



# Training Material on Protocol for Monitoring, Reporting and Managing Medicine Shortages

**Work Package 6**

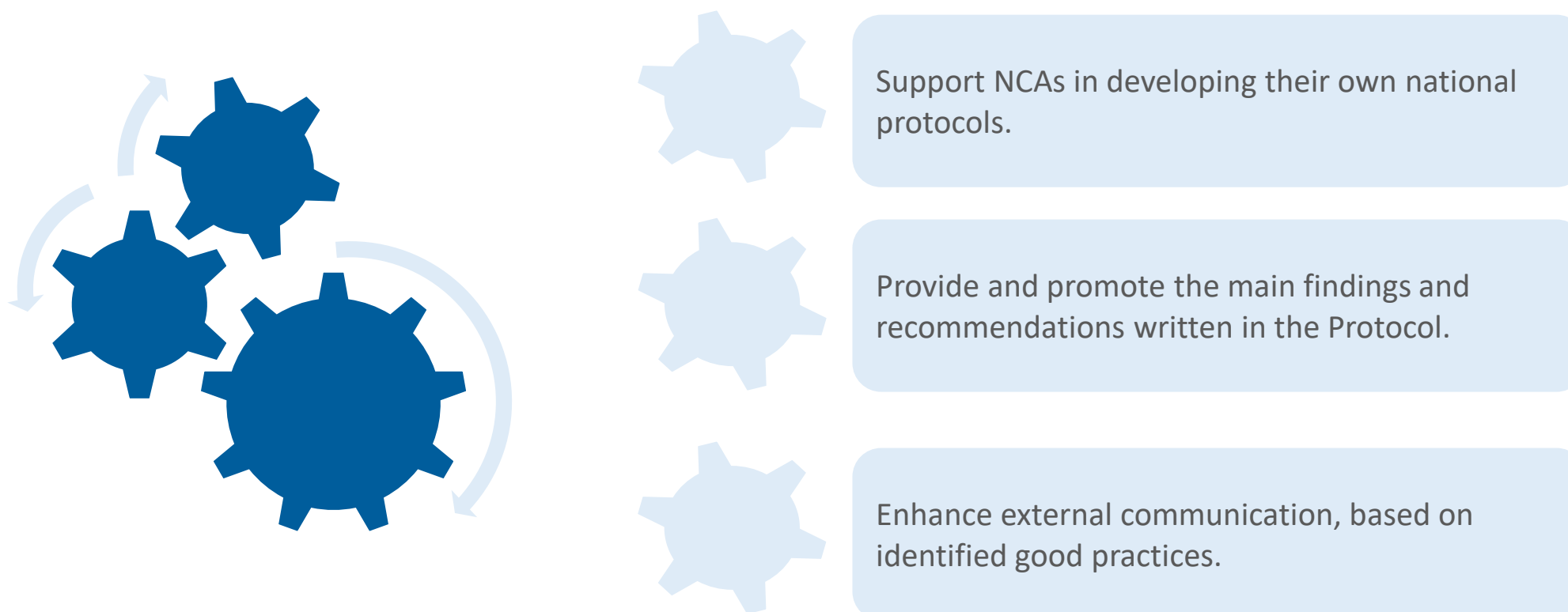
**Deliverable 6.5**

**Lead Beneficiary: JAZMP**

Dissemination level: Public

Date: May 2026

# The Aim of the Training Material



# Chapters

1

Notification of a Medicine Shortage

2

Data Quality Check

3

NCA Impact Assessment

4

Measures to Mitigate the Adverse  
Impact of Medicine Shortages

5

Shortage Management Decision Tree

6

Shortage Communication

7

Ongoing Monitoring

8

Conclusions



# 1. Notification of a Medicine Shortage

# Notification of a Medicine Shortage – MAH obligations

**The following recommendations apply for MAHs:**

- MAHs should notify shortages for all medicinal products with an expected duration of more than two weeks.
- MAHs should notify shortages as soon as they become aware of them.
- MAHs should be explicitly advised to include as much information as possible.\*
- The root cause of the shortage should be provided as mandatory information.
- MAH shortage notifications should be accompanied by an impact assessment.
- For medium- and high-impact shortages, a proposal for mitigation measures should also be included.
- MAH notification should also include information on other affected countries.

## 2. Data Quality Check

# Data Quality Check by NCA

The NCA should verify the quality of the shortage notification and promptly request any missing information

## MAH data required for impact assessment and shortage duration verification:

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

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

Root cause

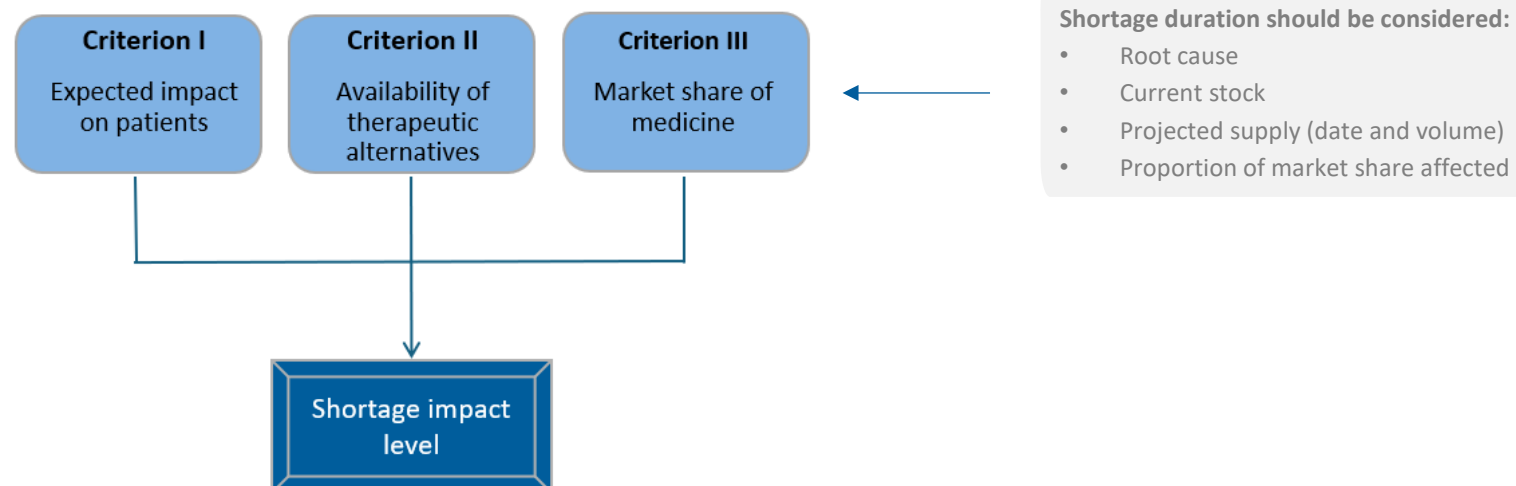
The NCA should also utilise additional data sources on sales, demand, and stocks to minimise reliance on MAH-provided information.

# 3. NCA Impact Assessment

# NCA Impact Assessment

Impact assessment is performed to determine the impact of a shortage on patients and, consequently, on the healthcare system.

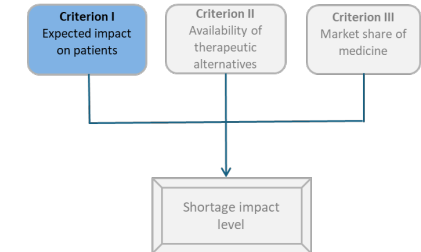
The impact assessment combines three main considerations:



# Criterion I - Impact on Patients

The impact on patients is determined by taking into account:

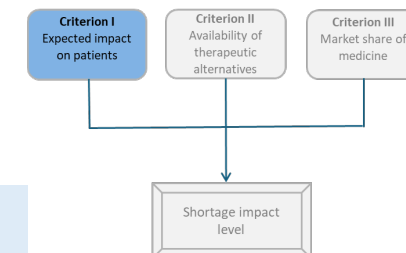
- The therapeutic indication
- The specific needs of the patient population
- The consequences of the shortage on the risk of disease progression if left untreated



## Criterion I: Impact on Patients

| Categories      | Examples                                                                              |
|-----------------|---------------------------------------------------------------------------------------|
| <b>Severe</b>   | Oncology patients, mid-cycle of a regimen                                             |
| <b>Moderate</b> | Vulnerable patient populations where some pharmaceutical forms may not be appropriate |
| <b>Mild</b>     | Simple dermatological conditions                                                      |

# Criterion I - Impact on Patients - Detailed Description



## 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**.

## Moderate Impact:

Indications with **serious implications** for the health of **individual patient or public health**.  
E.g. medicines for chronic, severely limiting diseases; for treatment of vulnerable patient groups.

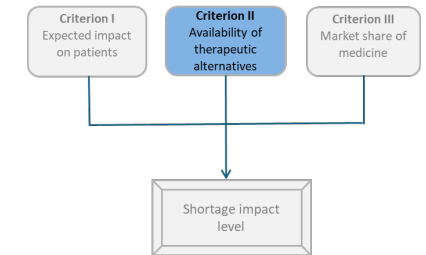
## Mild Impact:

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

Where a medicinal product has multiple therapeutic indications, the indication with the most serious implications for patients should determine the impact level.

More detail description can be found in the D6.2 Protocol or in the methodology for establishing the Union List of Critical Medicines.

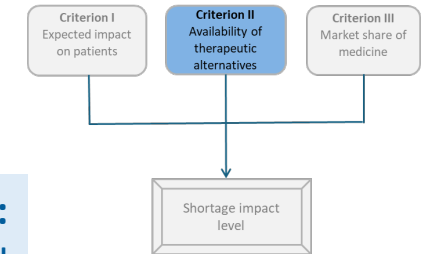
# Criterion II - Therapeutic Alternatives



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

- An alternative is appropriate if it meets 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.

# Criterion II - Therapeutic Alternatives – Detailed Description

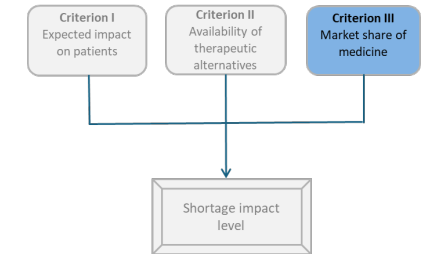


- a. **Therapeutic alternative is clinically possible and requires little or no input from medical personnel (*Exact*):** The therapeutic alternative has the same active substance, the same strength in the same pharmaceutical form (e.g. generic substitution).
- b. **Therapeutic alternative is clinically possible but requires little input from medical personnel (*Similar*):** Therapeutic alternative has 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.
- c. **Therapeutic alternative is clinically possible but requires input from medical personnel (*Accetable*):** Therapeutic alternative has a different active substance from the same pharmacological group (ATC 4 level).
- d. **Therapeutic alternative would require extensive clinical consultations (*Possible*):** Therapeutic alternative has a different active substance from a comparable pharmacological group (ATC 3 level).
- e. **Therapeutic alternative is not clinically possible (*None*):** No appropriate therapeutic alternative option is available.

More detail description can be found in the D6.2 Protocol or in the methodology for establishing the Union List of Critical Medicines.

# Criterion III - Market Share

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).

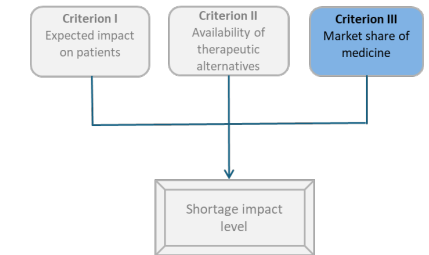


## Criterion III: Market Share

| Category | Description                                                                |
|----------|----------------------------------------------------------------------------|
| >50%     | Market share calculated from MAT volumes or volumes over a relevant period |
| 25%–50%  |                                                                            |
| <25%     |                                                                            |

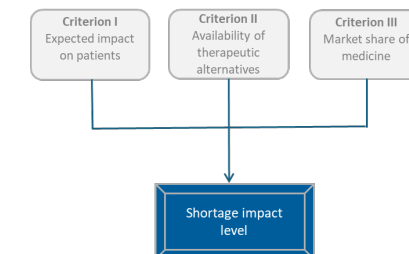
# Criterion III - Market Share – Detailed Description

- If the therapeutic alternatives have low market shares, their supply capacity may be inadequate to meet demand during the shortage. 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.
- 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).
- 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.
- 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.



# Impact Matrix

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



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.

# Impact Matrix - Detailed Description

## 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

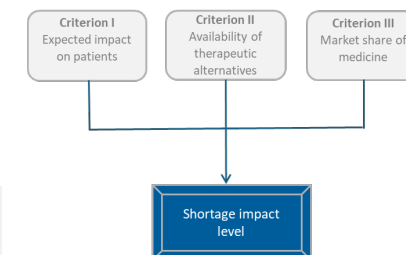
The required response to a medium impact shortage is based on the assumption that healthcare professionals can manage the situation if they have timely access to information about the supply of the medicine in shortage and the supply of therapeutic alternatives, and, in some cases, advice on alternative 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 Shortages

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.

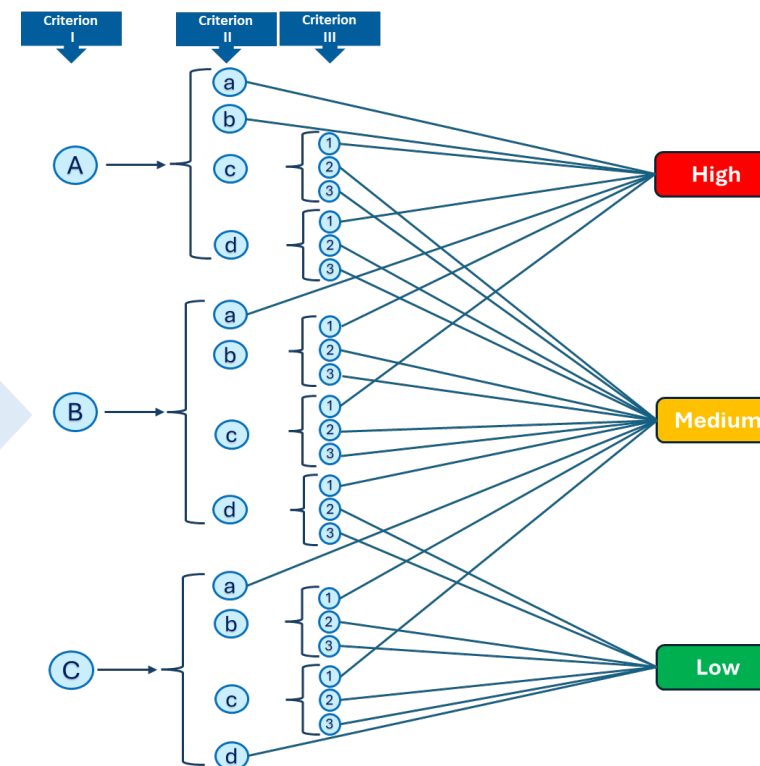
*Example: A batch failure of a heparin-based medicines. This switch to a therapeutic alternative is complex and post-surgical patients could potentially experience life-threatening consequences if this medicine was not available.*



# Shortage Impact Level Considering the Market Share

Three criteria, *impact on patients*, *therapeutic alternative* and *market share* are simultaneously used for assessing shortage impact level.

If the market share of the medicine is incorporated into the matrix the impact levels may change.

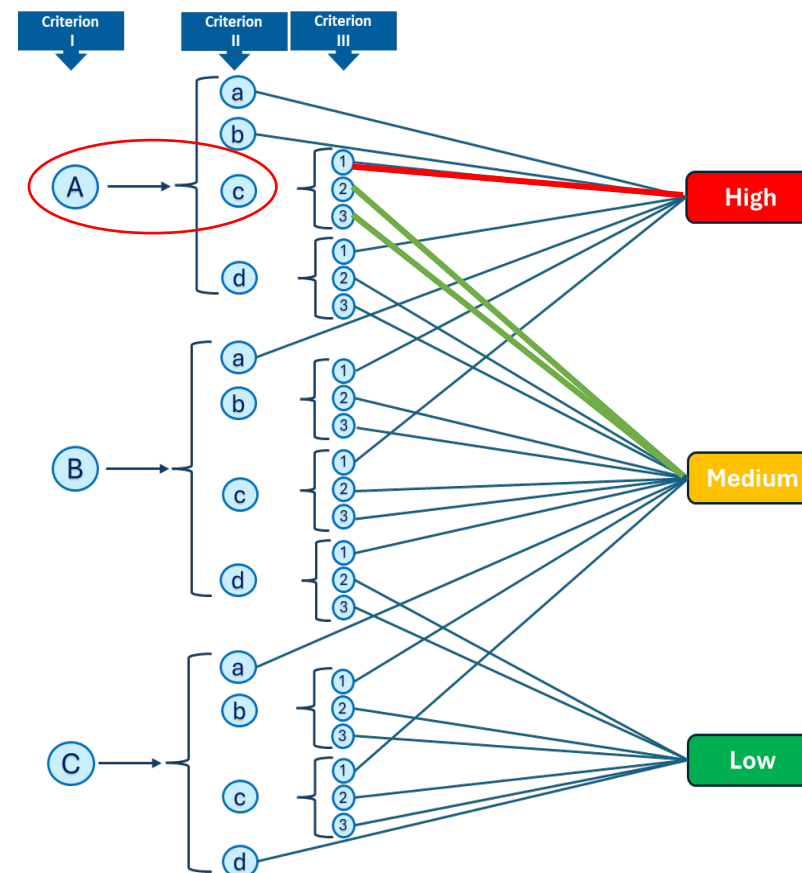


| Criterion I: Impact on patients |          | Criterion II: Therapeutic alternative* | Criterion III: Market Share |
|---------------------------------|----------|----------------------------------------|-----------------------------|
| A                               | Severe   | a Possible                             | 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.

# Shortage Impact Level Considering the Market Share (cont.)

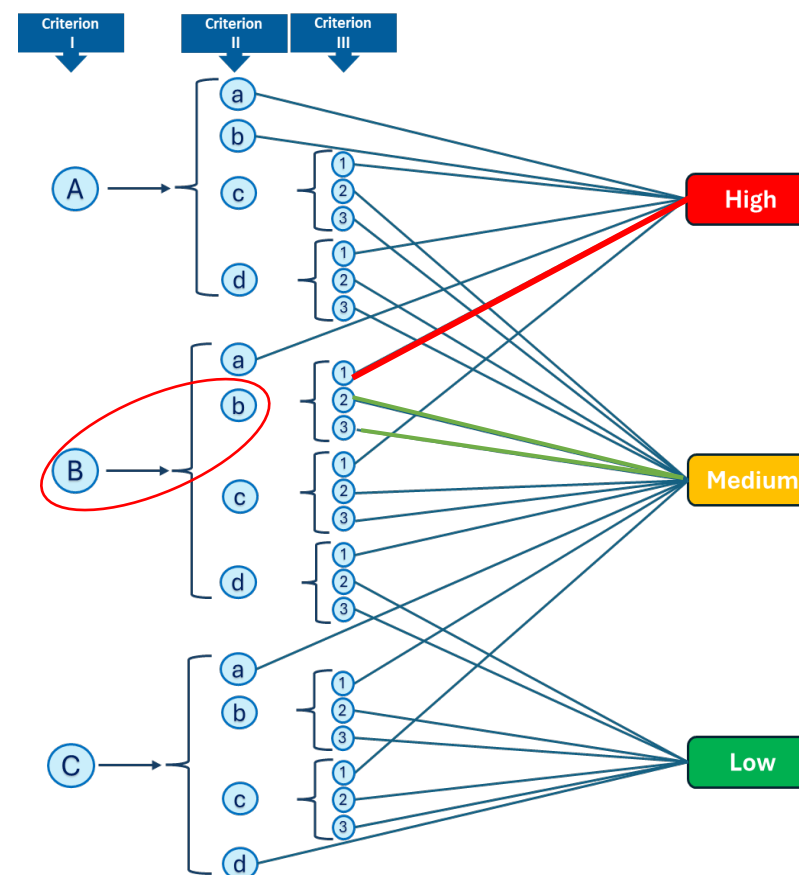
A market share of a medicine in shortage about 50% results in an immediate escalation of the impact to a higher level, whereas a market share between 25% and 50% does not automatically trigger such escalation but does require close monitoring.



| 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                                |                             |

# Shortage Impact Level Considering the Market Share (cont.)

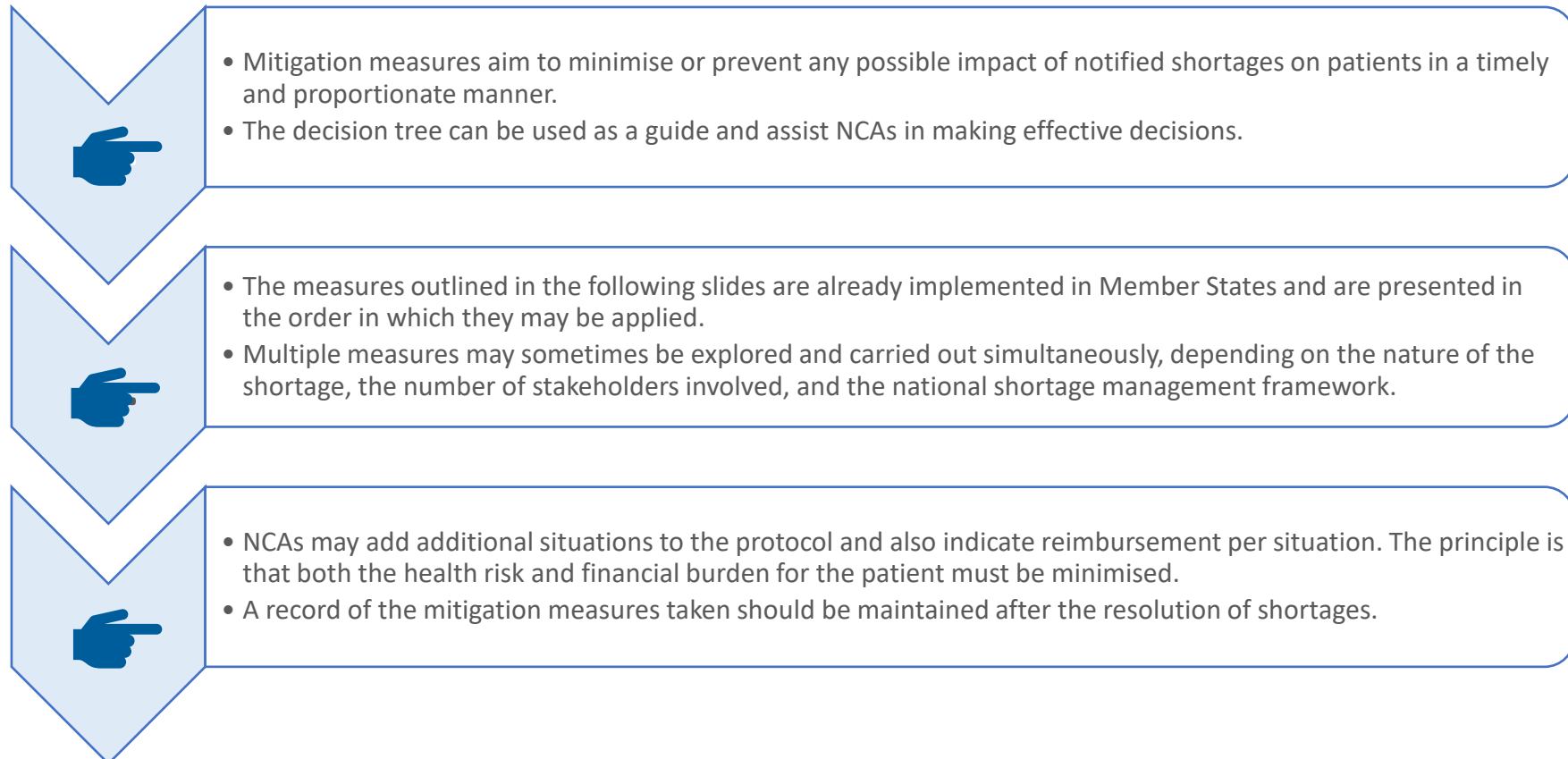
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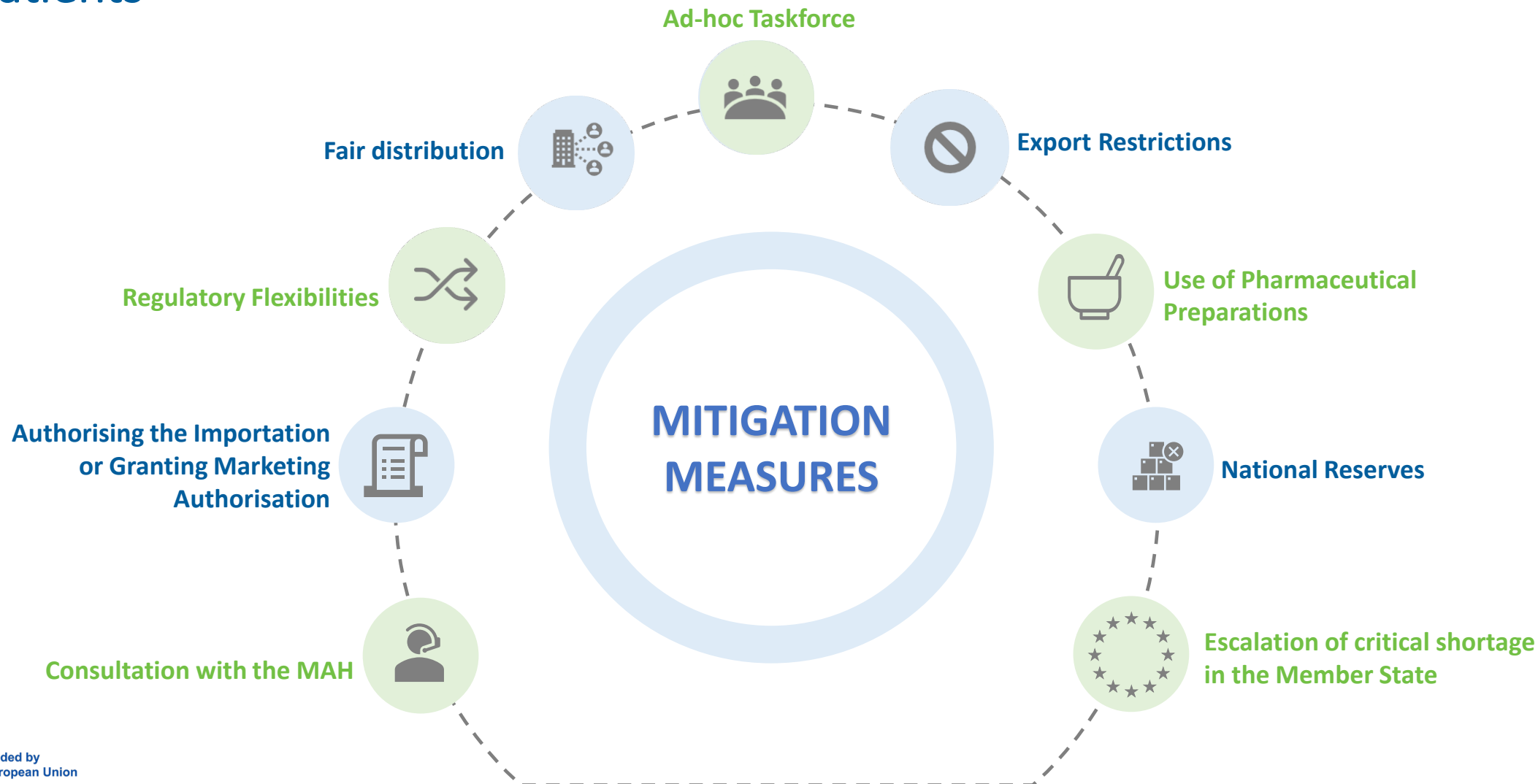
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| C                               | Mild     | c Similar                              | 3 <25%                      |
|                                 |          | d Exact                                |                             |

## 4. Measures to Mitigate the Adverse Impact of Medicine Shortages

# Measures to Mitigate the Adverse Impact of Medicine Shortages on Patients - Introduction



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



# Consultation with the MAH of the Medicine in Shortage



## Mitigation measures proposed by MAH

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.



## MAH can apply for exemptions

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.



## Additional regulatory flexibilities

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.

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



## **Import authorisation**

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.



## **Appeal**

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.



## **Possible simplifications and incentives**

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.

# Regulatory Flexibilities



## **Manufacturing 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.



## **Labelling and packaging exemptions**

Full or partial exemption from certain labelling and packaging requirements for authorised products (local language exemptions, reduced information on the packaging, alternative ways of providing certain labelling information etc). Exemptions from labelling requirements on a case-by-case basis (dispensing setting (hospital/community), relevant label information and original language).



## **Import of non-authorised products**

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.



## **Shelf-life extension**

Shelf-life extension for individual batches already released.

Additionally, the MSSG Toolkit outlines further measures that may be applied to address any medicine shortages.

# Fair Distribution of Medicines



## 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 (restricting the number of units dispensed or limiting dispensing to specific indications or patient groups) as well as restricting distribution within the supply chain, by focusing on a single distribution channel (retail or hospital).



## 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.

# Ad-hoc Taskforce



## Members

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.

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.



## Contribution

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.

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

# 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.

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

# National Reserves



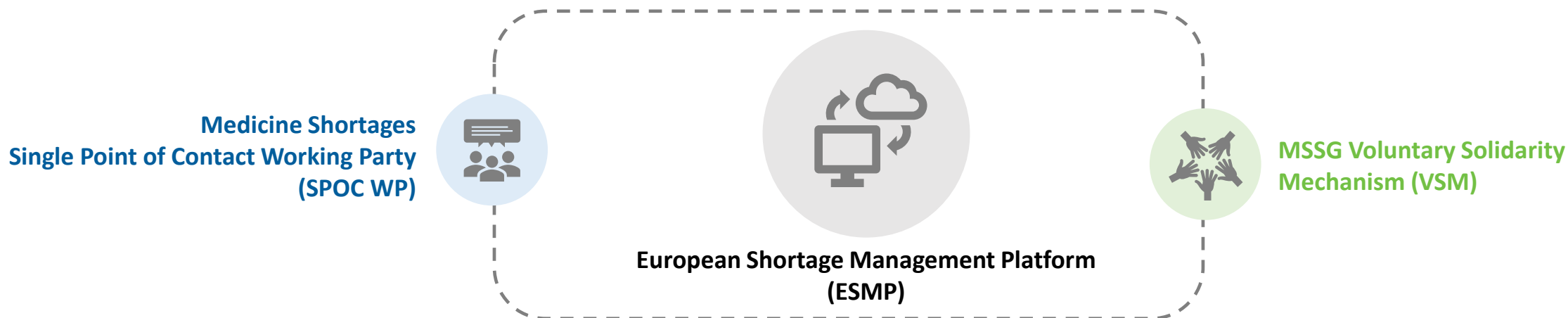
The established national stockpile reserves enable the country to meet the basic supply needs of its population and maintain an adequate supply level during emergencies.

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.



# Escalation process of critical shortages in the Member State to EMA/MSSG



# Medicine Shortages SPOC Working Party



- ❖ **Representatives of the NCAs** for medicinal products, who are the [single points of contact](#) in relation to **human and veterinary** medicine shortages in the EU
- ❖ Main tasks under normal circumstances:
  - Report to EMA any **critical shortage in a Member State** and any actions foreseen or taken to mitigate the shortage at national level without undue delay
  - **Monitor** any event that is likely to lead to a major event or a public health emergency that could affect the supply of medicines
  - Provide **recommendations to the MSSG** on all matters related to the monitoring and management of medicines shortages and other medicine availability issues
  - Collaborate with EMA to establish and update a **list of critical shortages of Union concern**
  - Provide **advice** on medicine shortage-related issues to EMA and the European Commission
  - Cooperate on shortage-related issues with **international regulators**

# MSSG Voluntary Solidarity Mechanism (VSM)



VSM is a procedure which allows a Member State to **request assistance** from other Member States in obtaining stocks of a medicine during a critical shortage. The Member State may request MSSG for VSM activation only **once all other measures and possibilities** to mitigate a **critical shortage** have been **exhausted**.

**VSM may be activated by the MSSG when the following conditions are met:**

- EMA and SPOC WP were notified of the critical shortage
- There are no or insufficient therapeutic alternatives available in the Member State concerned
- There are insufficient quantities of the medicinal product available in the Member State concerned to treat critical indications
- Import of stocks from third countries or other short-term measures do not provide a solution in a timely manner or in sufficient quantities
- There is a risk of stockout in the Member State concerned within one month or less

After a VSM request EMA will send a communication to all NCAs to enquire after available stocks of the medicine in question. EMA coordinates communication between issuing and donating Member States, MSSG, MAHs and potential international partners.

If no Member State is able to support, the issuing Member State will explore further options and will lead the discussions at the MSSG. The MSSG secretariat will include the topic in the agenda of the next meeting to explore together additional measures.

This mechanism should be used as a **last resort**.

# European Shortage Management Platform (ESMP)



[ESMP](#) enables **information exchange** for prevention, identification, and management of shortages to ensure medicines are available for patients in the EU and EEA.

- Submission of **VSM requests**
- **NCA critical shortage reporting**
- **Reporting** requirement for NCAs and MAHs during MSSG-led preparedness and crisis (public health emergency or major event).
- Routine reporting requirement for MAHs of shortages for CAPs

## Shortages monitoring and risk analysis tool (SMART)

- Real-time monitoring and analysis of supply and demand data across the EU/EEA
- Country-specific monitoring dashboards with structured visualisation

**Interoperability** of the ESMP will facilitate seamless machine-to-machine communication between national and industry databases, supporting efficient sharing of supply chain data.



# 5. Shortage Management Decision Tree

# Shortage Management Decision Tree

The decision tree can be used as a guide and assist NCAs in making step-by-step decisions and actions. Such approach increases transparency and consistency of the shortage management process.

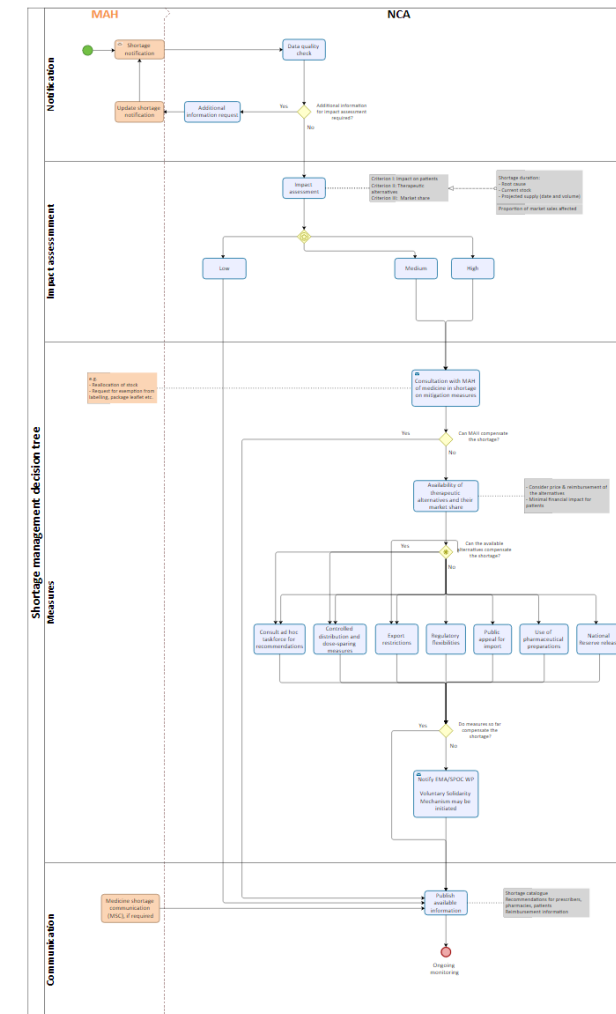
Key steps in the decision tree:

Notification

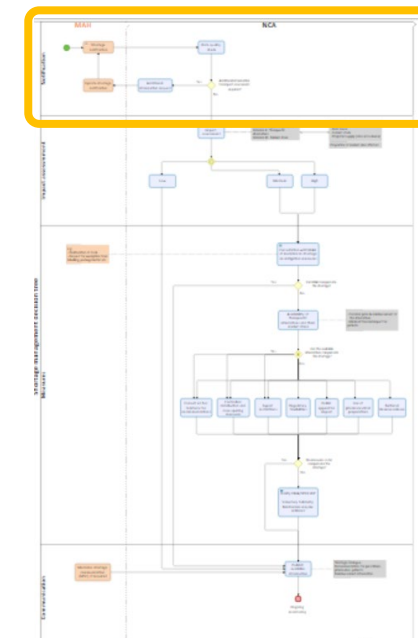
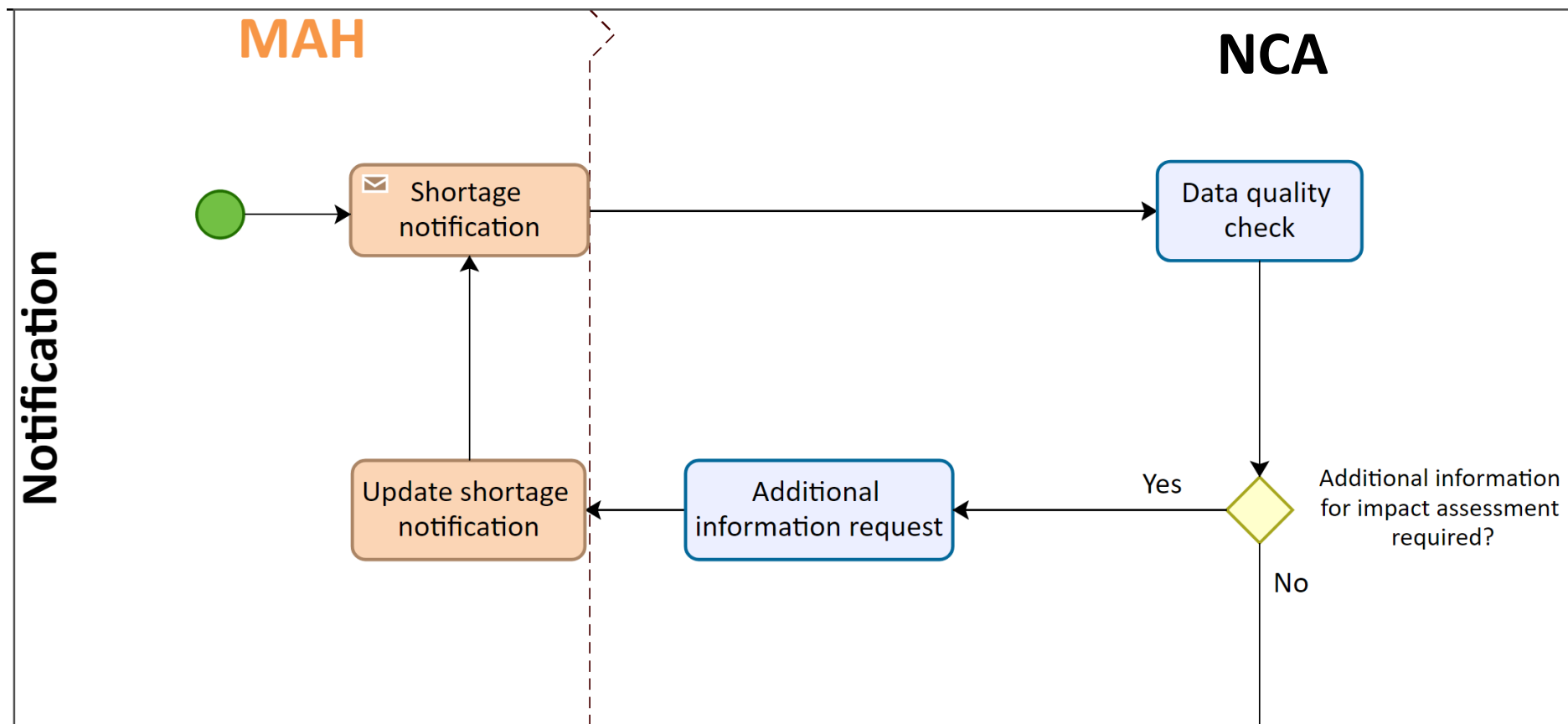
Impact assessment

Measures

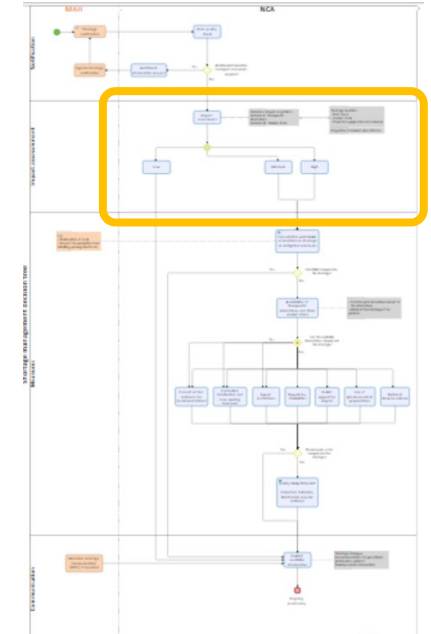
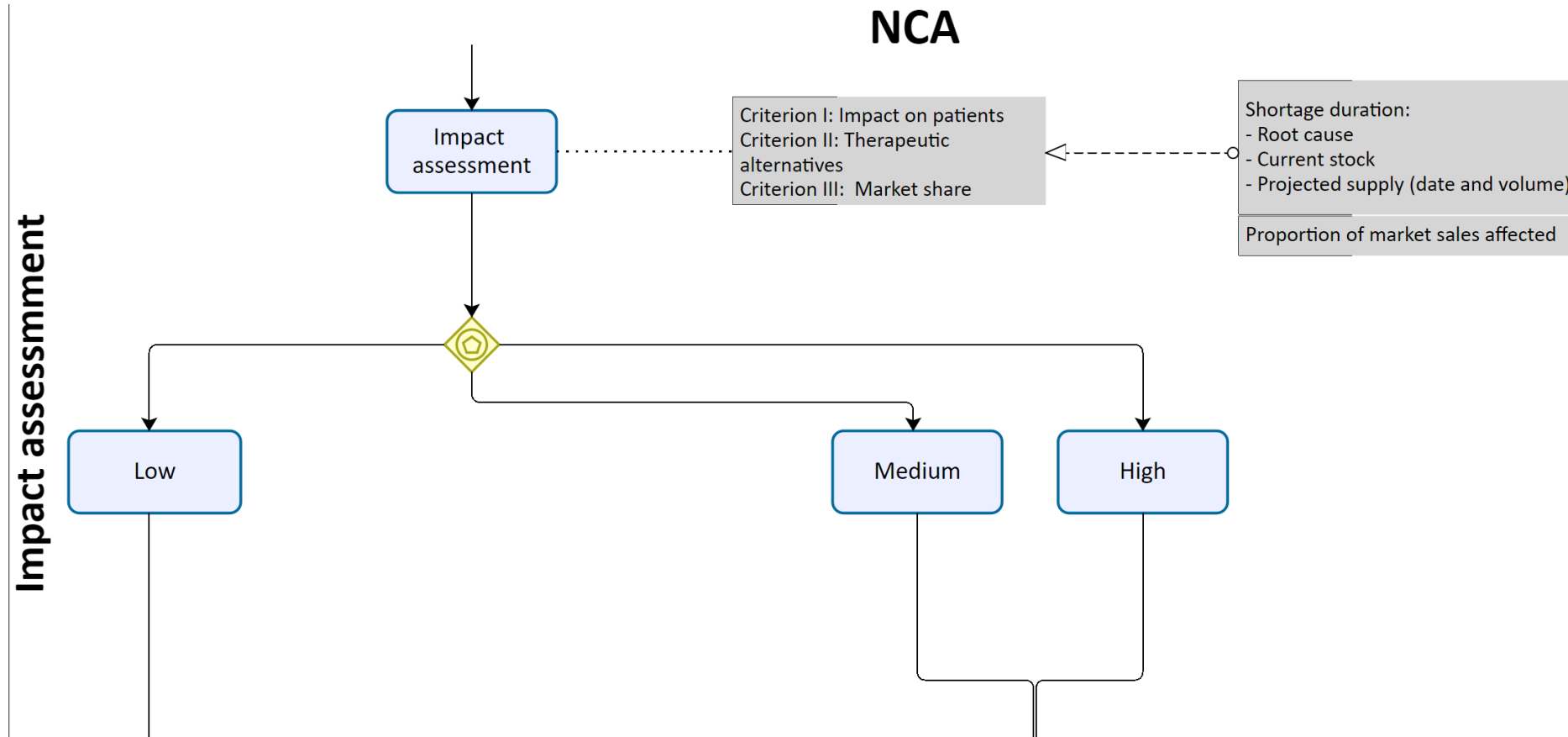
Communication

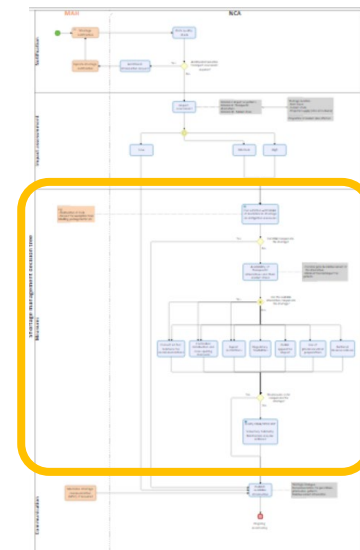


# Shortage Management Decision Tree



# Shortage Management Decision Tree



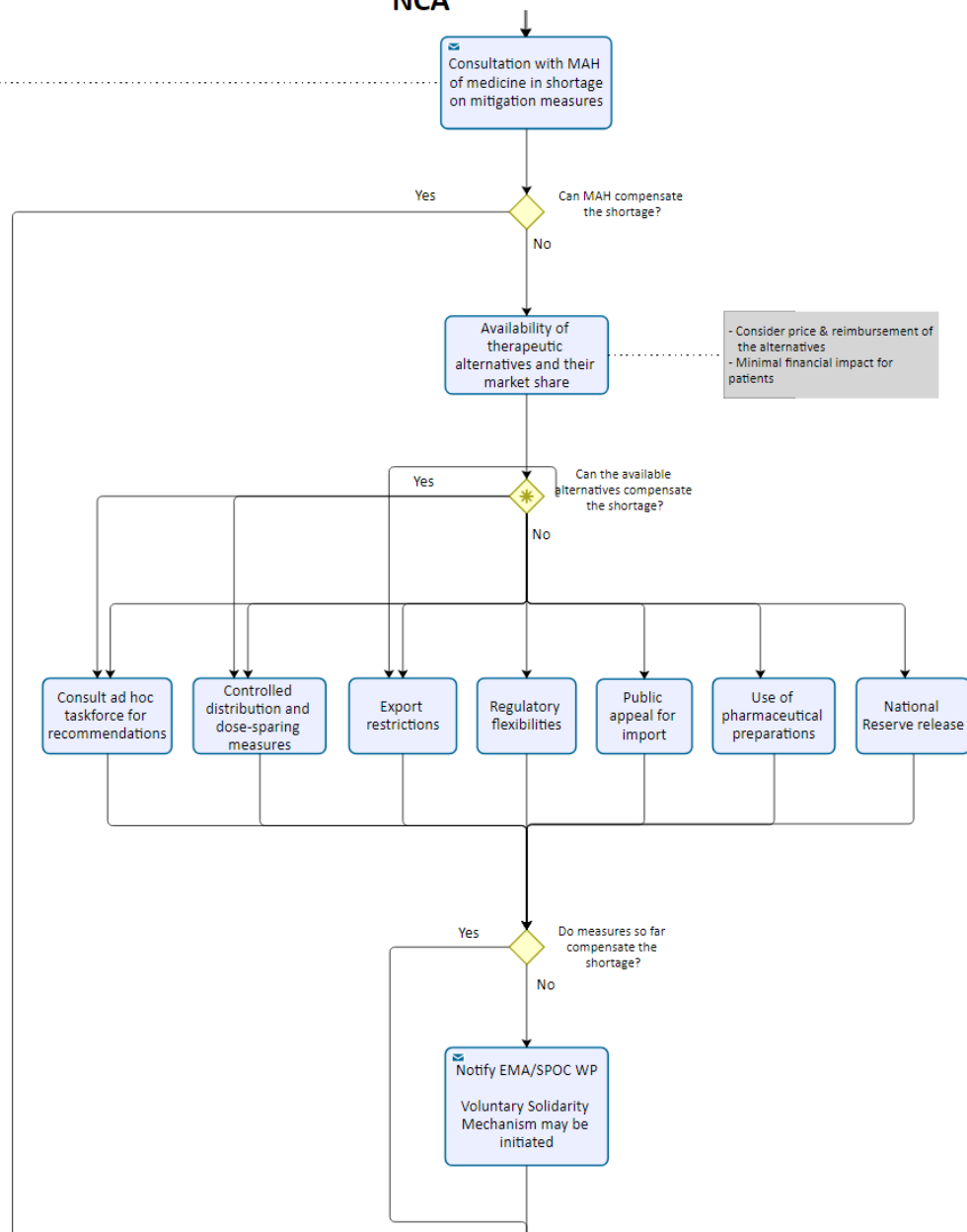


## MAH

e.g.  
- Reallocation of stock  
- Request for exemption from  
labelling, package leaflet etc.

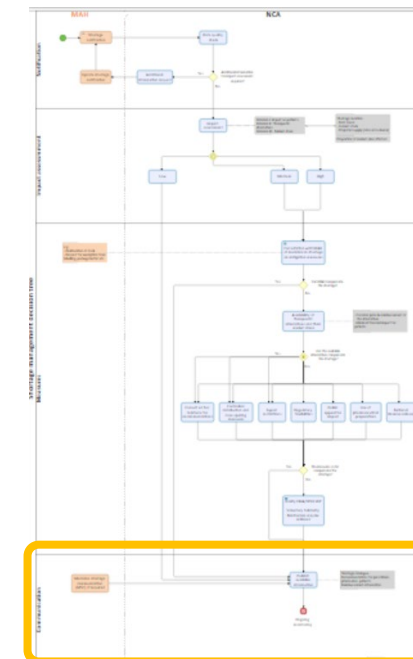
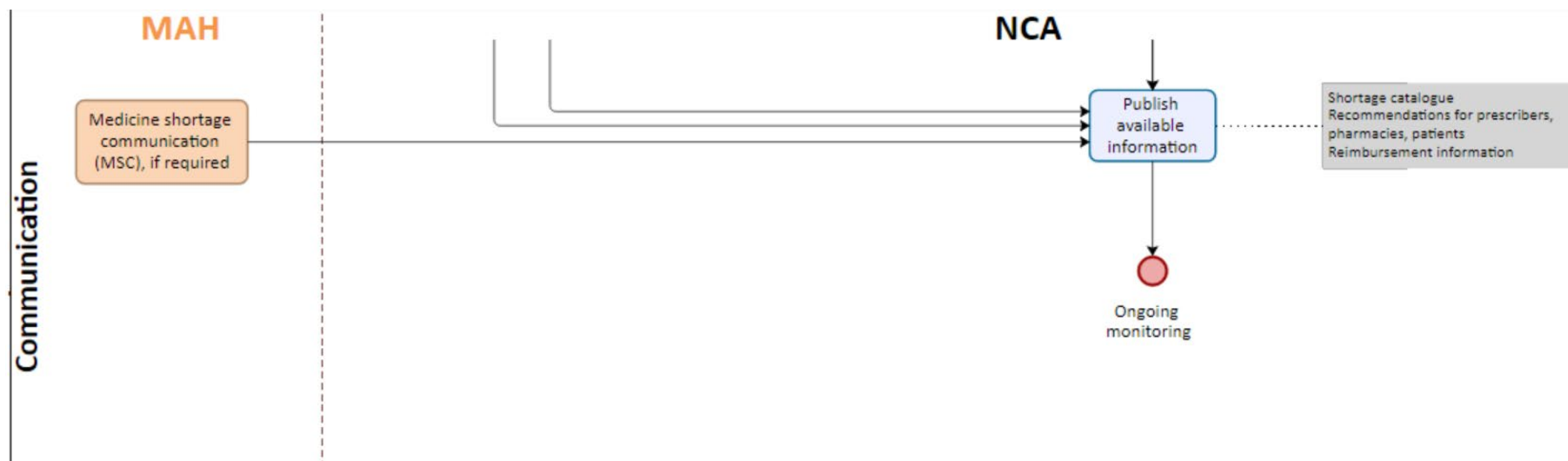
## NCA

## Measures



# Shortage Management Decision Tree

# Shortage Management Decision Tree



## 6. Shortage Communication

# Shortage Communication

After the NCA assessment is complete, all shortages confirmed by the MAH should be made publicly available in a shortage catalogue.

NCA website should provide information targeted at different audiences: advice on therapeutic alternatives, advice for prescribers, pharmacists, patients and price/reimbursement information.

Timely notification/information:

- To prescribers to prevent initiation of treatments in short supply.
- To community pharmacists to facilitate dispensing of therapeutic alternatives.
- On controlled distribution/dose-sparing measures to ensure continuity of care.

MAH may send medicine shortage communication (MSC), approved by NCA, to healthcare professionals. The MAH is asked to draft an MSC using EMA template. The NCA should also publish these communications on its website.

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

1

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.

2

Comprehensive information is essential to prevent stockpiling, promote the rational use of existing stocks, allow time to find safe, effective and affordable therapeutic alternatives.

3

4

Advice for pharmacies should include e.g.: a link to the package leaflet in national language for printing, or guidance on crushing/splitting or otherwise manipulating tablets for children when an oral solution is not available.

5

6

Additional channels of communication with healthcare professionals and patient organisations should be used to improve the dissemination of information for shortages with medium and high impact.

7

8

# Example of the Shortage Communication Through Additional Channels

## Advice for pharmacies

- From 1 July 2024, DMP has introduced rationing on Norwegian packages of Ozempic. [Read news about the rationing](#)
- Ozempic can only be dispensed for four weeks at a time.
- Consult a doctor if Ozempic cannot be obtained so that the patient can receive other treatment.

## Advice for doctors

- Patients who have received Ozempic on a white prescription will not be given Norwegian packages of Ozempic after 1 July.
- Consider whether patients can use another blood sugar-lowering drug.
- The pharmacy or patient will contact you if it is necessary to use another medicine.

## Advice for patients

- If your pharmacist is unable to offer you Ozempic, you or your pharmacist must contact your doctor to get a new prescription for another medicine.
- Follow the advice of your doctor and pharmacist.

## Reimbursement

From July 1, 2024, there will no longer be refunds on foreign packages of Ozempic.

[See more information about changes for reimbursement of Ozempic](#)



Use **additional channels** to inform healthcare professionals and patient organisations — especially for medium- and high-impact shortages.

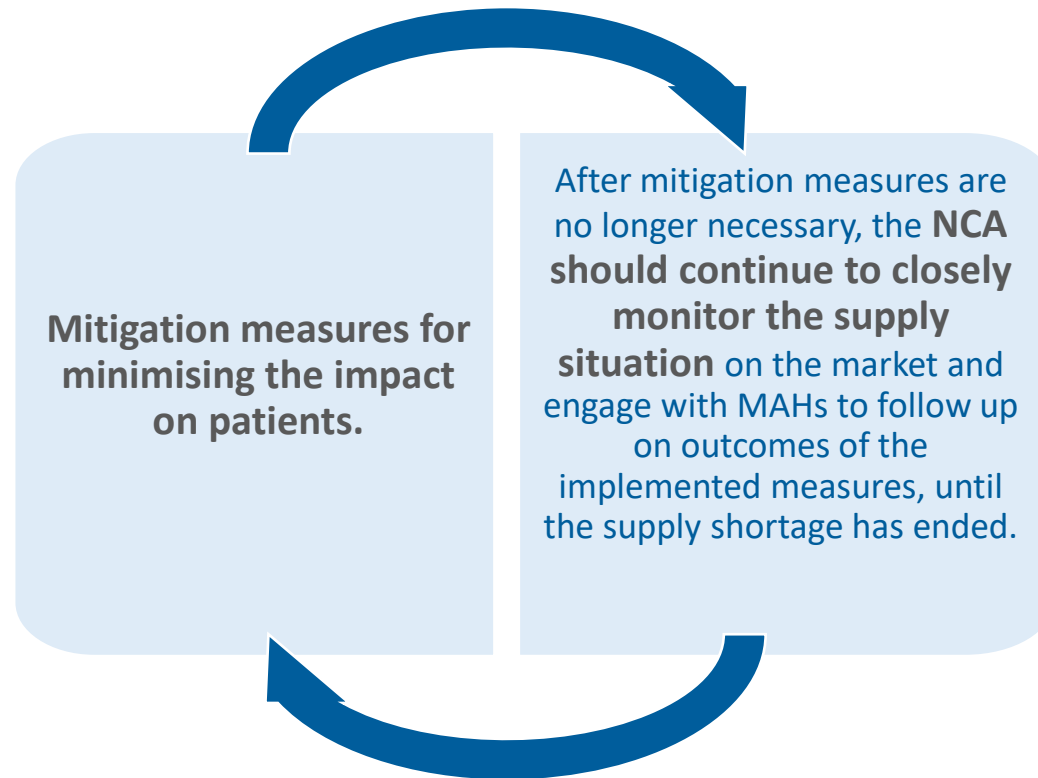


**Engage proactively** with the media in cases of significant clinical impact.



# 7. Ongoing Monitoring

## 7. Ongoing Monitoring of the Resolved Shortages



## 8. Conclusions

# Conclusions

The approach proposed in this document aims to improve the exchange of information between Member States and MAHs, and to strengthen:

- **Cooperation** between Member States to develop practical and rational responses to the challenges associated with medicine shortages.
- **Harmonisation** of assessment of the impact of medicine shortages on patients, as well as corresponding management strategies to effectively mitigate and manage shortages.
- **Standardisation** of national protocols, while still allowing each Member State to tailor their strategies to align with their national legislation, regulations and operational procedures.

More information can be found in the *D6.2 Report*.



# Training Material on Recommendations for Development of National Lists of Critical Medicines

**Work Package 6**

**Deliverable 6.5**

**Lead Beneficiary: JAZMP**

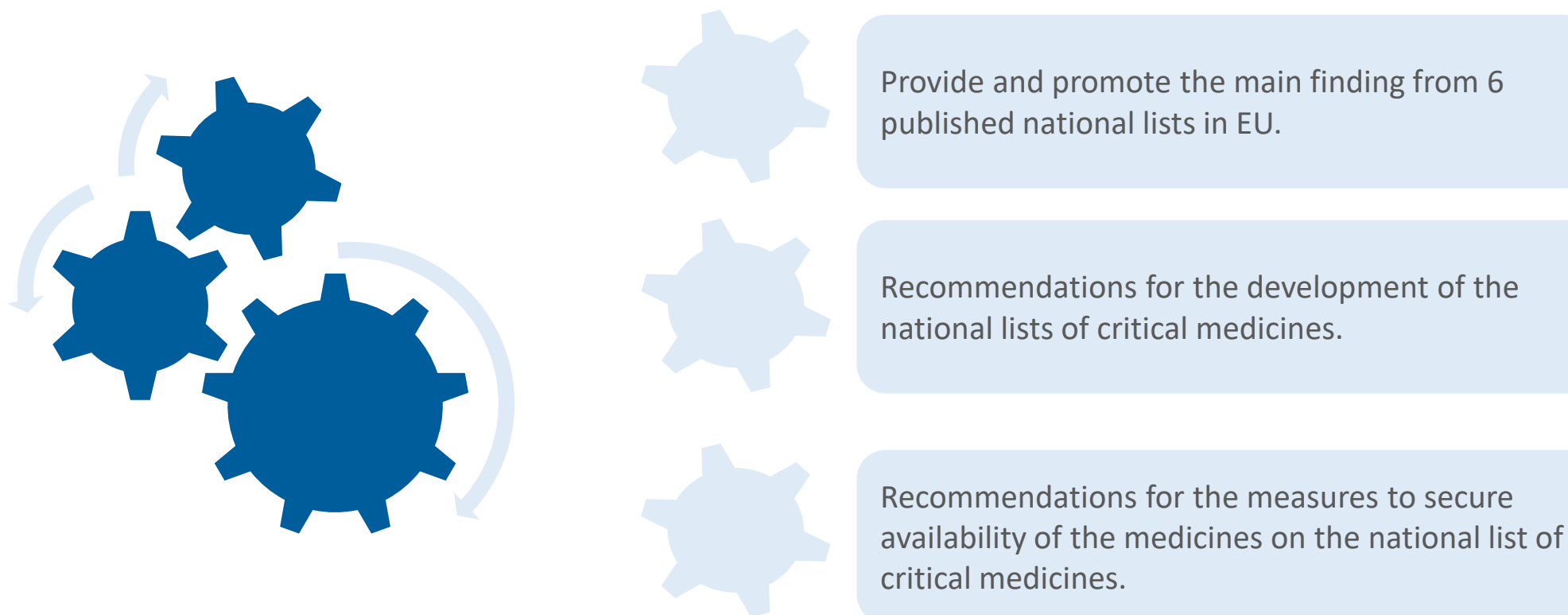
Dissemination level: Public

Date: May 2026

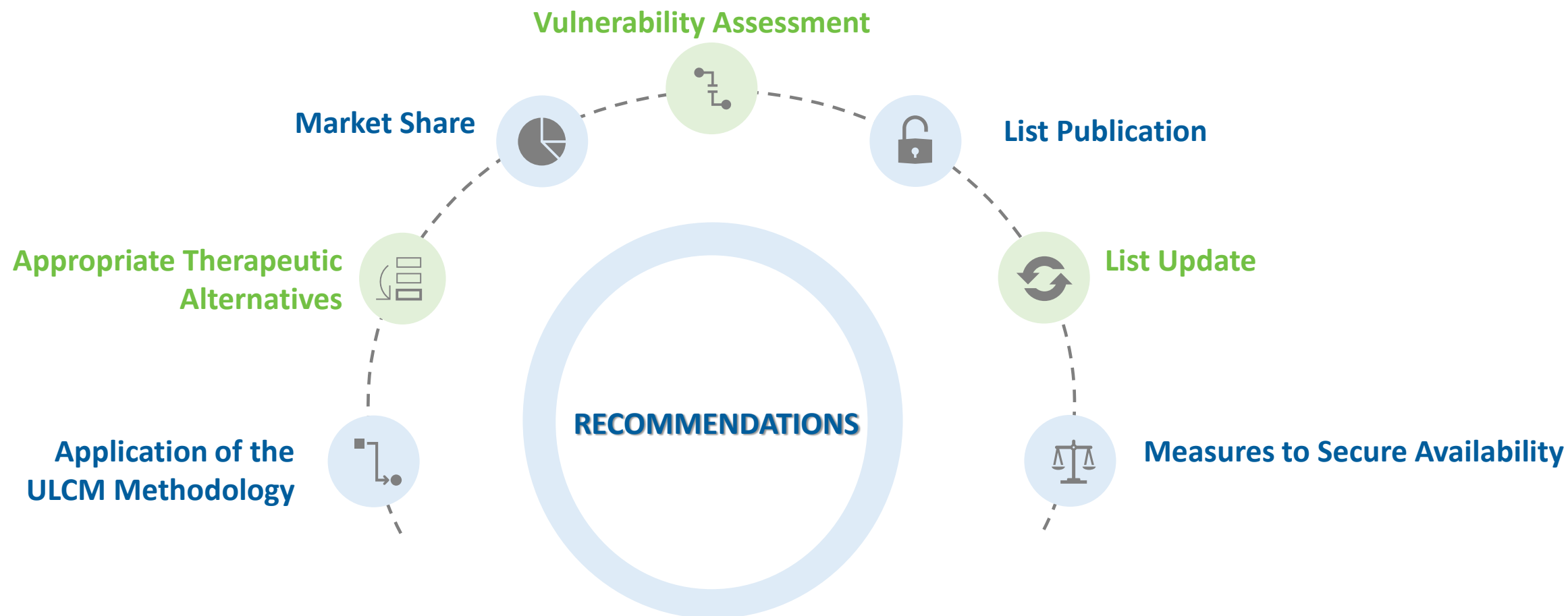


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# The Aim of the Training Material



# Development of National Lists of Critical Medicines



# Application of the Union List of Critical Medicines Methodology



- Member States should apply the ULCM methodology for identifying critical medicines with criteria:
  1. Therapeutic indication
  2. Availability of appropriate therapeutic alternatives
- Member States should leverage the national assessment of medicines for the ULCM as a basis for developing or refining their national lists.

*Methodology to identify critical medicines for the “Union List of Critical Medicines”* can be found on EMA website.

# Development of a New National List of Critical Medicines

## Suggested steps

1. Use the national assessment of medicines for the ULCM as a basis which took into account medicines listed on other published international and national lists of critical medicines.
2. Ensure that medicines authorised and marketed medicines in the Member State, as well as those made available on the national market through importation mechanisms are included in the assessment.
3. Compare the national assessment with the ULCM.
4. Review medicines on the list in collaboration with national learned societies, beginning with the ATC groups that are most critical to public health (Criterion 1).
5. Review therapeutic alternatives available for the medicines on the list (Criterion 2).
6. Assign the medicines to the applicable ULCM Risk Matrix categories.
7. Include market share of the medicine
8. Vulnerability assessment of Critical and At-risk medicines

|                                               |             | Criterion 1<br>(Therapeutic indication/ importance) |                   |                  |
|-----------------------------------------------|-------------|-----------------------------------------------------|-------------------|------------------|
|                                               |             | High risk                                           | Medium risk       | Low risk         |
| Criterion 2<br>(Availability of alternatives) | High risk   | Critical medicine                                   | Critical medicine | At-risk medicine |
|                                               | Medium risk | Critical medicine                                   | At-risk medicine  | Other medicines  |
|                                               | Low risk    | At-risk medicine                                    | Other medicines   | Other medicines  |

# Harmonisation of an Existing National List of Critical Medicines



## Suggested steps:

1. To ensure consistency among existing national lists Member States should apply the European Union's methodology for identifying critical medicines.
2. NCA compares its own methodology with that used for the ULCM, as well as the medicines on each list. The comparison could:
  - a) help identify medicines present on the ULCM but missing from the national list.
  - b) provide clearer insight into the criticality status of medicines, supporting communication with stakeholders who may question why a medicine is considered critical on one list but not the other.
3. All propositions described for the development of a new list of critical medicines also apply to the harmonisation of existing ones.

# Appropriate Therapeutic Alternatives



- A therapeutic alternative is **appropriate** if it meets all the following criteria:
  - a) The alternative medicine is authorised for the same therapeutic indication in the respective Member State
  - b) The alternative treatment is clinically feasible (switching does not require extensive clinical consultations and change in organisation of healthcare services)
  - c) The use of the alternative treatment does not have a negative impact on the patient's health and provides the same standard of care in alignment with national learned societies
  - d) The alternative medicine is available on the market of the respective Member State
    - Medicines that have experienced three or more shortages in the past three years or have a very low market share (lower than 2% of the total demand of referenced medicine) should be considered to be excluded from the count of therapeutic alternatives, as their contribution to actually compensate for the medicine in shortage and for maintaining patient access to treatment may be negligible.

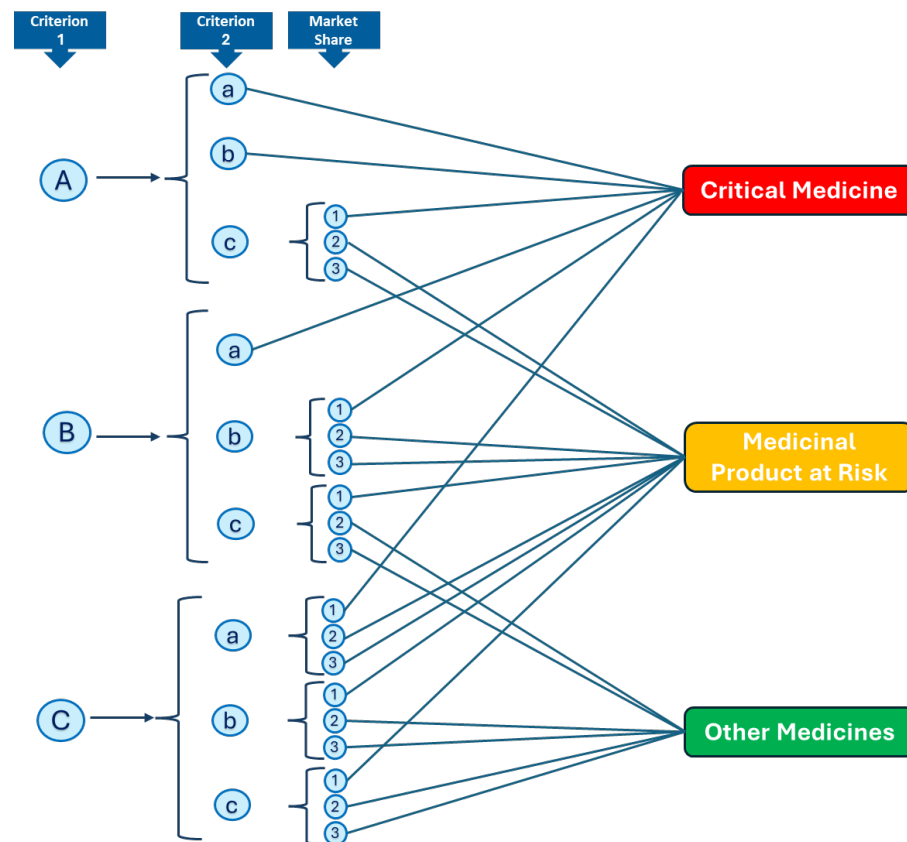
# Inclusion of the Medicine Market Share into the Risk Matrix



- For the national assessment it is recommended that the market share of the medicine is incorporated into the risk matrix, as this may influence the assessment of its criticality level.
- A high market share of a single medicinal product implies vulnerability for the healthcare system in the event of a shortage as the contribution of the therapeutic alternatives to maintain patient access to treatment may be negligible.

|                                                  |             | Criterion 1<br>(Therapeutic indication/ importance) |                          |                         |
|--------------------------------------------------|-------------|-----------------------------------------------------|--------------------------|-------------------------|
|                                                  |             | High risk                                           | Medium risk              | Low risk                |
| Criterion 2<br>(Availability of<br>alternatives) | High risk   | <b>Critical medicine</b>                            | <b>Critical medicine</b> | <b>At-risk medicine</b> |
|                                                  | Medium risk | <b>Critical medicine</b>                            | <b>At-risk medicine</b>  | <b>Other medicines</b>  |
|                                                  | Low risk    | <b>At-risk medicine</b>                             | <b>Other medicines</b>   | <b>Other medicines</b>  |

# Inclusion of the Medicine Market Share into the Risk Matrix



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

| Criterion 1: Therapeutic Indication |             | Criterion 2: Availability of Alternatives |                           | Market Share |        |
|-------------------------------------|-------------|-------------------------------------------|---------------------------|--------------|--------|
| A                                   | High risk   | a                                         | High risk: < 0–1 products | 1            | > 50%  |
| B                                   | Medium risk | b                                         | Medium risk: = 2 products | 2            | 25–50% |
| C                                   | Low risk    | c                                         | Low risk: > 2 products    | 3            | < 25%  |

# National Supply Chain Vulnerability Assessment



- The evaluation of the vulnerability in respect to the supply chain is needed to reduce the extent of critical medicines list to a more manageable number of medicines to prioritise efforts on those products most in need and to give patients the most benefit.
- MSSG adopted Methodology to Identify Vulnerabilities in Supply Chains of medicines on the ULCM.
- For other medicines that are on National list of critical medicines, it is proposed to use past shortage data to assess their supply chain vulnerability. Medicines that have experienced three or more shortages in the past three years could be flagged as critical medicines for which vulnerability is established.
- In addition, vulnerability assessment may be performed for At-risk medicines. If vulnerabilities are established they could be similarly flagged.

# List Publication



- All national lists of critical medicines should be fully publicly accessible, with clear documentation of the methodology used for list development to uphold transparency.
- The purpose of the list and obligations for different stakeholders should be clearly stated and supported with guidance documents.
- The list should include at least INN and pharmaceutical form.
- The list should be available in an easy-to-use format.

# List Publication – Detailed Description



## Public accessibility and easy search

All the national lists of critical medicines should publicly accessible but not all are provided in the format that is easy to search.



## Published methodology and obligations

Methodology used for identifying a critical medicine should be published and includes development process steps, stakeholders involved in the development, clarification of national measures, obligations and guidelines for MAHs of medicines on the list and other stakeholders.



## Increased transparency

For better understanding of the purpose of the list Member States should publish a separate document or section of the website with the Frequently Asked Questions. They should include information such as updating frequency as well as any plans for changes of the list in the future.



## Essential data for medicine identification

Published list should include at least INN and pharmaceutical form. It is useful to also include ATC code and date of inclusion/elimination of the medicine. Sometimes a critical medicine may be restricted to a specific combination product, intended use population or indication in which case the published list should indicate this.

# List Update



- Once the national list of critical medicines is established it should be regularly updated (e.g., biannually or annually) to reflect market changes and emerging risks.
- Member States should consider implementing automated IT systems for a regular review and update of the national list.

# List Update – Detailed Description

Existing national lists of critical medicines have to be regularly updated (e.g., biannually or annually) to reflect market changes and emerging risks.

## When updating the National list of critical medicines

### Take into account:

Generic medicines, with lower profit margins, are prone to withdrawal when costs, regulations, or pricing pressures make them unsustainable. After decades of multiple alternatives, only one or two may remain on the market.

Changes of clinical guidance and defined new standards of therapy, e.g. a medicine will become the predominant therapy with limited or no alternatives in the market.

Decrease in the criticality of a medicine, e.g. new market entrants at ATC4 level or loss of patent protection and new generic entrants, indicating market diversification due to the increasing number of available alternatives on the market.

The medicinal product categorised as “at risk medicine” has been the subject of recurrent, historical shortages with high impact.

Changes to national lists of critical medicines may trigger the submission of requests for ad-hoc review of ULCM to EMA.

# National Measures to Secure Availability



- The goal of keeping a national list of critical medicines is to identify medicines which should be prioritised and merit close attention.
- The measures should aim at regulatory protection of critical medicines, stimulating the interest of the national pharmaceutical industry in their manufacturing and marketing, and promoting their authorisation in Member States.
- When establishing obligations for MAHs of critical medicines, Member States should adopt a balanced approach, ensuring that requirements are proportionate and accompanied by appropriate incentives to support the continued accessibility and availability of critical medicines.
- The need for contingency stocks should be assessed in the broader supply ecosystem recognising the shared responsibility with other supply stakeholders and should be designed taking into consideration the principles of transparency, solidarity and be proportionate to the identified risks.

# National Measures to Secure Availability

To safeguard or improve the availability and accessibility of medicines on the list and lower the risk of their supply disruption, a wide range of measures are implemented in Member States.

Measures  
identified

Simplified  
administrative &  
regulatory  
procedures

1. Shorter validation periods, prioritised and expedited evaluation of the applications for authorisation or variation
2. Scientific and regulatory advice facilitating the submission of the registration dossier
3. Prioritisation of granting of slots as a reference Member State for marketing authorisation applications through European procedures to promote the availability of the critical medicines in more Member States

Financial  
benefits

1. Increase of the maximum price
2. Exemption from the application of rules, criteria, deadlines and other procedures governing price review
3. Exceptional price review
4. Exemption from regulatory fees
5. Different conditions in public tenders

MAH  
obligations

1. To report data on production, demand and stocks for certain products.
2. To develop a shortage management plan.
3. To build up an extra safety stock.

# Conclusions

## By implementing the presented recommendations:

- Member States contribute to a **coordinated EU-wide approach** of identifying medicines critical to the functioning of health systems across the EU/EEA, whose continuous supply must be safeguarded for patients.
- Critical medicines will be **prioritised for EU-level measures**, including supplier diversification, EU-based production, and regulatory measures.
- **Further measures** may include investment incentives and stronger procurement commitments to ensure continuous supply.



More information can be found in the *D6.4 Recommendations for the Development of National Lists of Critical Medicines. May 2026.*