



Assessing Europe's Competitiveness as a Location for the Life Sciences Industry

Narrative report



CRA Charles River
Associates

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Executive summary

Once a beacon of scientific excellence and a modern powerhouse in pharmaceuticals, Europe now risks further falling behind global peers, including China and the United States, which are outpacing Europe in attracting pharmaceutical investment, initiating more clinical trials and originating a greater share of novel pharmaceutical innovations.

Competitiveness has become a political and policy priority across sectors in Europe. The life sciences industry is one of Europe's most important strategic assets, delivering medical breakthroughs that are fundamental to Europe's health, economic stability, and security.

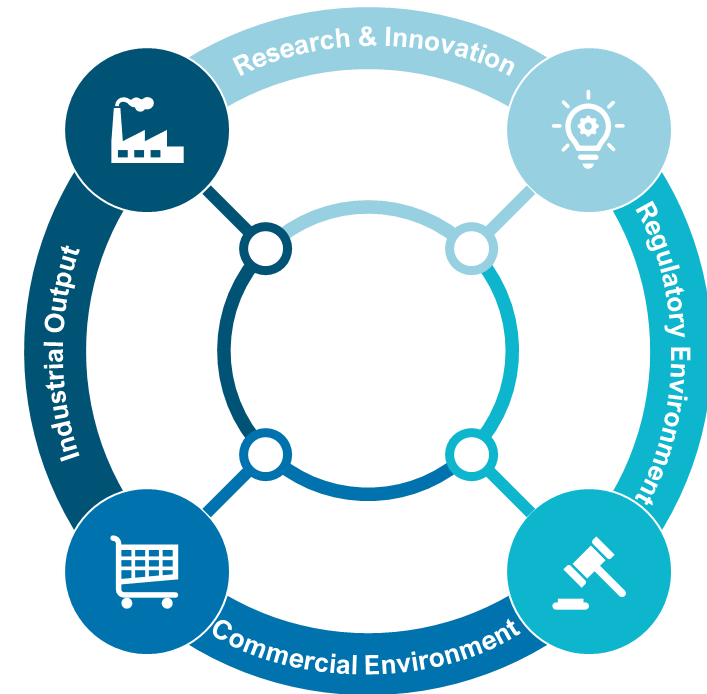
In the last two decades, Europe has experienced a decline in key drivers of competitiveness in the pharmaceutical sector. Without decisive actions to re-build a vibrant industrial ecosystem, this decline risks accelerating.

In practice, competitiveness in the life sciences sector is complex, shaped by a set of interconnected conditions. It is ultimately determined by how effectively it turns scientific capability into research and development (R&D) activities, which lead to approved products that reach patients and global markets at scale. The factors that drive life sciences competitiveness are many.

This report assesses the EU's life sciences competitiveness through this lens, focusing on four performance areas that most directly drive it: **research and innovation, the regulatory environment, the commercial environment, and industrial output.**

We compare the EU's attractiveness as a pharmaceutical investment location with that of global peers, including China, Switzerland, the United Kingdom (UK) and the United States (US).

Life sciences competitiveness is driven by four major performance areas.



Overall, the EU's strengths lie in the quality of foundational research and industrial resilience. Still, challenges in regulatory speed, IP incentives, and commercial environment risk diminishing its global competitiveness relative to peers.

Research & Innovation



- The EU performs strongly in scientific excellence (second only to the UK) and digital capabilities (though it trails the US).
- The region trails comparators in industry R&D investment growth rate, falls behind Switzerland in R&D incentives, and faces a growing gap in clinical trial attractiveness compared to China and the US. The EEA share of global trial starts declined by 50% between 2013 and 2023.
- Patent applications have grown modestly (6% over 2014–2024), but China's 170% surge highlights the EU's relative stagnation.

Regulatory Environment



- The EU is lagging in approvals of new active substances (NAS), declining 20% over the past decade (vs. China's 470% increase)
- EU's minimal use of expedited pathways (0% in 2024 vs. 53% in the US) is a pressure point.
- Regulatory approval timelines have improved (430 days in 2024, down from 464 in 2015) but remain longer than in China (390 days) and the US (356 days).

Commercial Environment



- The EU's performance in spending on pharmaceuticals is moderate at 1% of its GDP, compared to China (1.8%) and the US (2.0%)
- In terms of inward FDI, the EU performs moderately with €1.5bn in 2023, compared to China (€2.3bn) and the US (€4.3bn).
- The EU performs weakly in the launch of NAS (39% of global launches 2012–2021 vs. 85% in the US).
- Mandatory industry refunds, such as high clawback rates (up to 53% in some EU countries) compared to 0% in China, Switzerland, and the US, deter investments.

Industrial Output



- The EU excels here, with strong manufacturing investment growth (15% compound annual growth rate (2018–2022), surpassing China's 11%) and a persistent trade surplus, reflecting resilient supply chains and export capabilities. However, maintaining this position cannot be taken for granted in an increasingly competitive global landscape.

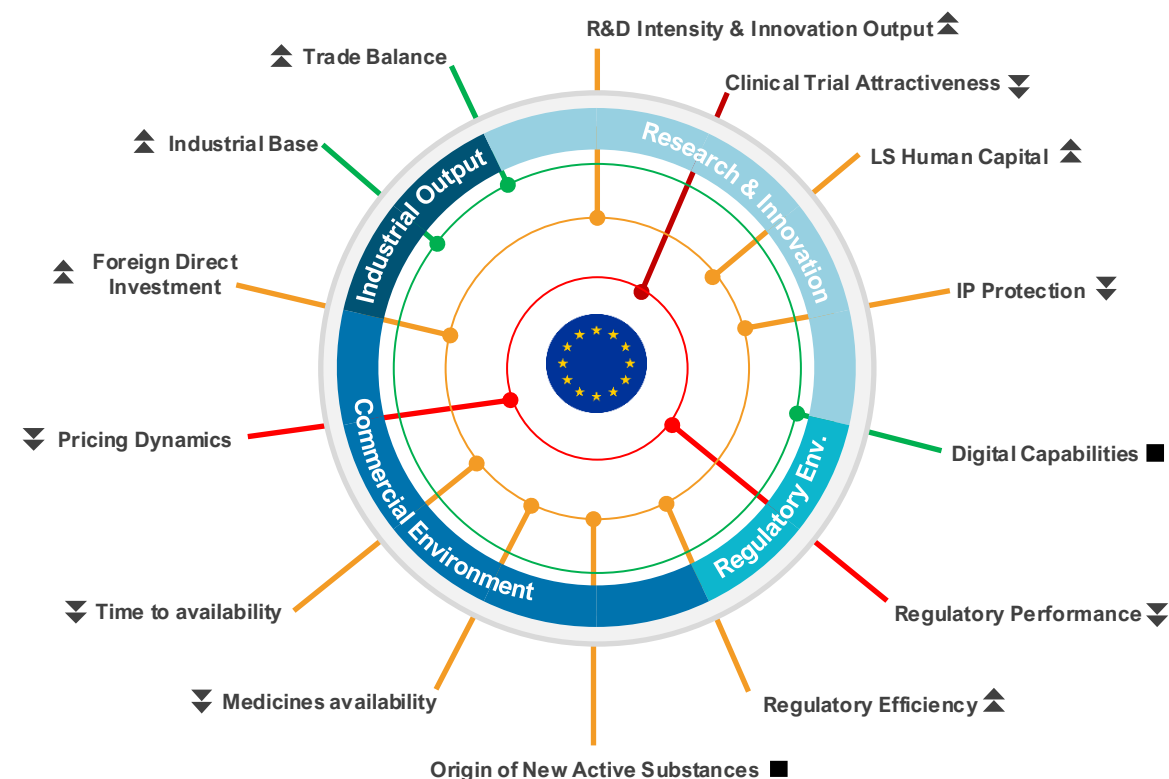
EU life sciences competitiveness at a glance

The EU retains deep scientific excellence, advanced digital capabilities, a strong industrial base, and high trade performance.

Yet, across the innovation pathway and uptake, the EU is ceding ground to the US and, increasingly, China – most visibly in the origin of new medicines, share of clinical trials, use of expedited regulatory pathways, as well as speed and breadth of medicines launches.

Europe's science and industrial base is an asset, but innovation conversion, as well as access breadth and speed, now define the EU's competitiveness gaps.

On those decisive metrics, the gap relative to the US persists, and the challenge from China is now unmistakable.



Key:

Performance (latest)

Trend (5-10 years)

Strong

Improving

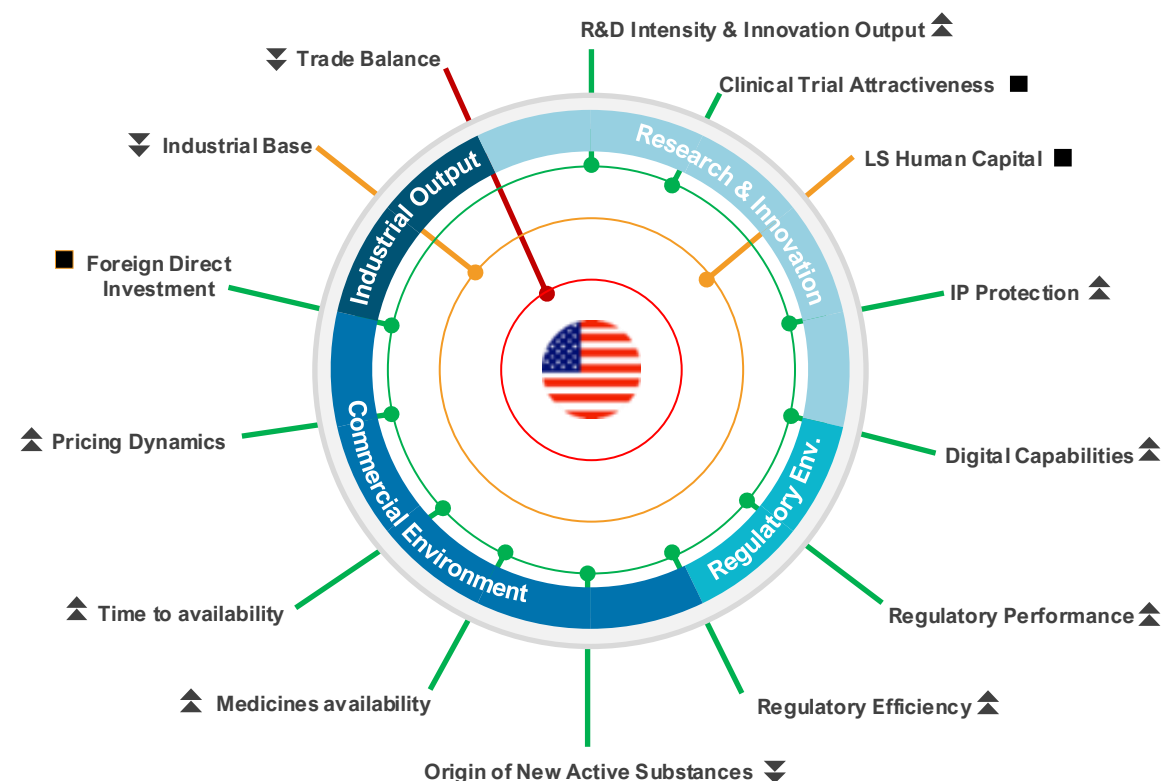
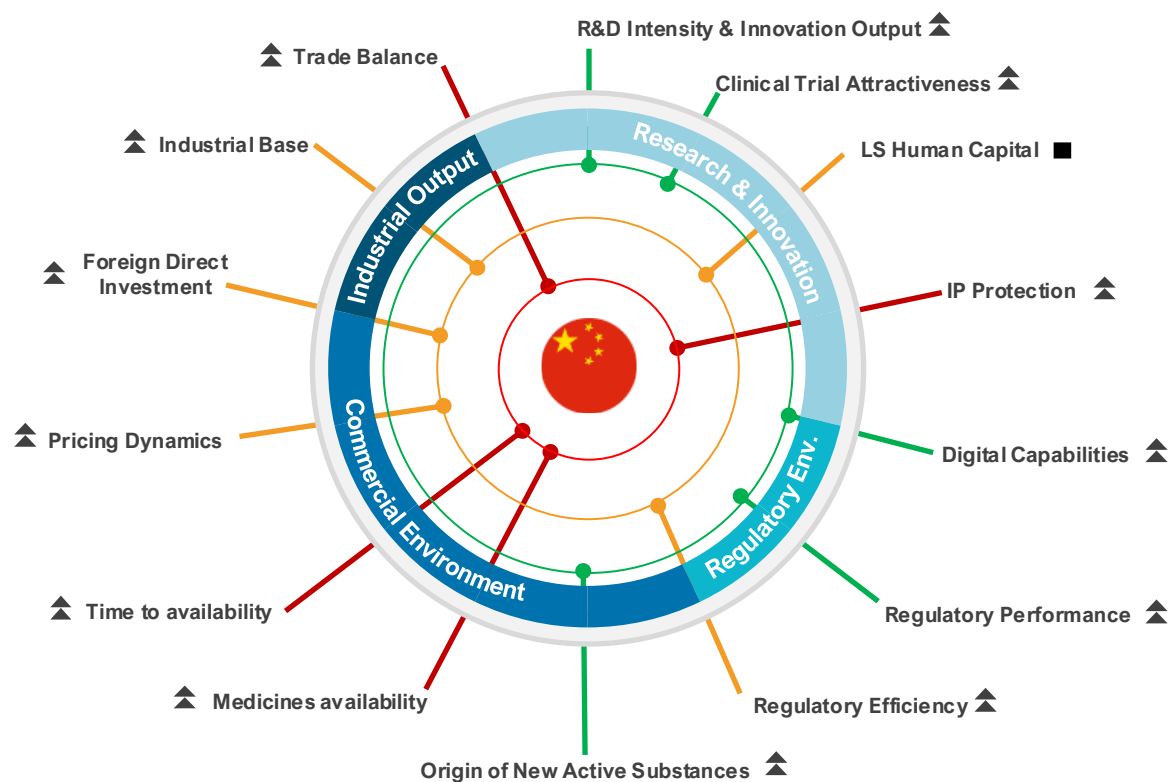
Moderate

Flat

Lower

Declining

China and US life sciences competitiveness at a glance



Key:

Performance (latest)

Trend (5-10 years)

● Strong

▲ Improving

● Moderate

■ Flat

● Lower

▼ Declining

The EU must act urgently over the next decade to strengthen its attractiveness relative to global leaders. Addressing weaknesses in key drivers of competitiveness could deliver significant gains in industry R&D investment, clinical trial activity, and the number of new active substances (NAS) originating in Europe.

Below are illustrative examples of closing the gap with global peers

 Closing the gap on industry R&D investment	 Closing the gap on the share of global clinical trial starts	 Closing the gap on the use of expedited review pathways	 Closing the gap on originating NAS
€105 billion <i>Additional industry R&D investment</i>	€17.9 billion <i>incremental total gross value added (GVA)</i>	200 new medicines <i>approved via expedited reviews</i>	100 medicines <i>originating from Europe</i>
- Closing the industry R&D investment gap with global peers would require the EU to attract more industry R&D investments than the current CAGR of 5.4%. - Growing at 8.5% CAGR, a rate higher than the US's (6.4%) but lower than China's (12.1%), could yield an additional €105bn worth of industry R&D investment in the EU over a 10-year period by 2035.	- To catch up with growth in China and North America in share of global clinical trial starts would require a 50% increase in activity compared to 2025 levels. - This would result in: - Nearly €18bn in the European economy. 82,000 new jobs. 158,000 more patients enrolled in clinical trials.	- The US is currently the leader in the use of expedited review pathways (59% of all approved NAS in 2024), many targeting areas of unmet medical need. - Closing this gap would result in at least 20 NAS per year approved via the expedited review pathway. - In 10 years, more than 200 NAS would have been approved using expedited review pathway in the EU – accelerating access for patients with limited or no treatment options.	- China currently leads in the share of NAS originated at 35% (28 NAS) in 2024, compared to 22% (18 NAS) in Europe. - Closing the gap with China would mean an additional 10 NAS developed in Europe per year, and at least 100 NAS over a 10-year period.

Introduction

Why this report?

Competitiveness has become a political and policy priority across sectors in Europe. The life sciences sector is one of Europe's most important strategic assets, delivering innovative medicines and vaccines that are fundamental to the long-term health and security of Europe.[1,2]

Once a beacon of scientific excellence and a modern powerhouse in pharmaceuticals, Europe now risks falling further behind global peers in research and innovation, where more ambitious, dedicated strategies are driving growth and outpacing Europe in attracting talent and cutting-edge developments.[1]

Europe stands at a pivotal crossroads amid a rapidly evolving global landscape. The acceleration of breakthroughs in biotechnology, personalised medicine, and AI-driven drug discovery is reshaping human health and economies alike. This, alongside intensifying geopolitical competition, supply-chain vulnerabilities, and widening gaps in scale-up capital, has raised a direct question for policymakers: can Europe convert scientific excellence into sustained leadership in innovation, investment, and patient impact?

In practice, competitiveness in the life sciences sector is a system outcome, shaped by a set of interconnected conditions: the ability to consistently generate breakthrough innovations, translate them efficiently into clinical and commercial products, manufacture and supply at scale, attract and retain talent and capital, and deliver timely patient access.

This report assesses Europe's life sciences competitiveness through that lens – focusing not only on research output, but on the full pathway from idea to impact. We compare the EU's attractiveness as a pharmaceutical investment location with that of four comparator countries: China, Switzerland, the United Kingdom and the United States. It draws on robust quantitative and qualitative analyses and insights to highlight where Europe is leading, where it is falling behind, and where targeted reform could unlock unrealised potential and improve Europe's competitiveness in life sciences.

This publication is expected to be updated periodically to support decision-makers who must balance multiple priorities to identify key policy interventions needed to realise Europe's competitiveness ambitions for its life sciences sector.

Comparator countries included in this analysis:



European Union (EU)



China (CN)



Switzerland (CH)



United Kingdom (UK)



United States (US)

Performance analysis:

Using publicly available information, we assessed the latest EU performance relative to global comparators, as well as performance trend over 5 -10 years, where data allow.

What factors drive life sciences competitiveness?

The factors that drive life sciences competitiveness are many. Ultimately, the competitiveness of the life sciences sector is determined by how effectively it turns scientific capability into approved products that reach patients and global markets at scale. This report frames that pathway through four performance areas that most directly drive life sciences competitiveness: **research and innovation**, the **regulatory environment**, the **commercial environment**, and **industrial output**.

Assessment framework

A set of indicators and sub-indicators under each performance area was used to assess country/regional performance

 Research & innovation	 Regulatory environment	 Commercial environment	 Industrial output
<i>R&D intensity</i>	<i>Regulatory performance</i>	<i>Origin of new active substance</i>	<i>Industrial base</i>
<i>Clinical trial attractiveness</i>	<i>Regulatory efficiency</i>	<i>New medicine launch</i>	<i>Trade performance</i>
<i>Life sciences human capital</i>		<i>Time to market (launch)</i>	
<i>Intellectual property protection</i>		<i>Pricing dynamics</i>	
<i>Digital capabilities</i>		<i>Foreign direct investment</i>	

Chapter 1: Research and innovation

A conducive research ecosystem is the starting point. Countries and regions that lead in innovation are those that not only create an enabling research environment to generate new ideas but also sustain a high-throughput innovation engine that moves efficiently from proof of concept to scalable development programmes, with mechanisms and incentives that protect intellectual property.

We assessed Europe's R&D performance against comparator countries across key performance indicators:

Key performance indicators



R&D intensity

- 1 R&D investment growth
- 2 R&D investment levers
- 3 Scientific excellence
- 4 Patent applications



Clinical trial attractiveness

- 5 Number of global commercial clinical trial starts



Life sciences human capital

- 6 Life Sciences talent



Intellectual property protection

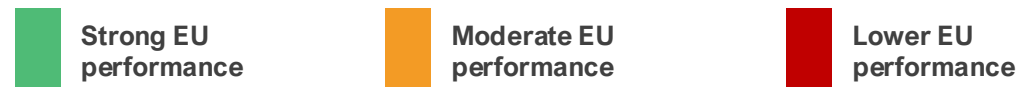
- 7 IP Index (IP protection strength)



Digital capabilities

- 8 Digital health maturity

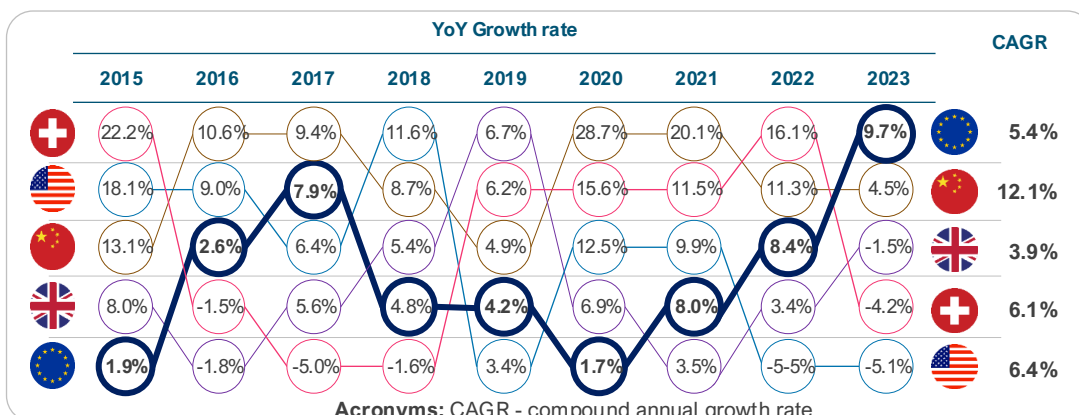
1. Annual R&D investment growth



The EU performs weakly in growth rate of R&D investment from local and foreign companies, with growth rate about half of that in the US and two times lower than China.

Key performance indicator					Source	Latest
<i>Growth rate (CAGR) of R&D investment by national and foreign pharma companies [3-6]</i>					EFPIA & ABPI	2023
1st	2nd	3rd	4th	5th		
						
12.1%	6.4%	6.1%	5.4%^	3.9%		

^EFPIA countries aggregate (excluding Switzerland and the UK)



NOTE: UK growth rates were derived from ABPI analysis of ONS 'business expenditure on research and development UK: 2024' available [here](#). Data prior to 2022 is based on estimates following a methodology change in how UK BERD data is collected.

Over the last decade, European pharmaceutical R&D investment has grown steadily, but at a pace that may not fully match global shifts.[3-7] Annual growth rates in R&D investment by national and foreign pharmaceutical companies from 2015 to 2024 reveal distinct regional trends, as measured by the CAGR.

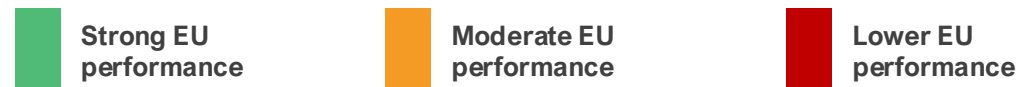
In EU countries, the CAGR is 5.4%, indicating steady growth. However, this pace falls behind growth rates in comparators. China exhibits the highest CAGR of 12.1%, followed by the US (6.4%) and Switzerland (6.1%). The lower growth rates in industry R&D investments in the EU highlight vulnerabilities in the EU's pharma ecosystem to attract investments.

The rapid acceleration observed in China, where investments surged notably in 2019 (28.7%) and 2020 (20.1%), reflects aggressive policy support for innovation and biotechnology. In absolute terms, the US is the global leader. R&D investments rose 65%, from €43bn in 2015 to €71bn in 2023, maintaining dominance, with expenditures nearly double those of the EU27.[3-6]

These trends have profound implications for the EU's pharma sector. Lagging growth relative to the US and China risks diminishing Europe's innovation leadership, potentially resulting in fewer breakthroughs in areas such as oncology and rare diseases.

While the EU's pharmaceutical R&D has grown reliably, sustaining global competitiveness cannot be taken for granted. In 2024, R&D investment growth in the EU was driven mainly by the health sector.[7] This demonstrates the sector's importance and the need for targeted policy measures to strengthen Europe's global standing and competitiveness.

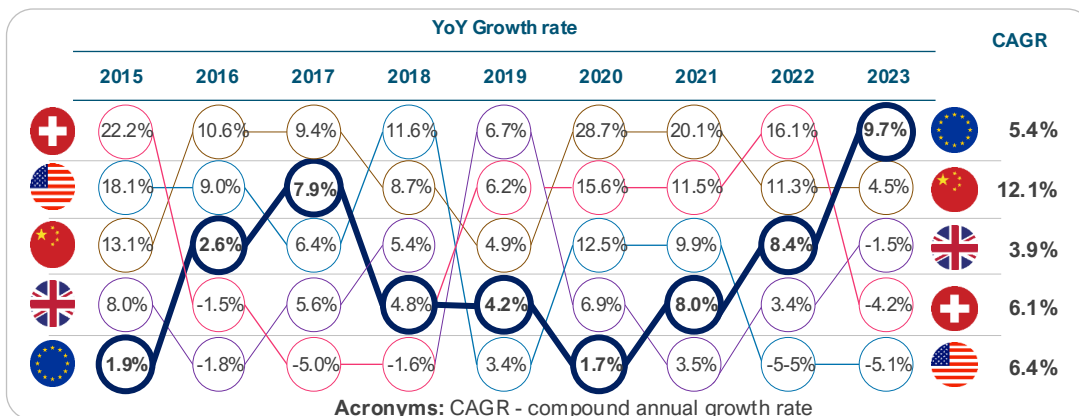
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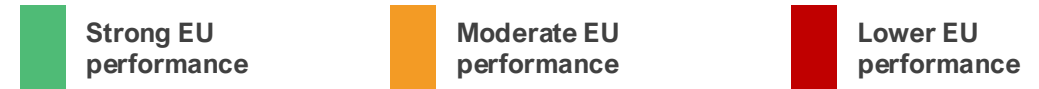
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2. R&D investment levers



The EU performs moderately in the number and value of R&D investment levers. The EU lags Switzerland and the UK in the number of measures, and China and Switzerland in terms of their value.

Key performance indicator				Source	Latest	
<i>Implied subsidy rate on R&D expenditure (range)* [8-12]</i>				EY & other sources	2023	
1st	2nd	3rd	4th	5th		
						
22% - 32%	13% - 22%^	12% - 27%	1% - 7%	0% - 1%		

*Simple benchmark comparison (large profitable firms). ^EU27 average

NOTE: Implied or assumed subsidy rate can vary within a country/region. Switzerland has historically not operated a federal R&D tax credit. R&D expenses are simply deductible as normal business costs, resulting in a neutral tax treatment. Switzerland instead incentivizes commercialisation of IP, not the inputs to R&D

There are 16 different types of R&D investment levers across countries [6]

Number of R&D investment levers available in comparator countries



R&D investment levers, such as tax credits and cash grants, are a core lever of competitiveness because they directly affect whether companies invest in long-term, high-risk research and where that investment is located.[12]

Based on the breadth of R&D support measures available, our analysis shows that the EU countries exhibit a relatively moderate level of availability, with an average of 6 instrument types per member state. [13] However, there is significant variation across the EU. This ranges from high performers such as the Netherlands (10) and Belgium (9) to lower performers like Romania (3).[13] Such diversity highlights the fragmented nature of R&D support in the EU. The EU's average (6) surpasses that of China (4) and the US (3), but trails Switzerland (8) and the UK (7).[13]

R&D tax credits or deductions are among the most commonly used investment levers across sectors as they play a decisive role in investment decisions. The value of R&D tax incentives (i.e., implied subsidy rate on R&D expenditure) widely varies across (and even within) countries. Data from OECD INNOTAX show that implied subsidy rate on R&D expenditures across the EU ranges from 0% to 39%.[20] R&D tax deductions typically range from 20% to 36% in high-signal EU member states, including France [14], Germany [15], and the Netherlands [16] In Switzerland, the R&D super-deduction (cantonal option) could be up to 50% [17], and up to 200% in China [18], making China and Switzerland more attractive for investment.

The EU, with an average implied subsidy rate of 16%, falls behind China (32%).[9-12,19,20,25] This, together with weakening EU incentive frameworks, particularly the reduction of the baseline RDP, may deter long-term investment. [27]

3. Scientific excellence



The EU performs strongly in the percentage of medical sciences publications which are amongst the most highly cited (top 1%) globally. Over the last decade, the EU has ranked only second to the UK on this performance indicator.

Key performance indicator					Source	Latest	
Highly cited papers published (% of total)* [28-30]					Multiple sources	2024	
1st	2nd	3rd	4th	5th			
2.1%	1.8%^	1.7%	1.3%	1.2%			

*Percentage of each country's medical sciences publications that are amongst the top 1% highly cited.

^Average of France, Germany, and Italy

The proportion of a country's (or region's) medical sciences publications that rank among the most highly cited globally (top 1%) serves as a key bibliometric indicator of research quality, scientific excellence, and impact in the health sector.

This indicator is highly relevant to pharmaceutical competitiveness, as it underscores the strength of a country's foundational research ecosystem, which is essential for driving pharmaceutical innovation.

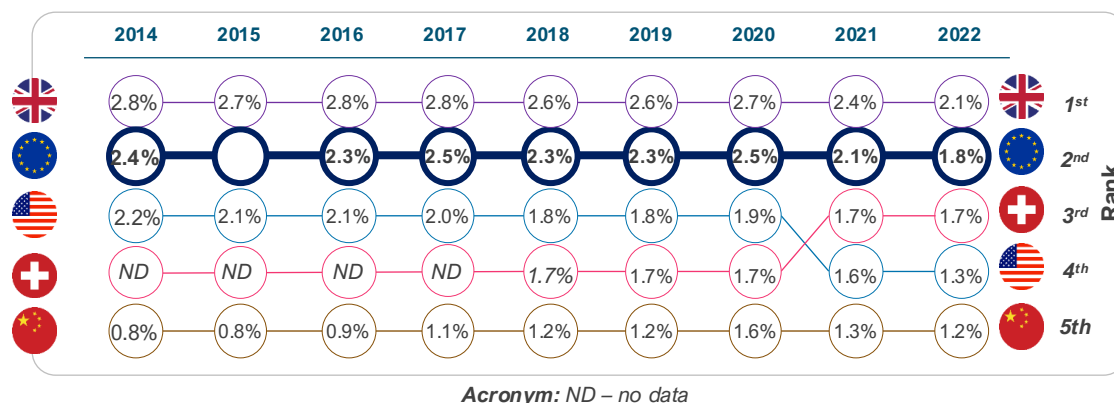
Relative to comparator countries, Europe's performance indicates resilience in research excellence, positioning it favourably against the UK and Switzerland—both renowned for high-impact outputs—and ahead of China and the US in terms of publication quality per output. [28-30]

Nonetheless, the trend over the last decade reveals a concerning reality: a 23% decline in performance in Europe between 2014 and 2022.

Although China lags comparators on this indicator, an interesting development is that it has increased by almost 50%, rising from 0.8% in 2014 to 1.2% in 2022. [30]

This demonstrates the scale of investment that drives China's transition toward scientific excellence and research impact.

If this trend continues, China is likely to overtake Europe soon, further eroding European competitiveness in research impact and scientific excellence.



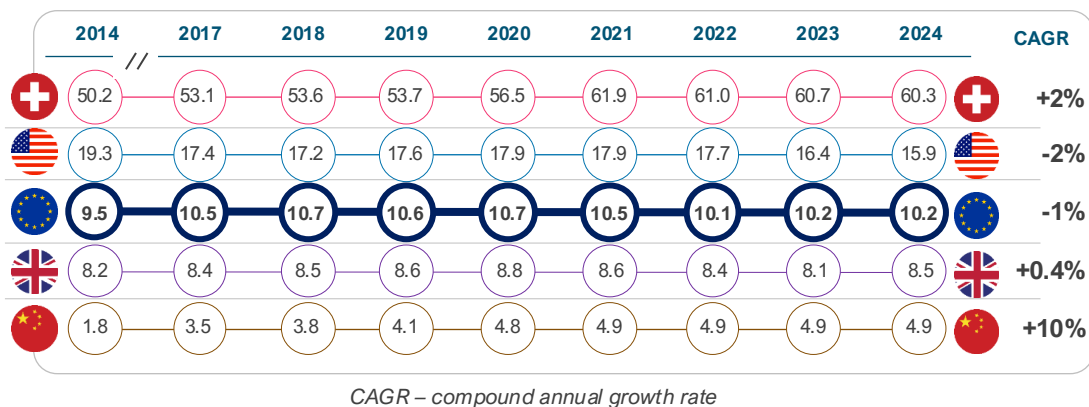
4. Patent applications



The EU performs moderately in terms of the number of patent applications relative to comparator countries. The share of global PCT applications from Europe has declined over the last decade.

Key performance indicator				Source	Latest	
Patent (PCT) applications per capita* [31]				WIPO	2024	
Rank	1st	2nd	3rd	4th	5th	
						
Per capita	60.3	15.9	10.2	8.5	4.9	
Total number	5,324	54,087	45,711	5,861	70,160	

*This is the number of PCT applications per capita (across all sectors). Population data retrieved from the World Bank



Patent activity is a critical driver of competitiveness, as it reflects a country's ability to generate, protect, and commercialise new technologies, and to attract investment in high-value, knowledge-intensive sectors.

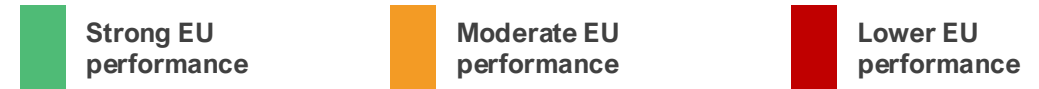
The number of Patent Cooperation Treaty (PCT) applications filed by entities within a country or region, therefore, serves as a widely used indicator of innovation performance (not specific to pharmaceutical or biotechnology sectors). Analysis of annual PCT filings from 2014 to 2024 indicates a **slower trajectory for EU countries** compared with global peers. [32]

In absolute terms, China (70,160) ranked first in 2024. China (58,990) overtook both the US (57,840) and the EU (54,040) in 2019. On a per capita basis, Switzerland leads, with an average of 56 applications per 100,000 population per year, compared with 18 in the US, 10 in Europe, and 4 in China.[17] Over the period, the EU recorded a CAGR of -1% per year, below China (10% per year) and Switzerland (2% per year), showing a relative decline.[31]

Sector-specific data shows a similar pattern in pharmaceuticals. According to the European Patent Office (EPO), pharmaceutical patent filings declined by 13% in 2024, even as total European applications increased slightly by 0.3%. [32]

If sustained, this trend could gradually weaken the EU's pharmaceutical competitiveness and long-term innovation capacity.

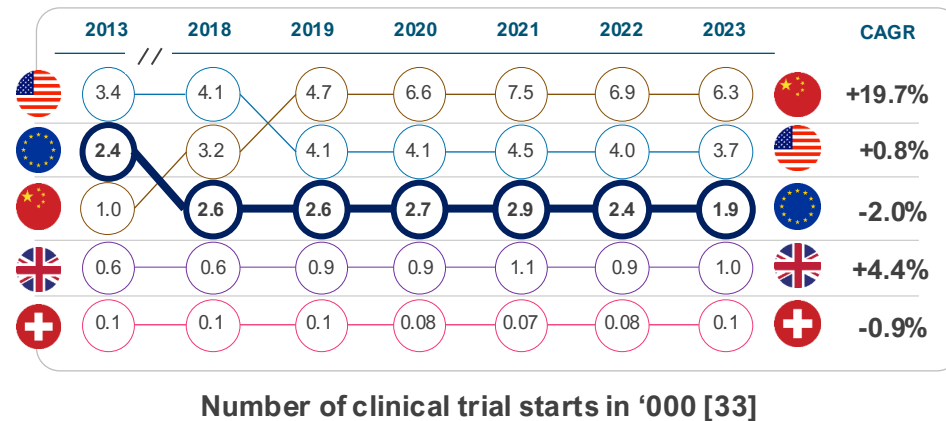
5. Clinical trial attractiveness



Europe is losing ground in attracting clinical trials compared to its global peers. The EU's share of global industry clinical trial starts declined by 50% between 2013 and 2023.

Key performance indicator				Source	Latest	
<i>Number of global clinical trial starts [33]</i>				IQVIA	2023	
1st	2nd	3rd	4th	5th		
			 *	 *		
6,392	3,747	1,978	1,025	101		

*This represents the number of commercial clinical trial starts only
US data represent the North America region. EU data represent the EEA region



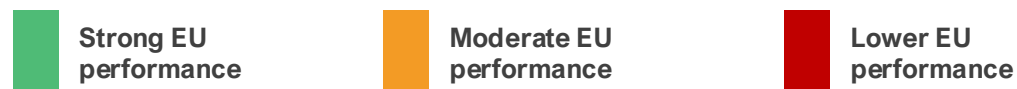
Clinical trial attractiveness refers to the extent to which a country or region is appealing to pharmaceutical sponsors for conducting clinical studies. This attractiveness is crucial for a country's competitiveness in the pharma sector, as it directly influences innovation, economic growth, and the country's global position within the industry.[3,33-35]

In the last decade, there has been a major shift in the geographic distribution of trials. In 2013, North America (including the US), the European Economic Area (EEA), and the rest of Europe (including Switzerland and the UK) accounted for 53% of global clinical trial starts (commercial and non-commercial). As of 2023, this figure stood at 33%. Over the same period, China's share increased from 8% to 29%, representing approximately 20% annual growth.[34,35]

Similarly, analysis of global commercial trial starts shows a similar trend. While EEA countries (except Spain) are losing share of global commercial trial starts, declining from 22% in 2013 to 12% in 2023, China continues to gain share, growing from 5% to 18% in that period.[34]

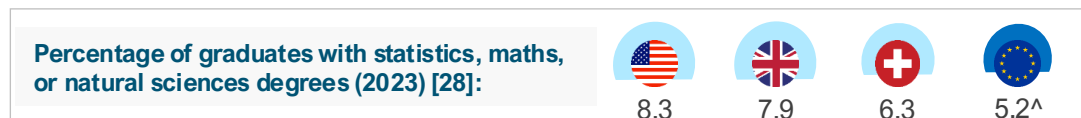
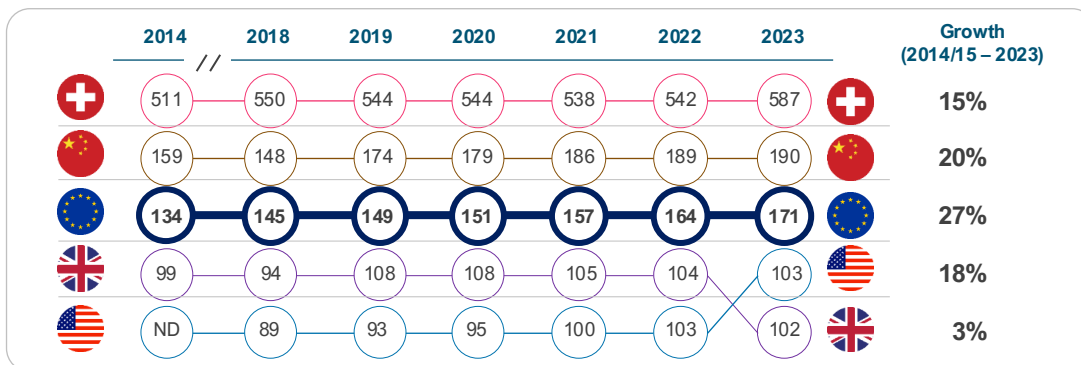
The rapid growth seen in China is not entirely surprising given its modernising society and market size. It is the worsening loss of market share in the EU that is concerning. Structural challenges, such as fragmented ecosystem and longer clinical trial start-up timelines have prevented the EU from growing to the level of opportunity that exists within the EU itself.[34] To strengthen its position as a global innovation leader, the EU should prioritise a more consistent implementation of the EU Clinical Trials Regulation and streamline processes for conducting multi-country trials.

6. Life sciences talent



Compared with comparator countries, EU countries perform moderately in human capital in the life sciences, as measured by the number of employees per capita in the pharmaceutical sector.

Key performance indicator					Source	Latest
Number of life sciences employees per capita (100,000 population) [3-7,36-37]					Multiple sources	2023
1st	2nd	3rd	4th	5th		
587	190	171 [^]	103	102		



[^]Aggregate of EU27 countries. ND – No data

Stock of human capital is an important driver of competitiveness in any sector.[38] A robust employment base fosters innovation by concentrating skilled professionals, such as scientists, engineers, and clinicians, who drive advancements in drug discovery, development, and manufacturing. Countries with high employment density in the life sciences sector are likely to attract higher levels of foreign investment if other competitiveness levers are in place. [38,39]

The EU27 demonstrated strong growth of 27%, rising from 134 to 171 employees per 100,000 population. This performance reflects collective advances across the EU in research, scientific excellence, and innovation, aimed at enhancing the sector's attractiveness.

In comparison, China achieved notable growth of 20%, elevating from 159 to 190, driven by substantial investments in biotechnology and pharmaceutical infrastructure amid its economic expansion.

Switzerland, already a leader in density, grew by 15% from 511 to 587, maintaining its position as a global hub for pharmaceutical giants and high-value research and development. The country's dynamism has been partly attributed to a powerful combination of world-class academic research, strong commitment to R&D, and a symbiotic relationship between academia and industry.[39]

Lastly, in terms of talent pipeline (graduates with natural sciences degrees), the EU falls behind comparators, with 5.2% compared to the US (8.3%).[40]

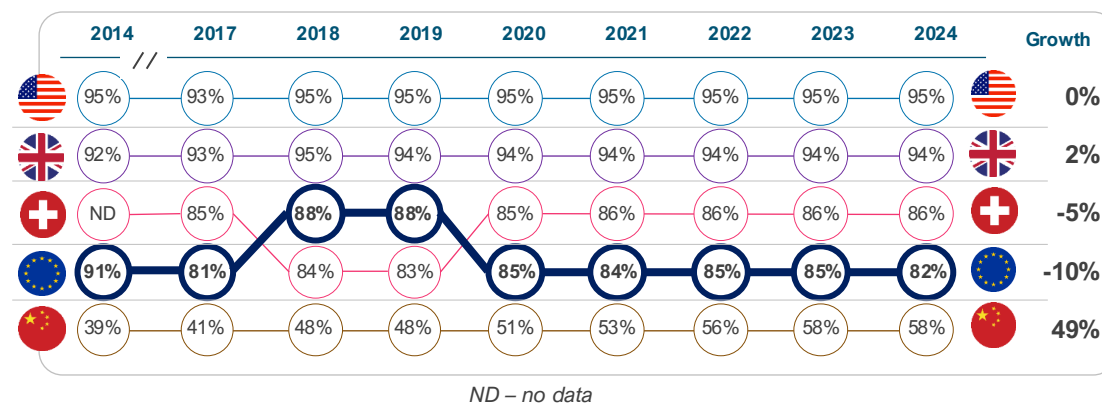
7. Intellectual property protection



Relative to comparators, the EU is a moderate performer in intellectual property protection, only better than China.

Key performance indicator					Source	Latest	
IP Index (IP protection strength) [41]					USCC	2024	
1st	2nd	3rd	4th	5th			
95%	94%	86%	82%^	58%			

^EU average (unweighted)



The U.S. Chamber of Commerce's International Intellectual Property (IP) Index provides a comprehensive annual evaluation of IP frameworks across global economies, assessing factors such as patent rights, copyright protections, enforcement mechanisms, and adherence to treaties.[41]

The EU demonstrates a robust IP framework, consistently achieving average scores in the 73–88% range from 2014 to 2024, but performs below its peers, falling behind the US, UK, and Switzerland.[41]

IP systems in the US, UK, and Switzerland are generally characterised by stronger enforcement, fewer limitations on patentability, and more comprehensive incentives to support innovation.[41]

In the pharmaceutical sector, the EU's IP competitiveness has remained relatively stable. However, in recent years, it has shown signs of decline (-10%), partly owing to harmonisation reforms that introduce uncertainties in regulatory data protection and supplementary protection certificates.[41,42]

While China lags other comparator countries in IP protection strength, its upward trajectory (growing 49% over the last decade) signals China's growing emphasis on IP as part of broader industrial strategies, potentially narrowing the gap with global peers if current trends continue.[27,41-43]

In sum, the EU's pharmaceutical IP regime is less competitive than many of its peers and is already signalling a decline. Maintaining robust IP protections is essential to strengthening its competitiveness.

8. Digital health maturity

Strong EU performance

Moderate EU performance

Lower EU performance

Similar to comparator countries, the EU is a strong performer in digital health maturity. The available dataset for this indicator is immature and warrants monitoring in the future.

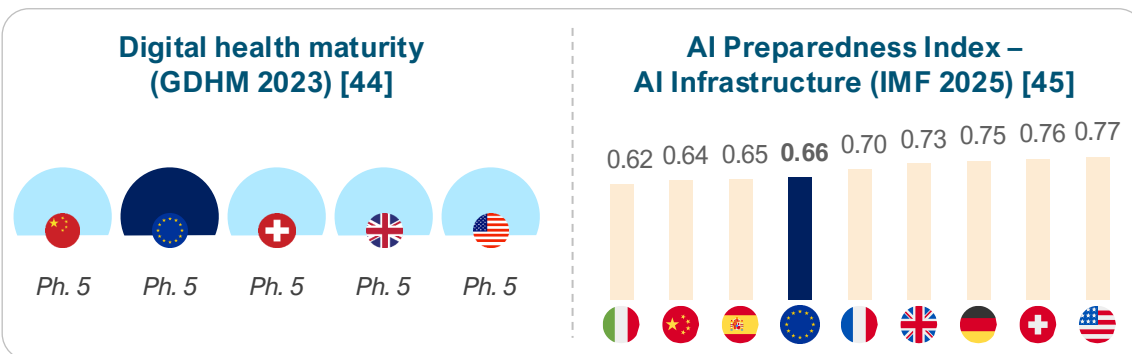
Key performance indicator	Source	Latest	
Digital maturity index [44]	WHO	2023	
Most EU countries and the four comparator countries are ranked at being at the highest phase of digital health maturity by the Global Digital Health Monitor in 2023			
The highest level of maturity is Phase 5, which signifies fully implemented, optimised, sustainable, and institutionalised systems that encompass advanced data governance structures and security, privacy, and device regulation, as well as robust infrastructure and scaled digital services.			

Digital health, including data and artificial intelligence (AI) capabilities, continues to revolutionise healthcare delivery. Pharmaceutical companies are leveraging digital tools and AI capabilities to enhance efficiency in R&D execution and business planning. This indicates that countries with these capabilities are likely to increasingly become competitive.

The Global Digital Health Monitor (GDHM) provides a recent assessment of digital health maturity across a set of pillars not limited to digital/data governance, investment, and infrastructure, among other indicators. In this index, countries are rated on a scale from Phase 1 to 5 for each pillar, based on their level of maturity. The latest index (2023) rated most EU countries (18 of 27) and comparator countries at Phase 5 maturity.[44]

In terms of AI infrastructure, the AI Preparedness Index (2025) developed by the International Monetary Fund ranks EU countries and comparators highly in AI capabilities, with the US (0.77) leading the way, ranking above other countries, such as Switzerland (0.76), the UK (0.73), China (0.64) and many EU countries, including Germany (0.75) and France (0.70).[45] The average across the EU is 0.66, much lower than in the US, indicating some competitive advantage for the US. Reports from countries such as Germany suggest a **lag in the digitalisation of pharmaceutical R&D** relative to the US. [46]

Other assessments of AI capabilities, such as AI commercialisation [47] and AI research ecosystem [48], show similar rankings, with the US on top. The US demonstrates advanced digital capabilities driven by an ecosystem in which digital and AI tools are deeply integrated into research and patient care.[49]



Chapter 2: Regulatory environment

The regulatory environment shapes both speed to market and investment confidence. Competitive systems combine rigorous standards with clarity, consistency, and modernised pathways suited to assess increasingly complex health technologies. A predictable, efficient, and innovation-friendly regulatory system enhances a country's competitiveness.

We assessed Europe's regulatory performance and efficiency against comparator countries across key performance indicators:

Key performance indicators



Regulatory performance

- 9** Number of new active substances (NAS) regulatory approvals
- 10** Proportion of NAS approved via expedited review pathways



Regulatory efficiency

- 11** Median regulatory approval timeline for NAS (days)

9. Regulatory performance – standard pathway

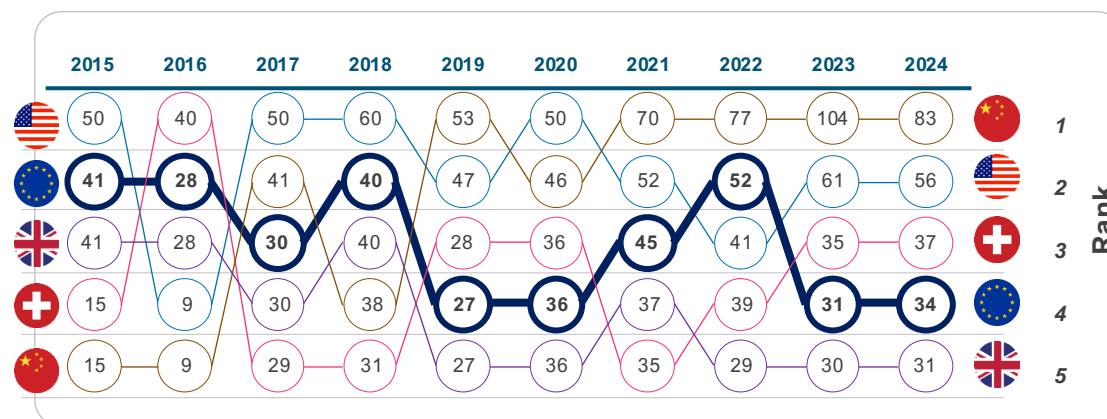
 Strong EU performance

 Moderate EU performance

 Lower EU performance

EU regulatory output has grown more slowly than key global comparators over the past decade. Over the same period, China's performance increased markedly, driven by a sharp rise in NAS approvals.

Key performance indicator				Source	Latest	
<i>Number of new active substances (NAS) regulatory approvals [50-57]</i>				Multiple sources	2024	
1st	2nd	3rd	4th	5th		
						
83	56	37	34	31		



NOTE: The EU and the UK shared the same regulatory mechanism prior to Brexit (2020).

The regulatory environment plays a pivotal role in determining a country's pharmaceutical competitiveness.

Jurisdictions with streamlined regulatory approval systems that facilitate timely market entry for pharmaceutical innovations, which in turn accelerates patient access and reduces development costs, are likely to attract greater private investments, thereby enhancing competitiveness.

Number of new active substance (NAS) approvals is a good indicator of regulatory performance. Analysis of NAS approvals between 2015 and 2024 indicates that the EU's regulatory output has grown more slowly than that of some global peers over the past decade. Over this period, the EU recorded a relative decline of around 20% in NAS approvals compared with global comparators. [50-52]

Over the same period, China's performance improved by over 470%, from 15 approvals in 2015 to 83 in 2024, with a peak of 104 in 2023. [50-52, 56-61]

These trends do not reflect a lack of regulatory quality in the EU, but rather point to differences in system scale, resourcing, and the adoption of bold regulatory reforms in China.

As global R&D activity continues to expand, ensuring that the EU regulatory framework is adequately resourced and continuously modernised will be essential to support timely assessments, uphold high standards, and sustain the EU's role in global health standard-setting.

10. Regulatory performance – expedited reviews

 Strong EU performance

 Moderate EU performance

 Lower EU performance

Use of expedited review pathways differs across regions, with low uptake in the EU compared with global peers.

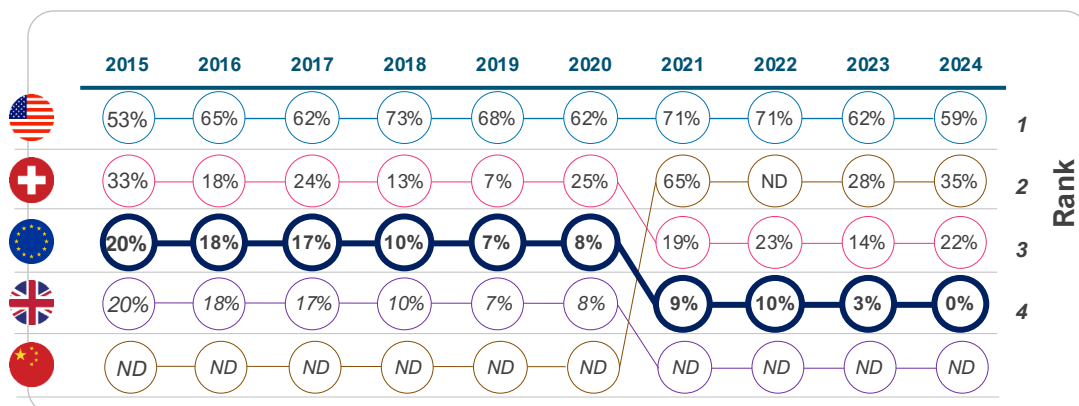
Key performance indicator					Source	Latest	
<i>Proportion of NAS approved via expedited review pathways [50-52, 56-57]</i>					Multiple sources	2024	
1st	2nd	3rd	4th	5th			
							
59%	35%	22%	0%	ND			

Expedited review pathways refer to ‘Accelerated Assessment’ by EMA (EU), ‘Fast Track’ by Swissmedic (Switzerland), and ‘Priority Review’ by the FDA/NMPA (US/China). These pathways are designed to expedite the evaluation and approval of pharmaceutical innovations.

Empirical evidence demonstrates that the EU employs expedited regulatory pathways significantly less frequently than global peers.[50-52,58-62]. In the last decade, the utilisation of expedited review mechanisms for regulatory approval of NAS within the EU declined from 20% in 2015 to 0% in 2024. By comparison, in 2024, expedited pathways accounted for 35% of approvals in China and 53% in the US.[50-52,58-62]

China’s recent regulatory reforms have played a crucial role in creating a robust end-to-end regulatory framework that aligns medicine approval processes with global standards.[61,63] In the US, expedited regulatory pathway tools are better interconnected; i.e., once a medicine receives Breakthrough Designation, it often receives Priority Review, Rolling Review, and Accelerated Assessment. In addition, the US has recently launched the FDA Commissioner’s National Priority Voucher to further expedite the evaluation of new medicines aligned with critical US national health priorities.[64]

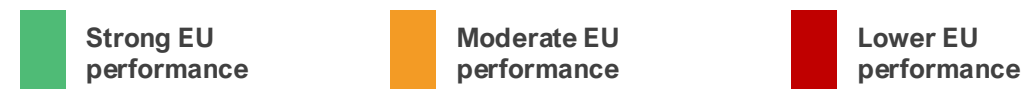
Whereas in the EU, expedited review is a complicated process. Sponsors must first apply for Priority Medicines Scheme designation, then reapply separately to receive Accelerated Assessment, and reapply again to receive Conditional Marketing Authorisation.[65] Simplifying procedures, while maintaining high regulatory standards, would strengthen the EU’s overall regulatory performance.



NOTE: The EU and the UK shared the same regulatory mechanism prior to Brexit (2020). ND – no data

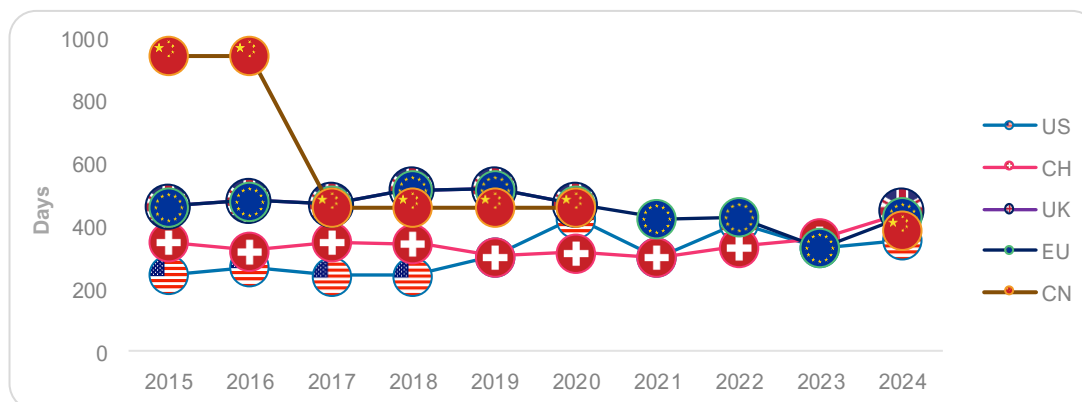
ND – no data

11. Regulatory efficiency – approval timeline



Regulatory speed has improved in the EU over the last decade, performing moderately relative to peers in recent years.

Key performance indicator					Source	Latest	
Median regulatory approval timeline for NAS (days) [50-52,66]					CIRS; ABPI	2024	
1st	2nd	3rd	4th	5th			
							
356	390	430	440	450*			



NOTE: The EU and the UK shared the same regulatory mechanism prior to Brexit (2020).

Regulatory speed is a key driver of competitiveness, as pharmaceutical sponsors are more likely to allocate resources to jurisdictions with predictable, expedited regulatory timelines.

Across jurisdictions, regulatory speed can be assessed using median approval timelines (from regulatory submission to regulatory approval).

Over the last decade, the EU's median approval timelines in the standard pathway declined, from 464 days in 2015 to 430 days in 2024, with a notable low of 333 days in 2023. [50-52]

However, the headline time-to-approval remains longer than that of China and the US. The median difference between China and the EU was ~40 days (430 vs 390 days), and ~74 days (430 vs 356) for the US vs the EU. Historically, the gap between the US and the EU has often been larger. [50-52]

While these trends suggest improvement in the EU's regulatory efficiency, the EU still lags behind global peers. The European Commission has proposed reducing standard assessment timelines to 180 days. This target is not yet a legal requirement until the legislation for the new EU Pharmaceutical package is formally adopted.[50-52]

Meeting this target will help narrow competitiveness and improve the EU's attractiveness to investors.

Chapter 3: Commercial environment

The commercial environment determines the extent to which innovation is funded and available to patients. Where commercial conditions are strong, companies often scale locally rather than relocating, and health systems adopt innovations without delay.

We assessed Europe's commercial environment performance against comparator countries across key performance indicators:

Key performance indicators



Origin of new active substances

12

Origin of regulatory-approved NAS (% of all NAS)



Medicine launch

13

Launch of new active substances (NAS) (% of all NAS)



Time to market (launch)

14

Median time from global launch to local launch (months)



Pricing dynamics

15

Cost-effectiveness thresholds for pricing and reimbursement

16

Pharmaceutical expenditure as a share of GDP

17

Mandatory industry refund rate on pharmaceutical revenues (%)

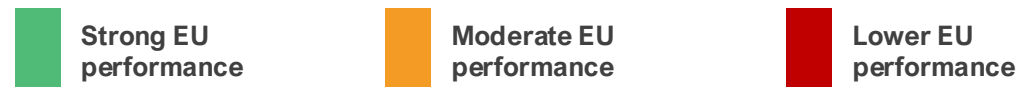


Foreign direct investment

18

Inward FDI in pharma (EUR)

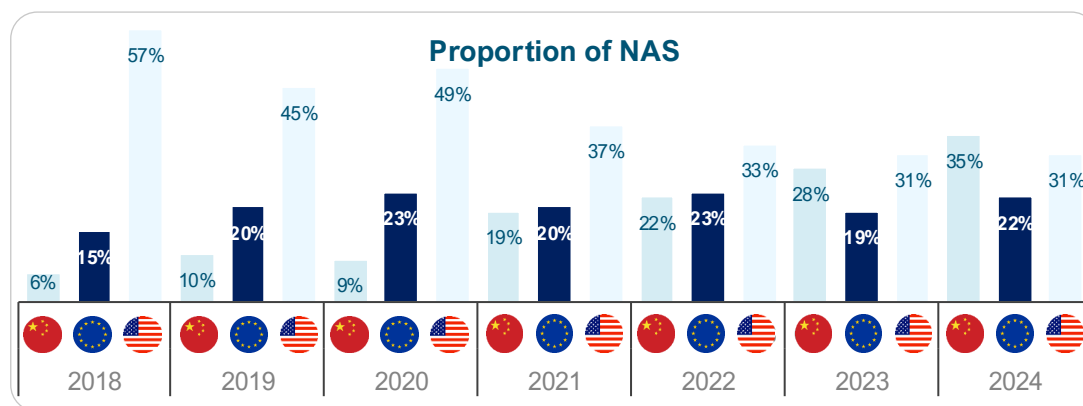
12. Origin of new medicines



Europe's performance in originating new active substances has remained broadly stable, while growth has accelerated in China and slowed in the United States.

Key performance indicator	Source	Latest	
Origin of regulatory-approved NAS (% of all NAS) [3-6]	EFPIA	2024	
1st	2nd	3rd	
China	United States	Europe*	
35%	31%	22%	

*This includes NAS originating from Switzerland and the UK as well.



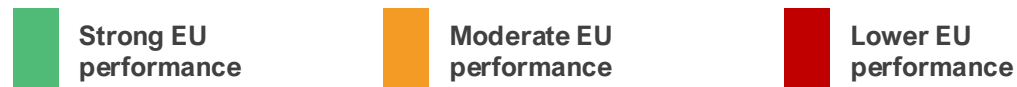
In the early 2000s, Europe accounted for the largest proportion of globally originating NAS. Over time, the distribution has evolved, with China increasing its contribution and a more mixed trend in the US.

Europe's performance (including Switzerland and the UK) has remained relatively stagnant from 2021 to 2024, fluctuating between 17 and 19 NAS annually. Data show that EU-headquartered firms launched only ~130 NAS in 2015–24, compared with ~257 by US firms, a stark difference in innovative output. [3-6] Europe's trajectory differs from that of the US, which has continued to originate a high number of NAS, averaging 24 to 35 per year. This performance is associated with its large, unified market and supportive ecosystem – including strong venture capital funding, a favourable reimbursement environment, fast regulatory pathways, and substantial public and private R&D investment.[67]

China has also recorded rapid growth in NAS origination in recent years, overtaking Europe in 2023 and exceeding both Europe and the US in 2024. Output increased from 4 NAS in 2018 to 28 in 2024. Over the period 2018–2024, China's growth rate exceeded that observed in Europe, reflecting sustained investment in research infrastructure, government support measures, improvements in IP protection, and the expansion of domestic biopharmaceutical capabilities. [3-6, 67,68] Furthermore, NASs originating from China are increasingly being launched in both the US and Europe.[56]

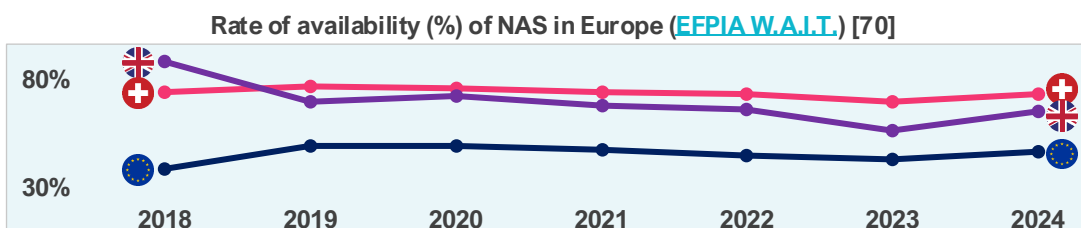
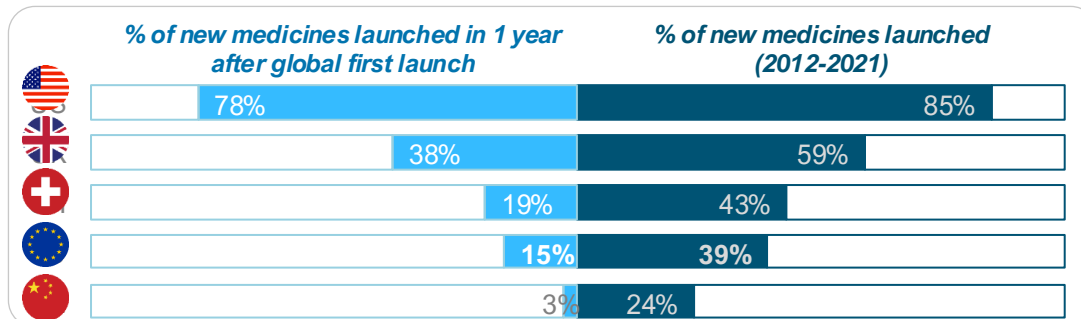
While Europe continues to originate a stable number of new medicines, strengthening the conditions that support innovation will be important to maintain its role in an increasingly competitive global landscape.

13. Medicine launch



The EU's performance is moderate in terms of the launch of new medicines, compared to the US and the UK.

Key performance indicator				Source	Latest	
<i>Launch of new active substances (NAS) (% of all NAS) [69]</i>				PhRMA	2021	
1st	2nd	3rd	4th	5th		
						
85%	59%	43%	39%	24%		



The launch of new medicines (i.e., new active substances) is a core indicator of pharmaceutical competitiveness because it captures how effectively a health system converts scientific innovation into commercial reality, patient access, and sustained investment.

An analysis of data on 460 new medicines launched globally between 2012 and 2021 shows that the EU lags all comparator countries except China.[69]

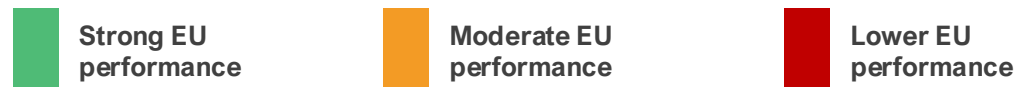
On average, EU countries achieved a launch rate of 39%, substantially lower than the US of 85%. When focusing on timeliness, the EU average for launches within one year of global first launch is 15%, compared with 78% in the US, 38% in the UK, and 19% in Switzerland.[69]

Disparities persist even among leading EU performers, such as Germany (61% launched overall and 44% within one year), compared to France (52% launched overall and 23% within one year). While Germany tops Europe, it remains well below US levels.[69] The EU's relative underperformance in launch speed jeopardises its competitiveness, capturing only 16% of NAS sales (2019 – 2023) in top markets compared to 67% in the US.[70,71]

A similar trend is observed in NAS availability (public reimbursement) **with wide variability within the EU**. In 2023, an average of 46% of NAS was reimbursed in the EU, lower than in Switzerland (73%) and the UK (65%).[70]

The EU's lagging performance in NAS launches and availability poses significant risks to pharmaceutical competitiveness, diminishing its role as a global innovation leader.[71]

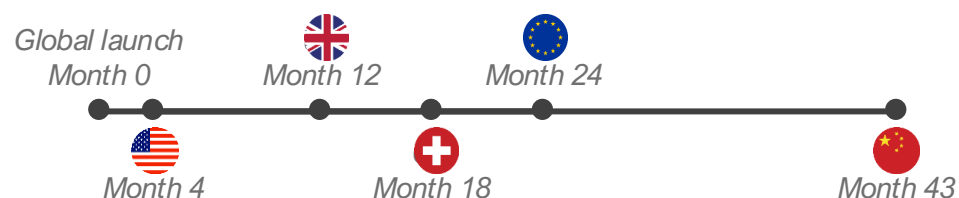
14. Time to market (launch)



Compared with peers, the EU performs moderately on the time to local launch of new medicines (NAS).

Key performance indicator				Source	Latest	
Median time from global launch to local launch (months) [69]				PhRMA	2023	
1st	2nd	3rd	4th	5th		
						

Average months from global first launch to local launch



The EU's performance on the time-to-launch of new medicines, measured as the average number of months between a new medicine's global first launch and its local launch, reveals notable disparities relative to global peers. The average delay in the EU stands at 24 months, though it widely varies across EU countries, **ranging from 128 days (4 months) in Germany to 840 days (28 months) in Portugal**. A similar trend is highlighted in EFPIA's W.A.I.T Indicator Survey.[70]

In comparison, the US demonstrates the shortest average delay at 4 months, enabling significantly faster access for patients. The UK and Switzerland follow with average of 12 and 18 months, respectively – both outperforming the broader European average. [69] The US consistently demonstrates superior performance in both the proportion of NAS made available and the speed of their launch, underscoring a regulatory and market environment conducive to rapid innovation deployment. The wide gap with the US underscores challenges to the EU's pharmaceutical competitiveness. Prolonged delays in the launch of new medicines may deter global investors from prioritising EU markets for initial launches, as seen in the US's dominance in global first introductions.

Fragmentation and slower access, with variations among member states, signal an unattractive environment. Such patterns disincentivise R&D investment within the EU, limit patient access, and erode the region's role as a hub for pharmaceutical innovation.[71]

To enhance competitiveness, the EU would benefit from policies that streamline and expedite regulatory approvals, strengthen IP protections, and promote reimbursement systems that truly reward innovation, aligning more closely with leading performers such as the US.

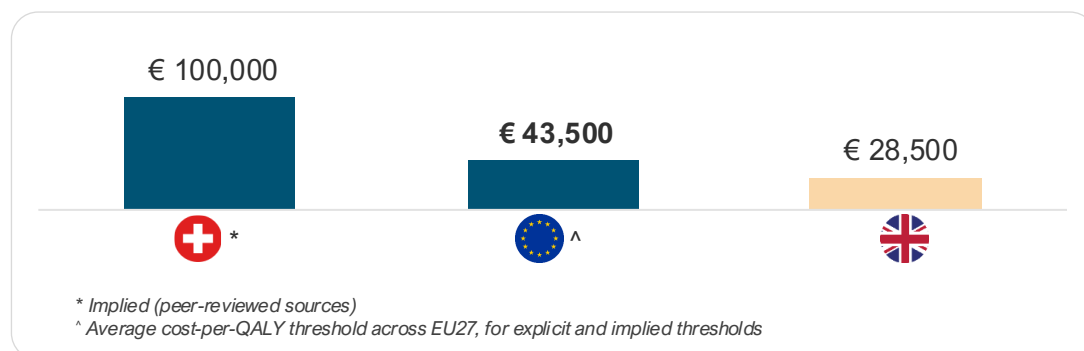
15. Cost-effectiveness thresholds



The EU shows moderate performance in willingness to pay (WTP) for a standard unit of health benefit (QALY) gained from new medicines at an average cost per QALY of €43,500.

Key performance indicator	Source	Latest	
Cost-effectiveness thresholds for pricing and reimbursement [72-75]	Multiple sources	2024	
1st	2nd	3rd	
			
High	Moderate	Low	

China, Switzerland, and the US do not use CET. CET for Switzerland is implied based on a peer-reviewed source.



A country's pharmaceutical cost-effectiveness threshold (CET) is a critical factor for investment attractiveness and competitiveness because it directly influences market access and pricing and reflects the value placed on innovation. A higher, or more flexible, CET can signal a more favourable market for innovative medicines, encouraging pharmaceutical companies to launch products and invest in research and development in that region. Conversely, low or strict thresholds lead to slower adoption of innovations and reduced investment.

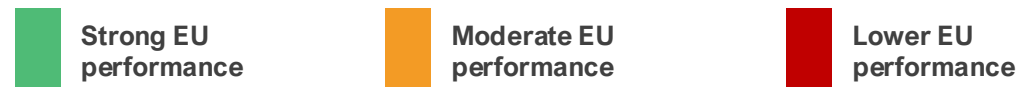
China and the US do not use CET; therefore, they are excluded from the analysis. Switzerland's CET is implied from a peer-reviewed source, but the country does not officially use CET. [73-75]

A recent analysis shows that, across EU countries, the average cost per QALY threshold is €43,500 (~1.26 times the average GDP per capita), lower than Switzerland's (€100,000), though higher than the UK's (€28,500).[72] The UK's CET is set to increase to €35,000 from April 2026.[76]

The average CET across other high-income countries, including Australia, Canada, Japan, New Zealand, Norway, and South Korea, is €36,100.[72]

We note the increasing stringency of reimbursement criteria across the EU, which is impacting the breadth of availability of new medicines. For example, an analysis of HTA outcomes in France, Germany, the Netherlands, and Sweden shows a decrease in the number of positive HTA recommendations in 2023 relative to the averages from 2019 and 2022.[77] The increasing stringency of market access policies in Europe is widening the competitiveness gap.

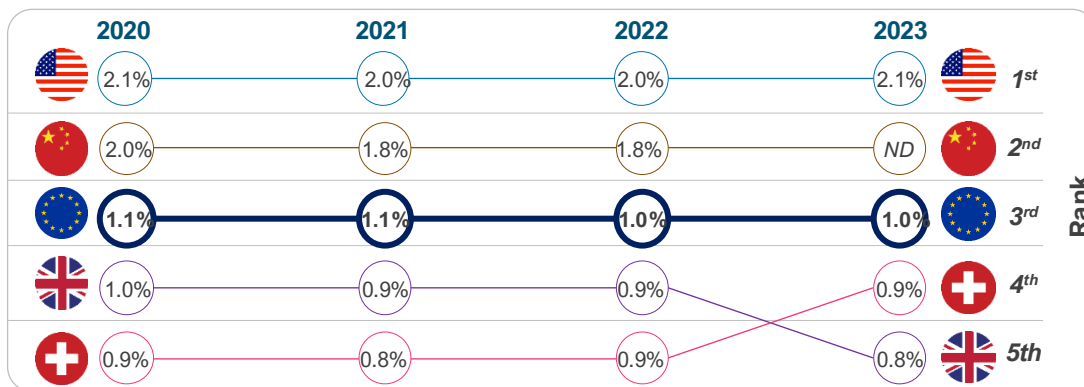
16. Pharmaceutical expenditure



Compared with the US and China, the EU, Switzerland, and the UK devote a lower share of GDP to medicines.

Key performance indicator					Source	Latest	
Public pharmaceutical expenditure as a share of GDP [78,79]					Multiple sources	2023	
1st	2nd	3rd	4th	5th			
2.1%*	1.8%*	1.0%	0.9%	0.8%			

*This represents total pharmaceutical expenditure. For China, the latest data available is for 2022.



ND – no data

NOTE: ESTIMATES OF PHARMACEUTICAL EXPENDITURES WERE DERIVED FROM MULTIPLE SOURCES; THEREFORE, CAUTION MUST BE TAKEN WHEN MAKING COMPARISONS.

Pharmaceutical expenditure (expressed as a percentage of GDP) serves as a proxy for a health system’s capacity and willingness (“market pull”) to fund and utilise pharmaceutical innovations at scale. When market pull is high and predictable, it strengthens pharmaceutical competitiveness by improving the expected returns to innovation, accelerating launch of new medicines, and supporting an ecosystem (clinical infrastructure, evidence generation, specialised supply chains) that attracts further investment. [80,81]

Analysis of pharmaceutical spending in comparator countries shows that the US and China exhibit higher shares of GDP on pharmaceuticals, driven by innovation and population scale, respectively. Whereas European countries, including Switzerland and the UK, emphasise cost containment through rebates and procurement, keeping shares lower.[79-81]

Evidence shows that pharmaceutical innovation increases when companies can expect a larger market, as bigger markets attract more new medicines.[82]

New medicine launches are also responsive to expected prices and revenues, while price regulation and spillover mechanisms are associated with launch delays and a smaller number of new medicines developed.[82]

Countries that combine adequate pharmaceutical spending with predictable, value-based reimbursement and timely access tend to be more attractive launch and investment markets – strengthening pharmaceutical competitiveness through a virtuous cycle of uptake, evidence generation, and reinvestment.

17. Mandatory industry refunds*

Strong EU performance

Moderate EU performance

Lower EU performance

High use of mandatory industry refunds, such as clawbacks, negatively affects pharmaceutical investment in Europe.

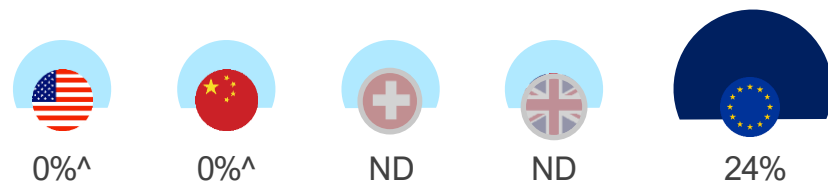
Key performance indicator			Source	Latest
Mandatory industry refund rate on pharmaceutical revenues (%) [66,78,83-86]			Multiple sources	2024
1st	2nd	3rd	ND	ND
				

*Mandatory industry refunds include mandatory rebates, mandatory sales tax, clawbacks (budget caps), and refunds under managed entry agreements.

ND – no directly comparable data

Mandatory industry refund policies exist only in European countries [78,83-87]

Mandatory industry refunds as a percentage of public pharmaceutical revenue (2024)



^ There is limited or no mandatory industry refund requirement.

ND – no directly comparable data

In Europe, mandatory industry contributions, such as clawbacks, are increasingly being used to contain pharmaceutical spending, with little regard for their implications for Europe's innovation ecosystem and patient access.

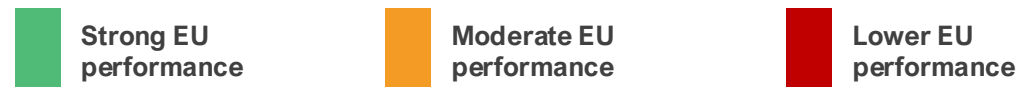
Clawbacks are payments that companies are required to make back to public payers when pharmaceutical spending exceeds agreed budgets. In Europe, these payments are typically applied after the fact and are calculated as a percentage of sales or as a share of budget overspend.

Clawbacks are widely used across the EU as a cost-containment tool, with more than 20 Member States applying some form of clawback mechanism. In several countries – including Belgium, France, Greece, Italy, and Romania – clawback levels are particularly high. [66,78,83,87] For example, in 2024, industry clawbacks accounted for around 53% of total pharmaceutical revenues across all channels in Greece, while in France, industry payments increased from €72 million in 2019 to over €1.6bn in 2023. [83,87] Overall, mandatory industry refunds in Europe have risen from around 13% to 24%, growing 3 times faster than public payer spending since 2018.[78]

By contrast, comparator countries such as the US and China do not apply national clawback systems, relying instead on more limited rebates or discounts. [84-86]

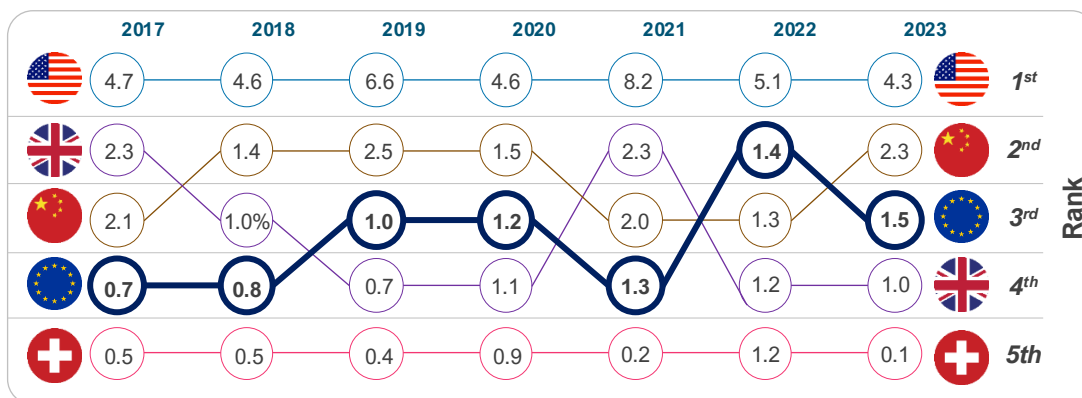
Robust evidence indicates that extensive use of clawbacks (and other cost-containment mechanisms) negatively affects pharmaceutical investment, innovation, and patient access, with implications for Europe's long-term competitiveness in life sciences. [88]

18. Inward FDI into pharmaceutical sector



The EU performs moderately relative to comparators in attracting inward FDI to the pharmaceutical sector.

Key performance indicator					Source	Latest	
Inward FDI in pharma (EUR bn) [28,89]					EFPIA & OLS	2023	
1st	2nd	3rd	4th	5th			
							
4.3	2.3	1.5*	1.0	0.1			



Inward foreign direct investment (FDI) refers to investment by foreign companies in domestic production, research facilities, and infrastructure. In the pharmaceutical sector, inward FDI matters because it supports clinical trials, research hubs, manufacturing capacity, and integration into global innovation networks, all of which contribute to long-term competitiveness.

In the EU, inward pharmaceutical FDI has increased steadily in recent years, rising from around €0.7bn in 2017 to €1.5bn in 2023.[89] However, the overall scale remains lower than in key comparator countries. The US continues to attract significantly higher levels of investment, reporting €4.3bn in a down year (2023), roughly 3 times the EU average. The 2021 spike (€8.2bn) indicates the US continues to attract transformational investments as firms rebase supply chains or build new platforms, as seen during the pandemic.[88]

China also remains a strong competitor for pharmaceutical capital, supported by market size, industrial policy, and scale advantages. In the first seven months of 2025, the biopharmaceutical sector accounted for a third of China's total inward announced FDI of approximately €10bn.[90]

The UK shows a declining trend since Brexit, while Switzerland's relatively low inflows reflect its role as a home base for global pharmaceutical companies rather than a lack of sector strength. [28,89,91].

Overall, the trend in the EU is moving in the right direction, but it still does not capture a proportional share of global mobile pharma capital. The challenge is not momentum; it is magnitude, particularly when compared with the performance of the US and China.

Chapter 4: Industrial output

Industrial output is a clear expression of competitive strength: the capacity to manufacture, supply, and export life sciences products at scale. This includes the depth of biomanufacturing capabilities, the maturity of supply chains, and trade policies to promote and sustain manufacturing leadership and export capacity.

We assessed Europe's industrial performance against comparator countries across key performance indicators:

Key performance indicators



Industry base

19 Pharmaceutical manufacturing investment growth (%)



Trade performance

20 Trade balance in pharmaceuticals

19. Industrial base

Strong EU performance

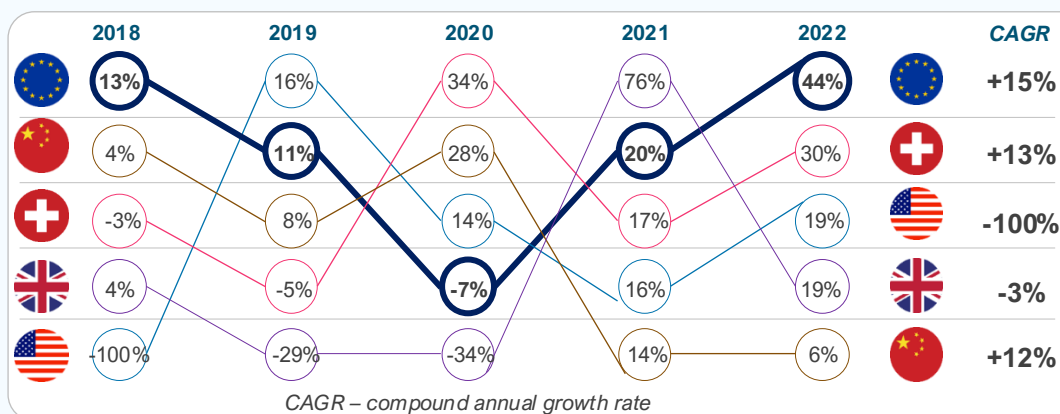
Moderate EU performance

Lower EU performance

EU countries perform strongly relative to comparators on pharmaceutical manufacturing investment growth between 2018 and 2022.

Key performance indicator				Source	Latest	
<i>Pharmaceutical manufacturing investment growth rate [92,93]</i>				UNIDO & NBS China	2022	
1st	2nd	3rd	4th	5th		
						
44%*	30%	19%	6%	-2%		

*This represents the unweighted average across EU countries.



We measured the growth rate of pharmaceutical manufacturing investment using the annual growth rate in Gross Fixed Capital Formation for pharmaceutical and medicinal-chemical manufacturing (ISIC 21) as a proxy (UNIDO data for the EU, Switzerland, the UK, and the US, and the National Bureau of Statistics for China). [92,93]

Between 2018 and 2022, EU countries demonstrated strong growth in pharmaceutical manufacturing investment, with a CAGR of 15%. This positioned the EU ahead of comparators.

China's performance, while steadily positive across all years and yielding a notable 12% CAGR, was outpaced by the EU. Compared with Switzerland, the EU's higher CAGR indicates a more consistent upward trajectory.

The UK's negative CAGR reflects pronounced instability, with sharp declines in 2019 (-29%) and 2020 (-34%) offsetting a temporary spike in 2021 (76%). The US experienced a severe contraction between 2017 and 2018, which may be connected to diminished domestic investment incentives at that time.[94,95]

These dynamics have significant implications for the EU's competitiveness in the global pharmaceutical sector. The EU's superior growth rate indicates a more expanded manufacturing infrastructure and greater resilience to external shocks, positioning it favourably relative to competitors.

Overall, sustained investment growth bolsters the EU's strategic autonomy, fosters job creation, and enhances its attractiveness to multinational firms, thereby reinforcing long-term economic and health security advantages.

20. Trade performance

Strong EU performance

Moderate EU performance

Lower EU performance

The EU's trade performance on pharmaceuticals is strong relative to comparators, with many top EU countries maintaining a positive trade balance in the last decade.

Key performance indicator

Source

Latest



Trade balance in pharmaceuticals [96]

UN Comtrade

2024



Trade balance in pharmaceuticals in 2024 (€B)



EU aggregate trade balance

€ 175.70



€ 38.36



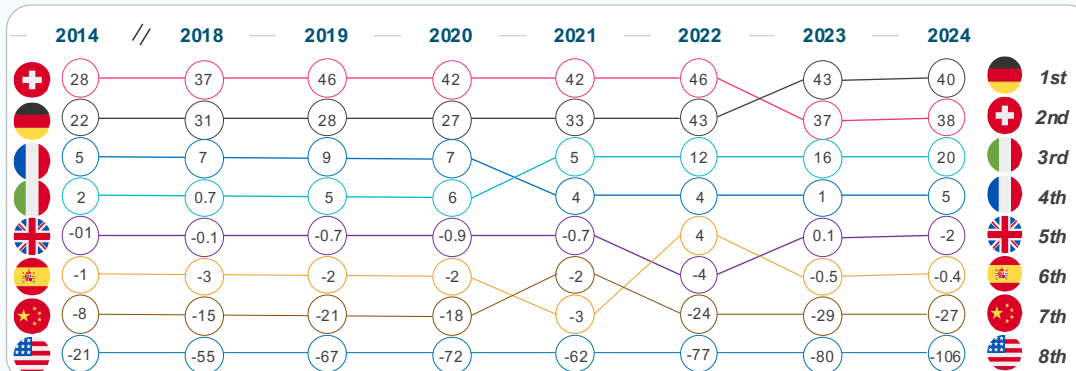
-€ 2.03



-€ 27.14



-€ 106.45



Trade balance in pharmaceuticals is a key indicator of the sector's global competitiveness. A positive trade balance implies several strategic advantages.

Analysis shows the EU has maintained a persistent and growing trade surplus, demonstrating its strength in exporting high-value pharmaceuticals and active pharmaceutical ingredients.[96,97] For instance, without the pharmaceutical industry, the EU trade balance would go from a surplus of €133bn to a €88bn deficit. Latest Eurostat data show that both EU pharmaceuticals exports (€366.5bn) and imports (€145.5bn) increased in 2025 compared to 2024. Exports increased more than imports, resulting in a trade surplus of around €221bn in 2025, up from around €194bn in 2024.[98] This surplus underscores the EU's ability to produce goods that meet international demand.

Compared to peers, EU exports of pharmaceuticals to the US amounted to €160.6bn in 2025 (compared to €121bn in 2024), while imports from the US in 2025 were €60.1bn (compared to €45.6bn in 2024). To China, pharmaceutical exports decreased from €16.9bn in 2024 to €13.9bn in 2025, while imports increased threefold, from €4.4bn in 2024 to €13.1bn in 2025, signaling an increase in China's domestic capacity to research and develop new medicines.[98]

While EU trade performance is strong, this should not be taken for granted. This trade performance must be contextualised amid challenges that could erode it, such as inefficient regulatory frameworks, which may necessitate reforms to streamline approvals and reduce bureaucratic hurdles. Proactive policies are needed to sustain trade performance against global pressures.[99]

Conclusion

This evidence-based assessment identified strengths and trends of the EU's life sciences ecosystem, together with key pressure points for improving competitiveness.



Strengths to build on

- **Scientific excellence & research base.** The medical research outputs of many EU countries remain high-quality according to bibliometric measures, providing a strong foundation for developing and scaling innovations.
- **Digital capabilities.** Digital capabilities are advanced, enabling platforms for digital health tools, AI-driven clinical trials, and data-driven regulation.
- **Industrial and trade performance.** In the EU, investments in pharma manufacturing continue to grow, while the pharmaceutical trade surplus remains, signalling robust manufacturing and export capacity. Yet sustaining this position cannot be taken for granted as global competition intensifies.



Priority pressure points for improving competitiveness

- **R&D investment levers.** Instruments are heterogeneous in breadth and value across the EU. Fragmentation and administrative burden reduce attractiveness relative to Switzerland and China.
- **Patents and capital formation.** Patent applications and inward pharma FDI trends indicate that the EU is not capturing a proportionate share of mobile innovation capital relative to global peers.
- **IP protection uncertainty.** The IP framework is less predictable than in the UK and the US.
- **Clinical trial attractiveness and innovation output.** Over the past decade, the EU's share of global trial starts has fallen to 12%, while China now accounts for ~30% of global trial starts.
- **Origin of new medicines.** China has overtaken both the EU and the US as NAS originator, increasing from 4 NAS in 2018 to 28 in 2024.
- **Regulatory framework.** Expedited pathways are underutilised compared to peers, while approval timelines, though improving, remain much longer.
- **Medicines launch.** EU markets have a smaller share of new medicine launches and typically have a later time-to-launch than the US, with a median EU time-to-launch of ~24 months versus ~4 months in the US.

Conclusion: Strengthening Europe's life sciences competitiveness

With the right policy choices, Europe can secure a competitive, innovative and resilient life sciences ecosystem for the future.



A stronger innovation ecosystem

The EU has a strong foundation in life sciences and a growing recognition of the sector's importance for Europe's economy and health resilience. By building on this foundation and making full use of available policy levers – such as **strong intellectual property, modern regulatory framework, and increased flow of funding** – Europe can regain its attractiveness for pharmaceutical innovation and investment.[1]



Access measures that value innovation

Europe's health care systems have ensured broad access to medicines, but evolving cost-containment practices highlight the need for a more balanced approach that better supports innovation while maintaining sustainability. **Increasing national net public spending and gradually eliminating national cost-containment measures** will be essential to sustain investment and ensure timely patient access to innovative therapies.[1]

Potential impacts of strengthening EU life sciences competitiveness

Addressing identified improvement areas could deliver high returns in industry R&D investment, clinical trials starts, and an increased number of new active substances originating from Europe.

Below are illustrative examples of closing the gap with global peers

 Closing the gap on industry R&D investment	 Closing the gap on the share of global clinical trial starts	 Closing the gap on the use of expedited review pathways	 Closing the gap on originating NAS
€105 billion <i>Additional industry R&D investment</i>	€17.9 billion <i>incremental total gross value added (GVA)</i>	200 new medicines <i>approved via expedited reviews</i>	100 new medicines <i>originating from Europe</i>
- Closing the industry R&D investment gap with global peers would require the EU to attract more industry R&D investments than the current CAGR of 5.4%. - Growing at 8.5% CAGR, rate higher than the US's (6.4%) but lower than China's (12.1%), could yield an additional €105bn worth of industry R&D investment in the EU over a 10-year period by 2035.	- To catch up with growth in China and North America in share of global clinical trial starts would require a 50% increase in activity compared to 2025 levels.[100] - This would result in:[100] - Nearly €18bn in the European economy. 82,000 new jobs. 158,000 more patients enrolled in clinical trials.	- The US is currently the leader in the use of expedited review pathways (59% of all approved NAS in 2024), many targeting areas of unmet medical need. - Closing this gap would result in at least 20 NAS per year approved via the expedited review pathway. - In 10 years, more than 200 NAS would have been approved using expedited review pathway in the EU – accelerating access for patients with limited or no treatment options.	- China currently leads in the share of NAS originated at 35% (28 NAS) in 2024, compared to 22% (18 NAS) in Europe. - Closing the gap with China would mean an additional 10 NAS developed in Europe per year, and at least 100 NAS over a 10-year period.

Annex: Additional information

This assessment, drawing from a comprehensive review of key performance indicators across research and innovation, regulatory environment, commercial environment, and industrial output, reveals a mixed picture: the EU maintains strengths in scientific excellence, digital health maturity, manufacturing, and trade performance, but lags in areas critical to attracting capital and innovation.

Key performance indicators (aggregate)		Latest	Trend	Key performance indicator		Latest	Trend
1. R&D intensity		2024	Improving	8. Origin of new active substance		2023	Flat
2. Clinical trial attractiveness		2023	Declining	9. Medicine launch		2023	Declining
3. Life sciences human capital		2023	Improving	10. Time to market (launch)		2023	Declining
4. IP protection (IP index)		2024	Declining	11. Pricing dynamics		2024	Declining
5. Digital health maturity		2023	Flat	12. Foreign direct investment (inward FDI)		2023	Improving
6. Regulatory performance		2024	Declining	13. Industrial base (pharmaceutical manufacturing)		2022	Improving
7. Regulatory efficiency		2024	Improving	14. Trade performance (pharmaceutical trade balance)		2024	Improving

Overview of KPIs - China

Key performance indicators (aggregate)		Latest	Trend	Key performance indicator		Latest	Trend
1. R&D intensity		2024	Improving	8. Origin of new active substance		2023	Improving
2. Clinical trial attractiveness		2023	Improving	9. Medicine launch		2023	Improving
3. Life sciences human capital		2023	Flat	10. Time to market (launch)		2023	Improving
4. IP protection (IP index)		2024	Improving	11. Pricing dynamics		2024	Improving
5. Digital health maturity		2023	Improving	12. Foreign direct investment (inward FDI)		2023	Improving
6. Regulatory performance		2024	Improving	13. Industrial base (pharmaceutical manufacturing)		2022	Improving
7. Regulatory efficiency		2024	Improving	14. Trade performance (pharmaceutical trade balance)		2023	Improving

Overview of KPIs – United States

Key performance indicators (aggregate)		Latest	Trend	Key performance indicator		Latest	Trend
1. R&D intensity		2024	Improving	8. Origin of new active substance		2023	Improving
2. Clinical trial attractiveness		2023	Improving	9. Medicine launch		2023	Improving
3. Life sciences human capital		2023	Flat	10. Time to market (launch)		2023	Improving
4. IP protection (IP index)		2024	Improving	11. Pricing dynamics		2024	Improving
5. Digital health maturity		2023	Improving	12. Foreign direct investment (inward FDI)		2023	Improving
6. Regulatory performance		2024	Improving	13. Industrial base (pharmaceutical manufacturing)		2022	Improving
7. Regulatory efficiency		2024	Improving	14. Trade performance (pharmaceutical trade balance)		2023	Declining



Summary analysis of key performance indicators across comparators

Overall, the analysis shows a widening competitiveness gap between the EU and its global peers.

Key performance indicator	Source	Latest					
1. R&D investment growth	EFPIA	2023					
2. R&D investment levers	Ernest & Young	2024					
3. Scientific excellence	Multiple sources	2014					
4. Patent applications	WIPO	2024					
5. Clinical trial attractiveness	IQVIA	2023					
6. Life sciences human capital	Multiple sources	2023					
7. Intellectual property protection (IP index)	USCC	2024					
8. Digital health maturity	WHO	2023					
9. Regulatory performance – standard pathway	Multiple sources	2024					
10. Regulatory performance – expedited reviews	Multiple sources	2024					
Key performance indicator	Source	Latest					
11. Regulatory efficiency – approval timeline	Multiple sources	2024					
12. Origin of new active substance	EFPIA	2023					
13. Medicine launch	PhRMA	2023					
14. Time to market (launch)	PhRMA	2023					
15. Cost effectiveness thresholds	Multiple sources	2024					
16. Pharmaceutical expenditure	Multiple sources	2023					
17. Mandatory industry refund rate	Multiple sources	2024					
18. Inward foreign direct investment	UNIDO	2023					
19. Pharmaceutical manufacturing investment	UNIDO	2022					
20. Trade balance in pharmaceuticals	UN	2024					



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