



Critical Medicines Act

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“You will propose a Critical Medicines Act to address the severe shortages of medicines and medical devices and reduce dependencies relating to critical medicines and ingredients, as well as to ensure the supply of affordable medicines.”

Mission letter for Olivér Várhelyi
Commissioner for Health and Animal Welfare

Objectives and scope

Strengthening security of supply
and availability of critical
medicines



*Critical medicines on the
Union list as envisaged in
the Pharma Reform*

Improved availability and
accessibility of other medicines
where a market failure exists



*Medicines of common
interest (e.g. orphans,
novel antimicrobials)*



KEY ELEMENTS OF THE ACT

ENSURING



**SECURITY OF SUPPLY AND AVAILABILITY
OF CRITICAL MEDICINES**

**ACCESSIBILITY AND AVAILABILITY
OF OTHER KEY MEDICINES**

STRATEGIC PROJECTS

Facilitate investments
in manufacturing
in the EU

PUBLIC PROCUREMENT

Incentivise
supply chain
diversification and
resilience

COLLABORATIVE PROCUREMENT

Harness the
combined
demand and
buying-power of
Member States

STRATEGIC PARTNERSHIPS

Support the
diversification of
supply chains

Key elements – Political agreement of 12 May 2026

Strategic Projects:

create, increase or modernise EU manufacturing capacity for critical medicines or their active substances. Extension of the fast-tracking measures to orphan medicines. Commitment to prioritise supply to the Union in case of financial support.

Public Procurement:

incentivise the resilience and diversification of supply chains in public procurement procedures. For critical medicines with high dependency, obligation to favour manufacturing in the EU (2 possible approaches).

Contingency stocks:

increase transparency and reporting obligations on national measures that impose contingency stocks for critical medicines. Obligation to prevent any negative impact on the availability of medicines in other EU countries.

Collaborative Procurement:

Commission will support collaborative procurement among Member States to address availability issues. Minimum of 5 countries to procure on behalf of MS. Possibility for EC to invite MS to submit a joint request.

International Partnerships:

International partnerships with third countries to broaden the supply chains and reduce dependencies.

Strategic projects

- Projects that create, increase or modernise EU manufacturing capacity of critical medicines, their active substances and other key inputs
- Recognition by designated authority at national level
- Benefits:
 - **Fast-tracking of administrative procedures** (permit granting, environmental assessment) – also for orphan medicines
 - **Regulatory and scientific support** (incl. EMA advice & prioritised GMP inspections)
 - **Facilitated financial support**, including through the STEP Seal
- Obligation: prioritise EU supply if received financial support

Public procurement

- **Mandatory use of resilience requirements** that support supply chain diversification for critical medicines
- Obligation for **procurers to favour EU production** for critical medicines with high dependency. Procurers to choose between:
 - Technical specifications requiring at least 50% of EU manufacturing across all lots in a multi-winner approach, or
 - Award criteria to proportionally reward the share of EU manufacturing and possible extra points if at least 50% of EU manufacturing;
- Procurers to consider **multi-winner approaches**
- Member States to develop strategy (**national programmes**) covering procurement practices and possibly P&R measures
- Commission guidelines on procurement practices

Contingency stocks

- Safeguards related to Member States' contingency stock requirements:
 - Obligation to **prevent any negative impact** on the availability of medicines in other EU countries
 - Principles of **proportionality, transparency and solidarity** to be followed
 - Increased **transparency and reporting obligations**
- Digital overview of national contingency stock requirements
- When the Voluntary Solidarity Mechanism is activated, MS to share up-to-date contingency stock data upon request
- When no suitable solution under VSM, possible MSSG recommendations to MS to facilitate optimal allocation of stocks

Collaborative procurement

- Possibility to use different tools of collaborative procurement (each subject to specific conditions and thresholds):
 - **Member States' cross-border procurement** facilitated by the EC
 - Threshold of 3 Member States
 - Available only for medicines of common interest and orphan medicines
 - **Commission procurement** on behalf or in the name of Member States
 - Threshold of 5 Member States
 - Available for critical medicines, medicines of common interest and orphan medicines
 - Commission may invite Member States to form **joint request**

Coordination & International cooperation

- Establishment of a **Critical Medicines Coordination Group ('CMCG')**
- CMCG shall work closely with the MSSG, the Agency and national competent authorities
- Consultation of stakeholders through joint meetings
- Commission to explore possibilities for:
 - Establishing **strategic partnerships** aiming at **diversification of supply chains**
 - Building on existing cooperation forms

Thank you



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