

# Recommendations for the finalisation of the Critical Medicines Act

12 March 2026

Cancer remains a major public health challenge in the European Union (EU). With 2.7 million new cases annually, it is the second leading cause of death and is projected to become the leading cause by 2035 [1].

Scientific progress has expanded the availability of oncology medicines, enabling patients to live longer and with improved quality of life. However, access to these medicines remains highly unequal across the EU. For example, while patients in Germany had access to 54 of the 56 oncology medicines approved in the EU between 2020 and 2023, patients in Malta could access only two [2].

Shortages of cancer medicines further exacerbate these inequalities. Many oncology medicines have a narrow therapeutic window, meaning they cannot easily be substituted. Cancer medicines are among the therapeutic classes most affected by shortages, which can seriously disrupt treatment and compromise patient outcomes [3–5].

The [Association of European Cancer Leagues \(ECL\)](#), a non-profit organisation bringing together 35 national and regional cancer leagues, together with the [European Fair Pricing Network \(EFPN\)](#), welcomes the proposed [Critical Medicines Act](#). If well-crafted, this initiative has the potential to significantly improve the availability of critical medicines, of which one in five is an oncology medicinal product [6], and to strengthen access to other cancer medicines where market failures occur.

To ensure that the legislation effectively addresses shortages and access inequalities, we propose the following recommendations for the finalisation of the legislative text.

## Strategic objective of the Union (Article 4)

ECL and EFPN support the inclusion of **affordability of critical medicines and medicines of common interest** among the strategic objectives of the Union.

Affordability is essential to ensure **equitable access to essential medicines across all Member States** and should be clearly reflected in the final text.

## Financial support for strategic projects by Member States (Article 15)

We support provisions allowing Member States to designate **strategic projects aimed at creating, expanding, or modernising manufacturing capacity within the EU.**

The final legislation should maintain **binding obligations for project promoters receiving public funding** to:

- ensure **EU-wide availability and affordability** of supported medicines, and
- guarantee **transparency in the use of public funding.**

Provisions allowing the **suspension, revocation, or recovery of financial support**, as well as the **imposition of financial penalties in cases of non-compliance**, should be retained in the final text.

## Union financial support for strategic projects (Article 16)

ECL and EFPN support the provision of **dedicated EU funding for strategic projects beyond existing budget envelopes.**

This is necessary to **avoid concentration of reshored manufacturing capacity in Member States with greater fiscal capacity or established pharmaceutical industries.**

Beneficiaries of Union funding should also be required to:

- **prioritise supply to the Union market**, and
- ensure that the supported medicinal product **remains available in all EU countries where it is marketed.**

The legislation should also include provisions allowing **suspension, revocation, or recovery of provided funding, as well as financial penalties** where beneficiaries fail to comply with these obligations.

## Contingency stocks and stockpiling (Article 20)

National requirements for contingency stocks can create **unintended spillover effects**, particularly for **smaller Member States**, by disrupting supply flows.

The final legislation should therefore provide for **Union-level guidelines on contingency stocks and national stockpiles**, including **maximum quantitative thresholds.**

This would help ensure **coherent stockpiling practices, minimise market distortions, and protect equitable access across Member States.**

## **Union coordination mechanism for critical medicinal products (Articles 20a (new), 20b (new) and 20h (new))**

ECL and EFPN support the establishment of a **Union coordination mechanism** to monitor the availability and distribution of critical medicines.

This mechanism should enable the **equitable redistribution of medicines as a last-resort measure** in situations where shortages or supply disruptions affect multiple Member States.

We also support the **creation of a Union stockpile**, to be activated when the Union coordination mechanism identifies **persistent or recurrent shortages across national contingency stocks and stockpiles.**

## **Collaborative procurement (Articles 21–24)**

Evidence shows that **European hospitals pay significantly different prices for the same oncology medicines.** A recent EFPN study found that prices can vary by **up to €3,961 (183%) for the same medicine**, both between countries and between hospitals within the same country. Importantly, **countries with lower purchasing power often face higher prices**, despite having more limited resources [7].

These disparities are largely driven by **price confidentiality**, which prevents hospitals and national authorities from comparing prices and weakens their negotiating position.

Strengthened **collaborative procurement mechanisms** could help:

- **reduce price disparities,**
- **improve affordability,**
- **increase the attractiveness of smaller markets, and**
- **facilitate equitable access to medicines across the EU.**

ECL and EFPN therefore support stronger provisions on collaborative procurement in the final legislation.

### **Commission facilitated Member States' cross-border procurement (Article 21)**

ECL and EFPN support provisions allowing the **European Commission to facilitate cross-border procurement procedures until the delivery of the medicinal products.**

We also support **extending participation to candidate countries** where appropriate.

### **Commission procurement on behalf of or in the name of Member States (Article 22)**

We support **lowering the threshold for Member States requesting Commission-led procurement from nine to five**, where such procedures aim to:

- improve **affordability of critical medicines**, and
- ensure **affordability of medicines of common interest**.

Participation of **candidate countries** should also be made possible.

### **Joint Procurement (Article 23)**

Similarly, ECL and EFPN support **lowering the threshold for joint procurement from nine to five participating Member States**, where such procurement contributes to improved affordability and access.

Participation of **candidate countries** should also be allowed.

## **Critical Medicines Coordination Group (Articles 25 and 26)**

We support strengthening the **governance, transparency, and inclusiveness** of the **Critical Medicines Coordination Group (CMCG)**. The final legislation should:

- include **representatives of patient organisations and healthcare professionals** in the group, and
- require members to **declare financial and other interests**, ensuring transparency and independence.

Including patient and clinical perspectives will help ensure that the group's work **reflects real-world treatment needs**.

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The **Association of European Cancer Leagues (ECL)** is a non-profit umbrella organisation bringing together 35 national and regional cancer leagues advocating for improved cancer control and care across Europe. Our vision is a Europe free of cancer.

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EU Transparency Register Number: 19265592757-25



The **European Fair Pricing Network (EFPN)** aims to achieve fair prices for cancer medicines and, more broadly, work towards a pharmaceutical market which produces accessible and truly innovative medicines for patients.

The network represents the Association of European Cancer Leagues (ECL), the Cyprus Association of Cancer Patients and Friends, the Dutch Cancer Society, the Netherlands Cancer Institute, the Nordic Cancer Union, the Norwegian Cancer Society, the Organisation of European Cancer Institutes (OEI), Stand Up To Cancer Flanders, and the Swiss Cancer League.

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