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Questions and answers on the Union list of critical medicines

On 12 December 2023, the European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency¹ published a [first version of the Union list of critical medicines](#).

What is the Union list of critical medicines?

The Union list of critical medicines identifies medicines for human use for which continuity of supply in the EU is a priority and shortages should be avoided as they are critical for EU healthcare systems to function properly and shortages leading to interruption in treatment could result in serious harm to patients.

Inclusion in the list does not mean that the medicines are likely to experience a shortage in the near future. It means that the prevention of shortages is particularly important as a shortage could cause serious harm to patients. The European medicines regulatory network will prioritise critical medicines for EU-wide actions aiming at strengthening their supply chain and minimise the risk of supply disruptions.

What makes a medicine critical (in the context of the Union list)?

A critical medicine is identified by combining two criteria, the seriousness of the disease they target and the availability of alternative medicines. Criticality of a medicine was assessed by EU Member States and EMA. The criteria were initially developed during the structured dialogue initiative² of the European Commission in 2021 and subsequently finalised by the HMA/EMA taskforce on availability of authorised medicines in June 2023. The process for identifying a critical medicine is explained in the [published methodology](#). Furthermore, a medicine has to meet additional criteria to be listed, including being critical in at least one-third (33%) of EU/EEA (European Economic Area) Member States.

What type of medicines are included in the list?

The list includes both innovative and generic medicines for human use covering a wide range of therapeutic areas, including medicines for rare diseases. The current list reflects the outcome of the review of 600 active substances and combinations of active substances from existing national lists of

¹ National Competent Authorities in the Member States of the European Economic Area (EEA), the European Medicines Agency (EMA) and the European Commission (EC).

² As reflected in the [Commission Staff Working Document](#)



critical medicines. It will be updated and extended in 2024 after the review of medicines that are not included in those national lists.

Does the list reflect the risk of shortage of a medicine?

Inclusion in the list does not mean that the medicine is likely to experience a shortage in the near future. It means that the prevention of shortages is particularly important as a shortage could cause serious harm to patients or present challenges to health systems. Critical medicines will be subject to an analysis of the supply chain and where vulnerabilities in supply chains are identified, the medicines will be prioritised for EU-wide actions to strengthen their supply chain and minimise the risk of supply disruptions.

How will the list be used?

The list is an important tool for EMA and the European medicines regulatory network to prevent shortages in the future and ensure security of supply. While the list itself does not reduce the immediate risk of shortages, it defines those medicines that require additional measures to strengthen their supply and avoid shortages in future. The European medicines regulatory network will closely monitor the medicines on the list and implement measures to minimise the risk of supply disruptions by leveraging existing processes and structures as defined in the mandate of [EMA's Medicine Shortages Single Point of Contact \(SPOC\) Working Party](#) and EMA's [Executive Steering Group on Shortages and Safety of Medicinal Products](#) (MSSG). Additional obligations for marketing authorisation holders and national competent authorities are further defined in the proposed revision of the EU pharmaceutical legislation.³

The European Commission plans to analyse the vulnerabilities in the supply chain of those critical medicines. The European Commission's [Communication on addressing medicine shortages in the EU of 24 October 2023](#) set out plans for regulatory and industrial policy measures to address those vulnerabilities. Such supply security measures may include recommendations for companies to diversify suppliers or increase production within the EU, investment incentives, additional regulatory obligations for companies, and procurement with strong contractual obligations for delivery. These measures will support the prevention and mitigation of shortages and ensure that there is appropriate and continued supply of critical medicines for patients and health systems across the EU.

What does this mean for marketing authorisation holders and national competent authorities?

The obligations for marketing authorisation holders and national competent authorities, for example in terms of the data to be supplied and monitored as well as other measures that can be taken at EU level, are yet to be defined. Measures that can be considered (as proposed in the European Commission's Communication) include monitoring requirements, incentives to diversify and attract manufacturing investments in Europe and procurement strategies to better support security of supply. There may also be requests for input into the assessment of the vulnerability of the supply chain, which is carried out by the European Commission. Additional obligations for marketing authorisation holders and national competent authorities will be further defined in the revision of the EU pharmaceutical legislation.

What does the list mean for patients and healthcare professionals?

There is no action needed from patients and healthcare professionals as a result of the publication of the list. Medicines on the list can continue to be ordered, prescribed and used as usual, with no need to

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193>

stockpile medicines. Stockpiling medicines can put further strain on supplies and cause or worsen shortages.

What does the list mean for other stakeholders such as wholesalers and distributors?

Any potential obligations for these stakeholders are yet to be defined.

How was the current version of the Union list drawn up?

All EU Member States reviewed medicines included in six existing national lists for criticality in their respective territory, as described in the methodology document.⁴ These lists were chosen because they were based on criteria aligned with those agreed for the Union list. A medicine is identified as critical by combining two criteria, the seriousness of the disease and the availability of alternative medicines. A medicine that meets the criteria for criticality is included in the Union list if it meets additional criteria including being critical in at least one-third (33%) of EU/EEA Member States.

The Union list is being progressively drawn up and will be released in two phases. The current list is the outcome of the first phase, which comprised a review of 600 active substances and combinations of active substances identified as critical in existing national lists of critical medicines (Finland⁵, France⁶, Germany⁷, Portugal⁸, Spain⁹ and Sweden¹⁰).

Therefore, the current version of the list is incomplete. The review will continue in 2024 in a second phase to extend the review to other authorised medicines in the EU not yet included in the first version.

Which stakeholders were involved in the development of the Union list?

Key stakeholder groups, including patients and healthcare professionals organisations and industry associations, were closely involved and consulted when developing the methodology to identify critical medicines for the Union list of critical medicines.¹¹

Will the Union list replace national lists of critical medicines?

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

Will the publication of the list lead to fewer shortages?

As there are no immediate actions for stakeholders following the publication of the list, no immediate impact on shortages is expected for these medicines. While the list itself does not reduce the immediate risk of shortages, it defines those medicines that require additional measures to strengthen their supply and avoid shortages in future. The introduction of these measures is expected to reduce the risk of shortages in the longer term.

The need to secure the supply of medicines across the EU and avoid shortages has been highlighted as a key priority in the EU Pharmaceutical Strategy for Europe, conclusions of the European Council,

⁴ Put forward in the [Commission Staff Working Document](#) on vulnerabilities of the global supply chains of medicines

⁵ [List of products to be stocked as mandatory reserve supplies - Fimea](#)

⁶ [Liste des médicaments en cours de relocalisation ou d'augmentation de capacités](#)

⁷ [BfArM - Reporting obligations - Liste der versorgungskritischen Wirkstoffe gemäß § 52b Absatz 3c AMG](#)

⁸ [Lista de medicamentos essenciais de natureza crítica](#)

⁹ [Medicamentos estratégicos | Agencia Española de Medicamentos y Productos Sanitarios \(aemps.gob.es\)](#)

¹⁰ [Uppdrag-lista-kritiska-läkemedel_Slutlig.pdf \(lakemedelsvarlden.se\)](#)

¹¹ This occurred during the structured dialogue initiative of the European Commission in 2021 and is reflected in the 2022 [Commission Staff Working Document](#) on vulnerabilities of the global supply chains of medicines

resolutions of the European Parliament and the proposed revision of the pharmaceutical legislation. Once adopted, the legislation will provide further clarity on obligations and implications.

What is the difference between a critical medicine and a critical shortage?

A critical shortage is a shortage of any medicine that cannot be resolved by national measures only and requires coordinated action at EU level. Critical shortages are escalated to EMA's Medicine Shortages SPOC working party and EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and are addressed through tools listed in the [MSSG toolkit](#).

A critical medicine is one for which no appropriate alternative is available and for which a shortage could result in serious harm or risk of harm to patients. The shortage of a critical medicine may be critical or not. A critical shortage may occur for any medicine, not just critical medicines.

The Union list does not include some medicines that are included on national lists of critical medicines – why is that?

There are several reasons why a medicine that appears to meet the criteria for criticality in a particular EU country, as described by the methodology (i.e. indication for a serious condition with no or few alternatives), may not be on the list:

- The medicine has not yet been reviewed for criticality at EU level. It should be noted that the Union list of critical medicines is being drawn up in phases. The current list is the outcome of the first phase and is based on six existing national lists. This means that medicines that were not part of the six national lists have not yet been reviewed for criticality.
- It may be that the medicine meets the criteria for criticality in one EU Member State but not in other EU Member States.

Medicines that are not included in the Union list are also important for healthcare systems and the European medicines regulatory network will continue to address the risk of supply disruptions through the existing framework for handling shortages.

The Union list does include some medicines that are not included on a particular national lists of critical medicines – why?

There are several reasons why a medicine on the Union list may not be included on a national list:

- The medicine may not be marketed in the respective EU/EEA country.
- It may be that in the relevant EU/EEA country, treatment alternatives are available which is not the case for other countries.
- It may also be that the medicine does not meet the criteria for criticality in the respective EU/EEA country (different criteria for inclusion may apply for the national list).

Are medicines from the WHO list of essential medicines automatically included in the Union list?

Medicines from the WHO list of essential medicines are not automatically included in the Union list of critical medicines. The current version of the Union list is based on medicines from six existing national lists of critical medicines, which are based on various data sources including the WHO list.

Why are only a few orphan medicines included in the current list?

The current version of the list is not complete and is based on the review of six national lists. An orphan medicine will be included in the Union list if it meets the criteria for criticality as defined in the

methodology (therapeutic importance and availability of alternatives), and if it meets additional criteria including being critical in at least one-third (33%) of EU/EEA Member States.

When will the list be complete?

The drafting of the Union list is done in phases and the publication of the first version of the Union list marks the end of the first phase. During 2024 the review will continue and extend to other authorised medicines in the EU not yet included in the first version.

Once final, the list will be updated to take into account the separate assessment of the vulnerability of the supply chain, which is being carried out by the European Commission. This work will highlight dependencies on markets outside the EU and low diversification of suppliers. This will guide EU-level actions to increase supply chain resilience and thus strengthen supply continuity of medicines to EU patients.

How will the list be maintained?

Once the list is complete it will be updated regularly to add new medicines that meet the criteria for criticality, or remove medicines that no longer meet the criteria for criticality.