

# 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.