16 June 2026

European Biotech Act Must Deliver Public-Interest Innovation and Equitable Access

As the EU co-legislators shape their respective positions on the European Biotech Act,[1] we, the undersigned organisations advocating for improved access to medical tools and healthcare, urge members of the European Parliament and Representatives of the Council of the European Union to ensure that the legislation strengthens the Union's biotechnology and biomanufacturing sectors while promoting innovation that is accessible and affordable in a timely manner, and responsive to public health needs.

We call on the co-legislators to reject any extension of the Supplementary Protection Certificates (SPCs), which would prolong market monopolies and delay access to more affordable medicines and other medical products. We also urge you to ensure that publicly supported strategic projects, research and innovation include binding and enforceable access commitments so that technologies developed with EU support are available and affordable to all who need them.

The justifications for these proposals are set out below, with specific draft amendments provided in the annex.

Rejecting the Extension of the Supplementary Protection Certificates

Across Europe, rising medicine prices are placing increasing pressure on public health budgets and limiting timely access to treatment. At the heart of this pressure are long periods of market exclusivity granted to pharmaceutical companies, which delay the entry of more affordable generic and biosimilar alternatives.

These exclusivities go beyond standard patent protection and are reinforced through additional mechanisms, including Supplementary Protection Certificates (SPCs).[2] As health systems face growing financial constraints, unequal access to medicines across Member States, and persistent unmet medical needs, extending SPC protection is the wrong policy response.

The market prices pharmaceutical companies charge for new medicines have increased steeply over the past decade, making many new treatments unaffordable even for high-income EU countries.[3] Further extending monopoly protections would run counter to efforts to ensure the sustainability of healthcare systems and improve access to medicines.

Evidence has highlighted the significant social costs of SPCs and questioned the assumptions used to justify the SPC regime, which includes the lack of fair opportunity to recover their R&D efforts and investments.[4] Moreover, stronger monopoly protection does not drive meaningful innovation.

---

[1] https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2025/1022/COM_COM(2025)1022_EN.pdf

[2] https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Supplementary-Protection-Certificates.pdf

[3] See e.g., https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/gkv-beitragssatzstabilisierungsgesetz

[4] https://link.springer.com/article/10.1186/s40545-019-0198-6

Instead, it can reinforce incentives to prioritise R&D for commercially attractive markets rather than areas of greatest public health need.[5]

Extending SPCs would keep medicine prices high for longer, delay competition from affordable generic and biosimilar alternatives available outside the European Union, and postpone access to treatment for those who need them. This would place additional strain on healthcare budgets and undermine equitable access to medical innovation across Europe.

We therefore urge the Biotech Act negotiators to **delete Article 27 of the European Commission's proposal and reject any extension of the SPCs.**
The EU should abolish the SPC mechanism, that is nothing but an unnecessary cost for society, which may cause avoidable suffering or deaths, and refrain from encouraging SPCs and similar mechanisms through free trade agreements.

Ensuring Public Return on Public Investment
When public funding supports the development of health biotechnology products, citizens are entitled to a return on that investment in the form of products that are affordable, available, and accessible. Yet the European Biotech Act, as proposed by the Commission, confers substantial public benefits on strategic project promoters — including priority access to finance, accelerated permitting, and regulatory support — without requiring transparency and accountability for the public support received, or attaching any corresponding obligation to ensure that the resulting products reach people who need them.

This gap must be closed. **We call on co-legislators to amend Article 14 of the Biotech Act to require that project promoters benefiting from public support ensure that resulting products are affordable, available, and accessible** in the Member States under fair and reasonable conditions. Where those products address significant public health needs in third countries, promoters should be required to submit a global access plan — covering registration targets, supply commitments, pricing approaches, intellectual property strategy, and engagement with manufacturers and development partners — consistent with established principles in EU legislation.[6]

Transparency is an essential complement to these access obligations. Without visibility on the public contribution to R&D and production costs, neither governments, health technology assessment bodies, nor people in need can judge whether the prices charged for publicly supported products are proportionate to the risk borne by taxpayers. We therefore **urge co-legislators to require beneficiaries to disclose, at a minimum, the total public support received from Union and national sources, and the share of R&D costs covered by public funds** — with the possibility for pricing and reimbursement authorities to request audited cost data.

---

[5] https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf
[6] This principle is already well established in EU legislation, for example, in Articles 114 and 125 of Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe. These articles require recipients of EU research funding to ensure that the results of their activities are affordable, available and accessible to the public under fair and reasonable conditions.

Access' commitments without enforcement are mere recommendations. The Biotech Act should provide that non-compliance with access and transparency obligations may result in the suspension, termination, or recovery of the public support granted. At the same time, the Commission should be mandated to actively support the uptake of access plans, issue implementation guidelines, and engage with international partners to facilitate access in low- and middle-income countries.

We therefore urge co-legislators to amend Articles 14, 22, and 25 of the Biotech Act, and to introduce a new Annex setting out the minimum elements of the access plan, so that public investment in health biotechnology translates into real public benefit — for people in Europe and beyond.

Signed by:

1. Association Internationale de la Mutualité (AIM)
2. Association of European Cancer Leagues (ECL)
3. BUKO Pharma-Kampagne
4. Centrale Nationale des Employés (CNE) Soins de Santé
5. European Association of Hospital Pharmacists (EAHP)
6. European Fair Pricing Network (EFPN)
7. France Assos Santé
8. Health Action International (HAI)
9. Médecins Sans Frontières (MSF)
10. Médecins du Monde International Network
11. Pharmaceutical Accountability Foundation (PAF)
12. People's Health Movement (PHM)
13. Salud por Derecho
14. TB Europe Coalition (TBEC)
15. Wemos

16 June 2026

Annex

AMENDMENTS – SPC extension, global access, access plans, transparency

Proposal for a regulation

(COM(2025) 1022 final – 2025/0406(COD))

Establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health (European Biotech Act)

Amendment 1

Recital 60

Text proposed by the Commission	**Amendment**
(60) Biosimilars can play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.	(60) Biosimilars can play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. ***In this regard, the Union's action in the field of health biotechnology shall be consistent with its commitments to sustainable development and global health, in particular the objectives set out in Article 208 of the Treaty on the Functioning of the European Union, the United Nations Sustainable Development Goals, and the EU Global Health Strategy.*** Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters**, including, where relevant, through voluntary licensing arrangements and technology transfer measures to facilitate access to biosimilar products in low- and middle-income countries, in line with the Team Europe MAV+ initiative**.

Or. en

Justification

This recital establishes the interpretative framework for the global access dimension of this Regulation. Article 208 TFEU requires that all Union policies take into account the objectives of development cooperation — a principle of policy coherence that applies equally to industrial and biotechnology policy. Without such a recital, the Biotech Act risks being read as exclusively oriented towards internal industrial objectives, in tension with the Union's broader treaty obligations and its Global Health Strategy commitments.

Amendment 2

Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	**Amendment**
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law***, including, where the project has received public funding and the resulting products address significant public health needs, non-exclusive licensing arrangements or other measures to facilitate access to such products in low- and middle-income countries, including through development partners or voluntary licensing;***

Or. en

Justification

Article 3(c)(iii) already recognises technology transfer and collaboration with third-country facilities as a legitimate objective of a health biotechnology strategic project. The proposed addition extends that logic to include, where relevant, measures facilitating access to publicly supported products in low- and middle-income countries (LMICs).

This is consistent with the EU Global Health Strategy and with Article 208 TFEU, as reflected in the new recital introduced by Amendment 1. The amendment is narrowly targeted: it applies only where the project has received public funding and the resulting products address significant public health needs. It does not mandate specific terms but opens the possibility of non-exclusive

licensing and collaboration with development partners — the model operationalised by mechanisms such as the Medicines Patent Pool — as a recognised objective of strategic projects with an international dimension.

Amendment 3

Article 14

Text proposed by the Commission	Amendment
Article 14 – paragraph 1 – subparagraph 2 (new)	
1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.	1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules. ***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. Where the resulting products address significant public health needs in third countries in critical need, project promoters shall submit a global access plan to supply***

	those countries, including through development partners or voluntary licensing. The minimum elements of the access plan are set out in Annex [IV].
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, termination, 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.

Article 14 – paragraph 3 – point d (new)	
3. The Commission, in cooperation with the Member States and, where appropriate, with the Steering Group referred to in Article 20, shall take the following measures to support the implementation of health biotechnology strategic projects and of high impact health biotechnology strategic projects, including through the EU Health Biotechnology Support Network referred to in Article 19: (a) support project promoters in identifying funding opportunities at Union level, and facilitate the liaison between project promoters and investors; (b) promote actions that strengthen the biotechnology innovation ecosystem; (c) facilitating access, in particular for SMEs, to relevant research and technological infrastructures, including where such infrastructures are funded through Union funding programmes, funds and financial instruments.	3. The Commission, in cooperation with the Member States and, where appropriate, with the Steering Group referred to in Article 20, shall take the following measures to support the implementation of health biotechnology strategic projects and of high impact health biotechnology strategic projects, including through the EU Health Biotechnology Support Network referred to in Article 19: (a) support project promoters in identifying funding opportunities at Union level, and facilitate the liaison between project promoters and investors; (b) promote actions that strengthen the biotechnology innovation ecosystem; (c) facilitating access, in particular for SMEs, to relevant research and technological infrastructures, including where such infrastructures are funded through Union funding programmes, funds and financial instruments; ***(d) promote equitable access to the health biotechnology products and services resulting from supported activities, including by facilitating the uptake of access plans submitted pursuant to paragraph 1, issuing guidelines on their content and implementation, and, where relevant, supporting engagement with international partners and development organisations to facilitate access to such products in low- and middle-income countries.***

Or. en

Justification

Article 14 – paragraph 1 – subparagraph 2 (new)

Article 14 governs financial and technical support to strategic projects but establishes no counterpart obligation on project promoters regarding the accessibility or affordability of resulting

products. The first addition fills that gap using wording that directly mirrors Articles 114 and 125 of Council Regulation (EU) 2021/2085 on Joint Undertakings, under which beneficiaries of EU-funded health research — including the Global Health EDCTP3 Joint Undertaking — are already required to ensure that resulting products are affordable, available and accessible under fair and reasonable conditions.

The global access plan requirement follows the approach established in the Critical Medicines Act, where joint procurement conditions include the submission of a global access plan to supply third countries in critical need, including through development partners or voluntary licensing. It is also consistent with the Stewardship and Access Plan framework applied by CARB-X, the global non-profit partnership funded by BARDA, the UK Government, Wellcome Trust and the Bill & Melinda Gates Foundation, which requires all funded product developers to include strategies for access in territories where they do not intend to market the product.

The two obligations are proportionate and complementary: the first ensures internal access within the Union; the second ensures that public investment also contributes to global health equity, consistent with Article 208 TFEU and the EU Global Health Strategy. The minimum elements of the access plan are set out in the new Annex [IV] introduced by Amendment 6.

Justification

Article 14 – paragraph 1 – subparagraph 3 (new)

This amendment introduces a transparency obligation as a counterpart to the public benefits conferred by recognition as a strategic project or high impact project under this Regulation. 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 risk borne 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.

Justification

Article 14 – paragraph 1 – subparagraph 4 (new)

The non-compliance subparagraph provides the enforcement mechanism without which the access obligations risk remaining aspirational. Access commitments without consequences for breach are not meaningful conditionalities; they are recommendations. The penalties foreseen — suspension, termination, or recovery of support — are proportionate and standard across Union funding instruments.

Justification

Article 14 – paragraph 3 – point d (new)

Article 14(3) establishes a series of positive obligations on the Commission to actively support the implementation of strategic projects, currently focused exclusively on competitiveness and ecosystem-building measures. The proposed addition of point (d) introduces equitable access as an equally legitimate objective of the Commission's supporting role, consistent with the access obligations placed on project promoters under paragraph 1.

The point has three components that follow naturally from the existing architecture of the Regulation. First, facilitating the uptake of access plans connects the Commission's institutional role to the operative obligation in paragraph 1: the Commission does not merely receive access plans passively but actively supports their implementation. Second, issuing guidelines on content and implementation of access plans is the natural counterpart to the Annex [IV] requirement and the mandate already implicit in paragraph 1; making it explicit in paragraph 3 gives it a clear legal basis. Third, supporting engagement with international partners and development organisations — such as the Medicines Patent Pool, GARDP, and GAVI — to facilitate access in LMICs gives institutional expression to the global access dimension established in the new recital and in Article 3(c)(iii), without creating mandatory licensing obligations on promoters.

This structure is consistent with the approach of the Global Health EDCTP3 Joint Undertaking, under which the granting authority actively monitors and supports compliance with access obligations throughout the project lifecycle, including through annual reporting requirements.

Amendment 4

Article 22 – paragraph 4 – point h (new)

Text proposed by the Commission	**Amendment**
4. The pilot shall pursue the following objectives: (a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity; (b) provide support to projects, SMEs, including start-ups and scale-ups, and mid-caps across the Union;	4. The pilot shall pursue the following objectives: (a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity; (b) provide support to projects, SMEs, including start-ups and scale-ups, and mid-caps across the Union;

(c) finance late-stage development initiatives, industrial scale-up and production capacity build-up;	(c) finance late-stage development initiatives, industrial scale-up and production capacity build-up;
(d) anchor growth and manufacturing activities in the Union in order to gain or maintain strategic autonomy and resilience;	(d) anchor growth and manufacturing activities in the Union in order to gain or maintain strategic autonomy and resilience;
(e) mobilise private investments, including from institutional investors such as pension funds;	(e) mobilise private investments, including from institutional investors such as pension funds;
(f) assist early and growth-stage companies through blended and concessional finance;	(f) assist early and growth-stage companies through blended and concessional finance;
(g) provide advisory support throughout the investment cycle.	(g) provide advisory support throughout the investment cycle;
	(h) ensure availability of Union medicinal products, medical devices and medical countermeasures that are innovative, safe, accessible, available and affordable, thereby promoting equitable access, in accordance with the obligations laid down in Article 14(1).

Or. en

Justification

Article 22 establishes the EU Health Biotechnology Investment Pilot, the central financing instrument of this Regulation. Its objectives in paragraph 4 are framed exclusively in terms of industrial competitiveness and capital mobilisation, with no reference to access or affordability of the resulting products.

The proposed new point (h) introduces access and affordability as an explicit objective of the pilot, using language drawn from the ECF Regulation (art. 37.1.c), which already establishes as an objective of Union support the fostering of health technologies that are 'innovative, safe, accessible, available and affordable, thereby promoting equitable access.' This formulation establishes the principle without creating a standalone obligation in this Article. The operative access obligation — including the access plan — is established in Article 14(1), to which point (h) explicitly refers.

Amendment 5

Article 25 – paragraph 5 (new)

Text proposed by the Commission	Amendment
1. High impact health biotechnology strategic projects may be given particular consideration for financial support under Union funds, programmes and instruments in accordance with the objectives set out in the regulations establishing those funds, programmes and instruments.	1. High impact health biotechnology strategic projects may be given particular consideration for financial support under Union funds, programmes and instruments in accordance with the objectives set out in the regulations establishing those funds, programmes and instruments.
[…]	[…]
4. The Commission shall ensure the coordination and the complementarity among the relevant Union funds, programmes and instruments that support actions under this Regulation.	4. The Commission shall ensure the coordination and the complementarity among the relevant Union funds, programmes and instruments that support actions under this Regulation.
	5. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).

Or. en

Justification

Article 25 establishes that high impact health biotechnology strategic projects may receive priority consideration for Union financial support, but contains no provision ensuring that such support is accompanied by corresponding access commitments. The proposed paragraph 5 addresses this gap through a concise cross-reference to Article 14(1), which establishes the operative access obligation and the access plan requirement.

This approach avoids repetition: rather than reproducing the access plan requirements in each article dealing with financial support, the Regulation establishes a single normative anchor in Article 14(1) and requires consistency with it across all instruments. This is consistent with good

legislative drafting practice and reflects the architecture already used in the Regulation for other cross-cutting obligations.

Amendment 6

Article 27

Text proposed by the Commission	Amendment
Article 27 Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union 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 Council69, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met: (...)	***deleted***

Or. en

Justification

Supplementary Protection Certificates unnecessarily extend pharmaceutical corporations' monopolies, which will keep lifesaving medicines out of people's hands. Further extending SPCs would keep medicine prices high for longer, delay competition from affordable generic and biosimilar alternatives available outside the European Union, and postpone patient access to treatment.

Amendment 7

Annex IV (new) – Minimum elements of the access plan

Text proposed by the Commission	**Amendment**
(absent)	***ANNEX [IV]*** ***Minimum elements of the access plan referred to in Article 14(1)*** ***The access plan shall be appropriate and proportionate to the nature and stage of development of the project. It shall demonstrate the strategies of the project promoter to ensure that the products and services developed based on, or partly based on, the results of the supported activities are affordable, available and accessible to the public at fair and reasonable conditions. The access plan shall include at least the following elements:*** ***(a) registration targets: the countries or regions in which the promoter intends to seek marketing authorisation or regulatory approval for the resulting products, including, where relevant, strategies to expedite registration in Member States and, where the products address significant public health needs, in low- and middle-income countries;*** ***(b) plans to meet demand: strategies to ensure sufficient and continuous supply of the***

	resulting products, including production capacity, supply chain resilience, and measures to avoid stockouts or shortages; ***(c) approaches to pricing and affordability: a description of the broad approach to pricing that reflects ability to pay and ensures that economic barriers to access are low;*** ***(d) intellectual property strategy: an explanation of how the promoter will ensure that intellectual property rights do not constitute a barrier to access, including, where relevant, plans to explore licensing arrangements, technology transfer, or collaboration with third parties such as non-profit product development partnerships;*** ***(e) engagement with regulators and manufacturers: a description of plans to engage with regulatory authorities and manufacturers, in particular in low- and middle-income countries, where the products address significant public health needs in those countries;*** ***(f) global access: where the resulting products address significant public health needs in third countries in critical need, the measures the promoter intends to adopt to facilitate access in those countries, including through development partners, voluntary licensing, or other arrangements that ensure supply at fair and reasonable conditions.*** ***The access plan shall be submitted as part of the application for recognition as a health biotechnology strategic project or for access to financial support under this Regulation, and shall be updated upon any significant***

	change in the product's development or market conditions. The Commission shall issue guidelines specifying the content and format of the access plan. ***"Project promoters shall use their best efforts to ensure that the resulting health biotechnology products and services are broadly available and accessible, as soon as possible and at fair and reasonable conditions, for up to four years after the end of the supported activity.*** ***In case a project promoter cannot fulfil the preceding obligation, the project promoter must, if requested by the granting authority, grant non-exclusive licences — under fair and reasonable conditions — to legal entities that commit to rapidly and broadly exploiting the resulting health biotechnology products and services and ensuring that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions.*** ***In case of transfer of the ownership or licensing of results, project promoters must pass on the obligations set out in this Annex to the legal entities exploiting the results.*** ***The granting authority shall be informed annually of the status of development and exploitation of the results until the expiration of the last applicable period of data protection, market exclusivity or patent protection in the Union relating to the resulting products, or for eight years after the end of the supported activity, whichever is late***

Or. en

Justification

This Annex establishes the minimum content requirements for the access plan referred to in Article 14(1). The elements listed are drawn from two established instruments in Union law and practice. The core structure — registration targets, demand planning, pricing approaches, IP strategy, and engagement with regulators and manufacturers — mirrors the access plan requirement established under the Global Health EDCTP3 Work Programme 2026, implementing Article 114 of Council Regulation (EU) 2021/2085. Under that framework, beneficiaries must include in their exploitation and dissemination plan a proportionate access plan covering registration targets, plans to meet demand, flexible IP approaches, engagement with regulators and manufacturers, and strategies that reflect ability to pay.

The global access element in point (f) draws on the Stewardship and Access Plan framework applied by CARB-X, which requires funded product developers to include strategies for access in territories where they do not intend to market the product, including through out-licensing, technology transfer, global partnerships with purchasing organisations, and engagement with development partners such as the Medicines Patent Pool.

The reporting obligation runs until the expiration of the last applicable period of data protection, market exclusivity or patent protection in the Union,. A fixed post-project period alone — as used in the Global Health EDCTP3 framework — is insufficient for the broader product spectrum covered by this Regulation, where development cycles for advanced therapies and biomanufacturing products significantly exceed those of clinical trials. The upper bound is anchored to exclusivity expiry rather than to marketing authorisation because the public interest in verifying affordable pricing, availability across Member States, and supply commitments is strongest precisely while the beneficiary holds market exclusivity — terminating oversight at authorisation would remove it at the moment it becomes most meaningful, an approach also adopted by CARB-X, whose access obligations run until expiration of the last patent or exclusivity period in the Union

The Annex is intentionally high-level: it sets minimum elements without prescribing specific pricing levels, licensing terms, or mandatory outcomes, leaving flexibility to project promoters. The Commission guidelines will provide further operational detail, consistent with the approach used in the EDCTP3 work programme.

You can find a comprehensive set of proposed amendments to ensure public return on public investments here.