THE VALUE AND COST OF A SUPPLEMENTARY PROTECTION CERTIFICATE EXTENSION IN EUROPE

Copenhagen Economics
5 June 2026

AUTHORS

Malwina Mejer, Senior Economist, PhD
Nikolaj Siersbæk, Managing Economist, PhD
Elisa Pau, Senior Economist
Lærke Kilsdal, Lead Economist
Julia Wahl, Partner

This study is an independent report funded by the European Federation of Pharmaceutical Industries and Associations (EFPIA). The views and conclusions in this report are those of the authors and do not necessarily represent the views of EFPIA.

About Copenhagen Economics

Copenhagen Economics is an expert-driven consulting company built on a deep knowledge of applied economics, and one of the leading economics firms in Europe.

We believe sound economic analysis can equip decision-makers with the hard facts and clear stories to make better choices for the benefit of society. We are committed to delivering compelling and pragmatic economics solutions with a candid approach.

A brief note on consultancy research

In line with established practice in our sector, research is designed so that:

- the client chooses the research question;
- we analyse and address the question to the best of our knowledge;
- findings and conclusions are our own.

For further information, see www.copenhageneconomics.com. We remain available for, and appreciate, any questions or comments.

Executive Summary

The value and cost of an SPC extension in Europe

The Biotech Act proposal aims to strengthen the competitiveness of the EU biopharmaceutical sector

On 16 December 2025, the European Commission adopted a proposal for a European Biotech Act. The Act was put forward with the objective of establishing a coherent framework to strengthen the Union's biotechnology and biomanufacturing sectors, including the pharmaceutical sector, by addressing structural barriers to innovation, improving the translation of scientific excellence into commercially viable products, enhancing the EU's global competitiveness and reinforcing the EU's research, development and production capabilities.[1]

A 12-month extension of Supplementary Protection Certificate is one of they key elements of the proposal

The Biotech Act proposes an extension of 12 months of the Supplementary Protection Certificate (SPC).[1] An SPC is an intellectual property (IP) right that provides an extension of patent-based market exclusivity for authorised medicinal products, with the objective of offsetting regulatory delays and preserving effective protection periods for innovative medicines.

The SPC extension reinforces the effectiveness of patent protection and, in turn, the EU's attractiveness for pharmaceutical investment. Given long development timelines, high failure rates and significant upfront research and development (R&D) investments, this exclusivity allows firms to recoup their past R&D investments and sustain future R&D. Furthermore, the duration and strength of patent and SPC protection, alongside other factors such as market size, regulatory efficiency or availability of skills, influence decisions on where to locate R&D and manufacturing activities.[3] In this context, stronger and more predictable IP frameworks can improve the EU's relative attractiveness for investment.

The Commission's SPC proposal covers products developed through biotechnology processes or advanced therapy medical products, benefiting from SPC protection and fulfilling four criteria covering product characteristics and localisation requirements for clinical trials and manufacturing; see Box 1.

EFPIA asked Copenhagen Economics to assess the impacts of the SPC extension

Back in December 2025, the European Commission did not publish an impact assessment underpinning the Biotech Act proposal alongside the legislative proposal. In March 2026, EFPIA therefore commissioned Copenhagen Economics to conduct an independent assessment of the proposed SPC extension. The objective is to provide a transparent, evidence-based evaluation of its potential economic effects, and to quantify, where possible, the economic benefits and costs of such an extension for European patients, healthcare systems, and the economy.

In this report, we assess the value and costs of the SPC extension

We assess the value that an SPC extension can bring to the EU, including

- its **impact on EU pharmaceutical sector competitiveness** and economic contribution, including R&D expenditure, employment, gross value added (GVA), number of clinical trials and innovation pipelines and global competitiveness
- its **impact on the availability of and access to innovative medicines** and the resulting value for patients, healthcare systems, and society

We compare these benefits with the associated costs, specifically

- the **impact on healthcare expenditure** arising from delayed entry of generic and biosimilar products.

Box 1. Commission proposal for a 12-month SPC extension

Article 27 of the Biotech Act[1] provides that the holder of an SPC, or of a patent that could qualify for SPC protection, may benefit from a 12-month extension of the SPC protection period if an underlying Union marketing authorisation is granted for **a medicinal product for human use developed using certain biotechnological processes** or for **an advanced therapy medicinal product**. In addition, the applicant must demonstrate that the following conditions set out in Article 27 are fulfilled:

(a) the medicinal product contains **a new active substance distinctly different** from that of any authorised medicinal product in the Union;

(b) the medicinal product has **a mechanism of action distinctly different** and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the **clinical trials** evaluating the efficacy of the medicinal product and supporting its marketing authorisation **were conducted in more than two Member States**;

(d) at least a manufacturing step, excluding packaging, quality testing and certification **is performed in the Union.**

(1) European Commission (2025). / (2) ibidem. / (3) OECD (2018).

Executive Summary

The value and cost of an SPC extension in Europe

Our assessment goes beyond the Commission proposal

Under the Commission proposal, the SPC extension is limited to a duration of 12 months and subject to a list of strict, cumulatively applied eligibility criteria. Given this narrow scope, the current proposal is more likely to reward only a small number of medicinal products rather than to create broad-based incentives for innovation.

Against this background, we evaluate the value and costs that an SPC extension would generate if its duration and scope were further extended and the proposed eligibility criteria were less restrictive. Specifically, we explore eight scenarios by varying:

- **Duration of the SPC extension,** by considering 12- and 24-month extensions
- **Scope of the SPC extension,** by covering products developed through biotechnological processes (biologics) only or all compounds
- **Eligibility for the SPC extension,** by applying the art. 27 criteria either cumulatively or assuming that fulfilling at least one criterion suffices

We then compare which of these scenarios generate the largest net benefit in the long term.

Methodology and data

To capture the value of the SPC extension, we utilise an estimate of the increase in R&D investments that a one-year increase in the mean effective protection period in the EU gives rise to[1], and derive from this the associated impacts on employment, GVA, the number of clinical trials, innovation pipelines, and global competitiveness. Our assessment is based on evidence published in the existing literature.

To quantify the costs of a 12-month SPC extension, we utilise historical product-level revenue data between 2015 and 2025 from IQVIA MIDAS® to calculate the average difference in revenue between the year with the highest revenue (e.g., the year of SPC expiry) and the year after (two years after when evaluating a 24-month extension).

To estimate the number of products that would benefit under different scenarios, we focus on the sample of medicinal products approved by the EMA between 2023 and 2025 and assess scope and eligibility using publicly available information. We consider only those medicinal products that will benefit from SPC protection and for which the SPC is the last protection right to expire. This allows us to estimate the impacts associated with extending the effective period of market protection.

We quantify all impacts for Europe, including EU27, Norway, Switzerland, and the UK. This is because reliable data on R&D investments by innovative pharmaceutical firms and sales data are available only for this specific geographical scope.

We assess the value and costs over a 15-year period to capture both short- and long-term effects. In the pharmaceutical industry, impacts on innovation and R&D activity materialise gradually over time; focusing only on the short-term period would risk underestimating the overall impact of the extension.

Europe could benefit from broadening the SPC extension beyond the current proposal

Overall, the comparison of impacts across scenarios, see Table 1 on the next page, suggests that broader SPC extensions with longer duration can strengthen incentives for pharmaceutical R&D investment and innovation activity in Europe and benefit patients through increased availability and early access, while also increasing pharmaceutical expenditure for public payers. This result highlights the inherent policy trade-off between supporting pharmaceutical competitiveness and innovation in Europe, improving opportunities for patient access to innovative treatments, and containing public pharmaceutical expenditure. Nevertheless, the findings show that scenarios with longer and broader SPC extension yield similar or higher net benefits than the Commission proposal, paired with a potentially larger positive impact on patients.

Number of medicinal product eligible for the SPC extension increases across scenarios

Eligibility criteria put forward in the Commission proposal impacts a limited number of medicinal products. Our analysis shows that restricting the scope to biologics and applying narrow eligibility criteria means that only two medicinal products per year would benefit from the SPC extension. This number increases to 27 products if the scope is extended to all compounds and broader eligibility criteria.

The cost for public payers increases with the number of eligible products, but the annual impact on pharmaceutical spending remains limited

An SPC extension increases costs for public payers by delaying biosimilar or generic entry, thereby prolonging higher originator prices and postponing potential savings from competition. We estimate that the average per-product cost of a 12-month SPC extension is EUR 25.7 million for biologics and EUR 58.6 million for all compounds. For a 24-month SPC extension, the average per-product cost increases to EUR 108.5 million for biologics and EUR 189.2 million for all compounds.

The level of spending increases proportionally with the number of product eligible. However, when considered in the context of overall pharmaceutical budgets, the impact of the SPC extension remains limited, corresponding to less than 0.5 per cent in Scenarios 1 to 4, 5 and up to 1.7 per cent in the broadest Scenario 8.

Notes: 1) Copenhagen Economics (2018).

SPC extension can strengthen EU pharmaceutical competitiveness and patient access, with benefits exceeding costs in most scenarios

An overview of key findings

Table 1. Comparison of selected impacts by scenario

European Commission

SCENARIOS					COST		VALUE				ECONOMIC IMPACT		
No.	Scope	Eligibility (Art 27)	Duration (months)	Medicinal products benefitting	Total cost of products that would benefit (bn EUR)	% pharma spending	R&D (bn EUR)	Number of clinical trials	Patient enrolment In clinical trials (phase II, III)	New medicines developed	Direct GVA (bn EUR)	Total cost to pharma budget (bn EUR)	Net economic impact (GVA/cost)
					Annual		Over 15 years				Over 15 years		
1	Biologics	Narrow	12	2	0.06	0.02 %	4.0	17	2,200	2	1.5 – 2.9	0.9	**1.7 – 3.2**
2	Biologics	Narrow	24	2	0.25	0.09 %	8.0	34	4,300	3	3.1 – 5.8	3.8	**0.8 – 1.5**
3	Biologics	Broad	12	12	0.31	0.11 %	20.0	85	10,900	8	7.8 – 14.7	4.6	**1.7 – 3.2**
4	Biologics	Broad	24	12	1.30	0.48 %	40.0	169	21,900	16	15.6 – 29.5	19.5	**0.8 – 1.5**
5	All compounds	Narrow	12	10	0.56	0.21 %	16.0	69	8,800	6	6.3 – 11.9	8.5	**0.7 – 1.4**
6	All compounds	Narrow	24	10	1.82	0.68 %	33.0	138	17,600	13	12.6 – 23.8	27.3	**0.5 – 0.9**
7	All compounds	Broad	12	27	1.34	0.50 %	45.0	192	24,500	18	17.6 – 33.2	20.1	**0.9 – 1.7**
8	All compounds	Broad	24	27	4.51	1.67 %	91.0	383	49,100	35	35.1 – 66.3	67.7	**0.5 – 1.0**

Note. All numbers are rounded. Colour coding in the last column indicates whether the net economic impact is

Strictly positive
Likely positive
Negative

Source: Copenhagen Economics.

For a detailed overview of the impacts, see page 28 in the Report.

Executive Summary

The value and cost of an SPC extension in Europe

The annual cost for healthcare budgets due to the SPC extension needs to be seen in light of the value that it brings over time in terms of the impact on patient outcomes, economic footprint and competitiveness of the EU pharmaceutical sector.

SPC extension can contribute to increased competitiveness and economic footprint of the EU pharmaceutical sector

Extending the effective protection period for innovative medicines increases expected returns, thereby strengthening incentives for companies to invest in R&D activities.

Our results indicate that R&D investments increase as the duration, scope and eligibility of SPC extensions become longer and broader. This reflects the fact that longer and broader protection increases expected returns on innovative products, while broader eligibility criteria increase predictability and reduce legal uncertainty. Specifically, R&D investment increases are more than ten times higher under the broadest scenario compared to the narrowest scenario for both a 12- and 24-month extension, specifically:

- For a 12-month extension, the increase ranges from EUR 4 bn in Scenario 1 (biologics, narrow eligibility) to EUR 45 bn in Scenario 7 (all compounds, broad eligibility) over 15 years
- For a 24-month extension, the increase ranges from EUR 8 bn million in Scenario 2 (biologics, narrow eligibility) to EUR 90 bn million in Scenario 8 (all compounds, broad eligibility) over 15 years

Increased R&D investments in turn generate broader economic effects in Europe**.** Higher investment levels support employment in R&D and non-R&D functions and contribute to increased GVA. Furthermore, since a significant share, 44 per cent, of R&D investment is directly spent on clinical trials (phases I to III),[1] increased R&D investments in Europe can translate directly into higher clinical trial activity in Europe.

The SPC extension can improve availability and access, benefiting patients

Increased clinical trial activity improves patient access to innovative medicines before marketing authorisation. It also increases the likelihood of successful innovation outcomes, leading to more new treatments reaching the market.

In both cases, patients benefit from increased availability and access. In turn, access to innovative medicines improves survival, reduces disease progression, and enhances quality of life, particularly in areas with high unmet medical need.[2]

Under the Commission proposal, an estimated number of additional 2,200 patients can be enrolled in clinical trials, and two new innovative medicines will be brought to the market over the period of 15 years. As scope and eligibility broaden, the number of patients participating in clinical trials and the expected number of new products developed and launched in Europe increases significantly up to 49,100 patient enrolled in clinical trials and 35 new medicines being developed in the EU over the period of 15 years.

In six out of eight scenarios, the estimated direct economic value generated is likely to outweigh the associated costs

The estimated direct economic value generated (proxied by *direct* GVA, i.e. the additional economic output associated with increased pharmaceutical activity) is likely to outweigh the associated costs from higher pharmaceutical spending in six out of eight scenarios. This is indicated by a GVA-to-cost ratio greater than one; see Table 1.

The results illustrate important trade-offs between fiscal cost, competitiveness impacts and patient benefits across scenarios.

- Under the Commission proposal, Scenario 1, the ratio of economic value generated relative to additional pharmaceutical expenditure remains **strictly positive**, although the resulting impact on patient benefits is rather limited. The ratio also remains strictly positive under Scenario 3, which reflects the broadest eligibility scope.
- Intermediate scenarios 2, 4, 5 and 7 appear to provide a more balanced profile, combining **likely positive** ratios of economic value generated relative to additional pharmaceutical expenditure with broader positive impacts on availability and access.
- Under scenarios 6 and 8, the ratios between additional value generated and additional pharmaceutical spending are likely to be **negative**, but the patient benefits are substantial with 17,600 and 49,100 potentially benefit from early access to innovative medicines through clinical trials and 13 to 35 new medicines being developed in the EU as a result of increased R&D activity.

With the Biotech Act, policymakers seek to strengthen Europe's biotechnology and biomanufacturing ecosystem, including its pharmaceutical sector. Our assessment suggests that an SPC extension can meaningfully contribute to this objective by strengthening incentives for pharmaceutical R&D, clinical trial activity and innovation in Europe, while also improving patient access to innovative treatments. Across most scenarios assessed, the estimated net economic impact exceeds the associated increase in pharmaceutical expenditure, indicating that the measure can represent a positive long-term investment for Europe. The remaining policy question concerns the level of ambition: how large an incentive policymakers wish to provide and how they weigh the resulting gains in innovation and patient benefits against the associated budgetary costs.

(1) EFPIA (2025). / (2) See European Parliament (2025) or OECD (2018).

Table of contents

1
SCENARIOS

We assess eight scenarios based on alternative choices regarding duration, scope and eligibility criteria for the SPC extension

The current Biotech Act proposal foresees a 12-month SPC extension applying only to products developed through specified biotechnological processes or ATMPs, with a valid SPC, subject to a list of strict, cumulatively applied eligibility criteria. Only products that are new active substances (NAS) with a mechanism of action distinct from existing treatments, for which developers conduct clinical trials in more than two EU Member States and carry out at least one stage of manufacturing within the EU, can benefit from the extension.[1]

Given this narrow scope, the current proposal is more likely to reward a small number of R&D projects rather than to create broad-based incentives for innovation and the Commission has not assessed the impact of alternative design options.

Against this background, we evaluate the value and costs that the SPC extension would generate if its duration and scope were further extended and the proposed eligibility criteria were applied less stringently.

12 versus 24-month duration

A longer duration of protection increases expected returns by extending the period over which R&D costs can be recouped. It **improves the risk–return profile of investments and may incentivise projects with higher uncertainty** or longer development timelines, including early-stage innovation. We therefore also consider a longer, 24-month, extension.

Scope spanning only biologics versus all compounds

Under the proposed Biotech Act, the SPC extension applies to a set of products developed through specified biotechnological processes, in practice covering typical biologics only.[2] This scope is narrower than the scope of the Biotech Act as a whole; see Article 2.[3] For example, matching the scope to the Article 2 definition could capture genomics-enabled medicinal product discovery, where genomic data are used to identify therapeutic targets and guide the design of new medicines of various classes. By viewing the application of biotechnology through this broader lens, the Act can incentivise innovative products that would otherwise not qualify for the SPC extension if the resulting product is not strictly a biologic or an ATMP under the current proposed definition.

Expanding the scope of the SPC extension to Article 2 would provide a more technology-neutral incentive framework, helping to ensure that the incentive remains relevant in the future and permitting innovators to prioritise research expenditure based on expected therapeutic value and scientific opportunity. In addition, broader coverage increases the expected applicability of the incentive, thereby strengthening its overall impact on investment decisions. We therefore also consider and test the bounds of the possible scenario where all types of compounds are in scope.

Narrow versus broad eligibility criteria

Under the current proposal, a medicinal product must meet four cumulative eligibility criteria to qualify for the extension (see Article 27), which significantly limits the number of products that could benefit. While narrow eligibility criteria may help control pharmaceutical spending by limiting the number of eligible medicines, having to fulfil several criteria at the same time may also create uncertainty about whether a product may ultimately qualify for the extension. This can reduce the predictability of returns, particularly at early stages of research, and may weaken investment incentives.[5] Firms may respond by prioritising projects with more predictable outcomes, leading to a reallocation of R&D efforts.

Broad eligibility criteria can strengthen investment incentives by **providing a more stable and predictable legal framework**. This may facilitate portfolio-wide investment decisions (including licensing) under conditions of high uncertainty and long development timelines. By increasing the clarity of expected returns ex ante, such incentives can support overall R&D activity, including higher-risk and early-stage innovation.

While longer duration, broader scope, and less restrictive eligibility increase the expected value and applicability of the incentive, thereby strengthening R&D investment incentives, they also come at a cost for healthcare systems, as they delay generic and biosimilar entry, extend periods of higher originator prices, and increase pharmaceutical expenditure for public payers. This highlights a core policy trade-off between strengthening incentives for innovation and maintaining timely access to lower-cost generic and biosimilar alternatives.

We therefore quantify both the benefits and the costs of eight scenarios combining these different policy choices, as outlined in Figure 1.

Figure 1. Design options for the assessment scenarios

Extension period
• **12 months** (in the proposal)
• **24 months**
Scope of protection
• **Biologics** (covered with certainty in the proposal)
• **All compounds**
Eligibility criteria
• **Narrow: Cumulative criteria** (in the proposal)
• **Broad: One criterion only**

Source: Copenhagen Economics.

(1) Article 27 in European Commission (2025). / (2) The wording of Article 27 in European Commission (2025) uses a definition of biotechnology products that is close to EMA's definition of biologics. We therefore consider that only biologics would be covered under the current proposal. See Appendix A for further details. / (3) Article 2 of European Commission (2025). / (5) Gans et al. (2007); Dohse et al. (2023); Wagner and Wakeman (2016).

Broadening the scope and eligibility criteria can increase the number of innovative products eligible each year from 2 to 27 products

The Commission proposal, i.e. narrow eligibility criteria combined with a scope limited to biologic products would mean that only two innovative medicinal products, i.e. around 5 per cent of all innovative medicines approved, would benefit from the SPC extension each year; see Figure 2. This estimate is based on the characteristics of medicinal products approved by the EMA between 2023 and 2025, considering only those medicines for which the SPC will be the last protection to expire.

Broadening either the scope *or* relaxing the eligibility criteria increases the share of innovative medicines benefiting from an extension to between 19 per cent (when both biologics and small molecules are included in scope) and 23 per cent (when broad eligibility criteria are applied). Under these scenarios roughly one in five innovative medicines would benefit from the SPC extension.

Finally, applying *both* a broad scope and broad eligibility criteria increases the share of medicinal products benefiting to 27, i.e. 52 per cent, meaning that roughly every second innovative medicine approved could benefit from the SPC extension.

For the detailed methodology, see **Appendix A**

Figure 2. Medicines that could benefit from SPC extension
Average number and share of innovative medicines approved between 2023 and 2025

SCOPE	ELIGIBILITY: Narrow (cumulative Art 27 criteria)	ELIGIBILITY: Broad (one criterion in Art 27)
Biologics	2 | 5%	12 | 23%
All compounds	10 | 19%	27 | 52%

Notes: We include only those products for which SPC is the last protection to expire.
Source: Copenhagen Economics based on input from IQVIA

2
IMPACT ON ECONOMIC FOOTPRINT AND COMPETITIVENESS

An extension of SPC protection for innovative medicines marketed in Europe can foster direct R&D investments in Europe

R&D investments

Longer effective IP protection provides an incentive to invest in R&D

IP rights incentivise pharmaceutical companies to take on substantial risks and invest in the long, complex, and costly process of bringing new, innovative medicines to patients.[1] Therefore, extending the effective protection period for innovative medicines in Europe has a positive effect on the level of pharmaceutical R&D spending in Europe.[2]

Impacts

We find that a 12-month SPC extension for biologics with narrow eligibility can foster an additional EUR 3,986 million in direct R&D investments over 15 years, see Figure 3. This impact increases to EUR 40,285 million under broad eligibility and a 24-month extension. Expanding the SPC scope to all compounds further magnifies that effect, generating EUR 90,696 million in additional R&D under broad eligibility and a 24-month extension.

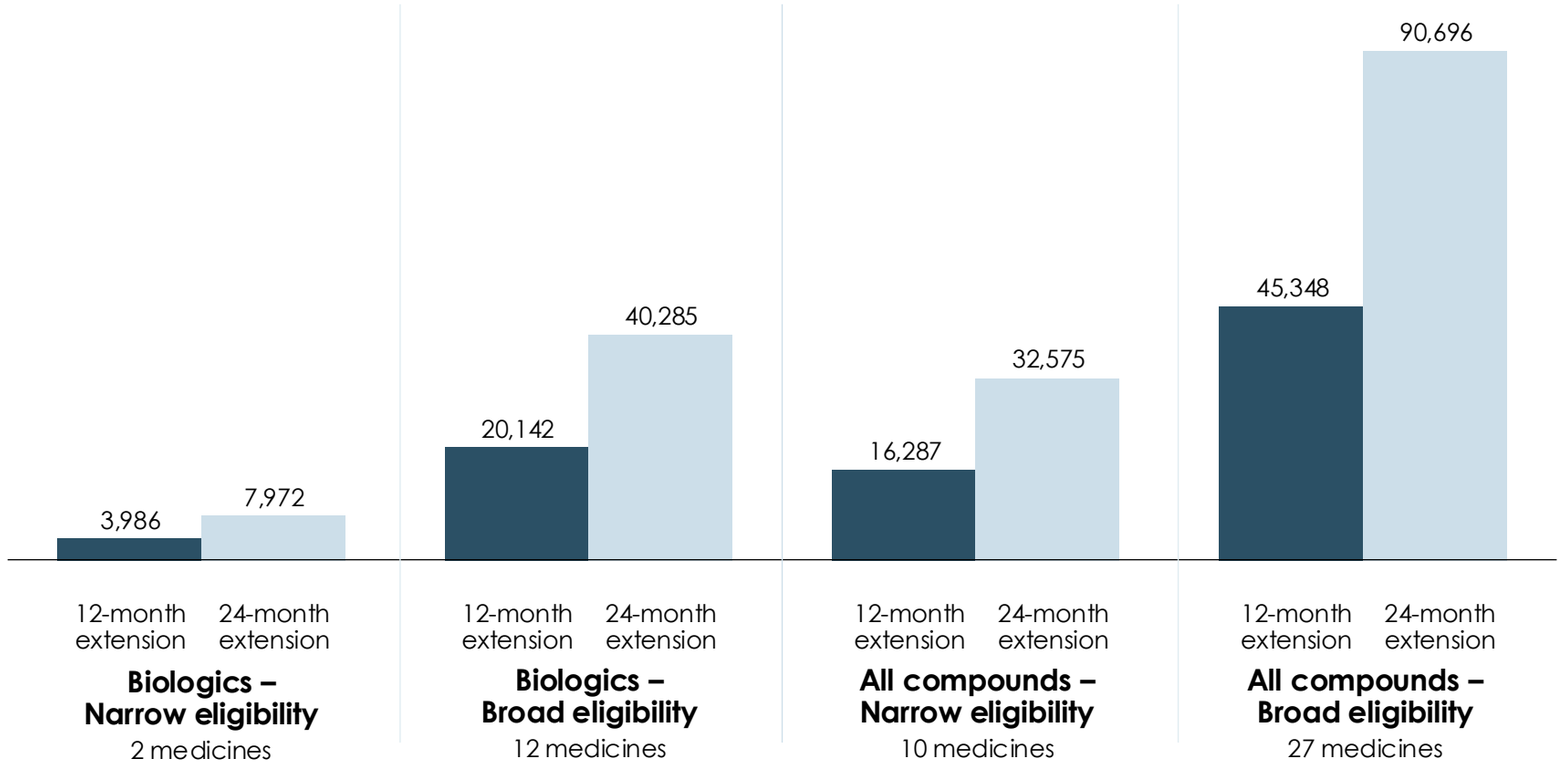
Longer protection periods and broader eligibility increase expected returns, thereby strengthening incentives for companies to invest in R&D activities across a broader range of products in their portfolio.

Methodology

We use existing estimates of the impact of a one-year change in effective protection on pharmaceutical R&D investment in Europe. We multiply these effects by the current R&D investment level in Europe to estimate nominal impacts and adjust for the share of medicines that could benefit under each scenario. The impacts are then aggregated over 15 years to estimate the cumulative effect.

For the detailed methodology, see Appendix B

Figure 3. The expected impact of SPC extension on R&D investments in Europe across eight scenarios
Million EUR over 15 years (2025 values)



Note: The 15-year estimate is based on short-run estimates in 4 of those years and long-run estimates in the remaining 11 of those years.
Source: EFPIA (2025), and Copenhagen Economics (2018)..

1) DiMasi et al.. (2016) or Wouters et al.. (2024). / (2) Copenhagen Economics (2023b) shows the significant increase in clinical trial activity in Japan after the introduction of Regulatory Data Protection.

Increased R&D investments in Europe can support direct pharmaceutical jobs in Europe

Pharmaceutical jobs

Increased R&D investments positively impact employment

Increased R&D investments lead to higher demand for both R&D and non-R&D functions, as firms, e.g. by expanding research activities, initiating additional projects, increase hiring. This, in turn, results in increased pharmaceutical employment.

Impacts

We estimate that a 12-month SPC extension for biologics with narrow eligibility can support an additional 269-508 pharmaceutical jobs in the short run and an additional 459-867 jobs in the long run; see Figure 4. This impact increases to 538 -1,016 in the short run and 918-1,734 in the long run if the SPC extension is granted for a 24-month period. Further extending the scope to all compounds and applying broad eligibility with a 24-month duration increases the impact to 11,558 jobs in the short run and 19,723 jobs in the long run.

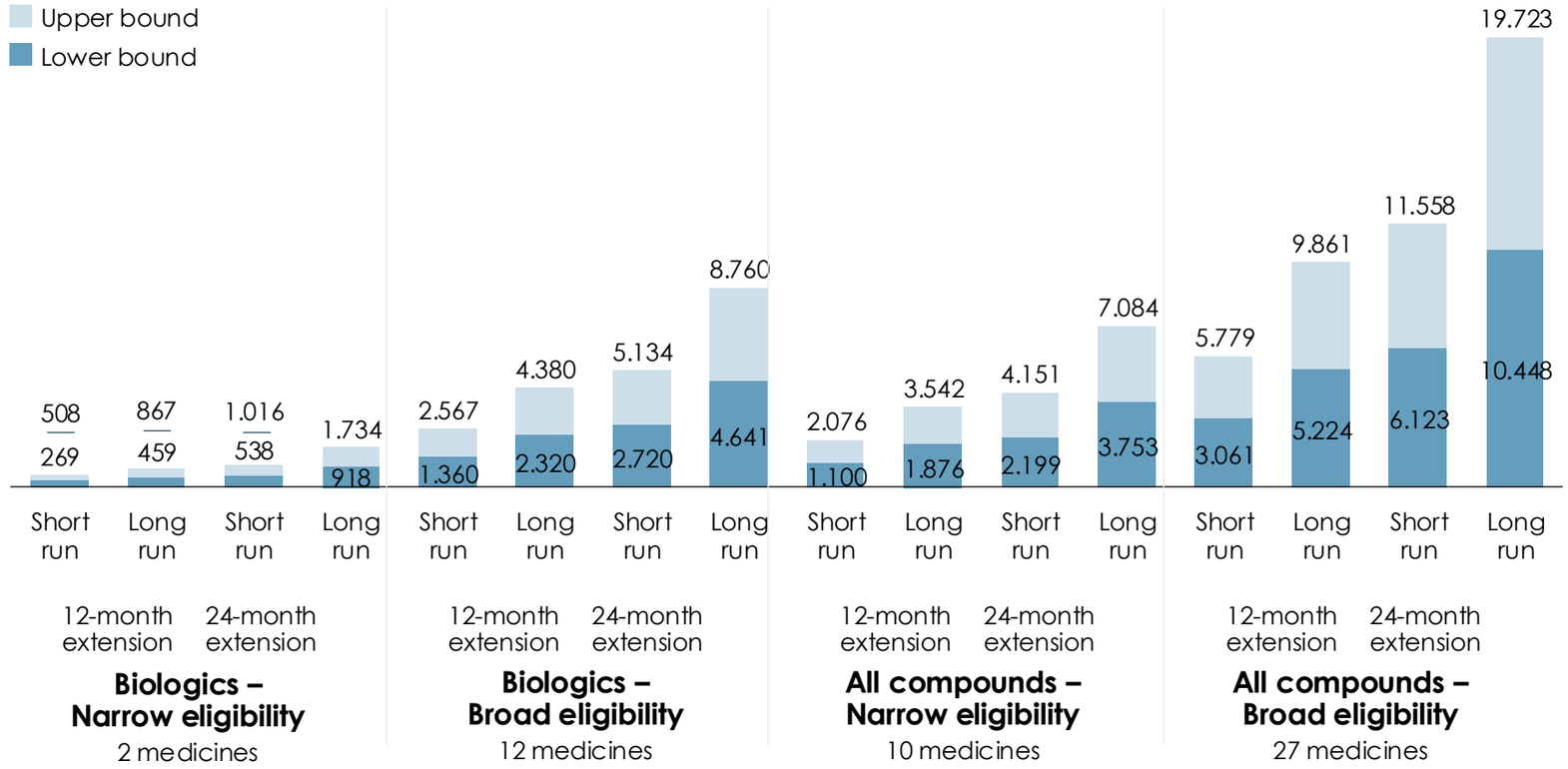
Methodology

Based on elasticities of employment in high tech sectors with respect to an increase in R&D investment reported in the peer-reviewed literature, we estimate the impact of increased R&D investments in the short run and long run.

The jobs presented here reflect total pharmaceutical employment, as an increase in R&D investments will not only increase the demand for R&D employees but also employees in non-R&D functions. The lower and upper bound are defined by the range of job multipliers available in the literature. The short and long run estimates result from estimates of the short and long run impact of a one-year change in effective protection on pharmaceutical R&D investment in Europe.

For the detailed methodology, see Appendix C

Figure 4. Direct jobs in the pharmaceutical industry supported by SPC extension across eight scenarios
Number of jobs



Note: Lower- and upper-bound estimates are based on lower- and upper-bound elasticity estimates of employment with respect to R&D expenditure in high-tech sectors as reported in Piva and Vivarelli (2017).
Source: Copenhagen Economics based on EFPIA (2025), Copenhagen Economics (2018), EFPIA and PwC (2024), and Piva and Vivarelli (2017).

Increased pharmaceutical employment can support additional jobs in the wider European economy

Jobs in the wider economy

Increased pharmaceutical employment positively impacts employment in the wider economy

Investment and employment in the pharmaceutical industry are also expected to generate spill-over effects in the wider economy through purchases from suppliers and household spending by employees.

Impacts

We estimate that a 12-month SPC extension for biologics with narrow eligibility can support additional 1,033-1,951 jobs in the wider European economy in the short run and 1,764-3,329 jobs in the long run; see Figure 5. This impact increases to 17,825-33,647 in the long run under broad eligibility and a 24-month extension.

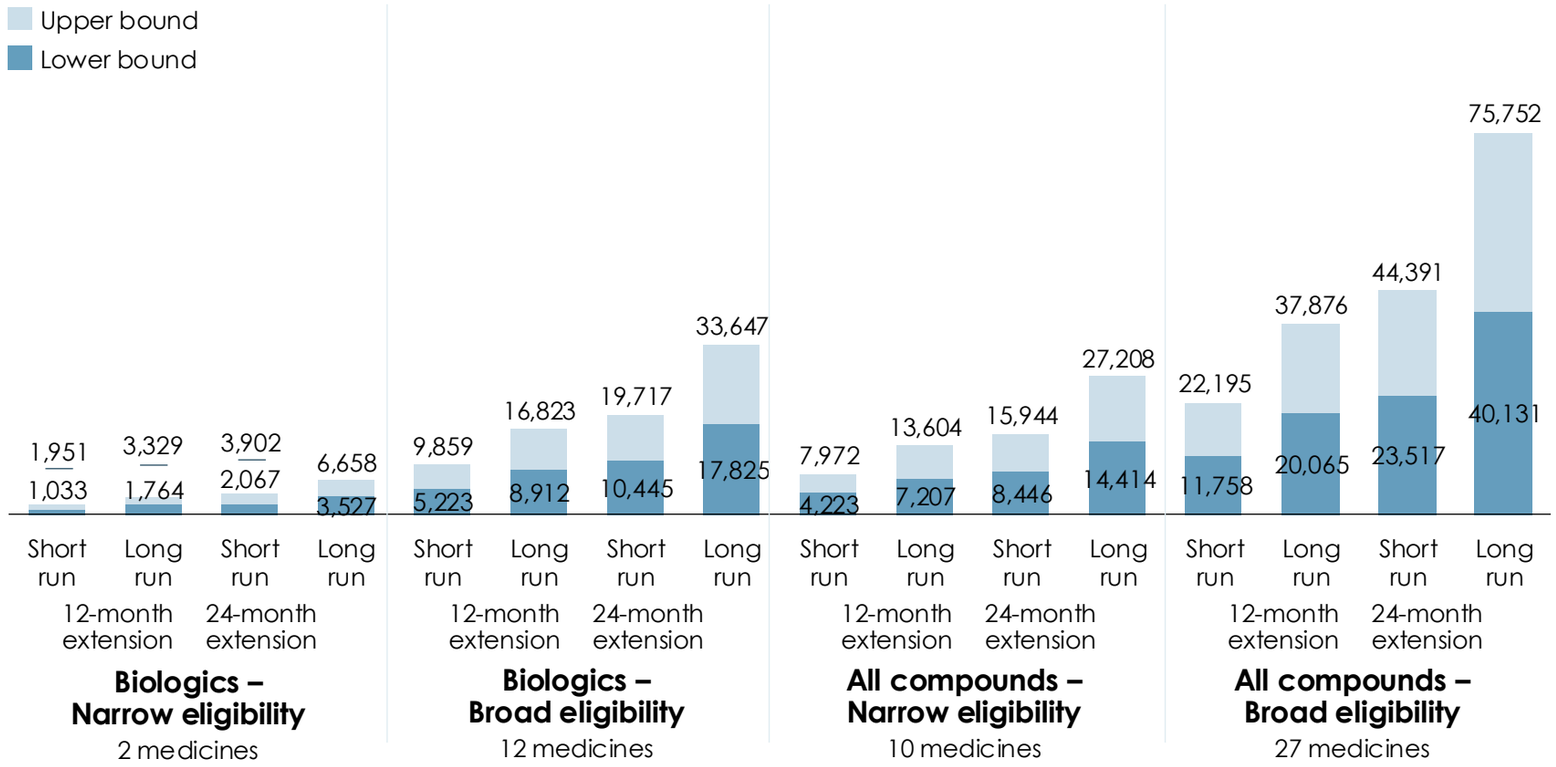
Further extending the scope to all compounds while applying broad eligibility and a 24-month duration increases the impact to 44,391 jobs in the short run and 75,752 jobs in the long run.

Methodology

We apply indirect and induced job multipliers to the number of direct jobs in the pharmaceutical industry as estimated previously.[1] This yields the total number of jobs in the wider European economy. The lower and upper bounds are defined by the range of job multipliers available in the literature. The short- and long-run estimates result from estimates of the short and long run impact of a one-year change in effective protection on pharmaceutical R&D investment in Europe.

For the detailed methodology, see Appendix C

Figure 5. Jobs in the wider European economy supported by SPC extension across eight scenarios
Number of jobs



Note: Lower- and upper-bound estimates are based on lower- and upper-bound elasticity estimates of employment with respect to R&D expenditure in high-tech sectors as reported in Piva and Vivarelli (2017).
Source: Copenhagen Economics, based on EFPIA (2025), Copenhagen Economics (2018), EFPIA and PwC (2024), and Piva and Vivarelli (2017).

(1) EFPIA and PwC (2024).

Increased employment through higher R&D investments in Europe can contribute to increased gross value added

Gross value added (GVA)

Increased R&D investment generates spillover effects and supports the wider economy

Increased employment through higher R&D investments will generate increased gross value added (GVA) in the pharmaceutical sector, which captures the value created in the sector, measured as output less intermediate consumption. In turn, this will generate spillover effects and support economic activity in the wider economy through purchases from suppliers and employee spending, so-called indirect and induced effects.

Impacts

We estimate a direct GVA contribution of EUR 1,544-2,914 million over 15 years, and a total supported European GVA of EUR 3,068-5,792 million over a 15-year period that can result from a 12-month SPC extension for biologics with narrow eligibility; see Figure 6.

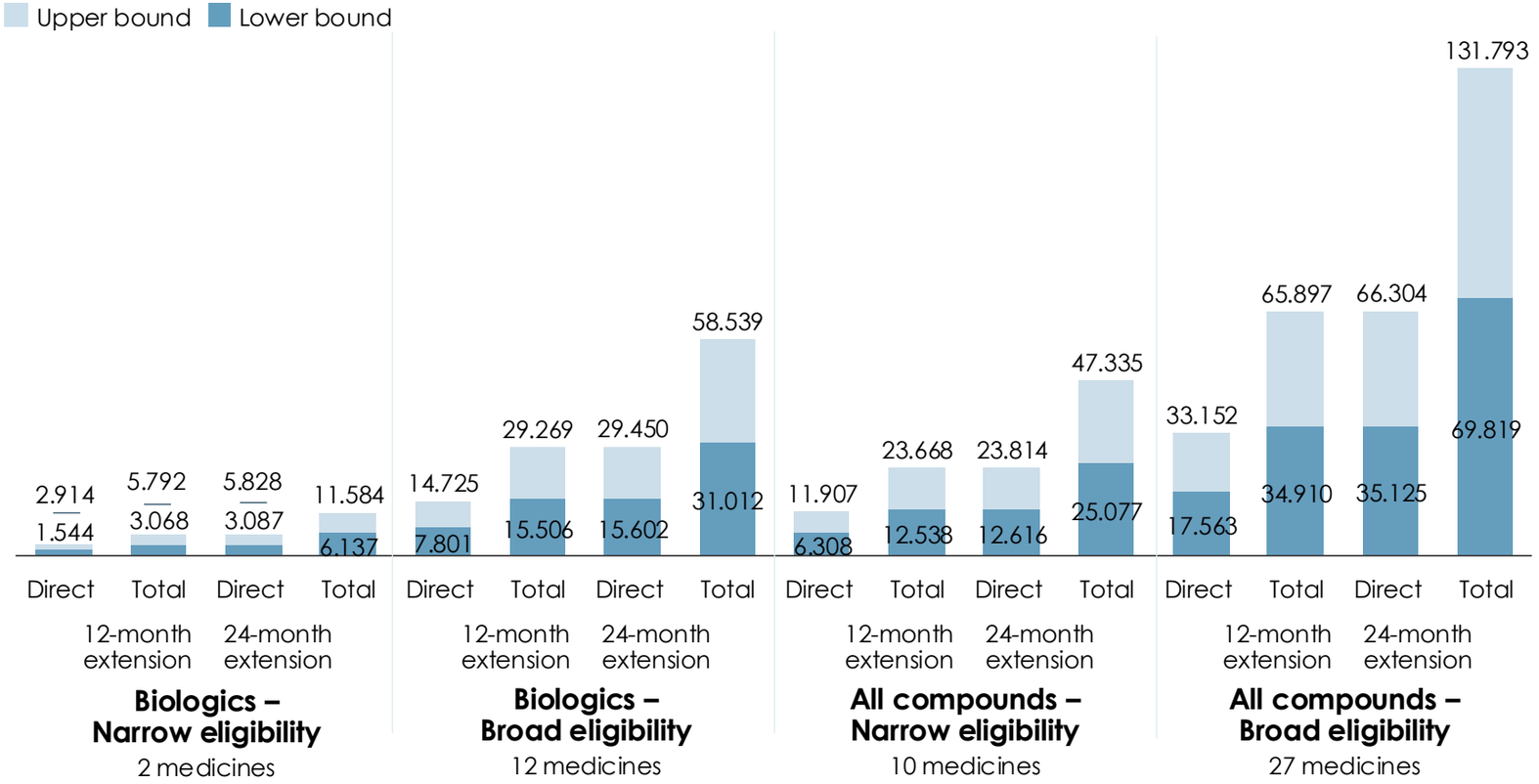
Granting 24-month extension with broad eligibility and covering all compounds increases the direct GVA impact to EUR 35,125-66,304 million and the total effect to EUR 69,819-131,793 million.

Methodology

We couple the average GVA contribution per employee with the estimated increase in the number of jobs in the pharmaceutical sector (lower and upper bounds). We then estimate the supported indirect and induced GVA by applying average pharmaceutical GVA multipliers[1] to the direct GVA effect. The lower and upper bounds are defined by the range of job multipliers available in the literature and therefore also apply to our GVA estimates.

For the detailed methodology, see Appendix D

Figure 6. Supported European GVA expected from SPC extensions across eight scenarios
Million EUR over 15 years (2025 values)



Note: The 15-year estimate is based on short-run estimates in first 4 years and long-run estimates in the remaining 11 of those years. Lower- and upper-bound estimates are based on lower- and upper-bound elasticity estimates of employment with respect to R&D expenditure in high-tech sectors, as reported in Piva and Vivarelli (2017). Estimates are not discounted.

Source: IQVIA (2022), EFPIA (2025), Copenhagen Economics (2018), Eurostat (2026, webpage), and EFPIA and PwC (2024).

(1) EFPIA and PwC (2024).

Increased R&D investments in Europe can increase the number of clinical trials initiated in Europe

Clinical trials

Increased R&D investments are expected to expand clinical trial activity

Today, almost 44 per cent of R&D investment in pharmaceuticals is directly spent on clinical trial activity, specifically phases I to III.[1] When R&D investments increase, companies initiate more trials, progress more potential medicines into resource-intensive later trial stages, and expand supporting infrastructure such as trial sites, personnel, and Contract Research Organisations[2]. Consequently, the number of clinical trials is expected to increase as a result of the SPC extension.

Impacts

We find that a 12-month SPC extension for biologics with narrow eligibility can lead to an additional 17 clinical trials initiated over 15 years; see Figure 7. This impact increases to 169 clinical trials under broad eligibility and a 24-month extension. Expanding the SPC scope to all compounds further magnifies that effect, leading to 383 additional clinical trials under broad eligibility and a 24-month extension.

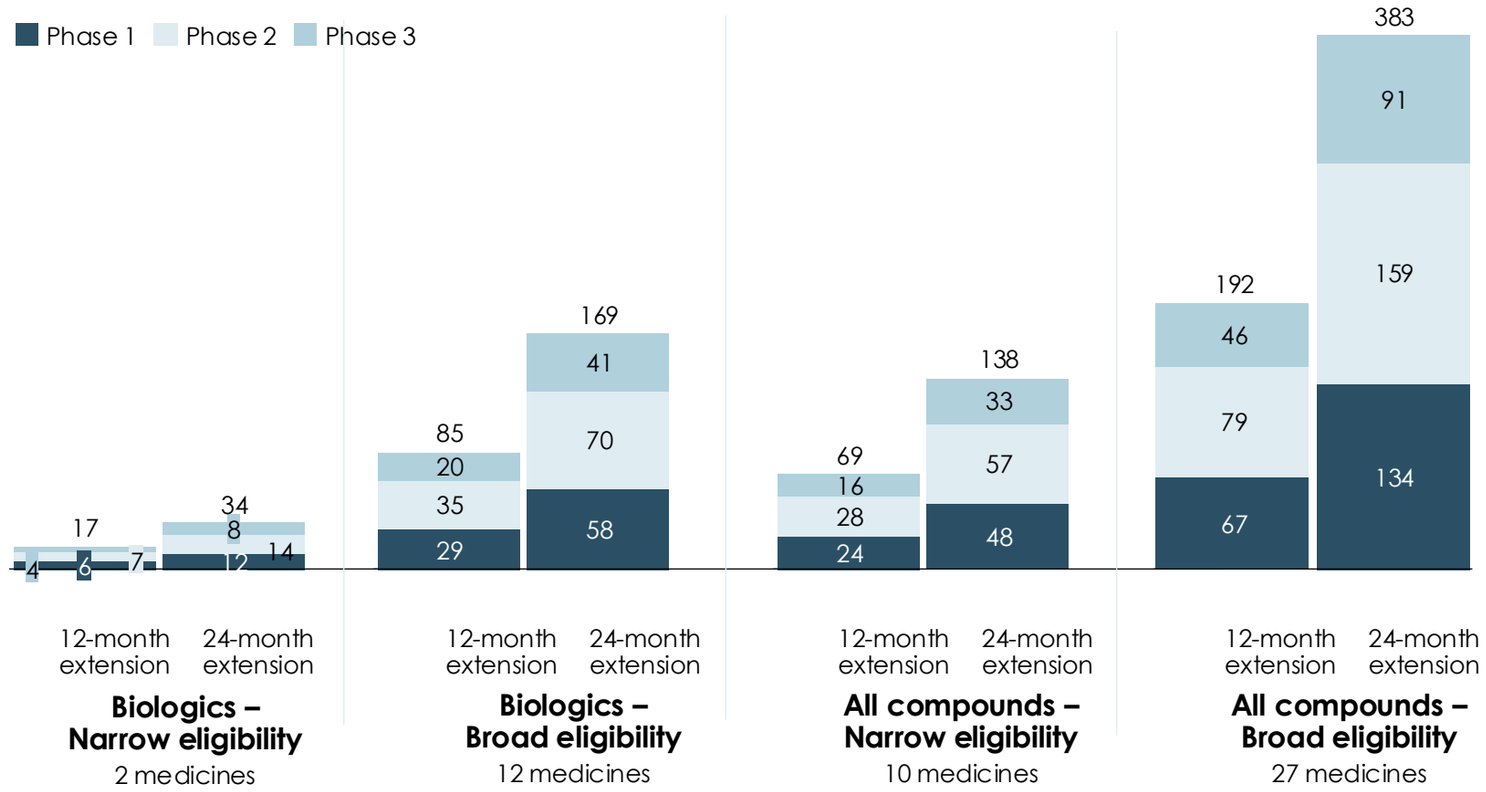
Methodology

We estimate the number of additional clinical trials through a model that splits the additional R&D investments into additional clinical trials by phase over 15 years. The model is based on assumptions about the distribution of pharmaceutical R&D investments across clinical trial phases, as well as the average trial length, cost, and average probability of success in each phase.

Note that the clinical trial impact modelled here arises purely from the SPC extension. Further reforms proposed in the Biotech Act may enhance this effect.

For the detailed methodology, see Appendix E

Figure 7. Expected impact of SPC extension on clinical trials initiated in Europe across eight scenarios
Number of trials initiated over 15 years



Notes: For estimates on cost of clinical trials, we adjust Di Masi et al.. (2016) estimates to March 2026 values using the US consumer price index (CPI). We convert the estimate from USD to EUR using an average exchange rate in March 2026 of 1.156 USD per EUR (European Central Bank, 2026, webpage)
Source: Copenhagen Economics based on EFPIA (2025), Copenhagen Economics (2018), Thomas et al.. (2016), Di Masi et al.. (2016), and clinicaltrials.eu (2026).

(1) EFPIA (2025). / (2) These are external providers of research services supporting medicine development and clinical trials.

The SPC extension can contribute to improving Europe's relative competitiveness, but it will have to be combined with other measures to restore European leadership

Over the last two decades, Europe has been losing ground in global R&D investments and clinical trial activity. In 2001, Europe attracted 41 per cent of all global **R&D investments**, which declined to **31 per cent in 2022**.[1] In parallel, the share of **clinical trials** dropped from 22 per cent in 2013 **to 12 per cent in 2023**.[2] Today, Europe's R&D intensity is moderate, and clinical trial activity is low relative to other regions.[3]

Improving the competitiveness of the EU pharmaceutical sector is a key objective of the Biotech Act.[4] By increasing expected returns, SPC extension can strengthen incentives for firms to locate R&D activities, including clinical trials, in Europea and, as a result, improve its position relative to other regions.

Impacts

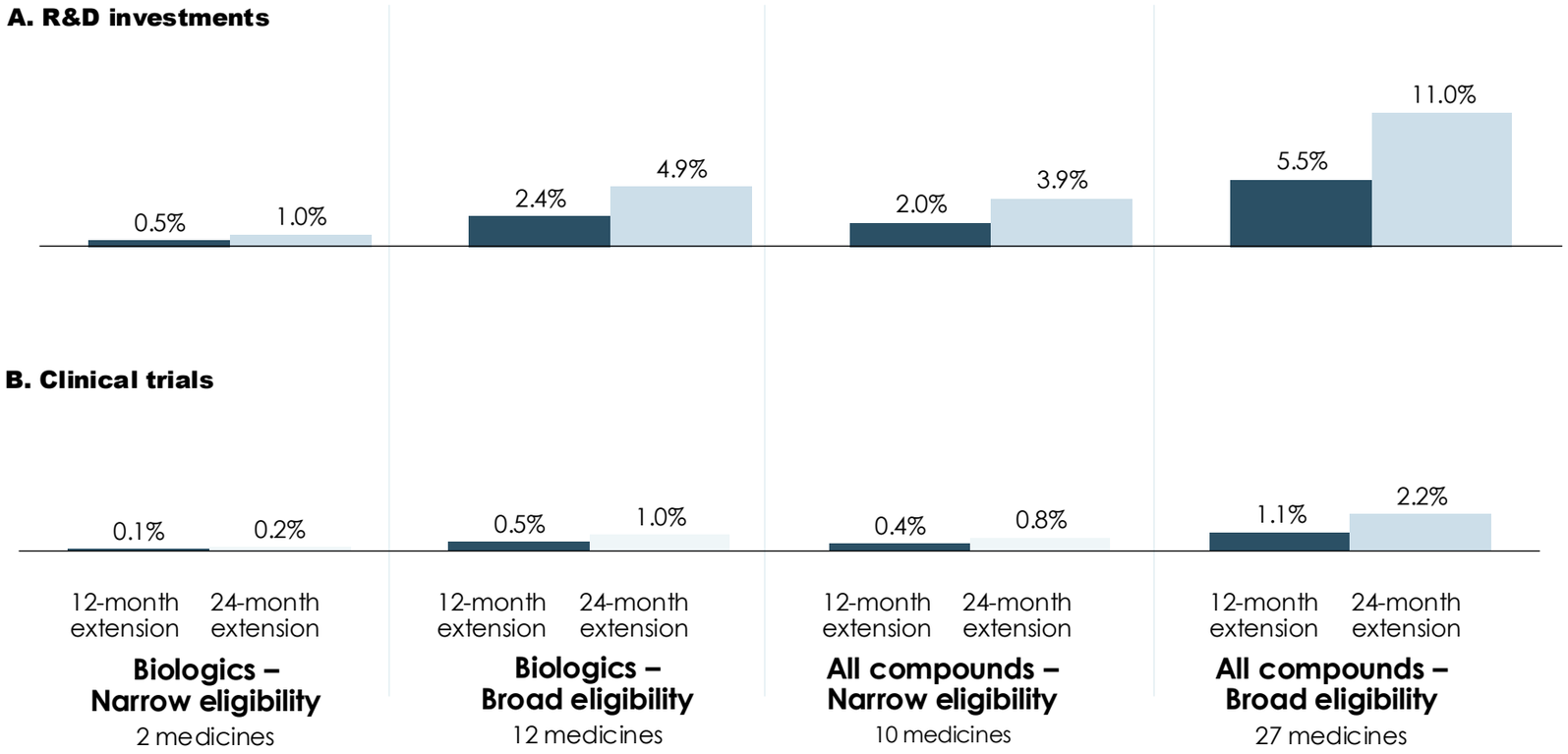
A 12-month SPC extension for biologics with narrow eligibility could increase R&D investment by 0.5 per cent and clinical trial activity by 0.1 per cent; see Figure 8 A and B. Expanding the SPC scope to all compounds with broad eligibility further increases the effect, resulting in a 5.5 per cent increase in R&D investment and a 1.1 per cent increase in clinical trial activity, brining a larger increase.

Hence, the SPC extension can contribute to improving the relative competitive position of Europe with regards to clinical trials and R&D investment, but further policy measures will be needed for Europe to regain a leadership position.[5]

Methodology

We rely on the estimated increase in R&D and clinical trial activity reported in Table 2, calculate the corresponding annual increase, and relate it to the current levels of R&D and clinical trial spending (2025 for R&D and 2023 for clinical trials).

Figure 8. Per cent increase in R&D investment (A) and clinical trial activity (B) across eight scenarios
Number of trials initiated over 15 years



Notes: Between 2013 and 2022, the number of EEA clinical trials states in phases I – III was stable at the level of 1150 trials started annually. In 2023, there was a sharp decline in the number of clinical trials in Europe and globally, so we use data for year 2022 when estimating the impact on clinical trials.
Source: Copenhagen Economics based on EFPIA (2025) and IQVIA (2024).

(1) Stadig (2026, webpage). / 2) EFPIA (2024). / (3) Assessment for the EU (CRA, 2026). / (4) European Commission (2025). / (5) In 2023 US accounted for 21 per cent of clinical trials in (IQVIA, 2024) and 65 per cent in R&D (CRA, 2026).

3

IMPACT ON AVAILABILITY OF AND ACCESS TO INNOVATIVE MEDICINES

4.1. NUMBER AND SPEED OF PRODUCT LAUNCHES

4.2. PATIENT ENROLMENT IN CLINICAL TRIALS

Increased R&D investment in Europe can lead to additional innovative treatments developed and launched in Europe

Innovative medicines

Increased R&D investments will expand development projects, thereby increasing the number of successful outcomes

Increased R&D investments expand the number of clinical development attempts. Assuming stable success rates, increased R&D activity leads to an increase in the number of expected successful outcomes, thereby increasing the number of new treatments developed. As these treatments are developed in Europe, we expect that they will also be launched in Europe. We expect the increase in available treatments to encompass both new treatments developed and launched in Europe and treatments developed elsewhere and now also launched in Europe thanks to larger revenue prospects in Europe.

Impacts

We find that a 12-month SPC extension for biologics with narrow eligibility can lead to the development of two additional medicines; see Figure 9. This impact increases to 16 medicines under broad eligibility and a 24-month extension. Expanding the SPC scope to all compounds further boosts this effect, leading to 35 additional medicines under broad eligibility and a 24-month extension.

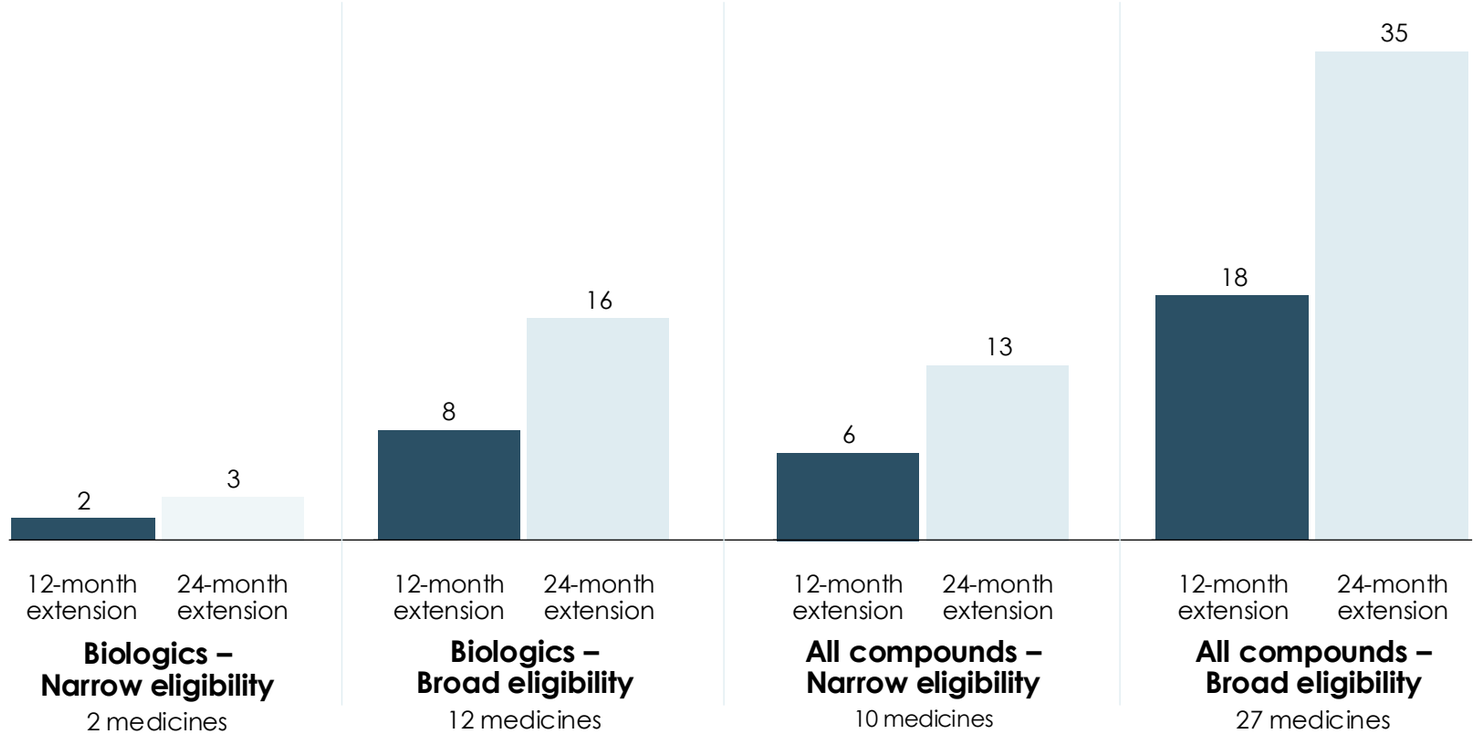
Methodology

We estimate the number of additional innovative medicines developed through the same model used to estimate the number of additional clinical trials. The model follows these clinical trials over time thereby estimating the number of new innovative medicines that these will generate.

For the detailed methodology, see Appendix E

Figure 9. Expected impact of SPC extension on the number of innovative medicines developed in Europe across eight different scenarios

Number of medicines developed over 15 years



Notes: For estimates on cost of clinical trials, we adjust Di Masi et al.. (2016) estimates to March 2026 values using the US consumer price index (CPI). We convert the estimate from USD to EUR using an average exchange rate in March 2026 of 1.156 USD per EUR (European Central Bank, 2026, webpage).
Source: Copenhagen Economics data from IQVIA, EFPIA (2025), Copenhagen Economics (2018), Thomas et al.. (2016), Di Masi et al.. (2016), and clinicaltrials.eu (2026).

Increased R&D investment in Europe can lead to additional patients benefiting from early treatment via clinical trials

Patient enrolment in clinical trials

The increased clinical trial activity can benefit patients who can access investigational treatments early

Increased clinical trial activity can improve access to innovative treatments by enabling earlier use prior to market authorisation. This may benefit patients, particularly in areas with unmet need, by expanding opportunities for early treatment, despite eligibility constraints and inherent uncertainties in the medicine development process.

Impacts

We find that a 12-month SPC extension for biologics with narrow eligibility can lead to 2,200 additional patients enrolled in phase 2 and 3 clinical trials over 15 years; see Figure 10. This impact increases to 21,900 patients under broad eligibility and a 24-month extension. Expanding the SPC scope to all compounds further increases that effect, leading to 49,100 additional enrolled patients under broad eligibility and a 24-month extension.

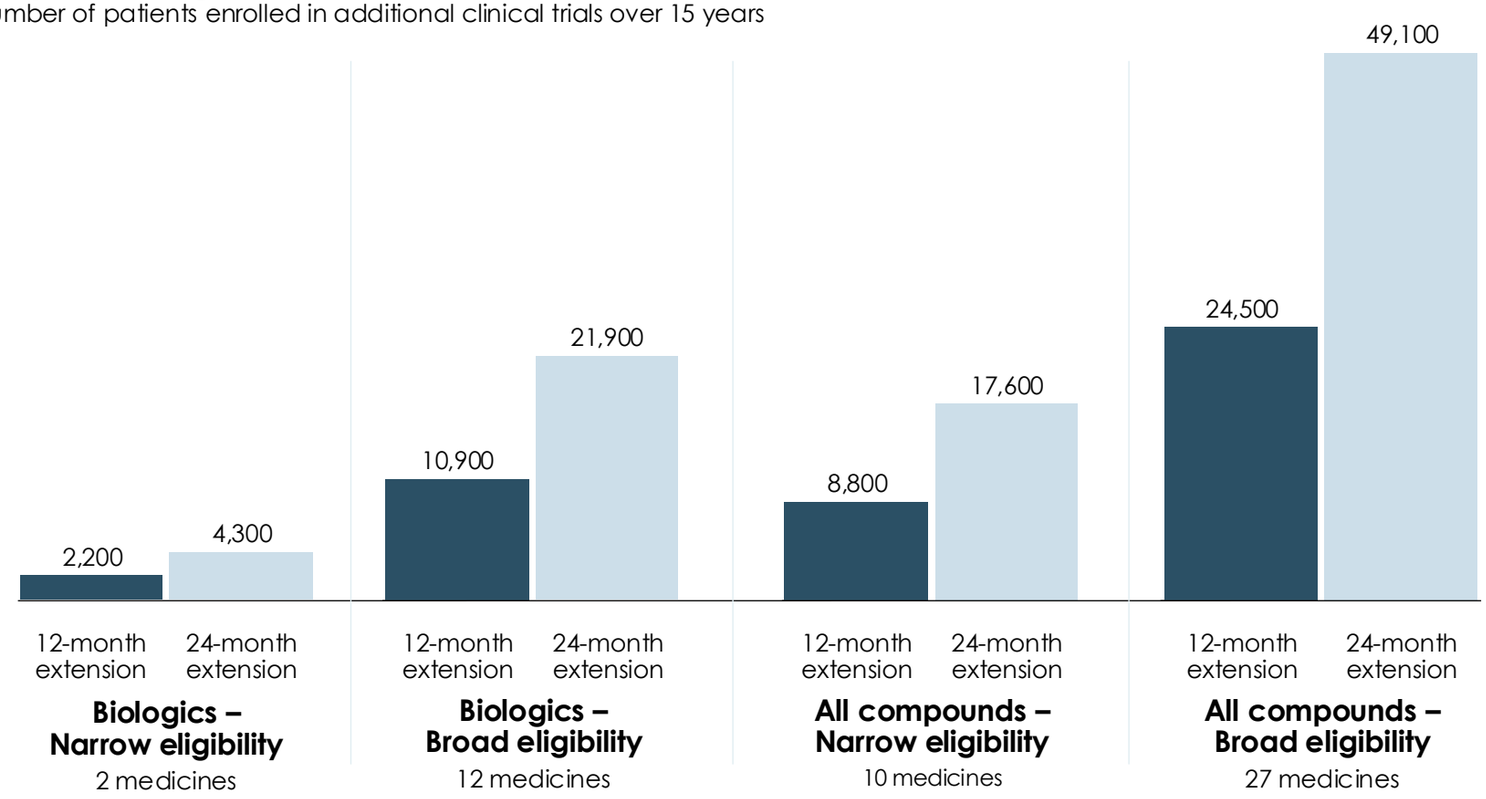
Methodology

We estimate the number of additional patients benefiting from early access to investigational treatments through the same model used to estimate the number of additional clinical trials based on the average number of patients enrolled in phase 2 and 3 clinical trials.

For the detailed methodology, see Appendix F

Figure 10. Expected impact of SPC extension on the number of patients enrolled in phase 2 and 3 clinical trials in Europe across eight different scenarios

Number of patients enrolled in additional clinical trials over 15 years



Notes: for estimates on cost of clinical trials, we adjust Di Masi et al.. (2016) estimates to March 2026 values using the US consumer price index (CPI). We convert the estimate from USD to EUR using an average exchange rate in March 2026 of 1.156 USD per EUR (European Central Bank, 2026, webpage). The number of patients is calculated based on the average number of patients enrolled in EEA industry-sponsored clinical trials initiated between 2017 and 2021. Figures are rounded to the nearest 100

Source: *Copenhagen Economics data from IQVIA, EFPIA (2025), Copenhagen Economics (2018),* Thomas et al.. (2016), Di Masi et al.. (2016), and clinicaltrials.eu (2026).

Access to innovative medicines improves health outcomes and brings related wider economic benefits

The SPC extension may increase patient access to innovative medicines through two main channels: the development and launch of additional innovative treatments in Europe, and earlier patient access to such therapies through increased clinical trial activity. The value generated therefore extends beyond industrial competitiveness. Improved access to innovative medicines can enhance patient health outcomes, which in turn can generate wider economic benefits through healthcare system savings and labour market gains.

Health impact for patients

Access to innovative medicines can improve survival, reduce disease progression, and enhance quality of life, particularly in areas with high unmet medical need.[1]

The following examples illustrate these effects clearly:

- Without innovative medicines launched since 1981, years of life lost before age 85 would have been more than twice as high.[2]
- 35 per cent of the increase in life expectancy between 1990 and 2015 can be attributed to biopharmaceutical innovation.[3]
- Specifically, innovative medicines improved survival and transformed the management of diseases such as HIV, Hepatitis C and cancer.[4]
- Thanks to the advent of a class of drugs known as tyrosine kinase inhibitors (TKIs), the 5-year survival rate for patients with chronic myeloid leukaemia has improved from less than 20 per cent to more than 90 per cent.[5]

Earlier access to innovative therapies, including through clinical trials, may also allow patients to benefit from treatment options before wider market availability, improving outcomes over the long term.

Savings in the healthcare system

Having more innovative medicines available can reduce pressure on healthcare systems by preventing complications, replacing long-term, more resource-intensive interventions, and thus bringing benefits in terms of healthcare system savings and more efficient use of healthcare resources.[6]

For example, new hepatitis C therapies increased cure rates from around 50 per cent to above 95 per cent, while reducing the long-term burden on healthcare systems through lower rates of severe liver disease that require resource intensive interventions.[7]

Specifically, innovative medicines can help mitigate the strain on healthcare resources, particularly healthcare professionals like nurses and physicians, which is characterised by staff shortages, high turnover, and psychological distress.[8] A notable example here is subcutaneously administered medicines, which allow for flexible self-administration by patients in their own homes instead of relying on intravenous administration by healthcare professionals in the hospital.[9]

Innovative medicines come with the cost of the medicine itself. The healthcare savings they generate contribute to partly offsetting some of the cost of the innovative medicines used to treat patients. Importantly, while the cost of the innovative medicine will decrease over time once intellectual property protection expires and generics/biosimilars enter the market, the savings that the innovation has given rise to will continue to materialise every year.

Labour market impacts

Innovative medicines can reduce disability and premature mortality and therefore allow the working population to stay productive for longer reducing absenteeism and presenteeism. Healthier populations are more likely to remain economically active for longer, generating wider economic and social benefits beyond the healthcare sector.

For example, availability of innovative treatments for rheumatoid arthritis improved workforce productivity and reduced work absence. Patients receiving innovative medicines had less than half sick days over two years compared with those receiving standard care (17.4 vs 36.9 days). Treatment also reduced presenteeism, indicating improved performance and productivity at work, and increased the likelihood of patients gaining or remaining in employment over the study period.[10]

This illustrates how investments in pharmaceutical innovation should be understood not only as a healthcare issue, but also as a contributor to productivity and economic resilience.

(1) European Parliament (2025). / (2) Lichtenberg et al.. (2019). / (3) Buxbaum et al.. (2020). / (4) OECD (2018). / (5) OECD (2018). / (6) For example, McEwan et al.. (2020) for an example in heart failure with reduced ejection fraction. / (7) Dennis et al.. (2021). / (8) Almeida-Meza et al.. (2025). / (9) McCloskey et al.. (2022). / (10) van Vollenhoven et al.. (2010).

Pharmaceutical innovation enables broader and more affordable patient access over time through generic and biosimilar entry

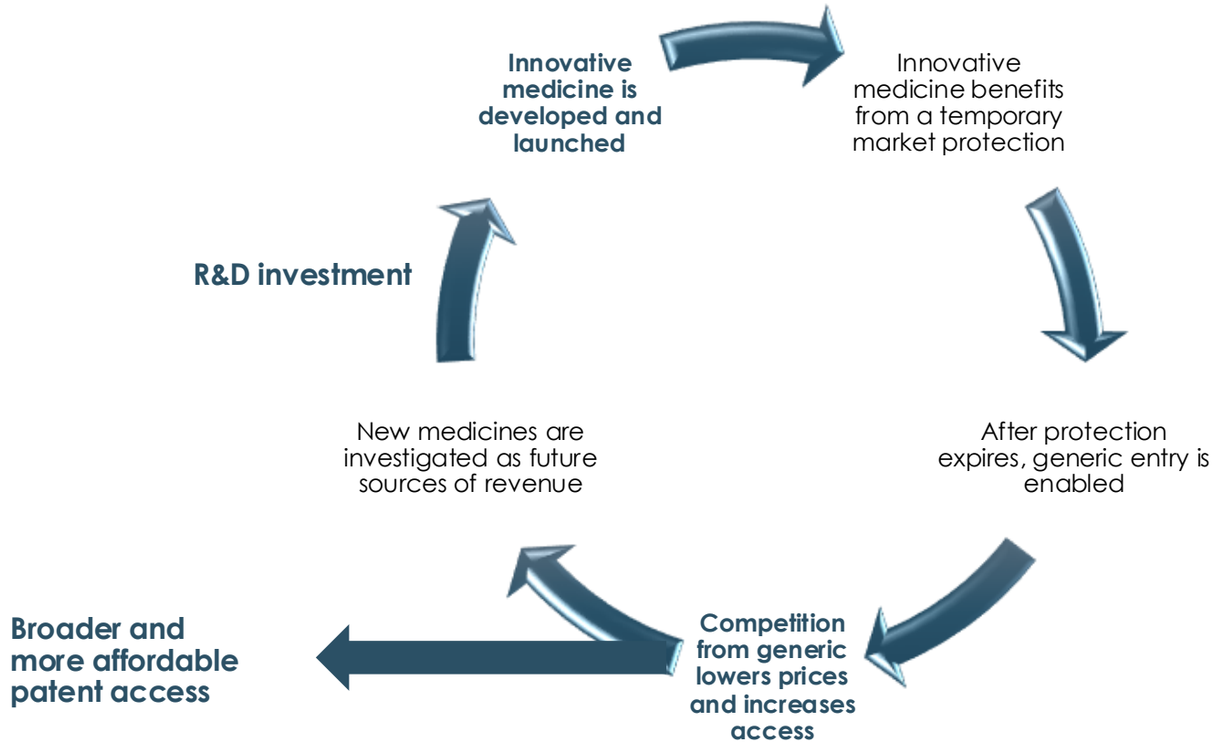
In addition to benefiting patients, healthcare systems, and society, innovative medicines create the foundation for broader and more affordable patient access over time, as generic and biosimilar versions can enter the market once exclusivity periods expire; see Figure 11.

Development of innovative medicines is a long, costly and high-risk R&D process. Temporary periods of patent and regulatory protection allow pharmaceutical companies to recover these investments and support future innovation. In this context, the SPC extension can strengthen incentives for pharmaceutical R&D in Europe by increasing the expected return on investment and supporting the development of additional innovative treatments.

Once exclusivity expires, generic and biosimilar manufacturers can enter the market at lower cost, as they can rely on the clinical and regulatory evidence previously generated by originator companies. Recent evidence suggests that, on average, **each innovative medicine is followed by around 2.5 generic or biosimilar medicines entering the market,[1] increasing competition and expanding patient access through lower-cost alternatives**.

Innovative medicines create the basis for future generic and biosimilar entrants; the presence of more innovative medicines grows future follow-on markets. This ultimately supports the competition generated through eventual generic and biosimilar entry, which in turn broadens access and helps sustain healthcare system affordability.

Figure 11. Through innovation cycle, access to innovative medicines created foundation for broader and more affordable patient access



Source: Copenhagen Economics, based on Copenhagen Economics (2023a).

(1) Copenhagen Economics (2023b).

4
IMPACT ON PHARMACEUTICAL SPENDING

An SPC extension increases pharmaceutical spending in Europe

Additional pharmaceutical spending over a 15 –year period

An SPC extension increases costs for public payers by delaying biosimilar/generic entry, thereby prolonging higher originator prices and postponing potential savings from competition.

Impacts

We estimate that an SPC extension can cost public payers between EUR 898 million and EUR 67,705 million over 15 years in the scenarios of a 12-month extension, biologics, narrow eligibility and 24-month extension, all compounds, broad eligibility, over 15 years, respectively; see Figure 12.

The cost of an SPC extension in the eight different scenarios are driven by two key variables:

First, the number of medicinal products that are eligible which ranges from 2 products per year in the case of biologics and narrow eligibility up to 27 products per year in the case of all compounds and broad eligibility; see page 10.

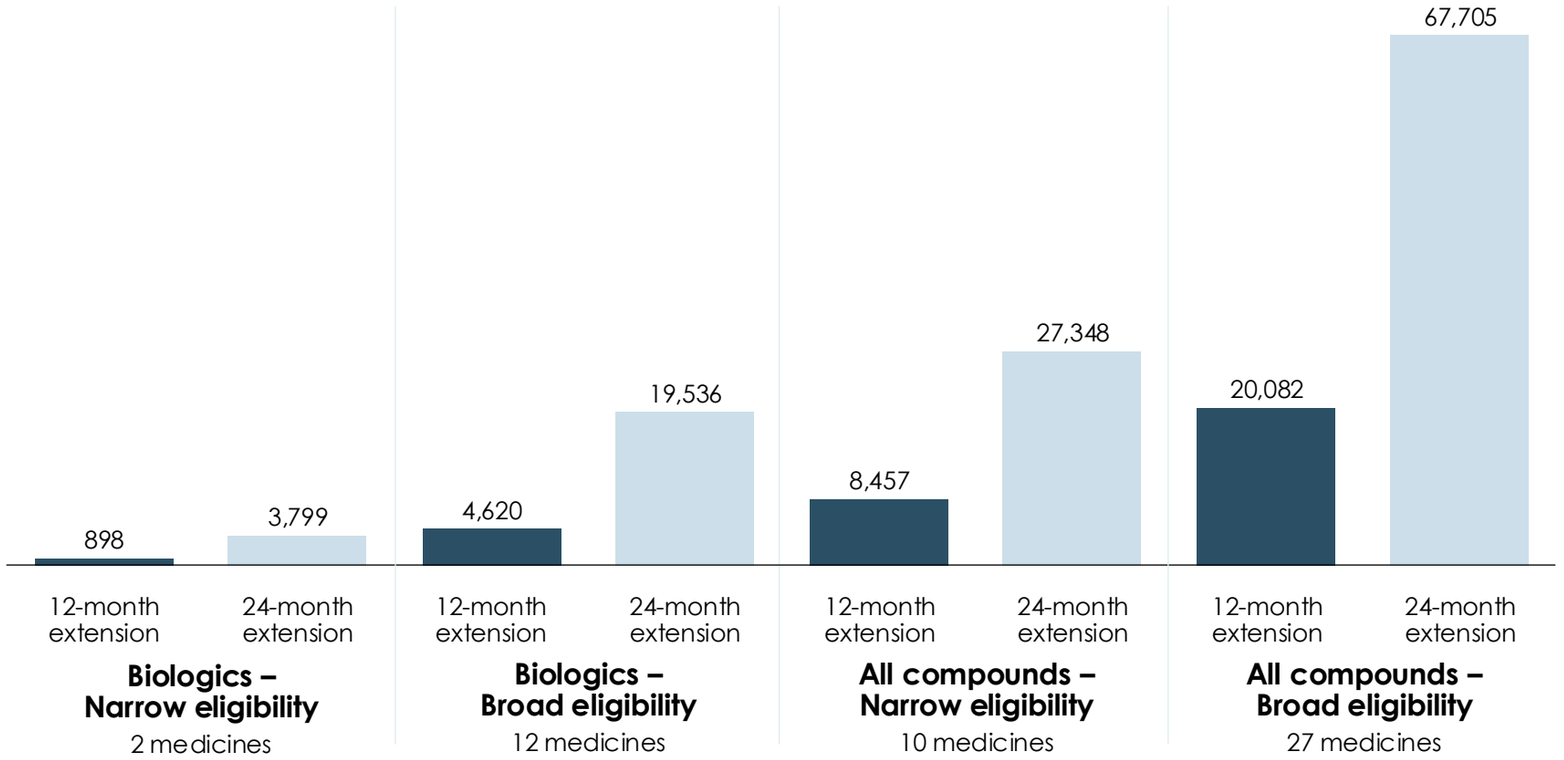
Second, the cost of an SPC extension differs between biologics and small molecules. The average per-product cost for a 12-month extension is EUR 25.7 million for biologics and EUR 68.7 million for small molecules, averaging EUR 58.6 million across all compounds.[1] This implies a further increase in costs in scenarios involving all compounds, on top of the effect from the number of eligible products.

Methodology

We estimate the cost for public payers of an SPC extension by using historical annual product-level revenue data based on list prices between 2015 and 2025 from IQVIA.[2] The data contains all medicines where SPC was the last to expire.

For the detailed methodology, see Appendix E

Figure 12. Expected pharmaceutical spending increase from SPC extensions across eight scenarios
Million EUR over 15 years



Note: The costs are estimated over a 15-year period. Costs are estimated based on products where SPC expired between 2015 and 2023 and revenue data between 2015 and 2025. The results over 15 years are not discounted.
Source: Copenhagen Economics based data from IQVIA, MIDAS FY2015 - FY2025, total European sales in USD (constant exchange rate), Rx only, at list prices.

(1) The lower cost for biologics likely reflects higher switching barriers and entry costs. (2) MIDAS FY2015 - FY2025, total European sales in USD (constant exchange rate), Rx only at list prices. / (3) The data from IQVIA is in USD, which we convert from USD to EUR using the average 2025 exchange rate of 0.885 EUR per USD, see European Central Bank (2026, webpage).

The annual impact on healthcare and pharmaceutical spending from an SPC extension is negligible

While the absolute impact of an SPC extension on pharmaceutical spending may appear substantial, it should be interpreted relative to the overall scale of healthcare and pharmaceutical budgets in Europe.

Impact

Across most scenarios assessed, the estimated increase in spending remains limited. We estimate that a 12-month SPC extension for biologics with narrow eligibility increases healthcare spending by 0.003 per cent and pharmaceutical spending by 0.02 per cent, representing a negligible impact on the respective budgets; see Figure 13.

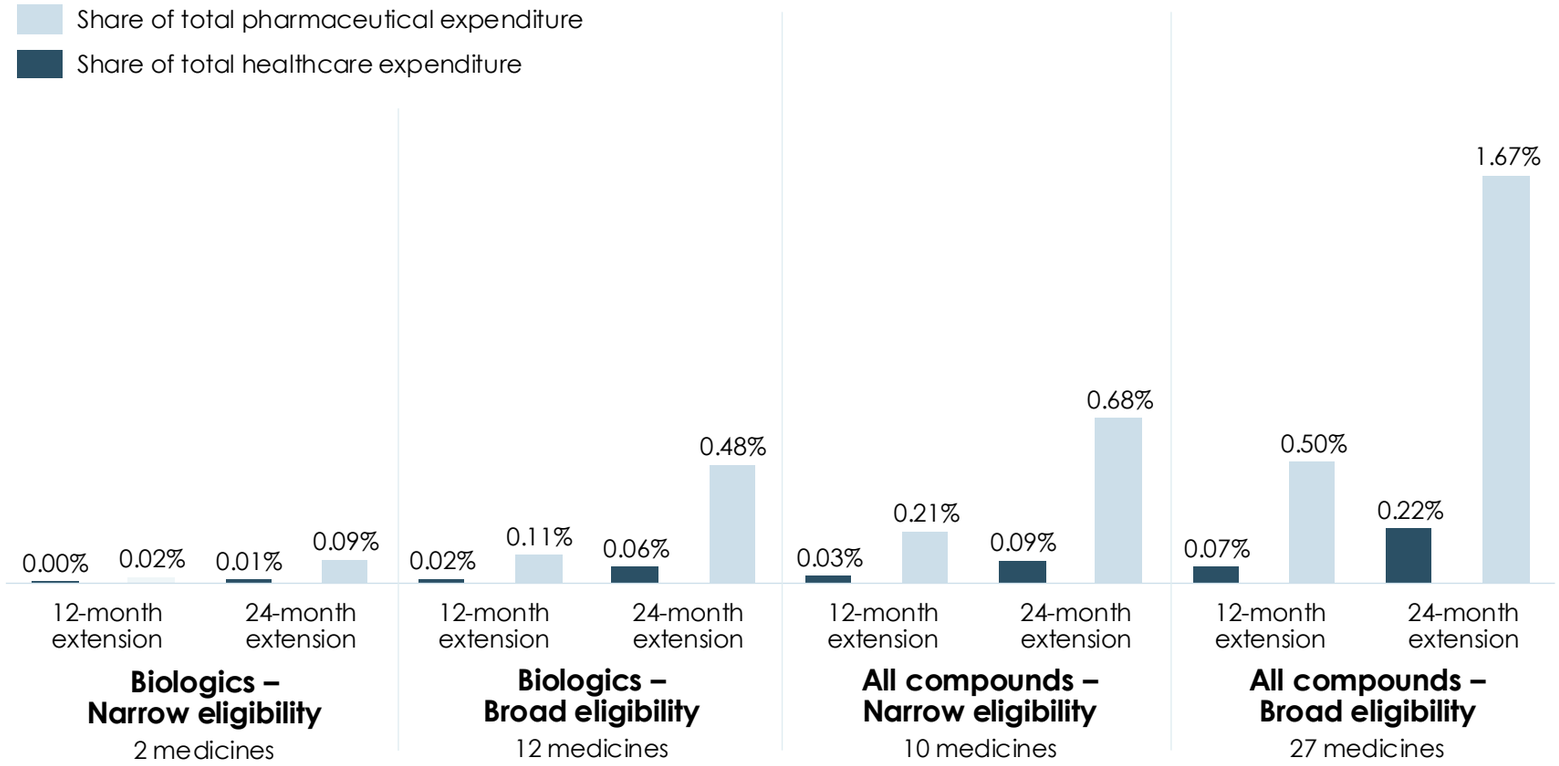
Expanding the scope to all compounds and applying broad eligibility criteria increases the estimated impact to 0.07 per cent of healthcare spending and 0.5 per cent of pharmaceutical spending. Only under the most expansive scenario, i.e. a 24-month SPC extension for all compounds with broad eligibility, does the increase in pharmaceutical spending exceed 1 per cent.

Methodology

To estimate the budgetary impact, we use the estimated increase in pharmaceutical spending reported in Table 1 and calculate the corresponding annual increase in spending. This increase is then expressed relative to total pharmaceutical and healthcare spending in Europe in 2023, the latest year for which comparable data are available. In 2023, countries in Europe spent EUR 269,846 million on pharmaceuticals[1] and EUR 2,032,199 million on healthcare overall.[2]

Figure 13. Expected pharmaceutical and healthcare spending increase from SPC extensions across eight scenarios

Share of total healthcare and pharmaceutical expenditures, 2023



Note: Data on pharmaceutical and healthcare expenditure corresponds to year 2023. Total pharmaceutical expenditure for Norway was not available, and we projected data from 2022 in this case.

Source: Copenhagen Economics, based on cost estimates as reported in Table 1 in this report and OECD data on health expenditure and financing (link), and Pharmaceutical expenditure (link).

(1) Pharmaceutical expenditure (link). / (2) OECD data on Health expenditure and financing (link),

5
ASSESSMENT OF IMPACTS ACROSS SCENARIOS

Comparison of results shows that all scenarios generate benefits to patients, and six out of eight scenarios are likely to generate a positive return on investment for the European economy

In the presented analysis, we assess three categories of impact associated with alternative SPC extension scenarios: impacts on the economic footprint and competitiveness of the European pharmaceutical sector, impacts on patient access to innovative treatments, and impacts on pharmaceutical spending borne by public payers. The analysis considers how changes in the duration, scope and eligibility conditions of SPC extensions may affect these dimensions under different policy scenarios.

The economic footprint in Europe and patient benefits are derived from increased pharmaceutical R&D investment in Europe associated with the extension of effective protection period due to extension of SPC protection. As the underlying model focuses specifically on Europe, the estimated impacts reflect the expected allocation of R&D activity within Europe.

Investments in pharmaceutical R&D in Europe increase with the duration, scope and eligibility of SPC extension

The results indicate that R&D investments increase as the duration, scope and eligibility of SPC extensions become broader. This reflects the fact that longer and broader protection increases expected returns on innovative products, while broader eligibility criteria increase predictability and reduce legal uncertainty.

Specifically, **the impact on R&D increases more than tenfold as the number of eligible products raises from 2 products annually under the narrowest scenario to 27 under the broadest scenario;** see Table 2 on the next page:

- For a 12-month extension the increase is from EUR 3,986 million in Scenario 1 (biologics, narrow eligibility) to EUR 45,348 million in Scenario 7 (all compounds, broad eligibility)
- For a 24-month extension the increase is from EUR 7,972 million in Scenario 2 to EUR 90,696 million in Scenario 8.

Increased R&D investments in turn generate broader economic effects in Europe. Higher investment levels support employment in R&D and non-R&D functions, contribute to increased gross value added, and increase clinical trial activity within Europe. These effects are expected to strengthen the overall economic footprint of the European pharmaceutical sector coming with an SPC extension.

Patients benefit from increasing R&D activity in Europe

Increased R&D activity leads to an increase in the number of expected successful outcomes, thereby increasing the number of new treatments developed. Moreover, increased R&D expands the number of clinical trials providing early access to innovative treatments. Increased clinical trial activity can also improve access to innovative treatments by enabling earlier use prior to market authorisation, i.e. in clinical trial phases II and III. This may benefit patients, particularly in areas with unmet need, by expanding opportunities for early treatment, despite eligibility constraints and inherent uncertainties in the medicine development process

Under the most restrictive scenario 1, estimated patient impacts remain limited due to the relatively small number of products benefiting from the extension. Under this scenario, an estimated number of additional 9,400 patients can be enrolled in clinical trials. As scope and eligibility broaden, the number of patients participating in clinical trials and the expected number of innovative products developed and launched in Europe increase more than tenfold.

In six out of eight scenarios, the estimated economic value generated is likely to outweigh the associated costs

While extended protection may support additional innovation activity and benefit patients, delayed competition can postpone access to lower-cost generic and biosimilar treatments and reduce short-term savings for healthcare systems. Given that the majority of pharmaceutical expenditure in Europe is publicly financed, these additional costs are expected to be borne primarily by public healthcare systems.

The results of our analysis indicate that, in six out of eight scenarios, the estimated direct economic value generated (proxied by *direct* GVA, i.e. the additional economic output associated with increased pharmaceutical activity) is likely to outweigh the associated costs from higher pharmaceutical spending. This is indicated by a GVA-to-cost ratio greater than one.

The results also illustrate important trade-offs between fiscal cost, competitiveness impacts, and patient benefits across scenarios.

- Under scenarios 1 and 3, the ratio of economic value generated relative to additional pharmaceutical expenditure remains strictly positive but the resulting impacts on patient benefits remain limited.
- Intermediate scenarios – 2, 4, 5 and 7 - appear to provide a more balanced profile, combining likely positive ratios of economic value generated relative to additional pharmaceutical expenditure with broader positive impacts on patient access.
- Under scenarios 6 and 8, the ratios between additional value generated and additional pharmaceutical spending are negative, but the patient benefits are substantial with 17,600 and 49,100 potentially benefit from early access to innovative medicines through clinical trials.

Overall, the comparison of impacts suggests that broader SPC extensions with longer duration may strengthen incentives for pharmaceutical R&D investment and innovation activity in Europe, while also increasing pharmaceutical expenditure for public payers. The results therefore highlight the policy trade-off between supporting pharmaceutical competitiveness and innovation in Europe, improving opportunities for patient access to innovative treatments, and containing public pharmaceutical expenditure.

High impact
Significant impact
Moderate impact
Limited impact

Table 2. Summary of impacts across scenarios
Impact over 15 years unless explicitly stated

Scopes	Biologics				All compounds			
Eligibility	**Narrow** (4 out of 4 Article 27 criteria)		**Broad** (1 out of 4 Article 27 criteria)		**Narrow** (4 out of 4 Article 27 criteria)		**Broad** (1 out of 4 Article 27 criteria)	
Duration	**12 months**	**24 months**	**12 months**	**24 months**	**12 months**	**24 months**	**12 months**	**24 months**
Medicinal products benefiting each year	2	2	12	12	10	10	27	27
	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario 4**	**Scenario 5**	**Scenario 6**	**Scenario 7**	**Scenario 8**
ECONOMIC FOOTPRINT AND COMPETITIVENESS								
R&D investments, EUR million	3,986	7,972	20,142	40,285	16,287	32,575	45,348	90,696
Pharmaceutical jobs	SR: 269 – 508 LR: 459 – 867	SR: 538 – 1,016 LR: 918 – 1,734	SR: 1,360 – 2,567 LR: 2,320 – 4,380	SR: 2,720 – 5,134 LR: 4,641 – 8,760	SR: 1,100 – 2,076 LR: 1,876 – 3,542	SR: 2,199 – 4,151 LR: 3,753 – 7,084	SR: 3,061 – 5,779 LR: 5,224 – 9,861	SR: 6,123 – 11,558 LR: 10,448 – 19,723
Jobs in the wider economy	SR: 1,033 – 1,951 LR: 1,764 – 3,329	SR: 2,067 – 3,902 LR: 3,527 – 6,658	SR: 5,223 – 9,859 LR: 8,912 – 16,823	SR: 10,445 – 19,717 LR: 17,825 – 33,647	SR: 4,223 – 7,972 LR: 7,207 – 13,604	SR: 8,446 – 15,944 LR: 14,414 – 27,208	SR: 11,758 – 22,195 LR: 20,065 – 37,876	SR: 23,517 – 44,391 LR: 40,131 – 75,752
GVA, EUR million	D: 1,544 – 2,914 T: 3,068 – 5,792	D: 3,087 – 5,828 T: 6,137 – 11,584	D: 7,801 – 14,725 T: 15,506 – 29,269	D: 15,602 – 29,450 T: 31,012 – 58,539	D: 6,308 – 11,907 T:12,538 – 23,668	D: 12,616 – 23,814 T: 25,077 – 47,335	D: 17,563 – 33,152 T: 34,910 – 65,897	D: 35,125 – 66,304 T: 69,819 – 131,793
Number of clinical trials	17	34	85	169	69	138	192	383
PATIENT BENEFIT								
New medicines developed	2	3	8	16	6	13	18	35
Patient enrolment in clinical trials	2,200	4,300	10,900	21,900	8,800	17,600	24,500	49,100
COST								
Pharmaceutical spending, EUR million	898	3,799	4,620	19,536	8,457	27,348	20,082	67,705
Annual impact pharmaceutical budget	0.02 %	0.09 %	0.11 %	0.48 %	0.21 %	0.68 %	0.50 %	1.67 %
NET ECONOMIC IMPACT								
Direct GVA – Pharma spending *Difference*	646 – 2,016	-712 – 2,029	3,181 – 10,105	-3,934 – 9,914	-2,149 – 3,450	-14,732 – -3,534	-2,519 – 13,070	-32,580 – -1,401
Direct GVA/ Pharma spending *Ratio, rounded*	**1.7 – 3.2**	**0.8 – 1.5**	**1.7 – 3.2**	**0.8 – 1.5**	**0.7 – 1.4**	**0.5 – 0.9**	**0.9 – 1.7**	**0.5 – 1.0**
Comment on ratio	**Strictly positive**	**Likely positive**	**Strictly positive**	**Likely positive**	**Likely positive**	**Negative**	**Likely positive**	**Negative**

Notes: R&D = research and development. GVA = gross value added. SR = short-run. LR = long-run. D = direct effect. T = total effect.

METHODOLOGICAL APPENDIX

Our approach to estimating impacts

In this Methodological Appendix, we describe the data sources and methodology used to estimate the number of products that would benefit from SPC extension under the eight scenarios (Appendix A) and then provide details on how we quantify both the costs and the economic value associated with an extension of SPC protection (Appendices B-F).

Regarding the cost and value assessment, on the value side, we start by estimating the effect of extended SPC protection on pharmaceutical R&D investment (Appendix B). Based on that, we quantify how additional investments translate into broader economic outcomes, including employment (Appendix C), gross value added (Appendix D), and the number of clinical trials (Appendix E). Together, these indicators provide a measure of the extent to which the SPC extension contributes to retaining and attracting pharmaceutical investment in Europe. Due to a lack of data, we are not able to quantify the impact on manufacturing.

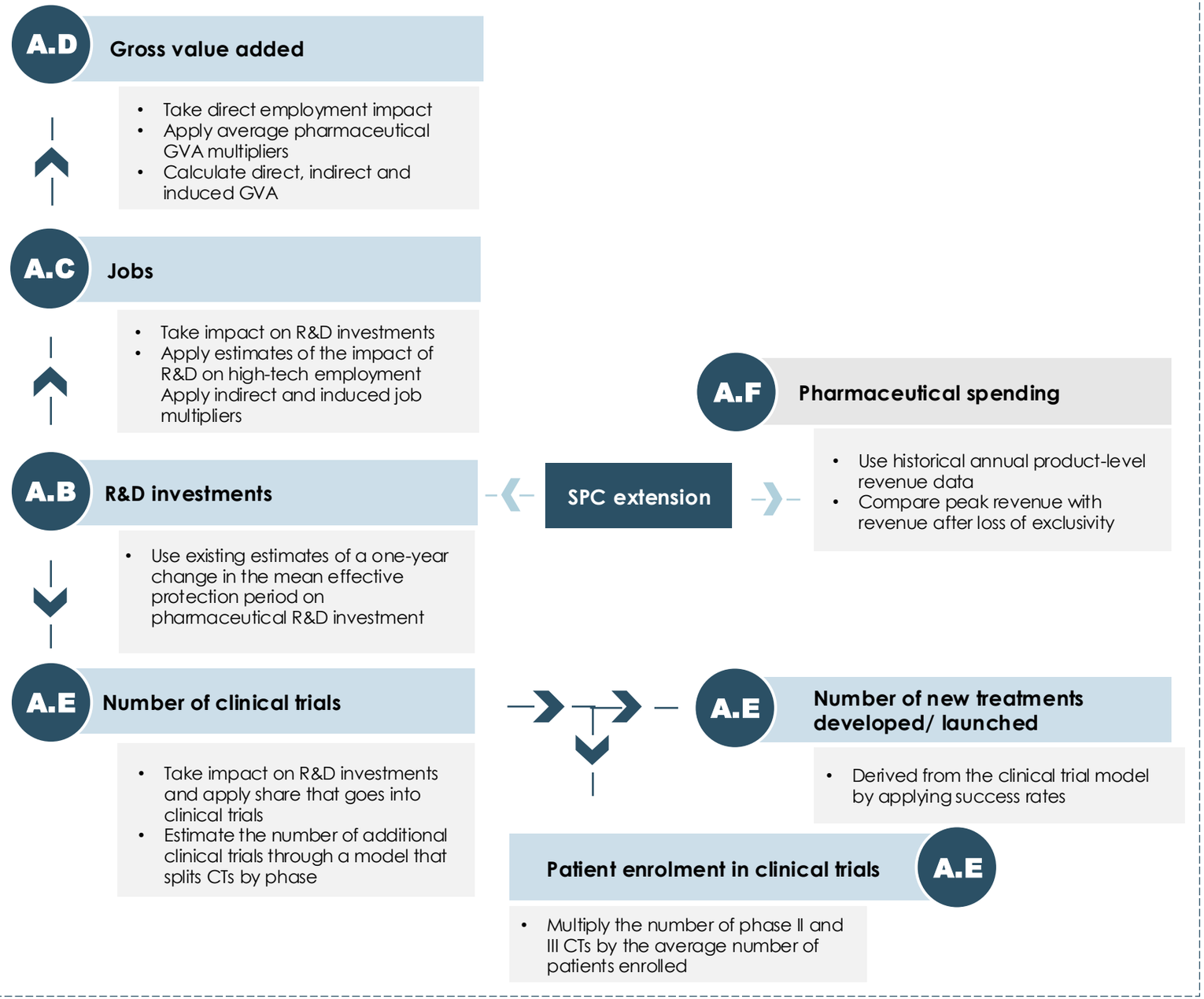
Our assessment also considers the benefit to patients in terms of availability of, and access to, innovative treatments. These effects are expected to arise via increased clinical trial activity.

On the cost side, the analysis considers the impact of SPC extension on pharmaceutical spending (Appendix E).

We quantify all impacts for Europe, including the EU27, the UK, Switzerland and Norway. This scope reflects the availability of innovative R&D and sales data for this specific geographical area.

The presented estimates show the value and cost for a period of 15 years to capture both short- and long-term effects. In the pharmaceutical industry, impacts on R&D and innovation materialise gradually over time; focusing only on the short term, we would risk underestimating the overall effect.

The remainder of this Appendix presents the methodological approach and detailed assumptions underpinning the estimation of each component included in the analysis.



Share of medicines that could benefit from SPC-extension

Appendix A

We estimate the share of products that would qualify for an SPC extension in each scenario using EMA medicines approved between 2023 and 2025

For innovative medicines approved between 2023 and 2025, IQVIA has collected information on the following characteristics at the product level:

- Whether the product is a biologic, i.e. is developed by means of biotechnological processes
- Whether the product contains a new active substance distinctly different from that of any authorised medicinal product in the Union
- Whether the product has a mechanism of action distinctly different from and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;
- Whether the authorisation of the product has relied on clinical trials evaluating the efficacy of the medicinal product conducted in more than two Member States
- Whether, for that product, at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union

In our calculations, we consider only those products for which SPC is the last protection to expire. Details on data sources are provided in Table A1 on the next page, and a list of active substances for which eligibility criteria were assessed is provided on page 33.

Based on this data, we calculate the products eligible each of the following four scenarios:

- "**Biologics – narrow eligibility**": Scope is limited to medicinal products that have been developed by means of biotechnological processes and eligibility criteria are treated cumulatively, i.e. all criteria must be satisfied for the product to be eligible for protection.
- "**Biologics – broad eligibility**": Scope is limited to medicinal products that have been developed by means of biotechnological processes and only one eligibility criterion must be met.
- "**All compounds – narrow eligibility**" : Scope covers both biological and small molecule medicines and eligibility criteria are treated cumulatively, i.e. all criteria must be satisfied for the product to be eligible for protection.
- "**All compounds – broad eligibility**": Scope covers both biological and small molecule medicines and only one eligibility criterion must be met.

We first calculate the number of products eligible under each scenario for a given year, considering only products for which the SPC is the last to expire. We then compute the average number (or share) across the years 2023–2025. Results are presented in Table A.2.

Two potential biases arise from our approximation:

First, we are likely to overestimate the number of products eligible.[1] This is because it is not possible, withing the scope of the analysis, to assess whether a medicinal product with a distinctly different mechanism of action also demonstrates a level of safety and efficacy at least equivalent to that of any authorised medicinal product in the Union for the same disease. Such an assessment would require additional clinical and comparative evidence that is not available within the scope of this study.

Second, the analysis may underestimate the number of eligible products. The analysis only considers products for which the SPC is the last protection to expire. However, where SPC protection expires earlier - up to 12 or 24 months before the expiry of another relevant protection period - the extension could still result in a marginal increase in the effective protection period. Such cases are not included in the analysis.

Table A.2. Medicines that could benefit from SPC extension
Average number and share of innovative medicines approved between 2023 and 2025

Scenarios	Average number of products benefiting	Average share of products benefiting
Biologics – narrow eligibility	2.3	4.6%
Biologics – broad eligibility	12.0	23.1%
All compounds – narrow eligibility	9.7	18.7%
All compounds – brad eligibility	27.0	51.9%

Source: Copenhagen Economics, based on data provided by IQVIA.

1/ See IQVIA Blog (2026) for the discussion on how the wording of the eligibility criteria be interpreted.

Table A1. Sources for criteria on scope and eligibility
Identification strategy developed by IQVIA

Criteria	Source
Scope	
Medicinal products for human use **developed by means of biotechnological processes**	The information is collected on the basis of EPAR product information data and is consistent with the scope of Annex I to Regulation 2001/83/EC, as referenced in the Biotech Act, which covers medicinal products developed by means of the following biotechnological processes: "recombinant nucleic acid technology" and "controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells."
Eligibility criteria	
the medicinal product contains **a new active substance** distinctly different from that of any authorised medicinal product in the Union	Definition based on the IQVIA Institute NAS classification: Novel active substances (NAS) are defined as medicinal products for which at least one active ingredient was globally novel at the time of first regulatory approval. Products are assessed at the level of the active substance rather than the indication, formulation, or commercial presentation, and are included if approval has been granted in at least one regulatory jurisdiction in scope. Generics, biosimilars, vaccines, diagnostic agents, imaging products, hospital solutions, new formulations, new combinations of previously approved active substances, and products falling under ATC classes K, T and selected V categories are excluded. Products that do not introduce a molecularly distinct, globally novel active ingredient, including cell- or tissue-based therapies, are not classified as NAS.
The medicinal product has a **mechanism of action distinctly different from** and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;	This assessment evaluated mechanism of action novelty strictly in the scientific sense (i.e. based on biological target and core mechanistic pathway), excluding formulation differences, delivery routes, indications, or regulatory classifications. For each product, comparators were limited strictly to medicines approved before or on the same date as the assessed product to ensure accurate historical context.
The **clinical trials** evaluating the efficacy of the medicinal product and supporting its marketing authorisation were **conducted in more than two Member States**;	EPAR Public assessment reports were used to identify relevant pivotal trials. Once the trial was identified, countries in scope were searched using the unique trial ID in EUCTIS or ClinicalTrials.gov.
At least **a manufacturing step**, excluding packaging, quality testing and certification is **performed in the Union**	The information is collected on the basis of EPAR and specifically, from individual product information under 'Product Information - with tracked changes'. Information in Annex II "A. Manufacturer of biological active substances"
Products protected by an SPC, where the SPC is the last form of protection to expire	
Medicinal products benefiting from SPC, where SPC is the last protection to expire	Exclusivity data was sourced from IQVIA's proprietary ARK Patent Intelligence database and reflects the protection landscape as of 28th April 2026. Using this database, products were classified as: • "**SPC**" where a Supplementary Protection Certificate had either been filed or granted. • **No SPC (but possible in the future)**", was applied to products for which patent protection is currently the last form of protection. For these products, a manual review was conducted by IQVIA's patent experts, who determined that the underlying patents are eligible for a potential SPC application. While no SPC had been filed as of the cut-off date, an SPC remains a plausible future outcome for these products. • "**No SPC**" where the last form of protection was market protection, orphan drug exclusivity (ODE), or other non-SPC protection mechanisms.

Source: Copenhagen Economics based on data provided by IQVIA.

Figure A2. List of active substances approved by EMA between 2023 and 2025 considered in this analysis

acoramidis
adagrasib
allogeneic umbilical cord-derived CD34-cells, non-expanded / dorocubicel
amino acids
atogepant
atropine sulfate
aztreonam / avibactam
belantamab mafodotin
belzutifan
beremagene geperpavec
Brensocatib
buprenorphine
cabotegravir
capivasertib
catumaxomab
cedazuridine / decitabine
cefepime / enmetazobactam
Chikungunya vaccine (live)
Chikungunya vaccine (recombinant, adsorbed)
ciclosporin
cipaglucosidase alfa
clascoterone
concizumab
COVID-19 Vaccine (recombinant, adjuvanted)
crisantaspase
crovalimab
dabrafenib
danicopan
dantrolene sodium, hemiheptahydrate
dasiglucagon
datopotamab deruxtecan
delgocitinib
deucravacitinib
deutivacaftor / tezacaftor / vanzacaftor
diflunisal
donanemab
dopamine hydrochloride
efanesoctocog alfa
efbemalenograstim alfa
elacestrant
elafibranor
elinzanetant
elranatamab
enalapril maleate
epcoritamab
epinephrine
eplontersen
erdafitinib
etranacogene dezaparvovec
etrasimod
exagamglogene autotemcel
ferric citrate coordination complex
fezolinetant
flortaucipir (18F)
fruquintinib
futibatinib
gadopiclenol
gallium (68Ga) chloride / germanium (68Ge) chloride
ganaxolone
garadacimab
gefapixant
givinostat
glofitamab
human normal immunoglobulin
imetelstat
inavolisib
influenza vaccine (live attenuated, nasal)
influenza vaccine (surface antigen, inactivated, adjuvanted)
influenza vaccine (surface antigen, inactivated, prepared in cell cultures)
insulin icodec
insulin icodec / semaglutide
iptacopan
ivosidenib
latanoprost
lazertinib
lebrikizumab
lecanemab
lenacapavir
linvoseltamab
lutetium (177Lu) chloride
macitentan / tadalafil
marstacimab
mavacamten
methylphenidate hydrochloride
miglustat
mirdametinib
mirikizumab
mirvetuximab soravtansine
momelotinib
Mycobacterium tuberculosis derived antigens (rdESAT-6 / rCFP-10)
nemolizumab
nipocalimab
niraparib / abiraterone acetate
nirogacestat
obecabtagene autoleucel
octreotide
odevixibat
odronextamab
olezarsen
omaveloxolone
palopegteriparatide
pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)
pegunigalsidase alfa
pegzilarginase
piflufolastat (18F)
pirtobrutinib
pneumococcal polysaccharide conjugate vaccine (21-valent)
polihexanide
quizartinib
rADAMTS13
recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E
repotrectinib
resmetirom
Respiratory syncytial virus mRNA vaccine (nucleoside modified)
respiratory syncytial virus vaccine (bivalent, recombinant)
retifanlimab
rezafungin
rilzabrutinib
ritlecitinib
rozanolixizumab
ruxolitinib
sargramostim
sebetralstat
sepiapterin
serplulimab
sipavibart
sirolimus
sodium thiosulfate
sotatercept
sparsentan
spironolactone
sugammadex
sugemalimab
talquetamab
teprotumumab
tiratricol
tislelizumab
tisotumab vedotin
tofersen
toripalimab
trametinib
tremelimumab
ublituximab
vadadustat
vamorolone
vibegron
vilobelimab
vimseltinib
vorasidenib
zanidatamab
zapomeran
zilucoplan
zolbetuximab
zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)
zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)

Methodology to quantify the impact on R&D investments

Appendix B

A study from 2018[1] demonstrated that a one-year increase in the mean effective protection period in EU countries is associated with a 6.97 per cent increase in pharmaceutical R&D investments in the short run and 11.89 in the long run. We outline, at a high level, the methodology in the study below, for a detailed outline of the methodology in the 2018 study, see Copenhagen Economics (2018), p. 92-101.

The 2018 study demonstrates the impact on pharmaceutical R&D investments from changing the mean effective protection period by one year

The 2018 study[1] is based on econometric analysis of data from 1996 to 2014 on 20 EU member states. As a result, the estimates can be interpreted as the within-EU effects of market protection on pharmaceutical R&D investments. The analysis utilises a dynamic panel data (DPD) model with system generalised method of moments (GMM) based on seminal work by Arellano and Bond[2] and Arellano and Bover[3] and further refined by Blundell and Bond.[4]

The DPD model estimated is the following:

$$(1)\ \log(RD\_spend_{it}) = \alpha * \log(RD\_spend_{i,t-1}) + \beta * effective\_protection_{it} + \boldsymbol{\delta} * \boldsymbol{X}_{it} + \eta_i + \nu_t + \varepsilon_{it},$$

where RD_spend_{it} is total pharmaceutical R&D investments in market $i = 1, \dots, N$ at time $t = 0, \dots, T$ and $effective\_protection$ is the mean effective protection period in a given year for the other EU countries with which a given country trades, weighted by the fraction of total pharmaceutical exports that country received from the country of interest. $\boldsymbol{X}$ are control variables, η are market time-invariant fixed effects, ν are year dummies, and ε is the error term. The estimate of β is the so-called short-run effect of the weighted mean effective market protection on pharmaceutical R&D investments, and $\beta/(1-\alpha)$ is the corresponding long-run effect.

In the **short run**, most production inputs are considered fixed, e.g., it is not possible to build a new R&D facility from one day to another. In the **long run**, all inputs can be changed and thus give rise to higher output than in the short run, which results in larger long-term effects. There is no fixed number of years assigned short- and long-run estimates, but for simplicity, the short-run effect can be considered as materialising shortly after the proposal is implemented while the long-run effect can materialise in, e.g., 5-10 years.

Both effects are estimated at the margin and reflect the association between a one-year change in the mean effective protection period and a change in R&D investments. This means that they apply directly to a 12-month extension of the SPC for medicines that will qualify for the extension and benefit from it.

From the DPD with system GMM, the study finds that $\beta = 0.0697$ $(p < 0.05)$ and $\alpha = 0.414$ $(p < 0.01)$. This implies that the estimated short-run effect of increasing the weighted mean effective protection period by one year is 6.97 per cent and the long-run effect is 11.89 per cent $(0.0697/(1-0.414))$.

The 2018 study is to our knowledge the most recent analysis on the relationship between effective market protection and R&D investments. Despite being published 8 years ago, the study is in our view still applicable since the relationship estimated is in terms of semi-elasticity, i.e., the percentage increase in R&D investments associated with a one-year increase in the effective protection period.

We quantify effects over a 15-year period

All estimates in this report are quantified over a 15-year period. Our 15-year estimates consist of a combination of the short-run and a long-run effects, and we use the short-run estimates in 4 or those years (years 1-4) and the long-run estimates in 11 of those years (years 5-15).

To quantify the impact, we take the share of innovative products eligible under each scenario, combine it with total pharmaceutical R&D investments of EUR 55 billion (2024)[5] and the results from the 2018 SPC study.

For example, under the 12-month SPC extension scenario, with biologic products in scope and narrow eligibility criteria, we estimate the increase in R&D investment as follows:

- Short-run increase: 0.0697 * EUR 55 billion * 0.046 = EUR 175.0 million per year.
- Long-run increase: 0.1189 * EUR 55 billion * 0.046 = EUR 298.7 million per year.
- Cumulative 15-year effect: EUR 175.0 million * 4 years + EUR 298.7 million * 11 years = EUR 3,986 million.

(1) Copenhagen Economics (2018). / (2) Arellano and Bond (1991). / (3) Arellano and Bover (1995). / (4) Blundell and Bond (1998) / (5) EFPIA (2025).

Methodology to quantify the expected impact on jobs

Appendix C

We use a three-step approach to model the impact on jobs:

1. **We collect existing, public data to be used in the estimation**

The baseline input necessary for the estimated impact on jobs stems from EFPIA:[1]

- RD_0: baseline pharmaceutical R&D investment in Europe: EUR 55,000 million in 2024[1]
- L_0: baseline direct pharmaceutical employment: 950,000 in 2024.[1]

2. **We estimate the SPC-induced change in R&D investments**

We use the estimate of the short-term and long-term impact on R&D investment from Appendix B and calculate percentage change with respect to the baseline R&D investments:

$g_{short} = \frac{\Delta RD_{short}}{RD_0}$ and $g_{long} = \frac{\Delta RD_{long}}{RD_0}$.

3. **We use estimated elasticities to move from R&D investments to direct pharmaceutical job creation**

We use an estimate of the elasticity of employment with respect to R&D investment from the literature, ε. The elasticity captures the percentage change in the number of direct jobs following a 1% increase in R&D investment. Specifically, peer-reviewed evidence using firm-level data for European R&D-performing firms estimates an elasticity in the range of 0.089 - 0.168 for high-tech firms, among which pharmaceutical companies.[3] This implies that a 1% increase in R&D investment increases the number of jobs by 0.089 - 0.168%. We use these estimates as lower and upper bounds, respectively.

Based on this, we can calculate the expected impact on the number of jobs in short-run:

$\Delta L_{lower,short} = \varepsilon_{lower} * g_{short} * L_0$ and $\Delta L_{upper,short} = \varepsilon_{upper} * g_{short} * L_0$

In the long-run, we use the long-run R&D share g_{long} in the equation above. Calculations and results appear in Table C1.

We distinguish between direct, indirect, and induced effects

The estimated impact on jobs described in step 3 is **the direct effect** of R&D investments on direct jobs, i.e. the number of jobs that are created in the pharmaceutical companies. We further estimate the indirect and induced effect.

The **indirect effect** captures jobs supported in the supply chain, as pharmaceutical companies purchase goods and services from suppliers, thereby supporting employment among these suppliers.

The **induced effect** captures jobs supported in the wider economy, as employees in pharmaceutical companies and their suppliers spend their wages on goods and services, supporting additional employment through household consumption.

A study from 2024 quantified the economic footprint of the pharmaceutical industry in Europe.[4] We utilise estimates and insights from this study to quantify the multipliers to get from direct to indirect effect and direct to induced effect; see Table C2.

Table C1. Example: estimated number of direct jobs from a 12-month SPC extension
Number of jobs supported by the pharmaceutical industry in Europe per year

	Lower bound	Upper bound
Short run	0.089 * 0.32% * 950,000 = 269	0.168 * 0.32% * 950,000 = 508
Long run	0.089 * 0.54% * 950,000 = 549	0.168 * 0.54% * 950,000 = 867

Note: Total employment (950,000) is based on 2024 levels as reported in EFPIA (2025). Differences are due to rounding.
Source: Copenhagen Economics, based on EFPIA (2025), and Piva and Vivarelli (2017).

Table C2. Multipliers for determining indirect and induced jobs supported
Number of jobs supported by the pharmaceutical industry in Europe in 2022

	Jobs supported	Multiplier[1]
Direct (A)	729,623	-
Indirect (B)	879,266	1.21 (B/A)
Induced (C)	1,193,457	1.64 (C/A)

Source: 1) EFPIA and PwC (2024), page 140. / 2) Copenhagen Economics, based on EFPIA and PwC (2024).

(1) EFPIA (2025). / (2) Text (3) Piva and Vivarelli (2017). / (4) EFPIA and PwC (2024).

Methodology to quantify the expected impact on supported GVA

Appendix D

To quantify the impact on GVA, we use the estimated direct number of jobs supported described in Appendix C, and "translate" this additional job estimate into direct GVA. We use the observed average GVA per pharmaceutical employee of EUR 225,300 in 2022.[1] This implies that when accounting for inflation, the GVA per employee in 2025 was EUR 251,929 per employee.[2]

We estimate the **direct GVA** by multiplying the estimated number of jobs in each scenario with the average GVA per employee in the pharmaceutical sector. For example, we estimate an increase of 269 jobs in the short-run as the lower bound estimate, which gives rise to EUR 68 million GVA directly supported (269 * 251,929).

Our estimates are likely to be conservative. By utilising the average GVA per employee in the European pharmaceutical industry, we assume that each additional direct job created by an SPC extension contributes the same average level of GVA per employee as observed in the industry overall.

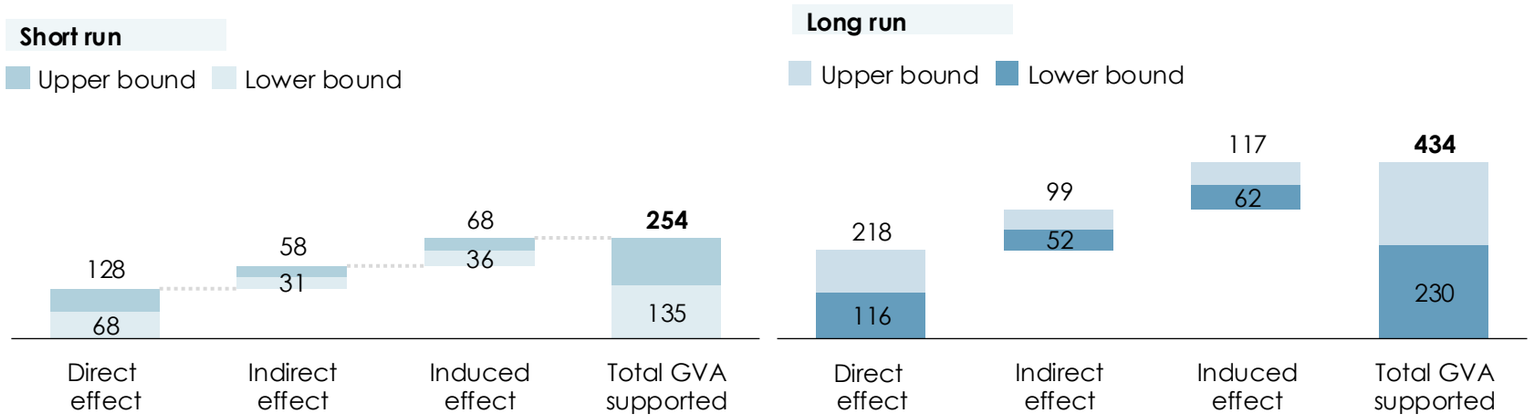
As for **the impact on GVA in the wider economy**, we distinguish between a direct, an indirect, and an induced effect. To do so, we use the relative indirect and induced GVA supported, respectively, to direct GVA supported to estimate multipliers; see Table D1. For example, the EUR 68 million GVA directly supported from the estimated increase in the number of pharmaceutical jobs (short-run, lower bound) is estimated to support an additional EUR 31 million indirectly (EUR 68 million * 0.45); see Figure D2. The results presented on page 5 are based on a 15-year time horizon using the short-run estimates in 4 of those years and the long-run estimates in 11 of those years. The results over 15 years have not been discounted.

Table D1. Multipliers for determining indirect and induced GVA supported
Million EUR GVA supported by the pharmaceutical industry in Europe per year

	GVA supported[2]	Multipliers[2]
Direct (A)	225,148	-
Indirect (B)	102,006	0.45 (B/A)
Induced (C)	120,380	0.53 (C/A)

Source: 1) EFPIA and PwC (2024), page 138. / 2) Copenhagen Economics based on EFPIA and PwC (2024).

Figure D2. Example: Supported European GVA from a 12-month SPC extension for biologics with narrow eligibility
Million EUR per year (2025 values)



Note: Lower- and upper bound estimates are based on lower- and upper-bound elasticity estimates of employment with respect to R&D expenditure in high-tech sectorsm as reported in Piva and Vivarelli (2017). The short- and log-run impact on estimates reflect short and long run R&D investments.
Source: Copenhagen Economics based on EFPIA (2025), Copenhagen Economics (2018), Eurostat (2026, webpage), Piva and Vivarelli (2017), and EFPIA and PwC (2024).

Notes: (1) EFPIA and PwC (2024). / (2) Own calculations based on EFPIA and PwC (2024) and Eurostat (2026, webpage).

Methodology to quantify the number of additional clinical trials, innovative medicines and patients benefitting from early treatments

Appendix E

We estimate the number of additional clinical trials through a simple model that splits the additional R&D investments into clinical trials by phase over 15 years

We estimate that the SPC extension will generate additional R&D investments in Europe, see Appendix B. A share of these investments will fund additional clinical trials. To estimate how many clinical trials will be initiated due to the SPC extension, we build a simple model that allocates the additional investments each year to clinical trials in the different phases.

The model assumes that the additional investments in year 1 will allocated to clinical trials phase 1, 2, and 3, in the same proportion observed in R&D investments by EFPIA members in 2023, corresponding to 7.5 per cent, 9.5 per cent, and 26.8 per cent respectively.

The additional investments in years 2 and following are then calculated as follows:

- Continuation of clinical trials initiated in previous years, taking into account the average length and average success rate of clinical trials in each phase; see Table E.1;
- Remaining investments each year are then allocated to new clinical trials in each phase assuming the same split by phase as in year 1.

Clinical trials are assumed to start at the beginning of each year for simplicity. They are also assumed to either succeed or fail at the end of the period corresponding to the average length of the corresponding trial phase. Due to lack of reliable data, we do not account for the cost of the approval phase and assume that all development expenditure happens in phases 1, 2, and 3.

For each scenario, we use inputs that match the scope of the SPC extension to the extent data is available from the literature; see Table E.1. For instance, an SPC extension with a narrow scope (biologics) is expected to incentivise (primarily) investments in developing biologics. In this scenario, we therefore use average costs of clinical trials, success rates, duration, and trial size for biologics.

We estimate the number innovative medicines developed in Europe over 15 years based on the average success rates of additional clinical trials initiated due to the SPC extension

We estimate the number of innovative medicines that can be developed and launched in Europe through the same model used to estimate the number of additional clinical trials initiated. The model follows these clinical trials over the 15 years applying the average success rates calculated in the literature; see Table E.1.

Similarly, we estimate the number of that could potentially benefit from early access to these new treatments based on the average size of clinical trials

The same model allows us to estimate the number of patients who can benefit from early access to investigational treatments through clinical trials. We only account for phase 2 and 3 clinical trials as phase 1 trials are conducted on healthy volunteers.

Table E.1. Inputs and assumptions to the model

	Phase 1	Phase 2	Phase 3	Approval
Share of R&D investments	7.5%	9.5%	26.8%	
Average cost per clinical trial (mEUR)[1]	31.3	72.5	316.0	-
Average success rate, all compounds	63%	31%	58%	85%
Average success rate, biologics	66%	34%	57%	88%
Average duration of clinical trial (years)	2.8	3.2	3.8	-
Median size (# of patients)	-	99	367	

Notes: 1) For estimates on cost of clinical trials, we adjust Di Masi et al.. (2016) estimates to March 2026 values using the US consumer price index (CPI). We convert the estimate from USD to EUR using an average exchange rate in March 2026 of 1.156 USD per EUR (European Central Bank, 2026, webpage). 2) The number of patients is calculated based on the average number of patients enrolled in EEA industry-sponsored clinical trials initiated between 2017 and 2021.
Source: *Copenhagen Economics data from IQVIA, EFPIA (2025), Copenhagen Economics (2018),* Thomas et al.. (2016), Di Masi et al.. (2016), and clinicaltrials.eu (2026).

Methodology to quantify the impact on pharmaceutical spending

Appendix F (page 1/2)

We estimate the cost for public payers of an SPC extension by utilising historical annual product-level revenue data based on list prices between 2015 and 2025 from IQVIA.[1] The data contains all medicines where SPC was the last to expire (both biologics and non-biologics).[2] Revenues cover EU27 + the UK, Switzerland, and Norway. We consider products where SPC expires between 2015 and 2023 to allow for a consistent 24-month post-expiry period (2024-2025). The data from IQVIA is in USD, which we convert from USD to EUR using the average 2025 exchange rate of 0.885 EUR per USD.[3]

For each product, we first determine whether the highest revenue (i.e., peak revenue) labelled R occurs in the year of SPC expiry or the year prior to expiry and label this year t_0. We then calculate the difference in revenue labelled ΔR_i for each product i between the year with the highest revenue and the year after (two years after when evaluating a 24-month extension). Because an SPC extension cannot reduce costs for public payers, negative values are truncated at zero.[4] The difference in revenue and thus the cost for public payers of extending SPC is then given by $\Delta R_i^{12m} = max(0, R_{i,t_0} - R_{i,t_0+1})$ for a 12-month extension and $\Delta R_i^{24m} = max\left[0, \left(R_{i,t_0} - R_{i,t_0+1}\right) + \left(R_{i,t_0} - R_{i,t_0+2}\right)\right]$ for a 24-month extension.

We then calculate the average difference in revenue for biologics and non-biologics, respectively, and for both a 12-month and 24-month extension as an estimate of the cost for public payers, e.g., $\overline{\Delta R}_{Biologics}^{12m} = {}^1/_N * \sum_{i=1}^{N} \Delta R_i^{12m}$ for a 12-month extension where N is the number of biologics.

The new post expiry period, e.g., $t = t_0 + 1, \ldots, \infty$ for a 12-month extension, will contain revenues consisting of a parallel shift in the revenue by one year (for a 12-month extension) or two years (for a 24-month extension); see stylized example in Figure F1. Under the assumption that revenues at some point in the future will become zero, i.e., $\lim_{t \to \infty} R_{i,t} = 0$, revenues observed after the new SPC expiry are not included because they will be offset by the same revenues occurring one year later.[5] Therefore, the net cost is only the difference between peak revenue during the extended protection period and observed revenue in the corresponding post-expiry year.

Figure F1. Stylised example of our approach
Million EUR of a hypothetical product

	2015	2016	2017	2018 (t_0)	2019 (t_0+1)	2020 (t_0+2)	2021	2022	2023	2024	2025	…	T-1	T	T+1
Observed revenues	100	120	140	160 (peak revenue, R_{i,t_0})	130 (SPC expires, R_{i,t_0+1})	110	90	85	82	80	78	…	2	0	0
Modelled revenues after a 12-month SPC extension	100	120	140	160 (peak revenue, R_{i,t_0})	160 (peak revenue, R_{i,t_0})	130 (SPC extension expires, R_{i,t_0+1})	110	90	85	82	80	…	4	2	0

Peak revenue is observed in the year prior to SPC expiry, i.e., $t_0 = 2018$ in this example

We model the cost of a 12-month extension for this hypothetical product by calculating the difference between the peak revenue (R_{i,t_0}) and the revenue in the year after (R_{i,t_0+1}), i.e., $\Delta R_i = 160 - 130 = 30$

The aggregate revenues in the years after SPC expiry are identical and cancel out, e.g., the 130 in revenue in the year after original SPC expiry is paid one year later[1]

Notes: Based on dummy data for illustration purposes only. / 1) Under the assumption that revenues are decreasing over time and will at some point in the future become zero.
Source: Copenhagen Economics.

Notes: 1) MIDAS FY2015 - FY2025, total European sales in USD (constant exchange rate), Rx only at list prices. / (2) Patents and protection of products in the EU4 (Germany, Italy, France, and Spain) was mapped by IQVIA, and these were considered to be representative of a "European loss of protection" date. / 3) European Central Bank (2026, webpage). / 4) These reflect situations where no or limited competition occurs after SPC expiry, and no cost of an SPC extension is thus expected for public payers. / 5) No discounting is applied.

Methodology to quantify the impact on pharmaceutical spending

Appendix F (page 2/2)

We estimate that the average per-product cost for a 12-month extension is EUR 25.7 million and EUR 68.7 million for biologics and non-biologics, respectively, while it is EUR 58.6 million across all compounds; see Table F1. We estimate that the average per-product cost for a 24-month extension is EUR 108.5 million and EUR 214.1 million for biologics and non-biologics, respectively.

We multiply the per-product costs by the number of medicines that will be eligible under the eight different scenarios; see Appendix A. Lastly, we multiply this estimate with 15 years to arrive at the cost over 15 years; see Table F2. The results over 15 years are not discounted.

The average cost across all compounds is EUR 58.6 million for a 12-month extension. This is in line with the EUR 54 million cost to public payers per product from one additional year of regulatory protection estimated by the European Commission.[1] If we utilise this overall average cost rather than the estimates in Table F1, the total cost of an SPC extension for biologics will be higher.[2]

We note that the average cost of an SPC extension is higher for non-biologics than biologics. This is driven by three blockbuster medicines. If these are omitted, the average cost for non-biologics is EUR 30.5 million and EUR 108.9 million per product for a 12- and 24-month extension, respectively.

We also note that the per-product cost of a 24-month extension for biologics is more than twice the per-product cost of a 12-month extension. Specifically, the per-product cost of a 24-month extension is around 4.2 times the cost of a 12-month extension. This likely reflects switching barriers and high entry costs, which may limit competition in the first year following protection expiry, with greater savings materialising only in the second year after biosimilar entry.

Table F1. Average cost of an SPC extension for eligible products
Million EUR per product

Product category	12-month SPC extension	24-month SPC extension
Biologics	EUR 25.7 million	EUR 108.5 million
Non-biologics	EUR 68.7 million	EUR 214.1 million
All compounds	EUR 58.6 million	EUR 189.2 million

Notes: Costs are estimated based on products where SPC expired between 2015 and 2023. Based on annual product-level revenue data from 2015-2025. Costs are not discounted.
Source: Copenhagen Economics based on data from IQVIA.

Table F2. Total cost of an SPC extension over 15 years
Million EUR over 15 years

Scenario	12-month SPC extension	24-month SPC extension
Biologics, narrow eligibility → 2 products per year	EUR 898 million	EUR 3,799 million
Biologics, broad eligibility → 12 products per year	EUR 4,620 million	EUR 19,536 million
All compounds, narrow eligibility → 10 products per year	EUR 8,457 million	EUR 27,348 million
All compounds, broad eligibility → 27 products per year	EUR 20,082 million	EUR 67,705 million

Notes: Costs are estimated based on products for which SPC expired between 2015 and 2023, and on annual product-level revenue data from 2015 to 2025. Costs are not discounted. The number of products eligible per year are outlined in Appendix A.
Source: Copenhagen Economics based on data from IQVIA.

Notes: 1) European Commission (2023). / 2) E.g., EUR 1,890 million (EUR 54 million x 2.33 products per year x 15 years) for a 12-month SPC extension for biologics, narrow eligibility over 15 years compared to

References

1/2

Almeida-Meza et al.. (2025). Futureproofing the healthcare workforce in Europe: understanding and addressing psychological distress and occupational outcomes. *The Lancet Regional Health–Europe*, *57*.

Arellano, M., & Bond, S. (1991). Some Tests of Specification for Panel Data: Monte Carlo Evidence and an Application to Employment Equations. *The Review of Economic Studies*, 58(2), 277.

Arellano, M., & Bover, O. (1995). Another look at the instrumental variable estimation of error-components models. *Journal of Econometrics*, 68(1), 29–51.

Buxbaum, J. D., Chernew, M. E., Fendrick, A. M., & Cutler, D. M. (2020). Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015: Study examines the conditions most responsible for changing US life expectancy and how public health, pharmaceuticals, other medical care, and other factors may have contributed to the changes. *Health Affairs*, *39*(9), 1546-1556.

Copenhagen Economics (2018). Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe. Available at https://copenhageneconomics.com/wp-content/uploads/2021/12/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf.

Copenhagen Economics (2023a). The economic impact of the pharmaceutical industry in Europe. Comparing the innovative and generic industries. Available at https://copenhageneconomics.com/wp-content/uploads/2021/08/The-economic-impact-of-the-pharmaceutical-industry-in-Europe_31AUG2023.pdf

Copenhagen Economics (2023b). Regulatory data protection for pharmaceuticals. How adopting regulatory data protection will impact patients, industry, and Brazilian society? Available at https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil_092023.pdf

Blundell, R., & Bond, S. (1998). Initial conditions and moment restrictions in dynamic panel data models. *Journal of Econometrics*, 87(1), 115–143.

CRA (2026). Assessing Europe's Competitiveness as a Location for the Life Sciences Industry. Available at https://www.efpia.eu/media/5mvbnamw/assessing-europe-s-competitiveness-as-a-location-for-the-life-sciences-industry.pdf

Dennis, B. B., Naji, L., Jajarmi, Y., Ahmed, A., & Kim, D. (2021). New hope for hepatitis C virus: Summary of global epidemiologic changes and novel innovations over 20 years. *World journal of gastroenterology*, *27*(29), 4818.

DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of health economics, 47, 20–33. https://doi.org/10.1016/j.jhealeco.2016.01.012

Dohse, D., Goel, R. K., & Saunoris, J. W. (2023). Patenting uncertainty and its impact on innovation: evidence from the United States. *The Journal of Technology Transfer*, *48*(5), 1839-1859.

EFPIA. (n.d.). Clinical trials. Available at https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/clinical-trials/.

EFPIA (2022). Europe's share of global medicines R&D shrinks by a quarter in 20 years. Press release available a https://www.efpia.eu/news-events/the-efpia-view/efpia-news/europe-s-share-of-global-medicines-rd-shrinks-by-a-quarter-in-20-years-as-sector-s-declining-trends-continue

EFPIA (2025). The pharmaceutical industry in figures. Available at https://www.efpia.eu/media/uj0popel/the-pharmaceutical-industry-in-figures-2025.pdf.

EFPIA and PwC (2024). Economic footprint of the pharmaceutical industry in Europe. Available at https://efpia.eu/media/xl4dt54k/economic-footprint-of-the-pharmaceutical-industry-in-europe-slides.pdf. Short version available at https://efpia.eu/media/3dajpl3x/economic-footprint-of-the-pharmaceutical-industry-in-europe-report.pdf.

European Central Bank (2026, webpage). US dollar (USD). Available at https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-usd.en.html.

European Commission (2023). COMMISSION STAFF WORKING DOCUMENT. IMPACT ASSESSMENT REPORT. Accompanying the documents: Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, proposal for a Regulation of the European Parliament and of the Council laying down. Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. Available at https://eur-lex.europa.eu/resource.html?uri=cellar:d75b91b3-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF.

European Commission. (2025). *Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act).* Publications Office of the European Union. Available at https://health.ec.europa.eu/publications/proposal-regulation-establish-measures-strengthen-unions-biotechnology-and-biomanufacturing-sectors_en.

European Parliamentary Research Service (2024). Cost of non-Europe in health policy. Available at https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2024)753192

Eurostat (2026, webpage). HICP - all items - annual average indices. Available at https://ec.europa.eu/eurostat/databrowser/view/tec00027/default/table.

References

2/2

Gans, J. S., Hsu, D. H., & Stern, S. (2008). The impact of uncertain intellectual property rights on the market for ideas: Evidence from patent grant delays. *Management science*, *54*(5), 982-997.

IQVIA (2024, October). Assessing the clinical trial ecosystem in Europe. Final Report. Available at: https://www.efpia.eu/media/0ipkatpg/efpia-ct-report-embargoed-221024-final.pdf.

IQVIA Blog (2026). The EU's Biotech Act proposal – A summary and review of its incentives.

Lichtenberg, Frank (2019). How many life-years have new drugs saved? A three-way fixed-effects analysis of 66 diseases in 27 countries, 2000–2013. International Health, 11(5), pp. 403-416.

McCloskey, C., Ortega, M. T., Nair, S., Garcia, M. J., & Manevy, F. (2022). A systematic review of time and resource use costs of subcutaneous versus intravenous administration of oncology biologics in a hospital setting. *PharmacoEconomics Open*, *7*(1), 3.

McEwan, P. et al.. (2020). Cost-effectiveness of dapagliflozin as a treatment for heart failure with reduced ejection fraction: a multinational health-economic analysis of DAPA-HF. *European journal of heart failure*, 22(11), 2147-2156.

OECD. (2018). *Pharmaceutical innovation and access to medicines*. OECD Health Policy Studies. OECD Publishing. https://doi.org/10.1787/9789264307391-en.

OECD (2026, webpage). Health expenditure and financing – all items – current prices. Available at https://data-explorer.oecd.org/

OECD (2026, webpage). Health expenditure and financing - HC51 Pharmaceuticals and other medical non-durable goods – current prices. Available at https://data-explorer.oecd.org/

Piva, M. & Vivarelli, M. (2017). R&D Expenditures and Employment: Evidence from Europe. *Global Discussion Paper, No. 18, Global Labor Organization (GLO)*.

Stadig, D. (2026). Europe's last chance to revive its pharmaceutical innovation power. ING Think. Available at https://think.ing.com/articles/why-it-is-the-eleventh-hour-for-european-pharmaceutical-innovation/.

Thomas, D.W., Burns, J., Audette, J., Carrol, A., Dow-Hygelund, C., Hay, M. (2016) Clinical Development Success Rates 2006-2015.

Wouters, O. J., Vogel, M., Feldman, W. B., Beall, R. F., Kesselheim, A. S., & Tu, S. S. (2024). Differential legal protections for biologics vs small-molecule drugs in the US. *Jama*, *332*(24), 2101-2108.

Wagner, S., & Wakeman, S. (2016). What do patent-based measures tell us about product commercialization? Evidence from the pharmaceutical industry. *Research policy*, *45*(5), 1091-1102.

van Vollenhoven, R. F., Cifaldi, M. A., Ray, S., Chen, N., & Weisman, M. H. (2010). Improvement in work place and household productivity for patients with early rheumatoid arthritis treated with adalimumab plus methotrexate: work outcomes and their correlations with clinical and radiographic measures from a randomized controlled trial companion study. *Arthritis Care & Research: Official Journal of the American College of Rheumatology*, *62*(2), 226-234.

CONTACT

Julia Wahl, Partner
jsw@copenhageneconomics.com

Nikolaj Siersbæk, Managing Economist, Ph.D.
nsi@copenhageneconomics.com

Malwina Mejer, Senior Economist, Ph.D.
mme@copenhageneconomics.com

Copenhagen Economics A/S

Langebrogade 3C
DK-1411 Copenhagen
Denmark

Lilla Nygatan 14
SE-111 28 Stockholm
Sweden

Erottajankatu 2
FIN-00120 Helsinki
Finland

Maison de la Radio
Place Eugène Flagey 18
BE-1050 Brussels
Belgium