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Questions and answers on the Union list of critical medicines

On 16 December 2024, the European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) published an update to the first version of the Union list of critical medicines.[2] This update follows the initial publication of the first version of the list on 12 December 2023. The list is an important tool to support the European Union's efforts in preventing shortages of critical medicines and to safeguard their supply. It has been published in anticipation of the implementation of new EU pharmaceutical legislation[3], which will further define implications and requirements.

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. This means that for these medicines shortages should be avoided, as they are critical for EU healthcare systems to function properly.

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 to strengthen 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 it targets and the availability of suitable alternative medicines.

The criteria were initially defined during the structured dialogue initiative[4] 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[5].

[1] This revision was published on 16 December 2024 and reflects the second phase of the review of authorised medicines in the EU.
[2] National Competent Authorities in the Member States of the European Economic Area (EEA), the European Medicines Agency (EMA) and the European Commission (EC).
[3] European Commission. Proposal for a *Regulation of the European Parliament and of the Council on the European Health Data Space. EUR-Lex. 2023. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193*
[4] As reflected in the Commission Staff Working Document
[5] https://www.ema.europa.eu/en/documents/other/methodology-identify-critical-medicines-union-list-critical-medicines_en.pdf

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Furthermore, a medicine is listed in the Union list only if additional conditions are met, such as the number of Member States considering the medicine critical or the marketing status of the medicine.

What type of medicines are included in the list?

The list 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 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. These substances were derived from existing lists within the European medicines regulatory network, including the list of main therapeutic groups[6], and national lists of critical medicines published at Member State level.

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. Instead, it highlights the importance of preventing shortages of these medicines, which could cause serious harm to patients or present challenges to healthcare systems. Critical medicines will be subject to an analysis of their supply chains. If vulnerabilities are identified, the medicines will be prioritised for EU-wide actions to strengthen their supply chain and minimise the risk of disruptions.

How will the list be used?

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 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.

The European Commission has analysed the vulnerabilities in the supply chain of selected critical medicines in the list. The main findings for the first tranche of 11 critical medicines were published in July 2024[7]. On 24 October 2023 the European Commission published a communication[8] to address medicine shortages in the EU, which laid out plans for regulatory and industrial policy measures to address supply chain vulnerabilities. These measures are yet to be defined but could include recommendations for marketing authorisation holders to diversify suppliers of active substances or increase production in the EU, investment incentives, additional regulatory obligations for marketing authorisation holders, and procurement with strong contractual obligations for delivery. These measures will help to prevent and mitigate shortages, ensuring an appropriate and continued supply of critical medicines for patients and healthcare systems across the EU.

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

The obligations of marketing authorisation holders and national competent authorities, such as those related to the data to be monitored, are yet to be defined. This will be done in the context of the revision of the EU pharmaceutical legislation which will provide further clarity on obligations and implications once adopted. In the interim, the European Commission has proposed measures in the communication published in October 2023, as noted previously. There may also be requests from EMA

[6] https://www.ema.europa.eu/en/documents/other/list-main-therapeutic-groups-mtgs-crisis-preparedness_en.pdf
[7] European Commission; Health Emergency Preparedness and Response Authority. Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report. 2024. Available from: https://health.ec.europa.eu/document/download/67294e68-3a9a-4a73-8c9f-899338bac7f9_en?filename=hera_scv-critical-medicines_1t_assessment_en.pdf
[8] https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf

to marketing authorisation holders for their input to support the assessment of vulnerabilities of critical medicine supply chains.

The Union list is also the basis for selecting medicines and prioritising certain activities, such as product mapping in EMA's product management service (PMS) and EMA's pilot of shortage prevention and management plans.

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 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. This will be done in the context of the revision of the EU pharmaceutical legislation which will provide further clarity on obligations and implications once adopted.

How was the Union list drawn up?

The first version of the Union list was based on medicines included in six existing national lists of critical medicines (Finland[9], France[10], Germany[11], Portugal[12], Spain[13] and Sweden[14]). Member States reviewed a total of 600 active substance groups identified as critical in these lists using the processes described in the methodology document[15].

The second version of the Union list is an expanded version of the first list and is the result of a review of additional medicines sourced from existing crisis preparedness lists, such as the list of Main Therapeutic groups established by the EMA 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.

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

Key stakeholder groups, including patient and healthcare professional organisations and industry associations, were closely involved and consulted when developing the methodology to identify critical medicines for the Union list of critical medicines.[16] A targeted consultation with patient and healthcare professional organisations and industry associations was undertaken during the second phase of this process, to identify additional active substance groups for review.

Will the Union list replace national lists of critical medicines?

The Union list of critical medicines 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 Union list could be used to develop national lists.

[9] List of products to be stocked as mandatory reserve supplies - Fimea
[10] Lutte contre les pénuries de médicaments - Ministère de la santé et de l'accès aux soins
[11] BfArM - Reporting obligations - Liste der versorgungskritischen Wirkstoffe gemäß § 52b Absatz 3c AMG
[12] Lista de medicamentos essenciais de natureza crítica
[13] Medicamentos estratégicos | Agencia Española de Medicamentos y Productos Sanitarios (aemps.gob.es)
[14] Uppdrag-lista-kritiska-läkemedel_Slutlig.pdf (lakemedelsvarlden.se)
[15] https://www.ema.europa.eu/en/documents/other/methodology-identify-critical-medicines-union-list-critical-medicines_en.pdf
[16] 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

Will the publication of the list lead to fewer shortages?

The inclusion of substances in the list ensures that there are measures in place for these medicines to reduce the risk of shortages in the long-term. Presence in the list is not indicative of a risk of shortages in the short-term. The publication of the list does not require stakeholders to take any immediate actions.

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[17], conclusions of the European Council, resolutions of the European Parliament and the proposed revision of the pharmaceutical legislation.

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

A critical shortage is a shortage of any medicine that requires coordinated action at EU level as it cannot be resolved by national measures alone. Critical shortages are escalated to EMA's SPOC working party and the Agency's MSSG. They are subsequently addressed through tools listed in the MSSG toolkit on recommendations on tackling shortages of medicinal products[18] and the MSSG recommendations to strengthen supply chains of critical medicinal products[19].

A critical medicine is one for which no suitable 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 or may not be critical. A critical shortage may occur for any medicine, not just for medicines that have been designated as critical.

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, as described by the methodology for the EU Union list, may not be on the list in a particular Member State:

- the medicine has not been reviewed for criticality at EU level;
- it may be that the medicine meets the criteria for criticality in one Member State, but not in others.

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 national list 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;
- treatment alternatives are available in that EU/EEA country, which may not be the case for other countries;

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).

[17] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en
[18] https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf
[19] https://www.ema.europa.eu/en/documents/other/mssg-recommendations-strengthen-supply-chains-critical-medicinal-products_en.pdf

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

Medicines from the WHO list of essential medicines[20] are not automatically included in the Union list of critical medicines. The Union list is derived from existing national lists of critical medicines, and other lists for crisis preparedness available at EU level, like the MSSG list of main therapeutic groups. These lists are based on various data sources including the WHO list.

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

An orphan medicine is 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, such as the number of Member States considering the medicine critical or the marketing status of the medicine.

Is the list now complete?

The Union list was drafted in phases, and the current version reflects the review of 75% of authorised medicines for human use in the EU/EEA. Work will continue to update the list to address the remaining 25% of medicines, as necessary. The list will guide EU-level actions to increase supply chain resilience and thus strengthen the continuity of medicines supply to EU patients. This can be done by regulatory recommendations issued by the MSSG for example.

How will the list be maintained?

The list will be reviewed periodically to either add new medicines that meet the criteria for criticality or to remove medicines that no longer meet the criteria.

[20] https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists