

CRITICAL MEDICINES ACT

Improving the availability and securing supply of critical medicines in the EU

March 2025

Towards the Health Union's goal to ensure that all EU patients have the medicines they need, when they need them

CRITICAL MEDICINES ACT AIMS TO:

- ▶ **Facilitate investments** for companies that increase EU manufacturing of critical medicines
- ▶ **Incentivise supply chain diversification and resilience** through public procurement
- ▶ **Leverage the aggregated demand** of participating Member States
- ▶ **Support diversification** by facilitating conclusion of **strategic partnerships**

WHAT DOES THE ACT COVER:

- Critical medicines, for which limited or no alternatives exist and shortages of supply may result in serious harm to patients.
- Critical medicines for which vulnerabilities have been identified in their supply chain, notably high dependencies on a single or limited number of third countries.
- Certain other medicines of common interest (e.g. for rare diseases) which yet may not be accessible in certain markets.



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

1. Strategic Projects: facilitating investments in manufacturing in the EU

Industrial projects which create, increase or modernise manufacturing capacity in the Union are considered **Strategic Projects for critical medicines**, bringing:

1. Easier access to funding, including through the [STEP Seal](#)
2. Fast-tracked administrative, regulatory and scientific support



Accompanying **New State aid guidance** to assist Member States which invest in such Strategic Projects.

- Companies will be **obliged to prioritise EU supply**, if they have benefitted from financial support for a Strategic Project.

2. Public procurement: incentivise supply chain diversification and resilience



New procurement guidelines for Member States and procurers

- Procurers will have to apply **procurement requirements other than price** in their public procurement procedures for critical medicines.
- Procurers will also have to **favour EU production** for specific critical medicines with high dependencies, and may do the same for other medicinal products of common interest, when justified.

3. Commission support for collaborative procurement

- EU countries can request European Commission support to use different collaborative procurement tools.
- This enhanced purchasing power can create economies of scale and reduce access disparities.

4. Diversification through strategic partnerships

- The EU will explore partnerships with like-minded countries/regions to diversify the supply chain and reduce dependencies on single suppliers.