



Recommendations for the Development of National Lists of Critical Medicines

Work Package 6

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List of abbreviations

API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical
CMA	Critical Medicines Act
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
INN	International Nonproprietary Name
MAH	Marketing Authorisation Holder
MoH	Ministry of Health
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
NCA	National Competent Authority
NPL	New Pharmaceutical Legislation
RoA	Route of Administration
SPOC WP	Medicine Shortages Single Point of Contact Working Party
TF-AAM	Task Force on the Availability of Authorised Medicines for Human and Veterinary use
ULCM	Union List of Critical Medicines
WHO	World Health Organization

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 designed 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 to reduce the incidence of shortages of medicinal products, among other measures.

Technical Work Package 6 (WP 6) is responsible for identifying established knowledge, procedures and best practices to address medicine shortages. One of the identified best practices is the development of national lists of critical medicines which serve as an important tool in preventing shortages and safeguard their supply. In this report, WP 6 aims to provide recommendations for the development of national lists of critical medicines.

The term critical medicine was first defined within the European Commission Structured Dialogue initiative in 2021. Critical medicines are medicines that are considered to be the most critical, due to their importance for the resilience of health care systems, public health and patient care at all times.¹

The definition of critical medicine was introduced in the proposal of the New Pharmaceutical Legislation (NPL) which states: ‘critical medicinal product’ means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients, and it is identified using the common methodology to identify critical medicinal products.²

The methodology to identify critical medicines was introduced by the European Commission Structured Dialogue initiative in 2021 and finalised by the HMA/EMA Task Force on the availability of authorised medicines for human and veterinary use (HMA/EMA TF-AAM). The working group was composed of shortage and clinical experts from across the EU and received input from the CHESSMEN WP 6. The methodology was adopted in June 2023 by the HMA/EMA TF-AAM Steering Committee.³

This methodology identifies medicines to be included in the Union List of critical medicines (ULCM). The ULCM identifies medicines that are critical for health systems across the EU/EEA and

¹ European Commission. *COMMISSION STAFF WORKING DOCUMENT. Vulnerabilities of the global supply chains of medicines. Structured Dialogue on the security of medicines supply.* 2022.

https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf

² European Commission. *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.* February 2026. [Link to the Proposal](#)

³ HMA/EMA. *Methodology to identify critical medicines for the »Union List of critical medicines«.* June 2023.

for which continuity of supply should always be guaranteed for European patients. The need to secure the supply of medicines across the EU and avoid shortages has been highlighted as key in the EU Pharmaceutical Strategy for Europe and the Commission proposal of the NPL reform. Although the supply of all medicines is closely monitored so that relevant actions can be taken to guarantee their availability, medicines identified as critical for public health will receive particular attention. They will be prioritised for EU-wide policy measures to improve their security of supply, including recommendations for diversification of suppliers, stimulating production within the EU or adhering to additional regulatory requirements or obligations. Other measures could include investment incentives and procurement approaches with more substantial contractual obligations for allocation and delivery.⁴

The first version of the ULCM was based on medicines included in six existing national lists of critical medicines. Member States reviewed a total of 600 active substance groups identified as critical in these lists using the processes described in the methodology document.⁴ The second version of the ULCM is an expanded version of the first version and is the result of a review of additional medicines sourced from existing crisis preparedness lists, such as the list of Main Therapeutic Groups⁵ established by the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). In addition, the second version considered active substance groups flagged by EMA stakeholder groups, which the European medicines regulatory network has reviewed based on the published methodology and specific prioritisation criteria, e.g. the number of Member States considering the medicine critical or the marketing status of the medicine.⁶ As of 13 December 2024, the ULCM comprises 276 International Nonproprietary Names (INNs). This number results from the review of three-quarters of all medicines licensed in Europe by Member States. Approximately 18,700 scoped medicinal products correspond to the critical medicinal product formulations outlined in the latest version of the ULCM.⁷

In June 2025, EMA MSSG established a draft process to finalise the procedures and criteria for establishing and reviewing the ULCM, allowing for review of the ULCM in preparation for the obligations set out in the NPL and Critical Medicines Act (CMA)⁸. Therefore, the operations for maintaining the ULCM will require fine-tuning over time. The review procedure should allow changes to the ULCM under a set cadence. This would enable MSSG to propose updates to the ULCM to the Commission for adoption once the NPL is approved. The focal group of the ULCM under the MSSG Voluntary Solidarity Mechanism/Policy Working Group will provide further support and steer to the update activities of the ULCM. The proposed procedure will be

⁴ HMA/EMA. *Methodology to identify critical medicines for the »Union List of Critical Medicines«*. June 2023.

⁵ EMA. *List of the "main therapeutic groups" (MTGs) in crisis preparedness*. July 2022.

⁶ EMA. *Questions and answers on the Union list of critical medicines*. Rev.1 December 2024.

⁷ HMA/EMA. *MSSG procedure for the annual update of the Union list of critical medicines*. June 2025.

⁸ European Commission. *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795*. March 2025. [Link to EUR-Lex](#)

implemented through a pilot project to test the proposed approach and will be published after the end of the pilot phase in 2026.⁷

EMA and the European medicines regulatory network will closely monitor the medicines on the list and implement measures to minimise the risk of supply disruptions. This will be done by leveraging existing processes and structures as defined in the mandate of EMA's Medicine Shortages Single Point of Contact (SPOC) Working Party and MSSG. Additional obligations for marketing authorisation holders and national competent authorities are further defined in the NPL reform.⁹

As a key measure to boost the security of supply of critical medicines, the Commission announced the launch of a Critical Medicines Alliance (hereinafter referred to as the Alliance) in its Communication.¹⁰ The Alliance was formally launched in April 2024. The main objective of the Alliance was to identify challenges resulting from vulnerabilities and the most appropriate actions and instruments to address the vulnerabilities in the supply chains of critical medicines, with the primary public health goal of reducing the risk of shortages of those critical medicines. The Alliance published its Strategic Report including a set of recommendations on 28 February 2025.¹¹ The Commission also announced in its Communication that strengthening the EU's security of medicines supply may require new legislation. In March 2025, the Commission published a CMA proposal. The general objective of the proposed CMA is to strengthen the security of supply and the availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security of the Union, and to improve the availability and accessibility of other specific medicines, where the functioning of the market does not otherwise sufficiently ensure their availability and accessibility to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

The specific objectives of the initiative are to:

- facilitate investments in manufacturing capacities for critical medicines, their active substances and other key inputs in the EU;
- lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures for critical medicines and other medicinal products of common interest;
- leverage the aggregated demand of participating Member States through collaborative procurement procedures;
- support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

To ensure a structured and coordinated approach to strengthening the security of supply of critical medicinal products, CMA envisages establishing of the Critical Medicines Coordination

⁹ EMA. *Questions and answers on the Union list of critical medicines*. Rev.1 December 2024.

¹⁰ European Commission. *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*. October 2023.

¹¹ CMA Alliance. *Strategic Report of the Critical Medicines Alliance*. February 2025.

Group composed of the Commission and Member States' representatives. The Critical Medicines Group's main task is to facilitate a) discussion on strategic orientation for financial support of Strategic Projects and strategic partnerships; b) exchanges and cooperation on national procurement policies; c) discussion on a need for collaborative procurement initiatives; d) advice on the order of priority for the vulnerability evaluation of critical medicines.

In the ULCM published on the EMA website at the time of this report, the assessment of criticality of a medicine is established on a clinical and public health basis, the vulnerability of the manufacturing and supply chain of the product has not yet been considered. In April 2024, the Health Emergency Preparedness and Response Authority conducted a pilot exercise to assess the structural and non-structural vulnerabilities in the supply chain of selected critical medicines in the list. The main findings for the first tranche of 11 critical medicines published in June 2024 found reliance on non-EU suppliers and market concentration risks, underscoring the need for strategic interventions to bolster resilience through diversified supply sources, flexible production capacity, and robust risk management.¹² Results of this pilot exercise and lessons learned (including data limitations, notably in the absence of the proposed pharmaceutical legislation) led the Alliance to identify the need to further improve the methodology assessing the vulnerability of products on the ULCM in order to prioritise efforts on those products most in need and to give patients the most benefit.¹³ Further complementary work on developing the vulnerability analysis methodology commenced in Q1 2025 under the MSSG governance, in anticipation of the NPL and CMA.

NPL and proposed CMA stipulate a distinct methodology to evaluate the vulnerabilities with respect to the supply chains of medicines on the ULCM. The vulnerabilities include but are not limited to lack of supply chain diversification and the level of dependency on countries outside the Union with respect to the critical medicinal products or their active substances or both.

CMA defines 'vulnerability in the supply chains' as risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union.

The methodology adopted by MSSG¹⁴ consists of two distinct phases. Four key indicators which inform the prioritisation for Phase 2 are assessed in Phase 1: manufacturer External EU/EEA dependency and Supply diversity, and MAH Market concentration and Diversity. Phase 2 builds on the Phase 1 screening with a detailed vulnerability assessment, incorporating information primarily requested from MAHs. The assessment is not considered finalised until both phases are completed. Following the assessment of the necessary data, critical medicines will be classified

¹² European Commission. *Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report*. June 2024.

¹³ CMA Alliance. *Strategic Report of the Critical Medicines Alliance*. February 2025.

¹⁴ EMA. *Methodology to Identify Vulnerabilities in Supply Chains of Critical Medicines*. November 2025.

into three non-mutually exclusive categories: ‘Resilient’, ‘Conditionally vulnerable’ and ‘Structurally vulnerable’.

The vulnerability evaluation will be performed by the MSSG according to defined prioritisation criteria. An alternative approach to prioritisation of the first set of INNs was agreed at MSSG in January 2026, to enable completion of initial assessments before the end of 2026.

The ULCM is not intended to replace existing national lists. Member States will continue to use existing lists to support national action based on national policy decisions. In Member States that do not have any lists in place, the ULCM could be used to develop national lists.¹⁵

The objective of WP 6 was to examine how existing national lists of critical medicines were developed, updated and published, as well as to identify the measures obligations placed on marketing authorisation holders. Based on this analysis, the aim was to provide recommendations for Member States without existing lists, outlining how such lists could be established and maintained, how they should be published and the related obligations for marketing authorisation holders.

The recommendations were submitted for final review to the Union List Focal Group, which operates under the MSSG Working Group on Voluntary Solidarity Mechanism and Policy.

¹⁵ EMA. *Questions and answers on the Union list of critical medicines*. Rev.1 December 2024.

2 Methodology

Seven Member States were identified to have established a national list of critical medicines or to be in the process of developing one: Austria, Finland, France, Germany, the Netherlands, Portugal and Spain.

Preliminary information about the national lists was collected from the respective NCAs' websites and national documents collected by WP 6 in the D6.1 Report on the Existing Documents on Shortages of Medicines.¹⁶ Additional information on the development, publication and updating of the existing national lists of critical medicines in EU/EEA countries as well as the implemented measures related to the medicines on the lists, such as obligations for different stakeholders, was obtained during structured interviews (Table 1) with the respective Member States.

Table 1. Structured interview questions

1.	What is the legislative framework for developing the national list of critical medicines?
2.	When was the first national list of critical medicines established?
3.	How many medicines are currently included on your national list of critical medicines?
4.	How did you start developing the list (e.g. first oncology, paediatric medicines)?
5.	Methodology (Roadmap) for development of the list (Please provide us the SOP if available): a. Criterion 1: How is the <i>medicinal product criticality</i> identified? Who is responsible for this task, and with whom do you consult or cooperate regarding clinical importance of medicines? b. Criterion 2: How is the <i>availability of appropriate alternatives</i> identified? Who is responsible for this task? c. Are any other criteria used? d. Are supply chain vulnerabilities assessed? Who is responsible for this task? e. Please describe the entire process if your Member State follows a different approach or methodology for developing the list of critical medicines. f. List all departments and external organisations who involved in the process.
6.	Which medicines are included in the assessment (e.g. authorised medicines, rare medicines, vaccines, exclusion of innovative medicines, etc.)?
7.	At what level are medicines evaluated (e.g. INN, medicinal product)?
8.	What is the methodology for updating the list?
9.	What is the frequency of updating the list (e.g. six months, annually)? How long does each revision take? How many people are involved in revision process?

¹⁶ WP 6. D6.1 Report on the Existing Documents on Shortages of Medicines. June 2023.

10.	What are obligations of MAHs for medicines on the list? a. Shortage prevention plan? b. Obligation to maintain safety stock? c. Other?
11.	What incentives are provided for MAH for medicines on the list (price, reimbursement, tender measures, national safety stock, regulatory stability, lower regulatory fees)? Are any other measures in place?
12.	Do any other stakeholders (e.g. wholesalers) have any obligation and/or incentives related to the medicines on the list? Please describe.
13.	Where is the list published, and which elements are made public (INN, Anatomical Therapeutic Chemical (ATC) classification, route of administration (RoA))?
14.	Is there any other important information you would like to share?

The methodologies to identify critical medicines used for the established national lists of critical medicines were compared to the ULCM methodology.

To consider also market share in the criticality assessment, the methodology described by Musazzi et al. (2020)¹⁷ was used to include it in the ULCM's risk matrix. Due to differences in Criterion 2 (Availability of Alternatives) between the two methodologies, an adjustment of the Musazzi's matrix was necessary (see Section 3.6).

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

3 Results

WP 6 reviewed the national lists of critical medicines from seven Member States (Table 2).

Table 2. Overview of seven reviewed national lists of critical medicines

Member State	Name of the list (English version)	Year of the first version	Number of INNs / medicinal products ¹⁸
Finland	Velvoitevarastointiluettelo (List of products to be stocked as obligatory storage)	1984	125/1327
Germany	Liste der versorgungskritischen Wirkstoffe gemäß § 52b Absatz 3c AMG (Supply-critical active substances in accordance with Section 52b subsection 3c AMG)	2020	330 INNs
Spain	Listado de medicamentos estratégicos (List of strategic medicines)	2022	382/640
Portugal	Lista de medicamentos essenciais de natureza crítica (List of essential medicines of a critical nature)	2023	327 INNs
the Netherlands	Nederlandse lijst kritieke geneesmiddelen volwassenen / kinderen (Dutch critical medicines list adults / children)	2024	634 INNs (adults) 601 INNs (children) In 3 categories
France	Liste des Médicaments d'intérêt thérapeutique majeur (MITM) List of medicinal products of major therapeutic interest	2024	1225/8107
Austria	Does not exist yet	In progress	N/A

3.1 Legislative Framework

A total of 4 (Finland, Germany, France and Portugal) out the 6 Member States with a published list of critical medicines have included the list into their national legislation. The remaining Member States are planning to do so.

The lists are not intended to identify medicines for crisis management, such as war or pandemic.

¹⁸ Number of INNs/medicinal products in the version of the list valid at the time review in October 2025

3.2 Development

All Member States included on their list only the medicines currently authorised and marketed in the Member State, with the exception of the Dutch critical medicines list for children, which includes pharmaceutical preparations.

3.2.1 Previous Lists Considered

For the preparation of the national list of critical medicines some Member States considered the medicines included in different national and international lists. These lists contain groups of medicines necessary for the public health system in general or for a particular healthcare situation.

The list below is not exhaustive. Member States considered different combinations of the lists mentioned below.

International lists

- WHO Model List of Essential Medicines which includes medicines that satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy, safety and comparative cost-effectiveness. They are intended to be available in functioning health systems at all times, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford;¹⁹
- Union List of Critical Medicines: medicines that are critical for health systems across the EU/EEA and for which continuity of supply should always be guaranteed for European patients;²⁰
- FDA List of Essential Medicines, Medical Countermeasures, and Critical Inputs: medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms;²¹
- European Association of Hospital Pharmacists (EAHP) European List of Emergency Medicines (ELEM): list containing essential medicines necessary for use in emergency situations disasters.²²

National lists

- Published national lists of critical medicines of other Member States

¹⁹ WHO. [Model Lists of Essential Medicines](#). Accessed June 2025

²⁰ HMA/EMA. *Methodology to identify critical medicines for the »Union List of Critical Medicines«*. June 2023.

²¹ FDA. [Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3\(c\) of the Executive Order 13944](#). October 2020. Accessed June 2025

²² EAHP. [ELEM](#). Accessed June 2025

- Member State assessment for the ULCM
- National list of essential medicines
- National medicine strategic reserve list
- National list of medicines for use in emergency care
- List of medicines considered essential in the management of the health crisis caused by COVID-19
- List of medicines with prior notification of shipments of medicines to other Member States, which includes medicines that may cause a healthcare problem in the event of supply problems
- Active substances listed on the national “Substitution exclusion list” which contains active substances and pharmaceutical form(s) for which substitution is not recommended

Other groups of medicines

- Medicines with repeated shortages in the past
- Medicines authorised through the Day 0 Mutual Recognition regulatory procedure due to their absence on the market, withdrawal or shortage problems
- Medicines included in requests for authorisation for exceptional use with clinical benefit
- Medicines included in national or European therapeutic guidelines
- Medicines for which withdrawals/suspensions have been requested at the request of a party, and which have been denied because they are considered to have a significant impact on healthcare

3.2.2 Process and Methodology

3.2.2.1 Finland

INNs included in the obligatory storage are identified in the Government Decree on Obligatory Storing of Medicines. The obligation to maintain storage primarily applies to medicines that safeguard vital pharmacotherapy, extensive general surgery and intensive care activities. The **list of products to be stocked as obligatory reserve supplies** is confirmed by the NCA, Fimea, and includes products which have a critical medical significance and which contain INNs listed in the Decree. Supply chain vulnerability of the products is taken into account, for example whether the product is manufactured locally or imported only. Past shortages of products are not considered.

The products to be stocked as obligatory storage include medicinal substances and medicinal products as well as the excipients, additives and packaging materials used in the manufacturing

of medicinal products. The NCA may also decide that the obligatory reserve supply does not include all pharmaceutical forms for certain INN.

3.2.2.2 *Germany*

The Advisory Council for Delivery and Supply Shortages is set up at the German NCA, BfArM, to continuously monitor and assess the supply situation of medicinal products. The Advisory Council comprises representatives of patient interests, as well as the representatives of medical practitioners, pharmacists, hospitals, full-range wholesalers, health insurance funds, the competent higher federal authorities and the competent authorities. The associations and organisations that participate on the advisory council are appointed by the Ministry of Health (MoH). After hearing the Advisory Council, the NCA prepares lists of supply-relevant and supply-critical active substances. In addition, the NCA in consultation with the Advisory Council prepares a list of finished medicinal products for which regular data transmission is considered necessary to adequately assess the supply situation.

The current German list of **supply-critical substances** includes INNs which are in some cases limited to a specific combination product, pharmaceutical form, route of administration, intended use population or indication.

The supply-critical active substances are substances which meet one or more of the following criteria:

- active substances for which only three or fewer MAHs, active ingredient manufacturers or batch release manufacturers are registered in the Federal Drug Application Database;
- active substances for which a critical supply shortage in accordance with Section 79 subsection 5 AMG occurred in the past;
- active substances on the ‘national list of products excluded from substitution’ which contains active substances and pharmaceutical form(s) for which substitution is explicitly prohibited.

For the declaration of a critical supply shortage in accordance with Section 79 subsection 5 AMG mentioned above, a previous critical assessment by the German NCA and the agreement to the declaration of the Advisory Council for Delivery and Supply Shortages is required. The critical assessment includes careful consideration of all relevant aspects on the shortage such as the therapeutic indication, the number of available alternatives, the market relevance/share of the medicinal product, duration of the shortage and affected patient groups.

In addition, certain medicinal products are subject to the obligation to regularly report data on available stocks and production, including the manufacturing site of the active substances actually used to manufacture the medicinal product, and the volume of sales of finished medicinal products if one or more of the following criteria apply:

1. medicinal products containing a supply-relevant active ingredient for which only one MAH, one active ingredient manufacturer or one batch release manufacturer is registered in the Federal Drug Application Database;
2. medicinal products containing an active ingredient for which a critical supply shortage in accordance with Section 79 subsection 5 AMG occurred in the past;
3. medicinal products for which, regardless of criteria 1 and 2, regular data transmission is deemed necessary by the decision of the Advisory Council.²³

At the time of writing this report, Germany is in the process of updating the list and amending the criteria above to reflect the methodology used for the ULCM. The plan is to adopt its two criteria: the seriousness of the disease and the availability of appropriate alternative medicines. To assess the potential of the therapeutic alternative to actually compensate for the medicine in question, the “Substitution exclusion list”, the history of shortages, as well as market share will be taken into account.

3.2.2.3 Spain

AEMPS, the Spanish NCA, began developing the **list of strategic medicines** in the end of 2020. The initial phase involved a selection of medicines contained in various published national and international lists, which contain groups of essential medicines, either for the health system in general or in response to the COVID-19 pandemic. From the set of medicines obtained, those for which there are only one or two authorised medicinal products with the same clinical description of the product were selected. This set of medicines was analysed according to two criteria, criticality of the indication and availability of alternatives to treat the condition. Since the publication of the first list in May 2022, the list has been updated every six months, gradually expanding the evaluation by ATC groups to include more medications that may be considered vulnerable. For example, antibiotics and oncological medicines were assessed first. The development and updating of the list are led by the NCA which consults learned societies when needed, on a case-by-case basis.

There are 3 types of medicines relevant to the health system defined in Spain:

- Essential medicines according to the WHO definition
- Critical medicines which are a subgroup of essential medicines for which there should never be supply problems in the health system
- **Strategic medicines** that are a subset of critical medicines for which it is considered necessary to adopt additional measures, whether regulatory, economic or of another nature, to ensure that they remain on the market both because of their need for basic health care and because of the vulnerability of their supply chain

²³ Liste der Fertigarzneimittel mit einer Verpflichtung zur regelmäßigen Datenübermittlung nach § 52b Absatz 3f AMG

To assign a medicinal product to the list of strategic medicines the criticality and vulnerability criteria are used.

- **Criticality:** the importance of the therapeutic indication assessed using clinical guidelines (evidence based; national guidelines); the safety profile of medicines was also considered.
- **Vulnerability:** medicines are considered vulnerable if there are only one or two authorised medicines with the same clinical product description available in the country. That is, medicinal products for which there are only one or two medicines that have the same active ingredient, dose, dosage unit and pharmaceutical form available. History of shortages is taken into account as well.

Following the publication of the ULCM, the same analysis and criteria are being applied to the medicines included in the ULCM which results in identification of medicines that are necessary on the national level and are newly included to the list of strategic medicines.

To further explore potential causes of vulnerability, a new group of medicines has been evaluated. These are medicines that, although included in some of the source lists mentioned in the methodology, and not being vulnerable due to the existence of three or more marketing authorisations, have a market share greater than 70%. The initial analysis for this new vulnerability criterion has focused on medicines for which some phase of manufacturing is carried out in Spain. The same methodology (criticality of indication and availability of alternatives) was applied to this set of medicines.

In addition to the list of strategic medicines, a list of non-authorised medicines that are needed for public health protection and list of foreign medicines that are most frequently imported were developed.

3.2.2.4 Portugal

Critical medicines are considered those essential medicines which require or justify the adoption of additional measures, whether regulatory, economic or otherwise, to guarantee their availability on the market, ensuring basic healthcare provision and addressing their vulnerability in the supply chain. Essential medicines are considered those for which there should be no supply problems in the health system.

Medicines that are considered essential for clinical practice at national level are defined by the National Pharmacy and Therapeutics Commission. The Commission is composed of physicians and pharmacists and representatives of two MoH entities. The list is approved by the Executive Board of INFARMED and published in the official gazette.

Only the medicines for which less than three MAHs are present in Portugal were candidates for the list. The history of shortages was taken into account as well; medicines with three or more shortages in the last five years were candidates for the list.

3.2.2.5 *The Netherlands*

The Netherlands is the only Member State which created a list for adults and a separate one specifically for children.

Proposals for critical medicines were made based on existing international and Dutch lists, including therapeutic guidelines. All available authorised medicines in the Netherlands were scored to see if they were on one or more of the studied lists. The proposals were then assessed by a multidisciplinary project group which included various groups of healthcare professionals – physicians and pharmacists in primary and secondary care. The overall process was led by the *Landelijk Coördinatiecentrum Geneesmiddelen* (National Coordination Centre for Medicines).

The lists are intended to provide insight into medicines that appear to be the most critical when their availability is at stake. The list includes both specialist and first-line medicines. A medicine is considered critical if a shortage of the medicine immediately or in the short-term leads to irreversible damage for the patient and/or the general population.

Following the assessment the medicines were divided into three categories considering the seriousness of consequences if medicine is not available:

- **Red:** medicines that are needed immediately (within a few hours) or in the short term (within 48 hours), otherwise they will lead to mortality;
- **Orange:** absence of the medicine leads to mortality or a greatly increased disease burden in the general population or for a patient (group) within three days to three months;
- **Yellow:** medicines that are necessary to safeguard normal medical and pharmaceutical care within the Netherlands.

3.2.2.6 *France*

Medicinal products or groups of medicinal products of major therapeutic interest (MITMs) are defined as those for which an interruption of treatment is likely to be life-threatening for patients in a short or medium term or significantly affects patients' treatment due to seriousness of the disease.

Up until the end of 2024, MITMs were not detailed specifically, MAHs had the responsibility to identify their specific medicinal products as MITMs according to the definition and declare them to the NCA once a year.

Since 2024, the law requires the NCA to publish the list of MITMs. There are now 8,107 medicines on this list, including the ones declared by MAHs in 2023 and 555 added by the NCA, including medicines that are outside the previously determined 14 ATC groups.

Under the legal definition of a MITM, the availability of therapeutic alternatives is not taken into account in determining whether a product qualifies as a MITM. In addition to the list of MITMs, MoH published a list of essential medicines in December 2023. Criteria for this list are dose frequency of the medicine and criticality of the medicine shortage.

3.2.2.7 Austria

Although no national list of critical medicines has been established in Austria yet, the methodology for identification of critical medicines has already been developed. While the methodology is already well advanced, this is still work in progress, also due to the pending methodology for the vulnerability assessment on EU level. The drafted methodology was developed and adapted from Musazzi et al. (2020).²⁴

The identification of medicinal products with a high risk of a severe impact on patients in the event of shortages and allocation to one of three risk classes (High, Medium, Low) is based on the following three criteria:

- therapeutic indication
- availability of therapeutic alternatives
- market share.

For determining suitable therapeutic alternatives, a consultation with external organisations (e.g. hospital pharmacists, Austrian medical association, Austrian medical societies, etc.) is foreseen. Only medicinal products which are authorised in Austria are taken into consideration.

²⁴ Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe. International Journal of Pharmaceutics*, 2020;579.

3.2.2.8 Comparison of Methodologies to Identify Critical Medicines

Differences in used criteria for the development of the lists are presented in the Table 3 below.

Table 3. Methodologies of ULCM and National lists of critical medicines

Member State	Criterion 1 Therapeutic Indication	Criterion 2 Number of Alternatives	Market Share	Vulnerability Assessment	Other
ULCM	X	X		In progress	
Finland	X			X	
Germany	X	X	X		In plan to update and apply ULCM methodology
Spain	X	X	X	X	
Portugal	X	X		X*	*Based on the history of shortages
the Netherlands	X				
France	X				
Austria	X	X	X		Methodology is still in development
Total: 7	7	5	3	3	

In addition to the differences listed above, for all national lists of critical medicines only medicinal products which are authorised and marketed in the respective Member State are considered, while ULCM includes also those available on their market through importation mechanisms.

3.3 List Update

The NCA in Finland reviews and updates the list of products to be stocked as obligatory reserve supplies annually based on new marketing authorisations, their withdrawals or changes (e.g. new indication approved). To add or remove INNs from being subject to the storage obligation, the Government needs to adopt a change of the Decree on Obligatory Storing of Medicines.

In Germany, the updates of the list have not followed a regular schedule since it was mainly done manually by reviewing information in the national database of marketing authorisations. Recently, an IT system was developed which will automate the update. It will have the capacity to review medicines in the database based on the determined criteria and produce a list of critical

medicines at any time. The future frequency of the automated list update and publication has not been determined yet.

Since the publication of the first list in Spain in May 2022, the NCA has been continuously updating the list and publishing a new version every six months (February and July), expanding the evaluation to include more medications that may be considered vulnerable.

The Portuguese list is updated at least annually or whenever deemed necessary. The first update took place in August 2024. The whole process from review to publication lasted three months. Five medicines added have been proposed by the pharmaceutical industry association and the pharmacies association. All were included due to the lack of therapeutic alternatives, except for human immunoglobulin for being a critical product and frequently in shortage.

After publication in 2024, the Dutch list was updated in 2025. Following updates are planned bi-annually (every two years).

In France the plan is that the list will be updated regularly on a rolling basis, taking into account new marketing authorisations, market withdrawals as well as new declarations from MAHs.

3.4 Measures to Secure Availability of Critical Medicines

Member States implement different measures to minimise the risk of supply disruptions for the medicines on their list. The measures may include additional monitoring by the NCA, obligations or incentives for MAHs and other stakeholders. Specific measures of each Member State are detailed below.

3.4.1.1 Finland

The parties required to maintain obligatory storage are pharmaceutical companies operating in Finland, importers of medicinal products, health care units and the National Institute for Health and Welfare (vaccines). Obligatory storage must be located in Finland. The size of the obligatory storage is calculated on the basis of different criteria for different type of parties, and it also depends on the medicine group. For MAHs and importers the quantity to be stocked is the number of products, equivalent to the average sales over a period of 10, 6 or 3 months. For health care units the quantity is the number of products, equivalent to the average consumption over a period of six months, three months or two weeks. The parties required to maintain obligatory storage must notify the quantities to be stocked to the NCA annually.

The NCA supervises compliance with the obligation and confirms the medicinal products to be included in the obligatory storage.

The National Emergency Supply Agency pays partial compensation to pharmaceuticals companies and importers for the cost of maintaining obligatory storage.

If a party has reason to believe that it cannot fulfil its obligation, it must promptly apply for a permit to maintain lower obligatory storage levels. The stock level may only fall under the

obligatory storage level when the NCA has granted a permit to maintain lower obligatory storage levels.

The NCA may exempt a party from maintaining obligatory storage either partially or in full upon application by the party.

3.4.1.2 *Germany*

The list represents the basis for the voluntary commitment to notify shortages to the NCA.

In addition to the voluntary reporting obligation, certain medicinal products are subject to an obligation to regularly report data on production, stocks, and sales volumes.

This obligation was implemented as a possibility to prospectively assess potential deficits or problematic situations regarding finished medicinal products considered critical.²⁵

3.4.1.3 *Spain*

Regulatory protection measures have been implemented for medicines listed as strategic medicines to support continued availability of the strategic medicines in Spain. These measures intend to stimulate the interest of the national pharmaceutical industry in their manufacturing and promote their authorisation in Spain. Some of these measures are:

- **Streamlined administrative and regulatory procedures:** implementation of the necessary mechanisms to speed up the administrative procedures and the evaluation of variations to the marketing authorisation, such as shorter validation periods for applications and a prioritised evaluation of the requested variations for these medicines.
- **Scientific and regulatory advice:** The NCA (AEMPS) offers scientific and regulatory advice to MAHs that intend to submit a registration dossier for a medicine with the same active ingredient, dose, dosage unit, and pharmaceutical form that has already been included in the list. This advice can be provided throughout the application process, facilitating the submission of the registration dossier. The evaluation of applications for authorisation for medicines submitted nationally are expedited as a matter of preference in order to promote the availability of these medicines on the market in the shortest possible time.
- **Support for internationalisation:** The NCA prioritises the granting of slots in Spain as a reference member state for applications for authorisation through European procedures to promote the availability of the medicines on the list in more Member States.

Currently, the possibility of reducing fees for medicines on the list is under discussion.

²⁵ [Supply Shortages Reporting Obligations](#). BfArM website. Accessed June 2025

3.4.1.4 Portugal

Measures available for the medicines included in the list do not apply automatically. MAHs of the medicines with the same INN and pharmaceutical form that is on the list may apply and request for a specific benefit. The application of the measures is subject to case-by-case assessment of each request by the NCA.²⁶

MAHs may apply for the following benefits for the medicines in the list:

- increase of the maximum price,
- exemption from the application of rules, criteria, deadlines and other procedures governing price review for a maximum period of five years,
- exceptional price review,
- exemption from regulatory fees (MA changes, renewal, regulatory and scientific advice)
- different conditions in public tenders,
- other as proposed by NCA Board of directors on a case-by-case basis.

If the benefits are approved, the MAH must:

- guarantee the supply of the quantities necessary to satisfy the consumption of the health system throughout the national territory;
- maintain a permanent stock level that ensures supply for a minimum period of 4 months of consumption;
- communicate stock levels to the NCA weekly through a dedicated platform.

If a shortage of the medicine occurs, MAH loses the benefits.

3.4.1.5 The Netherlands

There is no obligation for MAHs or any other stakeholders in place. The purpose of the list is to be used by the MoH to have national guidance for scoping policies on security of medicine supply and stockpiling. Further policy initiatives are being considered.

3.4.1.6 France

For each MITM in France, MAHs must develop and implement a shortage prevention plan. They are required to maintain a safety stock of two months intended for the national market. The requirement can increase to four months following the decision by the NCA, especially if the medicine was at risk of being in shortage or was in recurring shortage over the past two years. The modified requirement is reviewed every two years. In certain cases, the NCA may grant an exemption from obligation of two months safety stock upon request by MAH.

Any shortage or risk of shortage of an MITM must be reported to the NCA. Shortage management measures can then be put in place, in agreement with the NCA, to avoid or reduce the shortage

²⁶ INFARMED. *Esclarecimentos - Medicamentos essenciais de natureza crítica Portaria n.º 235/2023*. July 2023

duration and impact of the shortage and best meet the needs of patients during the shortage period. Wholesalers cannot export MITM when there is an ongoing shortage.

No incentives are currently in place. Pharmaceutical companies marketing MITMs may be subject to controls, including through inspections to verify their compliance with MITM identification, stockpiling or shortage notifications. Failure to comply with the obligations may result in sanctions such as financial sanctions or health policy decisions.

3.5 List Publication

The six Member States publish the national list of critical medicines on their NCA website. Table 4 presents the level of information published in the list of each Member State.

Table 4. Overview of published elements in the lists of critical medicines

Member State	INN	Product name	Ph. form	RoA	Strength	ATC	Other
ULCM							Date of inclusion
FI							MAH, new medicines highlighted
DE			*	*			*Only in specific cases
ES							Date of inclusion, date of elimination
PT							
NL							Medicine category
FR							National code, Link to national medicine database
Total: 7	6	2	5	4	3	3	

Ph. Form = Pharmaceutical form; RoA = Route of Administration

The formats in which the lists are published were also reviewed. Four Member States make the list available to download in Excel format (Finland, France, Spain, the Netherlands). Two of these also publish the list directly on a website with a search function for specific fields, two of them additionally publish the list in PDF, and one of them also offers it as a .txt file. Two Member States make the list available to download in PDF only.

The part of German NCA website about shortages includes history of creating the national list of critical medicines, cites related legislation, describes methodology used including criteria and collaborating entities as well as implemented measures. It also includes descriptions and links to other related national lists.

The Spanish NCA website has a dedicated site for the national list of critical medicines where the list is available to view and download. The site describes the history of the list development, its methodology with all the criteria and their updates, and implemented measures. It also includes a contact email for any questions.

The Portuguese NCA website cites the legislation related to the list, including the Deliberation which includes the list. Obligations for the MAHs are listed and in addition, a separate Q&A document published at the time of the first version with clarifications for MAHs is available.

The Dutch website describes the history, process steps and all the associations that collaborated in the development of the lists. There is a separate section with Frequently Asked Questions with clarifications as well as a more in-depth document with further explanation about the process.

The French NCA website specifies the legislation related to the list and highlights obligations for MAHs. It also includes links to further information and guidelines for MAHs.

3.6 Criticality Level Considering the Market Share

The existence of therapeutic alternatives alone may not be sufficient to mitigate the negative effects of a medicine shortage which is especially important in the case of critical medicines. If the therapeutic alternatives of the critical medicine have low market shares, their supply capacity may be inadequate to meet the demand during a shortage. The risk of shortage for low-market-share alternatives is further increased due to a ripple effect. A high market share of a single medicinal product implies vulnerability for the healthcare system in the event of a 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 patient demand 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).²⁷

Figure 1 illustrates how market share may be incorporated into the assessment of criticality of a medicine. This is based on the adapted methodology proposed in Musazzi et al. (2020).

A market share of above 50% results in an immediate escalation of the risk to a higher level, whereas a market share between 25% and 50% does not automatically trigger such escalation but does require close monitoring. Ranges of medicine market shares were empirically defined by the authors.

One Member State uses a market share cutoff of $\geq 70\%$, while another Member State is considering adopting a revised range of market shares: $\geq 80\%$, 21–79 %, and $\leq 20\%$.

²⁷ WP 6. D6.2 Report on the Common Protocol for Monitoring, Reporting and Managing Medicine Shortages.

Furthermore, it is recommended to exclude from the count of therapeutic alternatives those with very low market share (lower than 2% of the total demand of referenced medicine), as their contribution to actually compensate for the medicine in shortage and for maintaining patient access to treatment is negligible.

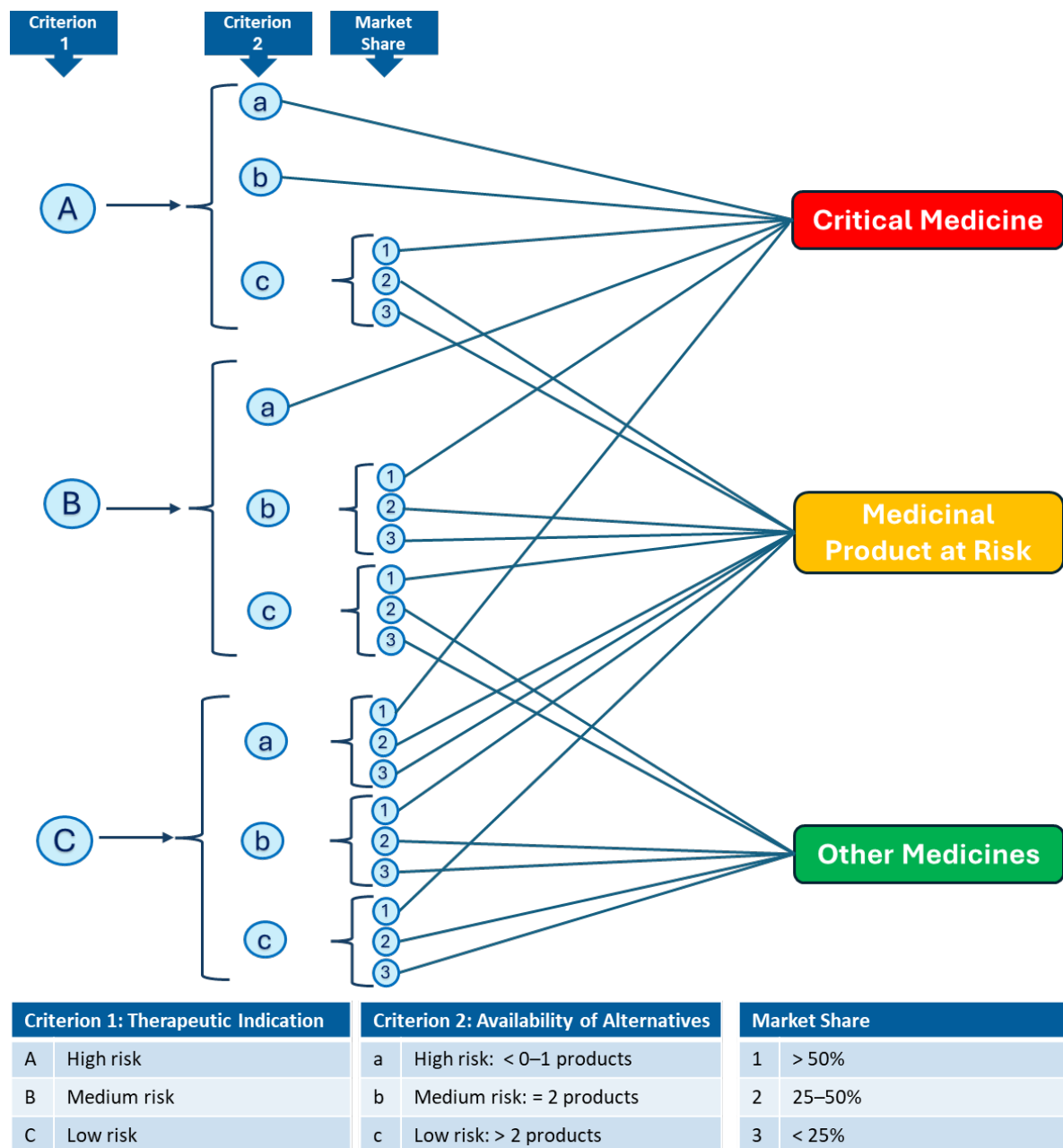


Figure 1. Risk matrix considering the market share of a medicine

When adapting the Musazzi's matrix, the description of the Criterion 2 – Medium risk in the ULCM should be revised to address the overlap in the quantitative descriptions.

The tables below present the current quantitative risk classification based on the number of appropriate alternatives identified and the proposed change.

Table 5. Criterion 2 – Availability of alternatives change proposal

Current ULCM			Proposal	
a	High risk: < 0–1 product		a	High risk: < 0–1 product
b	Medium risk: at least 2 products	⇒	b	Medium risk: = 2 products
c	Low risk: > 2 products		c	Low risk: > 2 products

4 Discussion

As can be seen from the report, only 6 out of 30 Member States (20%) have established national lists of critical medicines in the EU/EEA. Even these are not all aligned with the ULCM methodology.

All Member States participated in the preparation of the ULCM, that is, they assessed medicines from a list that included active substances from the lists described below:

- Six national lists of critical medicines published at Member State level that considered the medicines included in different national and international lists (e.g. WHO Model List of Essential Medicines, FDA List of Essential Medicines, Medical Countermeasures, and Critical Inputs and EAHP European List of Emergency Medicines)
- MSSG List of Main Therapeutic Groups necessary for emergency care, surgery and intensive care²⁸
- Active substance groups flagged by EMA stakeholder groups, including patient and healthcare professional organisations and industry associations

The ULCM includes both innovative and generic medicines for human use, including medicines for rare diseases, and covers a wide range of therapeutic areas. The current list comprises 276 individual molecules and reflects the outcome of the review of 2,200 active substance groups and combinations which account for 75% of authorised medicinal products in the EU. Approximately 18,700 scoped medicinal products correspond to the critical medicinal product formulations outlined in the latest version of the ULCM.^{29,30}

Member States included in their assessment for ULCM authorised and marketed medicines in their country, as well as those available on their market through importation mechanisms.

4.1 Development of a New National List of Critical Medicines

Based on the above, the lists with an assessment of the criticality of the most important medicines for maintaining public health at the national level already exist. Member States can leverage them for developing or refining their national lists, so it is unnecessary to start with the preparation of a list from scratch.

It would be beneficial to compare the Member State assessment for the ULCM with the final ULCM. This could enable the identification of critical medicines that are included in the ULCM but not in the respective national assessment.

²⁸ EMA. *List of the “main therapeutic groups” (MTGs) in crisis preparedness*. July 2022.

²⁹ EMA. *Questions and answers on the Union list of critical medicines*. Rev.1 December 2024.

³⁰ HMA/EMA. *MSSG procedure for the annual update of the Union list of critical medicines*. June 2025.

The next step could involve reviewing therapeutic groups in collaboration with national learned societies, starting with those most critical to public health, such as antibiotics, haematological medicines, and medicines used in intensive care unit.

When counting therapeutic alternatives as described in the ULCM methodology, NCA may also consult the WP6 report on definition of alternative therapy.

The report advises that an alternative is appropriate if it meets all the following criteria:

- the therapeutic alternative 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.³¹

When defining therapeutic alternatives, alignment with national learned societies is recommended as well.

As a next step, the availability of the therapeutic alternatives should be reviewed if their market share or history of shortages was not considered during the previous assessment. It is recommended to exclude from the count of therapeutic alternatives those that have experienced three or more shortages in the past three years. In addition, it is recommended to exclude from the count of therapeutic alternatives those with a history of shortages or that have a very low market share (lower than 2% of the total demand of referenced medicine), as their contribution to actually compensate for the medicine in shortage and for maintaining patient access to treatment is negligible.³²

For the national assessment of the potential of therapeutic alternatives to compensate for the medicine in question, it is recommended using the adapted methodology of Musazzi et al. (2020) which includes market share of the medicine.³² If the market share of the medicine is incorporated into the ULCM risk matrix, the criticality of medicine in question may change, as illustrated in Figure 1.

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.

The methodology of Musazzi et al. (2020) is a result of collaboration between Italian NCA, AIFA, and universities to find a standardised approach to identifying critical medicines. An algorithm to evaluate therapeutic alternatives available on the market was developed using internationally recognised medicine descriptors such as ATC code, defined daily dose and European Directorate

³¹ WP 6. D6.2 Report on the Common Protocol for Monitoring, Reporting and Managing Medicine Shortages.

³² Musazzi UM, Di Giorgio D, Minghetti P. *New regulatory strategies to manage medicines shortages in Europe. International Journal of Pharmaceutics*, 2020;579.

for the Quality of Medicines & HealthCare (EDQM) Standard Terms.³³ Caviglioli et al. (2025) suggested that the algorithm could be employed in preventive risk analysis to highlight medicines that have no or few valid therapeutic alternatives in the national drug databases. Another ongoing study is aiming to evaluate and profile medicinal products based on the market share, price and history of shortages.

4.2 Harmonisation of Existing National Lists

To ensure consistency among existing national lists and to align with the NPL reform, Member States should apply the European Union's methodology for identifying critical medicines when developing national lists. It is recommended that the NCA compares its own methodology with that used for the ULCM, as well as the medicines on each list. This comparison could help identify medicines present on the ULCM but missing from the national list. It would also provide the NCA with 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. All propositions described above regarding development of a new list of critical medicines apply to the harmonisation of existing ones, especially considering the market shares.

4.3 National Vulnerability Assessment

The NPL reform and CMA stipulate that a common methodology should be developed to evaluate the vulnerabilities of supply chains of critical medicines on the ULCM. The work on developing the vulnerability analysis methodology commenced in Q1 2025 under the MSSG governance, in anticipation of the NPL and Critical Medicines Act.³⁴

Such prioritisation is needed to allow efforts to be focused on the products most in need and providing the greatest benefit to patients.

The current ULCM mostly comprises generic, off-patent medicines that no longer benefit from intellectual property rights or other regulatory data protections. These affordable medicines have often become 'staple' products of EU health systems but are increasingly produced in ways that heighten vulnerability. Many critical medicines are supplied by only one or two manufacturers, leaving supply chains highly fragile and dependent. These suppliers have often outsourced manufacturing processes or moved production of their finished product outside of the EU and/or source their active pharmaceutical ingredient (API) from outside the EU. As a result, for many of its critical medicines the EU is reliant on a limited number of APIs suppliers or manufacturers, many situated outside of the EU. For generic medicines, it has been calculated that between 60% and 80% of the API production has been outsourced to China over the recent

³³ Caviglioli G et al. *Medicine Shortages: An Algorithm for Evaluating the Substitution with Equivalent or Alternative Products*. *Healthcare*. 2025;13(10):1139.

³⁴ CMAIalliance. *Strategic Report on the Critical Medicines Alliance*. February 2025.

years and an increasing part of other inputs to the manufacturing supply chain are being outsourced to Asia.³⁴

The Alliance recognised that each medicine has its own specificities and will necessitate a dedicated assessment. This includes the need to consider the difference between off-patent medicines where multiple suppliers may be operating and patent-protected medicines with one supplier. Future assessments of the vulnerability of the supply chains of critical medicines should also take into account the specificities of certain medicines, such as in the case of blood and plasma derived products or radio isotope products.³⁴

MSSG adopted Methodology to identify vulnerabilities in supply chains of medicines on the ULCM.³⁵ Updates of the ULCM will include vulnerability evaluation outcome. It is not foreseen that vulnerability assessment according to this methodology would be performed on the national level. Therefore, for medicines that are on a National list of critical medicines and not on ULCM, 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. The implementation of NLP reform is expected to improve data access for NCAs via the shortage prevention plans, thereby enhancing understanding of the root causes of shortages of critical medicines.

In addition, vulnerability assessment may be performed for At-risk medicines. If vulnerabilities are established, they could be similarly flagged. Note that the NPL does not foresee the vulnerability evaluation of “at risk medicines”.

4.4 National Measures to Secure Availability of Critical Medicines

The goal of keeping a national list of critical medicines is to identify medicines which should be prioritised and merit close attention. To safeguard or improve their availability and accessibility and lower the risk of their supply disruption a wide range of measures are implemented in Member States.

Simplified administrative and regulatory procedures as well as financial benefits have been adopted at national level aiming 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.

Several incentives have been identified in the different Member States.

- Streamlined administrative and regulatory procedures:
 - shorter validation periods for applications as well as a prioritised and expedited evaluation of the applications for authorisation or variation for critical medicines;
 - scientific and regulatory advice facilitating the submission of the registration dossier;

³⁵ EMA. *Methodology to Identify Vulnerabilities in Supply Chains of Critical Medicines*. November 2025.

- support for internationalisation – the NCA prioritises the granting of slots as a reference Member State for applications for authorisation through European procedures to promote the availability of the critical medicines in more Member States.
- MAHs of the critical medicines may apply for the following financial benefits:
 - increase of the maximum price,
 - exemption from the application of rules, criteria, deadlines and other procedures governing price review,
 - exceptional price review,
 - exemption from regulatory fees (MA changes, renewal, regulatory and scientific advice),
 - different conditions in public tenders,
 - others on a case-by-case basis.

Member States have also implemented one or more of obligations on MAHs of critical medicines:

- to report data on production, demand and stocks for certain products,
- to develop a shortage management plan,
- to build up an extra safety stock.

A balanced approach is needed to support the objectives of improving the availability of critical medicines and strengthening supply security across the EU. In implementing these obligations, it is important to ensure that requirements placed on MAHs of generic, off-patent medicines remain proportionate and are accompanied by appropriate incentives that help sustain market presence and manufacturing capacity, particularly in smaller markets. This would contribute to maintaining access to essential treatments while supporting resilient supply chains at both national and EU level.

However, as a main measure to mitigate the risk of medicine shortages, several Member States have introduced or are considering introducing contingency stock obligations, which, if extended beyond critical medicines, may impact the security of supply.

While stocks of medicinal products can help mitigate the impact of supply chain disruptions on health systems, obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and other Member States. Beyond that, root causes of shortages for different product groups are multifactorial and, therefore, contingency stocks of medicinal products do not address root causes of supply disruptions and shortages, and such measures cannot be used as a one-size-fits all solution.³⁶

Uncoordinated approach within the EU can lead to misallocation of products, particularly for medicinal products already at high risk of shortages due to market concentration. As a result,

³⁶ CMAAlliance. *Strategic Report of the Critical Medicines Alliance*. February 2025.

patients may increasingly experience disruptions to their health care due to further strain on supply chains, which may prevent from efficiently addressing shortages and undermine the principle of solidarity, as stocks are restricted to national markets. Furthermore, excessive contingency stocks increase the likelihood of stock write-offs (especially if stock rotation is not possible), which is both wasteful and financially burdensome. Excessive and uncoordinated contingency stocks can also exacerbate market consolidation, as it places additional pressures on already strained generic medicine markets and supply chains.³⁷

A clear framework on contingency stocks covering both national and EU contingency stocks is needed to mitigate the potential negative consequences of current national contingency stocks. It is also important to facilitate the reallocation of stocked medicinal products to Member States in case of shortage, ensuring that solidarity mechanisms are effective, and Member States have mechanisms that allow them to share the stock in time of need.³⁷

CMA Article 20 imposes obligations on Member States in relation to contingency stock requirements. It states that measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.

4.5 List Update

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

When updating the national list of critical medicines, the market dynamics of generic medicines/off-patent medicines and those of innovative/on-patent medicines should be taken into account.

- Generic medicines, often characterised by lower profit margins, are more vulnerable to market withdrawals. Manufacturers may withdraw these products if regulatory obligations, production costs, or pricing pressures render them commercially unsustainable. As a result, after decades of availability of multiple exact generic alternatives, there are suddenly only one or two left 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.

³⁷ CMAI Alliance. *Strategic Report of the Critical Medicines Alliance*. February 2025.

Considering that the list review and update is an activity performed on a regular basis, it makes it a great candidate for automation. This is already planned in Germany where the IT system that automates the update is going to have the capacity to review the medicines in the database based on the determined criteria and produce a list of medicines at any time.

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

EMA MSSG recently established a draft procedure for the annual update of the ULCM.³⁸

4.6 List Publication

All the existing national lists of critical medicines are publicly accessible, but not all are provided in the format that is easy to search. To uphold transparency the methodology used for identifying a critical medicine should also be published. For a better understanding of the purpose of the list some Member States published a separate document or section of the website with the Frequently Asked Questions. They also include 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, updating frequency as well as any plans for changes of the list in the future. EMA published a similar document for the ULCM.³⁹

To clearly identify the critical medicines, the published list should include at least INN and pharmaceutical form, which most of the existing national list have. 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.

³⁸ HMA/EMA. *MSSG procedure for the annual update of the Union list of critical medicines*. June 2025.

³⁹ EMA. *Questions and answers on the Union list of critical medicines*. Rev.1 December 2024.

5 Recommendations

- Member States should apply the European Union’s methodology for identifying critical medicines to ensure consistency across national lists.
- Member States should include in their assessment medicines authorised and marketed medicines in their country, as well as those made available on their market through importation mechanisms.
- Member States should leverage the national assessment of medicines for the ULCM as a basis for developing or refining their national lists.
- For national assessment the description of Criterion 2 – Medium risk used in the ULCM could be revised to avoid ambiguity. The current wording “at least 2 products”, should be replaced with “= 2 products” to ensure consistency and clarity.
- For the national assessment of the potential of therapeutic alternatives to effectively compensate for the medicine in question, it is recommended that the market share of the medicine be incorporated into the risk matrix, as it may influence the assessment of its criticality.
- Medicines that have experienced three or more shortages in the past three years and those that have a very low market share (e.g. lower than 2% of the total demand of referenced medicine) should 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.
- 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.
- All national lists should be 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.
- Updates of the ULCM will include vulnerability evaluation outcome. For medicines that are on National list of critical medicines but not on ULCM, 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.
- 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.

6 Conclusion

By implementing these recommendations, Member States can contribute to a coordinated, EU-wide approach to identifying medicines that are critical to the functioning of health systems across the EU/EEA and whose continuous supply must be safeguarded for patients in Europe.

While the supply of all medicines is closely monitored at both national and EU levels to enable timely interventions, those identified as critical to public health will receive particular focus. They will be prioritised for EU-level policy measures aimed at strengthening supply security, including recommendations to diversify suppliers, stimulate production within the EU or apply additional regulatory obligations. Further measures may include investment incentives and procurement strategies featuring stronger contractual commitments regarding allocation and delivery.

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