ECL recommendations for the European Biotech Act

30 June 2026

Cancer is the second cause of death in the European Union (EU) although in several countries such as Belgium, Denmark, France, the Netherlands and Spain, it has already surpassed cardiovascular diseases [1] and is set to become the leading cause of death in the EU by 2035 [2].

Biotechnologies are revolutionising cancer treatment making it possible for cancer patients to live longer with a better quality of life. For example:

- **Monoclonal antibodies (mAbs)** can block cancer growth signals, mark cancer cells for immune destruction, or deliver toxic substances directly to tumours.
- **Immune checkpoint inhibitors** allow T cells to recognise and attack cancer cells.
- **CAR-T cell therapy** returns modified cells to the patient, where they act as a personalised living therapy.
- **Cancer vaccines** prevent HPV-related cancers such as cervical cancer or treats existing cancers.
- **Antibody-drug conjugates (ADCs)** deliver the drug specifically to cancer cells, reducing damage to healthy tissue.

The Association of European Cancer Leagues (ECL), a non-profit organisation bringing together 35 national and regional cancer leagues welcomes the proposed European Biotech Act. If well-crafted, this initiative has the potential to significantly improve cancer patients access to safe, effective, high-quality and affordable biotechnology products, including advanced therapies and biosimilars. To that end, we provide our recommendations how certain areas of the draft Regulation could be improved below.

Health biotechnology strategic projects (Article 3)

Health biotechnology innovation contributes not only to the Union's industrial competitiveness but also to **public health**, **patient wellbeing** and the **sustainability of healthcare systems**.

Many innovations originating from **publicly funded research institutions** generate substantial societal value but fail to reach patients and healthcare systems because return on investment is not sufficient to support their further development, validation, implementation or maintenance. This is especially true for innovations addressing rare cancers and other small patient populations, where expected returns do not justify the required investment, resulting in a lack of new treatment development.

Therefore, health biotechnology strategic projects should also encompass **projects that primarily create societal value** by facilitating the translation, implementation, accessibility and long-term uptake of health biotechnology innovations.

Text proposed by the Commission	Amendment
Article 3 – paragraph 1 – point f (new)	
	(f) contributing to improving public health outcomes, healthcare quality and patient access within the Union, in particular where low return on investment is foreseen, through one or more of the following activities: ***(i) Improving accessibility, affordability, availability and equitable use of health biotechnology innovations, particularly for patients with unmet medical needs, rare diseases or limited commercial market potential;*** ***(ii) developing, validating, implementing, scaling up or maintaining non-commercial or social-profit health biotechnology innovations;*** ***(iii) supporting the translation of publicly funded research results into clinical practice, public health policies or healthcare services where no sufficient commercial incentive exists to ensure implementation;*** ***(iv) establishing, expanding or coordinating infrastructures, services or support structures that facilitate the societal uptake, dissemination, implementation and long-term maintenance of research-based innovations in healthcare systems;*** ***(v) supporting the regulatory, methodological, clinical or organisational activities necessary to enable the further development and implementation of academically developed health biotechnology products, services or interventions that provide significant societal benefit.***

Financial and technical support (Article 14)

To ensure appropriate public return on investment, **provision of public funding** to health biotechnology strategic projects needs to be tied to **access and affordability obligations**.

In addition, **transparency in the use of public funding** must be guaranteed. Without visibility on the public contribution to the development and production of health biotechnology products, it is impossible for public authorities, health technology assessment bodies, payers, and patients to assess whether the pricing or terms of access to the resulting products are proportionate to the price paid by taxpayers. Transparency on public investment in medicines is a necessary condition for accountability and for ensuring that publicly supported products are priced and made available in a manner proportionate to their public funding.

Finally, the Regulation should include clear provisions allowing for suspension, revocation, or recovery of financial support received in case of **non-compliance**. Without such **corrective measures**, access and affordability obligations risk remaining aspirational.

Text proposed by the Commission	Amendment
Article 14 – paragraph 1 – subparagraph 2 (new)	
	Where public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions.
Article 14 – paragraph 1 – subparagraph 3 (new)	
	Projects receiving public funding or recognised as health biotechnology strategic projects or high impact health biotechnology strategic projects under this Regulation shall comply with appropriate transparency requirements. Such requirements shall include, as a minimum,

	the disclosure to the Commission of information on the total amount of public support received from Union and national sources, and on research and development costs fully or partially covered by public funds. Contracting authorities and national authorities responsible for pricing and reimbursement may require beneficiaries to provide audited information on research and development, production and distribution costs associated with the resulting products.
Article 14 – paragraph 1 – subparagraph 4 (new)	
	Non-compliance with the obligations set out in this paragraph by an undertaking that has received financial support for a health biotechnology strategic project may result in appropriate penalties, including the suspension, revocation, or recovery — in full or in part — of the financial support granted, particularly in cases where the undertaking fails to ensure the availability or affordability of the resulting products in the Member States.

Extension of the supplementary protection certificate (Article 27)

A 12-month extension of the **Supplementary Protection Certificate** (SPC) can create additional **barriers to access**. This would delay the arrival of cheaper generic and biosimilar alternatives on the market, undermining the balance between innovation and affordability attained in the revision of the European pharmaceutical legislation and leading to **higher costs for health systems**, which already face unprecedented price pressure.

In addition, data shows that the SPC had a limited effect in tackling the objective of attracting R&D to the EU and preventing delocalisation [3].

To ensure access to affordable innovation, **ECL recommends removing the extension of the SPC** from the draft Regulation.

Incentives to manufacturers should not come at the cost of affordable innovative medicines, especially if their development has been enabled through European taxpayers' money. Instead, they should be targeted, time-limited and linked to unmet medical need.

Text proposed by the Commission	Amendment
Article 27	
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council [...]	***deleted***

Revision of the Clinical Trials Regulation (Article 58)

A central part of the clinical trial authorisation process is the **Clinical Trials Information System (CTIS)**. While a single point of entry for clinical trials applications is a positive development and the system has improved substantially since its inception, the system is at times cumbersome and requires redundant inputs in multiple places. **The CTIS should be more user friendly and less burdensome to use**. The iterative process that has been applied thus far has been focussed on technical bugs as well as adding further functionality, but the emphasis should be on **streamlining the core CTIS application**.

Text proposed by the Commission	Amendment
Article 58 – paragraph 1 – point 44 – point a	
2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and	2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and

Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.	Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency. ***The Agency is instructed to conduct a review of the database, with particular emphasis on streamlining its core functionality to make it more user-friendly, in close consultation with all affected stakeholders, and to make adjustments to the database as deemed necessary upon completion of the review, but no later than 30 June 2028.***

We welcome **shortened timelines for regulatory approval of clinical trials**, including removal of an extra 50-day assessment period for ATMP clinical trial applications. This can accelerate patients‘ access to trials and innovative treatments. However, the impact of these shortened timelines on regulatory agencies and the effectiveness of their oversight should be monitored and evaluated.

Text proposed by the Commission	**Amendment**
Article 58 – paragraph 1 – point 49 – point a	
Five years after the date referred to in Article 99, second subparagraph, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an	Five years after the date referred to in Article 99, second subparagraph, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an

assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025; The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.	assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, ***the impact of the changes to regulatory approval timelines as set out in Article 58 on the effectiveness of regulatory oversight*** and the measures required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025; The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.

ECL encourages co-legislators to ensure that the European Biotech Act strenghtens Europe‘s innovation capacity while delivering befefits for cancer patients and healthcare systems.

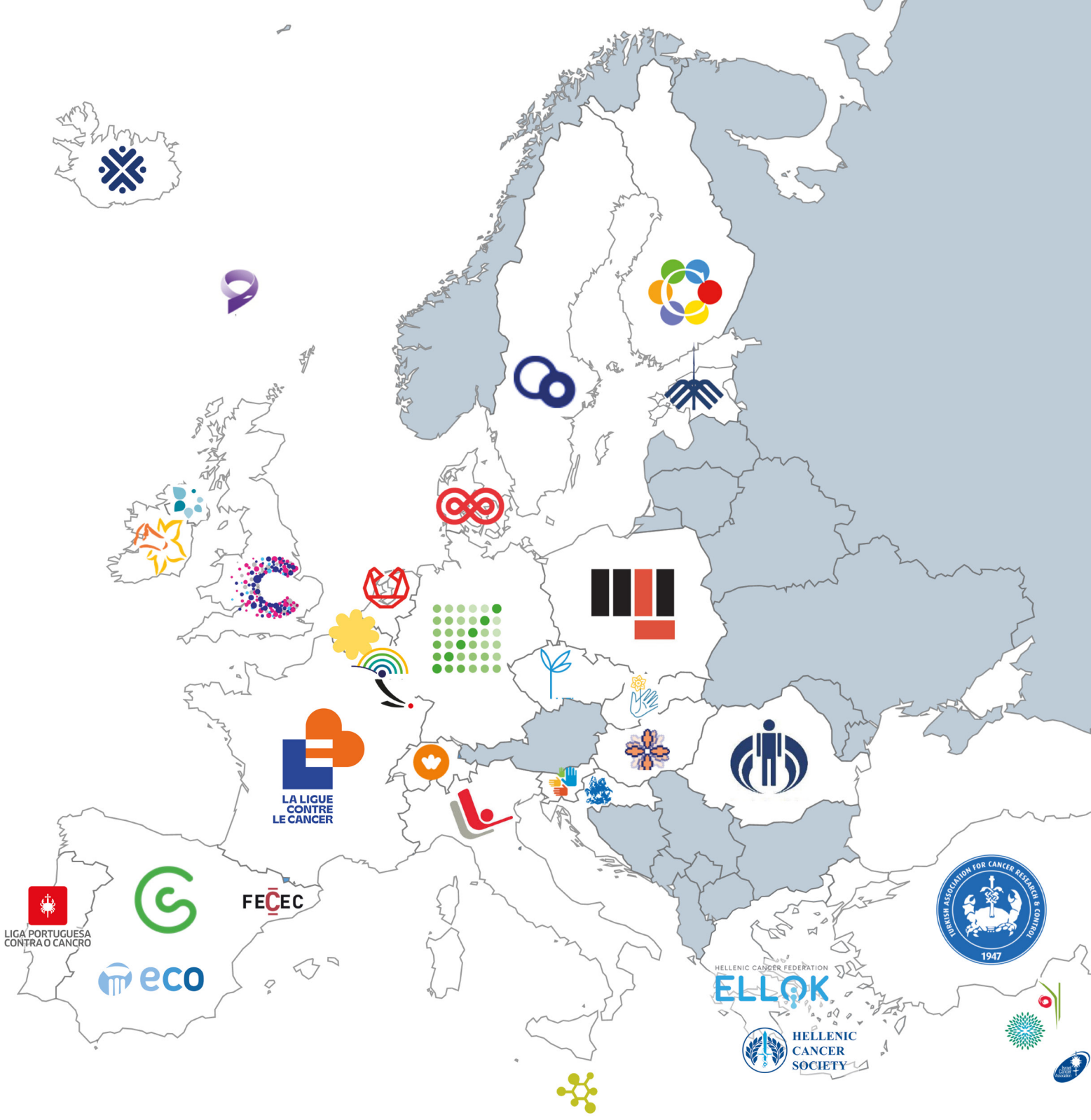
Contact: Toma Mikalauskaitė, Head of Policy at the Association of European Cancer Leagues (ECL), toma@cancer.eu

References:

1. OECD/European Commission (2024), *Health at a Glance: Europe 2024: State of Health in the EU Cycle*, OECD Publishing, Paris, https://doi.org/10.1787/b3704e14-en.

2. OECD (2024), *Beating Cancer Inequalities in the EU: Spotlight on Cancer Prevention and Early Detection*, OECD Health Policy Studies, OECD Publishing, Paris, https://doi.org/10.1787/14fdc89a-en.

3. COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.



Association of European Cancer Leagues (ECL)
Chaussée de Louvain 479, 1030 Brussels

+32 2 256 2000 ECL@cancer.eu
www.cancer.eu @cancerleagues

EU Transparency Register Number: 19265592757-25