medicinal products or only on selected medicinal products (e.g. supply-critical)?
	Responsible institution to report
	Any other comments?
If you don't have in place regular monitoring of demand and stock data: Regulation (EU) 2022/123 Article 11 (1, 2)	Data on expected number of patients to treat: How and from whom you plan to obtain data?
	Data on volume of demand: How and from whom you plan to obtain data?
	Data on the levels of stock: How and from whom you plan to obtain data?
Do you plan to use data from EMVS?	
Any other comments?	
Examples of good practice	Do you have an example of good practice on monitoring that you would like to share within JA?

Part II: REPORTING	
Parameter	**Question**
Legal frame for reporting	Reporting obligation for shortages
	Reporting timelines
	Who is obliged to report?
	Are there any penalties not to report?
	Are the penalties enforced? How?
	Are there any incentives for reporting for early or timely reporting?
Reporting potential and existing shortages	Responsible institution to report
	Do you have in place National shortage catalogue/register?
	Link to the National shortage catalogue
	Is the content of catalogue easily searchable?
	How frequently it is updated? Do you have a real-time platform?
Reported data (legal and voluntary)	Who is actually reporting (legal/voluntary): *MAH, Representatives of MAH, Manufacturers, Wholesalers, Hospital pharmacies, Public pharmacies, Physicians, Patients*
	What to report: *Are reported all medicines, only Rx, only reimbursed Rx…*
Impact assessment - Assessing the potential impact of a shortage	Do you have in place impact assessment method?
	Should MAH provide impact assessment as part of the notification?
	Should MAH provide short-term plan for addressing the issue in case of medium or high impact shortage as part of the notification?
	What should include short-term plan for addressing the issue?
Published data	When do you publish notification in the shortage catalogue?
	Are all notifications published or only selected?
	Published data in the shortage catalogue: *Medicinal product, Reason for shortages, Timeframe, Alternative therapies*
	If Yes who determines alternative?
	Same medicinal product (ATC5), different brand
	Same medicinal product (ATC5), different strength
	Therapeutic alternative (ATC4)
	Which stakeholders have access to published data?
	Are all data accessible to all stakeholders?
	How long is information stored?
Any other comments?	
Examples of good practice	Do you have an example of good practice on reporting that you would like to share within JA?

Part III: MANAGING	
Parameter	**Question**
Stakeholder dialogue	Do you as NCA take an active role in co-ordination of response to a shortage across the stakeholders? Which stakeholder?
	Which are the measures that you proactively take:
	Co-ordination of stakeholders on import of the equivalent or alternative medicinal products (authorised/unauthorised)?
	Co-ordination of stakeholders (e.g. prescribers, advisory board, learned societies …) on issuing treatment recommendation during shortage of medicinal product?
	Who is issuing alternative treatment recommendations?
	Co-ordination of stakeholders on communication to public/patients?
	Any other measures?
Regulatory measures - simplified regulatory procedures	Do you have a system in place to permit the importation of equivalent or alternative locally unauthorised medicines from other Member States/third countries?
	Do you have a facilitation system in place to use multilingual labelling packages or exemptions to the labelling and package leaflet obligations in national language?
	Do you use/have a possibility of fast-track variation regulatory procedures, e.g. to permit MAHs to swiftly source starting materials, reagents, intermediates or active substances from alternative suppliers (changes of suppliers or manufacturing/control sites) as per guidance_regulatory_covid19_en.pdf (europa.eu) also for non-Covid medicines?
	Do you use/ have a possibility of a facilitated granting of national marketing authorisations of medicinal products that are authorised in another EU/EEA Member State, e.g. Day Zero MRP/RUP?
Financial measures	Which financial incentives do you have in place for imported medicinal products?
	Who covers the price difference of “alternative” medicine vs. referenced medicine in shortage?
	Which financial incentives do you have in place for regulatory procedures?
Notification to prescribers	Do you have in place push notification to prescribers?
	Do you inform prescribers through push notification also regarding alternative treatment?
	Any other way of informing prescribers?
Notification to pharmacies	Do you have in place push notification to pharmacies?
	Do you inform pharmacies through push notification also regarding alternative treatment?
	Any other way of informing pharmacies?
Notification to patients’ organisations	Do you have in place notification to patients’ organisations?
	Which channels do you use for such notification?
	Do you inform patients’ organisations regarding alternative treatment? How?
Information to the media	Do you provide information to the media proactively on shortages and shortage situation?
	How do you handle media inquiries?
	Have you experienced that media reporting has increased hoarding?
Widen professional competences of pharmacists	Is generic substitution at the ATC5 allowed?
	Who pays the price difference if referenced medicine is in shortage?
	Is therapeutic substitution at the ATC4 allowed?

Part III: MANAGING	
Parameter	**Question**
	Is changing to the same medicine with a different strength when still available, and adjusting therapy posology accordingly allowed?
	Pharmacists should be able to switch medicines with different administration routes of the same medicine. What is your opinion about this statement?
	Shared electronic communication tools between pharmacists and prescribers (e.g. shared electronic health records) can enable substitution effectively and safely. What is your opinion about this statement?
	Do you manage shortages with galenic manufacturing or preparation of magistral medicinal product? Any comments on this measure?
Notification to existing suppliers and/or market entrants	Do you notify existing suppliers and/or market entrants to increase production to fill the gap between supply and demand? Any comments on this measure?
National production	Do you have possibility of national production manufacturing sites?
Further measures	Kindly specify
Planned measures	Kindly report any measures that are currently discussed or planned to manage shortages?
Any other comments?	
Examples of good practice	Do you have an example of good practice on managing that you would like to share within JA?

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8 Annex 3: *WP 6 T6.2 Report on the CHESSMEN Multi-stakeholder Workshop*, 27 November 2024. December 2024.

CHESSMEN

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

CHESSMEN Multi-stakeholder Workshop, 27 November 2024 - Report

Work Package 6

JAZMP

Dissemination level: Public

Date: December 2024

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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]

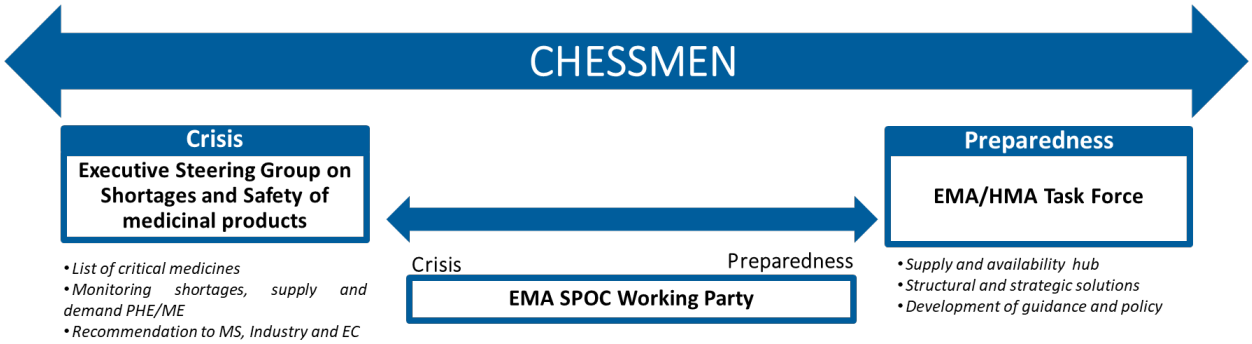
The challenge is complex and there is no single solution. A comprehensive set of measures is therefore appropriate and necessary at EU level which support national measures, in particular as most shortages are managed and resolved at national level. Member States have to manage their medium to high impact 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

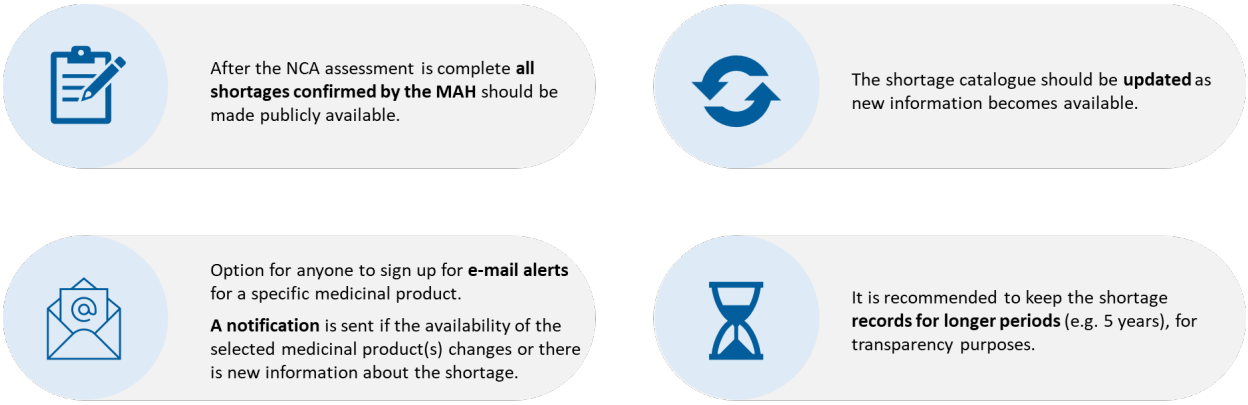
Chair: Melita Tovornik (JAZMP, CHESSMEN WP 6 Lead)

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.



NCAs 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

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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