EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the publication of version 2 of the Union list of critical medicines (ULCM)

PCWP/HCPWP and all eligible organisations meeting
20 November 2024

Presented by Joao Ferreira,
Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

Agenda

1. Background: 2023 Recap
2. Objectives and scope – How will the list be used?
3. Process to establish the list - phased implementation
4. Phase 2 outcome: key deliverables & feedback from stakeholder consultation
5. Planned Communication
6. Conclusions and Next steps

ULCM frontload by the European medicines regulatory network (EMRN)

A quick recap (2023 timeline)

October 2022
EC Structured Dialogue initially defined the methodology for the identification of critical medicines.

April 2023
The ULCM is defined in NPL reform (as per Art 131), with direct implications for industry and NCAs.

May 2023
Member States' requests (EPSCO level) – non-paper.

Amendment of the TF-AAM work programme.

June 2023
The EMRN further refined the methodology before implementation

October 2023
EC Communication on tackling shortages defines the list as a 'measure to be accelerated'.

EMA/628805/2023
6 December 2023

Union list of critical medicines - version 1

ATC level 5	ATC description (The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO))	Date of inclusion
	A - Alimentary tract and metabolism	
	A02B - Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)	
A02BC05	ESOMEPRAZOLE	1 December 2023
	A03B - Belladonna and derivatives, plain	
A03BA01	ATROPINE	1 December 2023
	A03F - Propulsives	
A03FA01	METOCLOPRAMIDE	1 December 2023
	A07A - Intestinal antiinfectives	
A07AA09	VANCOMYCIN	1 December 2023
A07AA12	FIDAXOMICIN	1 December 2023
	A07B - Intestinal adsorbents	
A07BA01	MEDICINAL CHARCOAL	1 December 2023
	A10A - Insulins and analogues	
A10AB01	INSULIN HUMAN (fast-acting)	1 December 2023
A10AC01	INSULIN HUMAN (intermediate-acting)	1 December 2023
A10AD01	INSULIN HUMAN (intermediate - or long-acting combined with fast-acting)	1 December 2023
	A12C - Other mineral supplements	
A12CC02	MAGNESIUM SULFATE	1 December 2023
	A16A - Other alimentary tract and metabolism products	
A16AB02	IMIGLUCERASE	1 December 2023
	B - Blood and blood forming organs	
	B01A - Antithrombotic agents	
B01AA03	WARFARIN	1 December 2023

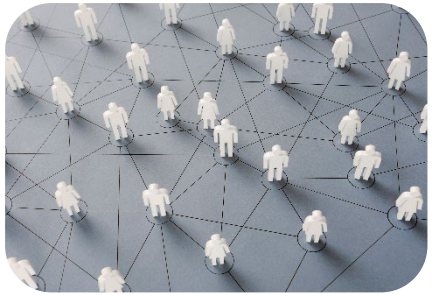
ULCM version 1 published in December 2023

Objectives and scope – How will the list be used?

Availability

Ensure critical medicines for EU health systems are always available.

- Enable short- to medium-/ long-term supply security measures.



Regulatory actions

EMA/ EMRN monitor medicines on the list to minimise supply disruptions.

- Measures leverage existing processes/ structures defined by EMA's SPOC Working Party and MSSG (based on existing toolkits).

Industrial capacity/support

The EC's DG GROW and HERA analysed supply chain vulnerabilities of selected critical medicines (11 molecules). Critical Medicines Alliance (CMA) is developing industrial policy recommendations.

Industrial policy measures could include 1/ supplier diversification or increased production within the EU, 2/ investment incentives, and 3/ procurement with strong contractual obligations for supply.

Policy/legislation

Planned: The proposed EU pharma legislation revision will define additional obligations for MAHs and Member State NCAs.

Future: The Critical Medicines Act is a key priority of the next Commission's mandate (complements new pharma legislation revision with industrial policy measures).

Phased implementation of the Union list: Progressive release

Phase 1 (concluded)

Scope: **600** active substance groups (ASGs) reviewed (**71K** licensed medicines)

Duration: 3 months (July-September 2023)

Source: leveraged existing work from **6** national lists of critical medicines (ES, FR, FI, PT, SE, DE)

Phase 2 (*ongoing*)

Scope: ~**1.6K** active substance groups subject to review (>**177K** authorised medicines)

Duration: *8 months (February-September 2024)*

Source: EMA List of Main Therapeutic Groups, HERA MCM Catalogue, Stakeholder input (*NEW:* targeted consultation)

MCM = Medical Countermeasures

Phase 2 - Targeted stakeholder consultation (1/2)

Duration:

- March – June 2024 (3 months).

Objectives:

1. Flag critical medicines under review in Phase 2 (considering the agreed methodology).
2. Identify additional active substance groups (ASG) for review by Member States (during Phase 2).

Analysis:

- Distribution: 36 stakeholder organisations shared input:
  - 12 Learned societies/HCP organisations.
  - 10 Patient/Consumer organisations.
  - 14 Industry Trades/individual MAHs.

Feedback (categorisation):

- Numbers: 130+ individual comments received.
- Topic allocation:
  - Criticality (substance level) & re-evaluation.
  - Methodology (transparency/applied conditions) & policy.

Substance coverage:

- 650+ active substance groups were targeted, including Phase 1 substances (not in scope).

Phase 2 - Targeted stakeholder consultation (2/2)

- **Response plan (substance level):** 650 Active substance groups (ASGs) targeted

Number of substances (proportion)	Phase no.	Classification	Review priority	Status
134 (21%)	2	Missing substances (not/never reviewed) at Phase 2 start	HIGH	• Processed in Phase 2
255 (39%)	2	Initially considered for Phase 2	HIGH	• Processed in Phase 2
165 (25%)	1	Classified as "critical" by MSs and published	N/A	• Completed, no further action
100 (15%)	1	Reviewed by MSs, but did not meet criteria for inclusion = not published	LOW	• Not subject to reassessment in 2024

ASG - active substance groups

Phase 2 outcome – at a glance

Distribution of ASGs per pharmacotherapeutic group (*no. of ASGs*)

- Antineoplastic agents **L01** (16)
- Antihemorrhagics **B02** (4)
- Vaccines **J07** (4)
- Antimycotics for systemic use **J02** (1)
- Immunosuppressants **L04** (1)
- Immune sera and immunoglobulins **J06** (1)
- Therapeutic radiopharmaceuticals **V10** (1)

EU-wide data analysis

- 29 EU/EEA countries reviewed data sets
- Medicines are included if they meet additional conditions, including being rated critical by over half of EAA countries (15).

Projected figures

- Additional 28 active substances and combinations (core version: 270 ASGs)

ASG - Active Substance Groups

Phase 2 – key deliverables (in 2024)

Volumes

Member States completed the full review of an additional 1.6K active substance groups (ASGs), over 3 review cycles.

Coverage

ULCM version 2.0 is the outcome of a comprehensive review of ~75% of all medicines authorised in Europe.

Stakeholder (SK) consultation

30+ SK organisations shared feedback, ~130 new substances not/never reviewed were included in Phase 2 review dataset.

Policy work

Support to EC requests (HERA, TRADE, SANTE) to inform policy making activities (e.g. NPL reform, Critical Medicines Alliance, foreign investments).

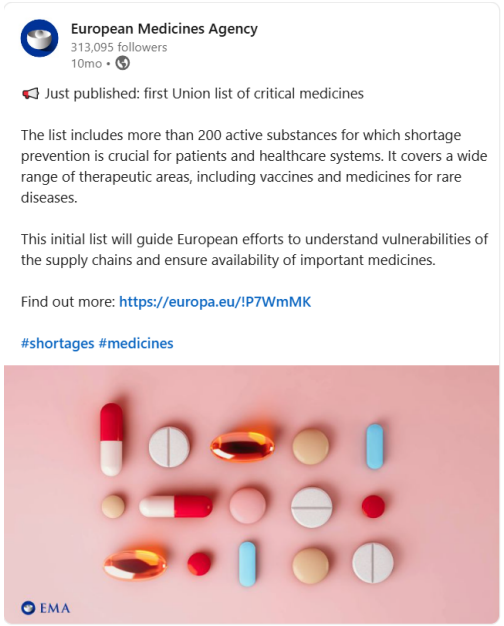
Communication

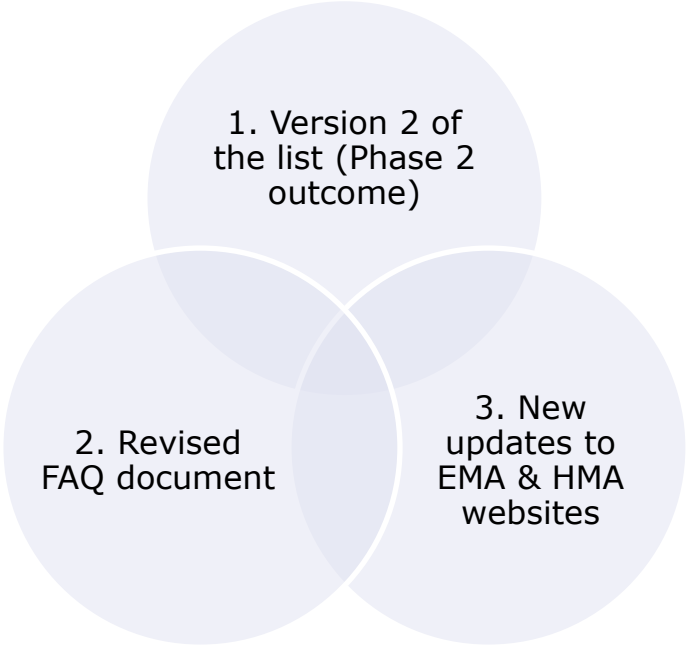
Updates to SK groups on the list rollout (bilateral meetings, plenary presentations) & revision of communication materials

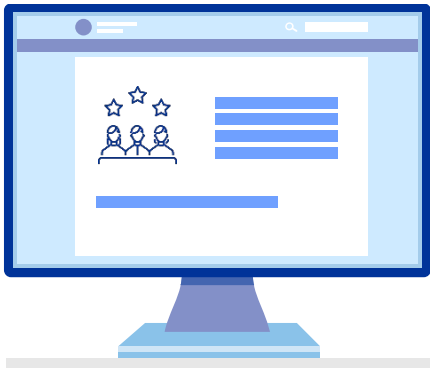
Prioritisation

Enable routine shortage mgt. activities, and future activities/tools which will become mandatory (SPPs/ESMP), inform MSSG recommendations

Updated communication package (for publication in wc/ December 16th)







Meetings planned for Q4 2024

Governance structure	Meeting Date	Action
Working Group of the Union List	07/11/24	**For discussion**
HCP & PC Working parties	20/11/2024	**For information**
Industry Standing Group (ISG)	21/11/2024	**For information**
HMA/EMA TF-AAM Steering Committee	25/11/2024	**For endorsement**
Medicine Shortages SPOC WP **MSSG**	06/12/2024 11/12/2024	**For information**
HMA II	05-06/12/2024	**For adoption**
EMA Management Board	11-12/12/2024	**For adoption**

HMA: Heads of Medicines Agency,
SPOC: Single Point of Contact,
MSSG: Executive Steering Group on Shortages and Safety of Medicinal Products,

TF AAM: HMA / EMA Task Force on Availability of authorised medicines for human and veterinary use,
ISG: Industry Standing Group

Conclusions & Next steps

Further ULCM operations must align with the **outcome of the NPL reform** and the future set of procedural rules.

Establishing the ULCM "core version" (circa 270 ASGs) concludes **~1.5 years of data categorisation activities** by the EMRN.

MSSG may propose **(regulatory) recommendations** for critical medicines from the Union list, considering the vulnerabilities in the supply chain.

Regular updates to the Union list will be necessary based on **clear criteria** (e.g., review timelines vary for innovators/off-patent products).

Given the workload implications for MSs, **maintenance activities** between 2025 and 2026 will be undertaken on an "ad-hoc" basis (e.g., change requests) annually.

Enhanced product **transparency in Version 2**, with the Route of Administration (RoA) concerned, displayed together with ASGs (ATC code 5).

Any questions?

Further information

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High-level process flow

1. **Data collection**
(e.g. Phase 1 = 6 national lists)
(Coordination: **EMA**)

2. **Categorisation** based on agreed methodology
(Lead: **Member States**)

3. **Data processing**
(determine which medicines will end up on the Union list; conditions apply)
(Coordination: **EMA**)

4. **Endorsement** by HMA/EMA Management Board and **Publication** of the Union list
(Coordination: **EMA**)

HMA = Heads of Medicines Agencies
TF-AAM = Task Force on Availability of Authorised Medicines for human and veterinary use

1. Develop **criteria** for the mapping of supply chain vulnerabilities
(Lead: **DG HERA/GROW**)

2. Map/ i**dentify vulnerabilities**
(Lead: **DG HERA/GROW**)

In-scope of HMA/EMA TF-AAM work plan

Out of scope of TF-AAM (ongoing at **Commission** level)

Methodology: criteria

Categorization of medicines in three groups

Critical medicines | Medicines at risk | Other medicines

Risk classification based on two criteria (with three risk levels each)

Criterion 1

Therapeutic indication

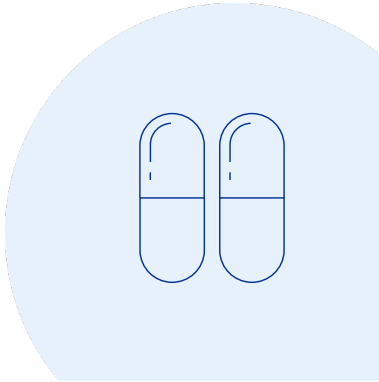
High, medium, low risk

Criterion 2

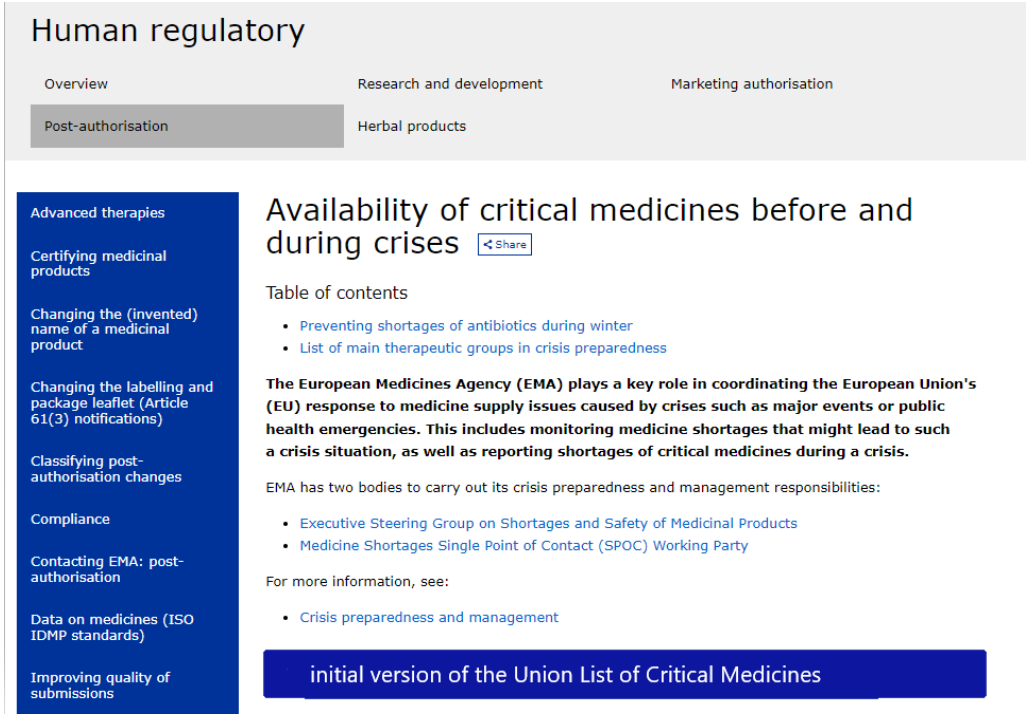
Availability of alternatives

High, medium, low risk

→ *Categorization according to a risk matrix*



Union list vs other lists



Topic	Name of List	Responsible body	Scope	Purpose
Security of supply	Union list of critical medicines	EMA/HMA	Medicines (active ingredients) critical for public health at the EU level	Support tracking of EU manufacturing capacity and ensure security of supply and availability of critical medicines at EU level.
Crisis preparedness	List of main therapeutic groups of medicines	MSSG	Main therapeutic groups that are necessary for emergency care (hospital setting)	This list informs the preparation of critical medicines lists for a public health emergency and major event.
Crisis response	List of critical medicines for a major event	MSSG	Medicines authorised for the major event	To ensure supply of medicines relevant for the major event. Medicines on the list will be subject to close monitoring of supply and demand.
	List of critical medicines for a public health emergency	MSSG	Medicines authorised for the public health emergency	To ensure supply of medicines relevant for the public health emergency. Medicines on the list will be subject to close monitoring of supply and demand.