ECL and EFPN recommendations for the EU pharma package trilogue

23 September 2025

Each year, approximately 2.7 million people are diagnosed with cancer in Europe – and this number is expected to grow [1].

Despite the medical and technological developments that have resulted in a growing number of cancer medicines being available on the market, many patients still face unmet medical needs. For these cancer patients, targeted treatments are either unavailable or limited.

Moreover, not every patient automatically benefits from innovative treatments, because medicines are unaffordable or simply not available in their country of residence. For example, between 2020 and 2023, cancer patients in Germany had access to 54 out of 56 EU-authorised medicines, while patients in Malta could only access two [2]. The result is deepened inequalities across Europe.

Negotiators representing the European Parliament and the Council of the European Union have an opportunity to make the EU pharmaceutical framework, which includes the EU Pharma Directive and the EU Pharma Regulation, more patient-centred by addressing these unmet medical needs and ensuring availability and timely access to safe, effective, and affordable medicines for all patients in need. We call on them to make the most of this opportunity, and to that end, we share our views on how this can be achieved.

EU Pharma Directive

Hospital Exemption (Article 2)

The hospital exemption (HE) plays a crucial role in ensuring timely access to safe, effective, and affordable advanced therapy medicinal products (ATMPs), particularly in cases of unmet medical needs where the pharmaceutical industry is unwilling to invest in developing treatments due to limited return on investment.

To harmonise the application of HE across Europe and ensure better visibility on all available treatments prepared under the HE, EU legislators should include a requirement to **publicly disclose information on the authorisation, suspension or withdrawal of hospital exemption approvals** as provided in the European Parliament's position.

In addition, **cross-border exchange of treatments prepared under HE should be allowed** as proposed by the Parliament, as this guarantees EU-wide patient access.

Finally, we call on the co-legislators to ensure that a **support mechanism for academic or non-profit developers is put in place, enabling them to comply with regulatory requirements** when bringing ATMPs from HE to market authorisation, in line with Recital 18(a) proposed by the Parliament.

Transparency on R&D costs (Article 57)

Currently, pharmaceutical companies are not obliged to declare any direct or indirect financial funding from public authorities or not-for-profit organisations that supported the development of innovative cancer treatments. This leaves national authorities in the dark about the true costs behind a medicine when entering negotiations about the price of new treatments.

In line with the Parliament's position, there should be an obligation for companies to publicly declare any **direct or indirect financial support received from public authorities and not-for-profit organisations for the research and development (R&D) of new cancer treatments**. Such information, when provided in an accessible, full, and timely manner, can help national authorities in price negotiations and improve sustainability of health systems without threatening R&D investments [3].

Regulatory data and market protection (Articles 80 and 81)

We call on the co-legislators to **reduce the baseline regulatory data protection (RDP) period**, currently set at eight years, to allow for earlier entry of generics and biosimilars into the market. Doing so would save European health systems approximately €1.13 billion annually [4].

In addition, a **modulated system of incentives** should be set up allowing additional periods of RDP to reward efforts from the European pharmaceutical sector that bring high societal and healthcare value, **with a cap of eight years**.

Finally, **the availability and affordability of medicines in all EU countries should be improved by obliging companies to supply medicines upon the request of individual EU member states**, so that the needs of patients in that country are met as provided in the Council's position (Article 56a as well as Article 5a in the EU Pharma Regulation). We also recommend that a reporting mechanism on access to medicinal products is put in place as per Parliament's suggested Article 86a.

This approach would help strike a fair balance between supporting pharmaceutical innovation that meets societal needs and promoting affordable access for patients in Europe, as well as sustainable healthcare systems.

EU Pharma Regulation

Repurposing (Article 48)

The repurposing of existing medicinal products can expand access in an affordable manner, providing significant benefits to cancer patients. Currently, many hospitals generate evidence on new indications for existing medicines, but patients are left without access because manufacturers are unwilling to submit the corresponding marketing authorisation applications. Therefore, we support the co-legislators' proposal to **allow the submission of evidence by not-for-profit entities for all indications** without limiting the repurposing to the areas of unmet medical need.

Joint procurement (Article 73a)

We strongly support mandating the European Commission to facilitate **joint procurement of centrally authorised medicinal products** on the member states' behalf, upon their request, as provided in the Parliament's position (Article 73a). Joint procurement can help achieve lower prices and make small markets attractive for suppliers, offsetting current inequalities among EU member states and tackling shortages. It can also guarantee equitable access to new medicines with proven added value in all European countries.

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References

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ECL
Association of European Cancer Leagues

The **Association of European Cancer Leagues (ECL)** is a non-profit umbrella organisation made up of 34 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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EFPN
EUROPEAN FAIR PRICING NETWORK

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 (OECI), Stand Up To Cancer Flanders, and the Swiss Cancer League.

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