

The Union List of Critical Medicines

Current progress and reflections to enhance HCPs consultation

EMA Healthcare Professionals' Working Party Meeting

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Key EU/EMA actions on medicine shortages



**EU-level monitoring of shortages –
Medicine Shortages Single Point of Contact (SPOC) Working Party**



**Centralised data collection and analysis –
European Shortages Monitoring Platform (ESMP)**



**Coordinated EU response to critical shortages –
Medicines Shortages Steering Group (MSSG)**



**Priority oversight of essential medicines –
Union list of Critical Medicines**

Union List: criteria for inclusion and key steps



Criteria for inclusion



Member state
assessment & categorisation



Stakeholder consultation



List finalisation -
annual review

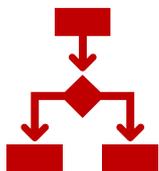
		Criterion 1 (Therapeutic indication/ importance)		
		High risk	Medium risk	Low risk
Criterion 2 (Availability of alternatives)	High risk	Critical medicine	Critical medicine	At-risk medicine
	Medium risk	Critical medicine	At-risk medicine	Other medicines
	Low risk	At-risk medicine	Other medicines	Other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

Perceived challenges and points for reflection



Information gaps

HCP involvement occurs at a relatively advanced stage of the process and with limited visibility into the underlying assessments conducted by Member States for selected criteria (therapeutic relevance, availability of alternatives).



Limited understanding

This partial visibility limits HCPs' understanding and may generate uncertainty around the rationale for prioritising certain molecules over others, considered as critical from a clinical viewpoint.



Impact on feedback

Combined with the absence of a feedback loop, this may influence the depth and breadth of input that HCP organisations are able to provide.

Risk categorisation

High risk

- The disease to be treated is potentially fatal, irreversibly progressive or, if left untreated, will pose an immediate threat, or cause severe impairment to the patient. This applies similarly to acute situations (emergencies), chronic situations or situations with potentially fatal outcomes.
- If the treatment is unavailable or interrupted, it will jeopardise the vital prognosis of patients in the short or medium term or represent a significant loss of opportunity for patients regarding the severity or potential evolution of the disease.
- The treatment **must be administered immediately or within regular dosing intervals.**⁴
- The product is part of a national disease control program (e.g., vaccination campaign)⁵

Methodology to identify critical medicines for the “Union List of critical medicines”

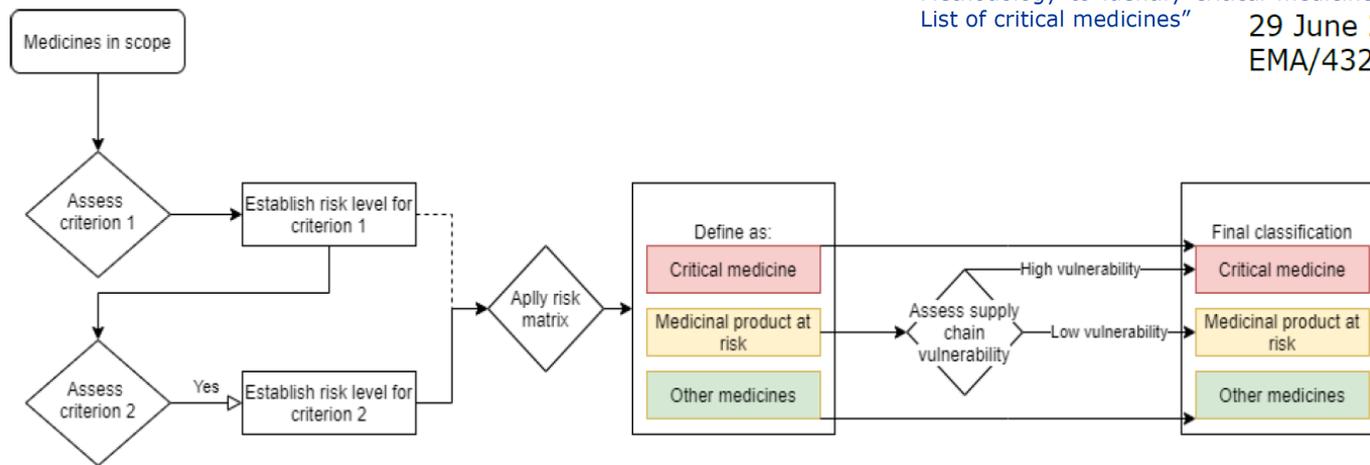
29 June 2023

EMA/432940/2023

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Risk categorisation - example

Methodology to identify critical medicines for the "Union List of critical medicines"
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1	C03CA01	FUROSEMIDE		intravenous use, intramuscular use
2			C07A - Beta blocking agents	
3	C07AA05	PROPRANOLOL		oral use
4	C07AG01	LABETALOL		intravenous use
5			C08C - Selective calcium channel blockers with mainly vascular effects	
6	C08CA06	NIMODIPINE		intravenous use, intracisternal use
7			C08D - Selective calcium channel blockers with direct cardiac effects	
8	C08DA01	VERAPAMIL		intravenous use

Potential improvements – for discussion



Enhancing transparency to enhance feedback quality

Provide HCPs with additional information/rationale on the assessments (therapeutic importance, availability of alternatives) that led to the inclusion of medicines in the draft Union List, for more informed and comprehensive feedback.



Leveraging Clinical Practice Guidelines (CPG)

Leverage CPGs to ensure the highest standards of care are considered in the assessment of criticality and that state of the art is used as a benchmark in the evaluation of therapeutic pathways and of possible alternatives.



Introducing a structured feedback loop

Consider establishing a structured feedback loop following adoption, while keeping HCPs informed on supply-monitoring and other relevant developments on critical and at-risk medicines, to anticipate potential implications for patient care.