ECL recommendations for the finalisation of the European Parliament's position on the European Biotech Act

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The Association of European Cancer Leagues (ECL), a non-profit organisation bringing together 35 national and regional cancer leagues, appreciates the efforts of Members of the European Parliament to improve 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.

We provide our recommendations for finalisation of the European Parliament SANT and ITRE Committees' report on the European Biotech Act below.

Health biotechnology strategic projects (Article 3)

European Cancer Leagues strongly support amendments **1367** and **1368** because they would ensure that the European Biotech Act addresses patients' needs where commercial incentives alone may be insufficient.

The amendments explicitly promote accessibility, affordability and equitable use of health biotechnology innovations, with particular attention to unmet medical needs, rare diseases and areas with limited commercial potential. They also support translating publicly funded research into clinical practice and maintaining the infrastructure needed to bring research-based innovations into healthcare.

Financial and technical support (Article 14)

We endorse amendments **1700**, **1703 – 1707**, **1709 – 1710** because public investment in health biotechnology should deliver a clear public and patient return.

Where public money supports strategic biotechnology projects, the resulting products and services should be affordable, available and accessible to patients under fair and reasonable conditions. Transparency on public funding and R&D, production and distribution costs is essential to enable public authorities and payers to assess the public contribution and make informed pricing and reimbursement decisions. Finally, access and affordability commitments need meaningful enforcement; otherwise, they risk remaining aspirational.

This is particularly important for cancer patients, for whom biotechnology is already transforming treatment but whose access to innovative therapies remains unequal across Europe.

Cross-border infrastructure and patient access (Article 15 a (new))

ECL supports amendment **115** as it connects Europe's biotechnology ambitions more directly to cross-border research collaboration and patient benefit. By enabling high-impact projects to develop interoperable rare-disease registries, genomic data repositories and biobanks in cooperation with European Reference Networks (ERNs), it could help overcome fragmentation and strengthen research collaboration. Its focus on clearer pathways to clinical trials and authorised treatments also recognises that innovation delivers its full value only when patients can access it.

Extension of the supplementary protection certificate (Article 27)

We strongly support amendments **2048 – 2051**, **2053 – 2056** and **2059** that remove the proposed 12-month extension of Supplementary Protection Certificates (SPCs) because extending market exclusivity risks delaying the entry of more affordable and more broadly available biosimilars, increasing medicine expenditure for patients and already financially pressured healthcare systems.

The measure also needs to be considered against the evidence on whether longer SPC protection effectively attracts R&D and manufacturing to Europe. The Commission's evaluation of the existing SPC framework found that SPCs had limited effect in attracting R&D to the EU and preventing its relocation, with the location of pharmaceutical innovation influenced by a much wider range of factors, including skills, research infrastructure and public and private funding [1].

Therefore, the Biotech Act should prioritise targeted, time-limited incentives linked to genuine unmet medical needs, rather than extending exclusivity across eligible products. This would better balance the objective of supporting biotechnology innovation with the equally important objective of ensuring timely, affordable access to innovative cancer medicines, including biosimilars.

Revision of the Advanced Therapy Medicinal Products Regulation (Article 57)

ECL endorses amendment **263** because it strengthens the role of ERNs in the delivery and follow-up of advanced therapy medicinal products (ATMPs) for patients with rare, ultra-rare and complex cancers. By enabling qualified ERN-associated healthcare providers to serve as preferred sites for administration, patient monitoring, safety reporting and long-term follow-up, it can improve continuity of care and facilitate cross-border access to specialist expertise. Explicit eligibility for multinational clinical trials and post-authorisation evidence generation would also support the collection of evidence in areas where patient populations are small, and expertise is concentrated in specialised centres.

Revision of the Clinical Trials Regulation (Article 58)

ECL supports mendment **958** because it promotes faster and more equitable patient access to innovative treatments by avoiding unnecessary duplication of clinical trials. Where clinical trials conducted in highly regulated third countries meet ethical and scientific standards equivalent to those required in the EU, their data should be

recognised and used, provided it is relevant to the European population. Requiring unnecessary repetition of such trials within the EU can delay access to potentially life-changing treatments, increase development costs and place an avoidable burden on clinical trial participants.

Faster access to clinical trials

We support amendments **285 – 288**, **291**, **296**, **297**, **303**, **306**, **308** and **311** as they streamline and shorten the clinical trial authorisation process, improve coordination and predictability between Member States, and reduce unnecessary delays.

In addition, ECL strongly supports amendment **335** introducing an accelerated and coordinated authorisation procedure for multinational clinical trials, including trials for rare and ultra-rare diseases, orphan medicinal products, paediatric conditions, ATMPs and critical medicines.

Finaly, we support amendments **389** and **390** as they bring the new clinical trial provisions into application sooner, allowing the benefits of a faster and more streamlined authorisation process to reach patients and clinical trial sponsors earlier.

However, the impact of these shortened timelines on regulatory agencies and the effectiveness of their oversight should be monitored and evaluated as per amendment **2904**.

Reducing duplication and improving site start-up

We support amendments **302**, **304**, **305**, **307**, **358** and **359** reducing duplication between EU-level, national and local assessment. These amendments would help avoid situations where issues already assessed centrally are reopened at national or local level. This is important to give hospitals and participating centres greater legal and administrative comfort to run feasibility, contracting, pharmacy and governance processes in parallel rather than sequentially.

Amendments **2752** and **2753** on site-contracting and budgeting templates can further reduce delays between approval and site activation.

Predictable requirements for investigational medicinal products

ECL supports amendments **2758 – 2764**, **2767 – 2769** and **2772** because they strengthen the consistency, predictability and efficiency of the EU framework for investigational medicinal product core dossiers. By establishing the European Medicines Agency as the central depositary, coordinating dossier verification and updates, and clarifying the conditions for cross-sponsor use, the amendments provide a more coherent basis for the reuse of regulatory information across corresponding clinical trials. They can help reduce unnecessary administrative duplication, facilitate multinational clinical research and improve regulatory predictability for complex cancer trials, including ATMP and cell-therapy studies.

In addition, we endorse amendment **2833** supporting distance delivery of investigational medicines where safeguards for storage, traceability, pharmacy oversight and patient advice are ensured.

Academic, pragmatic and combined studies

We support amendments **369** and **2525** to strengthen academic, hospital-led and pragmatic studies. These amendments support proportionate rules for minimal- and low-intervention trials and address reimbursement barriers for standard-of-care treatments.

In addition, amendments **336 – 339**, **2678** and **2680** establish a more coherent and consistent framework for assessing multinational combined studies involving medicines, devices, IVDs or companion diagnostics. By strengthening the role of the Clinical Trials Expert Committee in coordinated assessment and making its conclusion the common reference point for the Member States concerned, the amendments can reduce divergent assessments, unnecessary duplication and regulatory uncertainty for multidisciplinary oncology studies.

Cross-border trial access

ECL supports amendment **2880** as it strengthens the role of the Clinical Trials Coordination and Advisory Group in promoting equitable access to multinational clinical trials through practical recommendations on cross-border participation in clinical trials.

Clinical Trials Information System

A central part of the clinical trial authorisation process is the Clinical Trials Information System (CTIS). While a single point of entry for clinical trial 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 focused on technical bugs as well as adding further functionality, but the emphasis should be on streamlining the core CTIS application. Therefore, we support amendment **2846**.

ECL encourages Members of the European Parliament to ensure that the European Biotech Act strengthens Europe's innovation capacity while delivering benefits for cancer patients and healthcare systems.

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References:

1. European Commission, Evaluation of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products and Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products, SWD(2020) 292 final.