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Between a rock and a hard place: Can Europe leverage the changing geopolitical context to boost its biopharma competitiveness?

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Executive Summary

Biopharmaceuticals are one of Europe's most research-intensive industries with a strong trade, research and industrial dimension[2] and a significant contribution to Europe's economic strength, scientific progress and strategic autonomy. Geopolitical pressures risk further eroding Europe's global position in biopharmaceutical competition. US tariff policies risking pharmaceutical trade agreements, accusations of European "freeloading" on US innovation, and China's rapid advancement in R&D and manufacturing create a complex competitive landscape that could expose the EU to new vulnerabilities.

However, these challenges present strategic opportunities for Europe to assert global leadership through decisive action. Between US-China competition, Europe's strongest advantage lies in fostering innovation through four key pillars:

1. **Scale up innovation capacity and biotech ecosystem:** Europe must boost its homegrown biotech ecosystem by increasing European Investment Fund budgets, implementing the EU Startup and Scale-up Strategy with reduced bureaucracy, leveraging the European Competitiveness Fund for strategic biopharmaceutical research, and creating a DARPA-style European Innovation agency to drive breakthrough innovation.

2. **Strengthen clinical trials infrastructure:** As cornerstones of biopharmaceutical innovation, clinical trials in Europe require faster approval processes, consistent standards through full implementation of the EU Clinical Trials Regulation, incentives like additional regulatory data protection, and multi-stakeholder initiatives for cross-border trials benefiting patients across the continent.

3. **Secure Europe's leadership in biomanufacturing:** Europe must apply Clean Industrial Deal principles to biomanufacturing, develop coherent supply chain strategies emphasizing agility in a volatile geopolitical environment, and simultaneously pursue EU partnerships with third countries while strengthening the internal biopharmaceutical value chain.

4. **Transform health investment into an economic and security strategy:** The EU should recognize health spending as an investment rather than merely a cost, address the fragmented access environment and persistent delays across member states, improve sustainability of joint procurement initiatives, and reframe health as a strategic asset that drives both economic prosperity and security through innovative healthcare systems.

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2 It accounts for 5% of value added to the economy from all manufacturing – representing over 20% for Belgium and Denmark in 2020. Pharmaceuticals represent almost 11% of EU exports, and it directly employs around 937.000 people (figures quoted in re report of Mario Draghi on "The future of European competitiveness, 2024).

Introduction

We live in a time when an article in the Financial Times can reasonably ask without too much eye-brow-raising whether a weight-loss drug can become a weapon of war.[3] If anything, it means that today's geopolitical context spares no sector and requires businesses and policymakers to rapidly adjust to uncertainty and economic coercion.

Geopolitical shifts and intensifying global competition are strong drivers for policies to advance European-made technology and a more interventionist approach to secure critical industry sectors in Europe. The Chips Act, the Critical Raw Materials Act, and the Clean Industrial Deal seek to strengthen Europe's industrial base while combating climate change and reinforce its security and global standing through economic strength. These are strategies that act on key levers along a sector's value chain. More recently, significant loan, borrowing and spending plans have been announced to strengthen Europe's security, as outlined, for example, in the White Paper for European Defense.[4]

Mario Draghi's report on competitiveness[5] highlights the strategic role of research and innovation with pharmaceuticals singled out as a critical sector. Biopharmaceuticals are one of Europe's most research-intensive industries with an extensive trade, research and industrial dimension[6] and strong growth potential.[7] The significance of health security and resilient supply chains became clear during the COVID-19 pandemic with action set out in the recently proposed Critical Medicines Act.[8] The security dimension of biotechnology has been given more prominence within the scope of the Economic Security Strategy,[9] and at NATO level,[10] but has not yet received a similar level of strategic public investment as we have seen in the US through its DARPA and BARDA agencies.[11]

However, Europe faces two competing challenges: the weakening of Europe's competitiveness in biopharmaceuticals and the strong competition from the US and China. The fraught geopolitical context brings polarisation, new trade barriers for pharmaceuticals and the ensuing likelihood of value-chain disruptions and higher prices. Europe is particularly exposed as the US was the EU's main trading partner for medicinal and pharmaceutical products in 2023[12] and China's role is increasing in the biopharmaceutical value chain, notably in R&D and biomanufacturing.[13]

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[3] https://www.ft.com/content/27611730-af18-4540-92de-acef2b3209d9

[4] Joint White Paper for European Defense Readiness 2030, European Commission, 19 March 2025, JOIN(2025) 120 final

[5] https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en

[6] It accounts for 5% of value added to the economy from all manufacturing – representing over 20% for Belgium and Denmark in 2020. Pharmaceuticals represent almost 11% of EU exports, and directly employs around 937.000 people (figures quoted in the report of Mario Draghi on "The future of European competitiveness, 2024)

[7] Global human biopharmaceutical, or "biologics", market accounted for almost $270 billion in 2021 and is projected to continue to grow at high single digit rates (https://innovationcouncil.org/wp-content/uploads/2022/08/EMD2209-Making-Biologics-WP_V8-MSIG.pdf)

[8] COM(2025) 102 final

[9] https://ec.europa.eu/commission/presscorner/detail/en/ip_24_363

[10] https://www.nato.int/cps/ra/natohq/official_texts_224669.htm

[11] In 2024, the Biomedical Advanced Research and Development Authority (BARDA) received a budget of $1.0 billion, source : https://www.ghtcoalition.org/blog/march-budget-madness

12https://ec.europa.eu/eurostat/statistics-explained/index.php?title=International_trade_in_medicinal_and_pharmaceutical_products&oldid=636772

13 See for example : https://www.mckinsey.com/▯/media/mckinsey/industries/life%20sciences/our%20insights/vision%202028%20how%20china%20could%20impact%20the%20global%20biopharma%20industry/vision-2028-how-china-could-impact-the-global-biopharma-industry.pdf

The biopharmaceutical sector has its own specificities in terms of drivers of cost efficiency and value creation through R&D. Europe's strongest card is its innovation capacity. Recent developments should trigger a much greater sense of urgency, a push to give biopharmaceuticals, as part of innovation-intensive sectors, more prominence in a European investment plan. Strong coordination is essential to leverage Europe's existing strengths and seize the momentum created by US policies to turn them in Europe's favour. However, given Europe's publicly funded healthcare systems, an area in which the EU has limited competence, without the cooperation of member states to create a more dynamic demand-side environment, EU-level measures will remain of limited impact.

Recent geopolitical developments are a challenge and a potential opportunity for Europe's efforts to build its biopharma sector

The biopharmaceutical sector does not lend itself to today's geopolitics. It is globalised in its clinical trials, manufacturing structure and supply chains, with an R&D ecosystem that thrives on dynamic research partnerships and investment strategies across many geographies. Efforts in Europe to address the competitiveness gap for its biopharma industry risk being complicated by today's geopolitical environment, with three main points of tension likely to come into play over the short to medium term: firstly, the threat of unprecedented tariffs imposed on pharmaceuticals by the second Trump administration; secondly, the argument of Europe 'freeloading' on US pharmaceutical prices and potential measures to force the hand of manufacturers and/or the EU; thirdly, the US' economic and technology strategy towards China.

Tariff risks: While pharmaceuticals and the starting materials and substances used to produce them, have traditionally been excluded from tariffs (WTO 1994 Agreement on Trade in Pharmaceutical Products), due to the negative impact this would have on patients' access to vital medicines, they are expected to be subject to tariffs by the US (though it is unclear what will be subject to tariffs (finished drug products, APIs). Pharmaceutical supply chains are complex and globalized. Tariffs on pharmaceuticals could have a significantly negative effect on costs and prices[14] and trigger or exacerbate supply chain issues (including through their cumulative effect and the application of tariffs on multiple countries and regions). The impact of tariffs will be more severe for generic drugs, given their already narrow margins, the globalization of different steps in the manufacturing process, the existing weaknesses in the supply chains, such as for sterile injectable generics which have more complex production processes, and given the volumes of prescriptions, they are likely to be more immediately felt by patients through higher insurance premiums or higher out of pocket payments.[15] Tariffs could also increase the costs and time of running clinical trials, for example by delaying the production of investigational products imported from the EU, rising costs of medical devices used in clinical trials, etc., particularly impacting small and medium-sized biotechs that may be lacking revenue from existing products.[16]

14 In a recent survey by the US trade association BIO, 94% of companies polled said they expect tariffs on the EU to drive up manufacturing costs: https://www.bio.org/press-release/new-survey-us-biotechs-warn-tariffs-could-impede-access-cures-stifle-innovation

15 Generics represent 92% of U.S. retail and mail pharmacy prescriptions, and about three-quarters of volume (doses) in the smaller hospital setting: https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/

16 https://www.linkedin.com/pulse/tariffs-impact-clinical-trials-2025-alvin-cheeks-cbowe/; https://www.clinicaltrialsarena.com/features/trumps-tariffs-will-trickle-down-the-clinical-trial-chain/;

Pressure on pharmaceutical price levels: With most of the return on investment in pharma R&D generated in the USA, the argument has often been invoked that Europe is 'freeloading' R&D costs without paying the same level of pharmaceutical prices as the US. During the first Trump Administration, a report[17] by the White House Council of Economic Advisers argued that while US consumers and taxpayers finance over 70% of estimated OECD profits on patented biopharmaceuticals during a single year, most foreign governments set drug prices below those in the US, eroding return on investment. The report further suggested that "enhanced trade policy or policies that tie public reimbursements in the United States to prices paid by foreign governments that free-ride" should be considered. More recently, the 'America First Policy Institute'[18] proposed a range of measures all of which aim at ultimately forcing an increase of pharmaceutical prices to US levels, ranging from aligning the prices manufacturers charge in the US with the prices they charge in other wealthy countries through a Most Favored Nation (MFN) Model, to prohibiting manufacturers from participating in Medicare if they charge other countries lower prices for their products than they charge Medicare, to using tariffs and other trade restrictions to pressure countries to abandon "freeloading policies". Such policies would, if considered, seek to increase pressure on public payers in EU member states and force the hand of manufacturers given the important levels of revenue generated in the US.

Hardening of US-China relations: The US remains the leading market for pharmaceuticals[19], with China expected to have continued volume growth.[20] In parallel, the interdependencies of the US and Europe with China across the full value chain of biopharmaceuticals and biotech are significant and growing. Chemicals and pharmaceuticals represent an important part of the total sales of US owned affiliates in China (see graph), and with COVID, more attention has been paid to China's position as a major supplier of APIs for 'critical medicines'. In addition, a large percentage of drugs sold in the US market rely on Chinese starting materials,[21] indicating the important undertaking a delinking from China would represent.

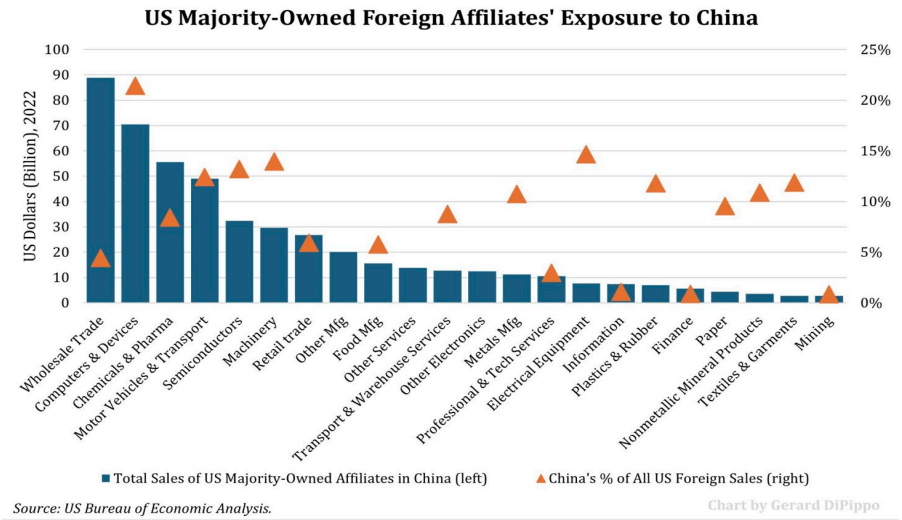

Chart by Gerard DiPippo, RAND China Research Centre

[17] https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf
[18] https://americafirstpolicy.com/issues/put-americans-first-by-ending-global-freeloading
19 https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf
[20] https://www.iqvia.com/-/media/iqvia/pdfs/china/viewpoints/iqvia-institute-general-use-of-medicines-2024-for-print.pdf
[21] For example, according to OYOBO data, 87% of drugs sold in the U.S. market rely on Chinese starting materials

- China is also rising as a significant actor in biopharmaceuticals, including in biomanufacturing, priority areas for policy support by the government with the 'Made in China 2025' initiative targeting biotech as a key industry[22]. China is investing substantially in biotech and genomics research with a growing ecosystem of contract development and manufacturing organisations (CDMOs), which are an integral part of the biomanufacturing ecosystem.[23] As part of the Made in China Strategy, the Shanghai government announced that it will offer around $4 billion in subsidies for biopharma companies that are conducting clinical trials, establishing up to four clinical-research platforms by 2025, speeding up the translation of fundamental research, particularly in areas such as genomics, synthetic biology and gene editing.[24] US firms rely substantially on Chinese contract research and development manufacturing organisations. The US Biotechnology Innovation Organisation (BIO) released a survey in May 2024 in which it found that 79% of responding US companies[25] had at least one contract with China-based CROs or sourced products from China-based CDMOs, with companies indicating that they would need as many as eight years if they were required to change manufacturing partners in the event of a strict decoupling strategy.
- China is reportedly responsible for around 23% of the global pipeline of innovative drugs[26] with an upward trend and China's biotechs are fuelling a third of big pharma's pipelines. According to recent data,[27] China's investment in R&D has surpassed that of the European Union and is rapidly approaching the level of the United States. China is becoming a source of efficiency in R&D when many companies are focusing on cost and speed to bring projects to market, with multinational companies turning to China for drug development and licensing agreements.

At the same time, the US has over the past years increased measures to protect its national security interests in the field of biotech/biopharmaceuticals.

- The Biosecure Act planned under the Biden administration, created out of a concern over access by China to sensitive genetic and healthcare data and which aimed at prohibiting US federal agencies from contracting with or extending loans or grants to any company that has certain commercial arrangements with a "biotechnology companies of concern".[28] While it has not been passed into law, it signalled a raised awareness of biotech's security aspects, and led companies to re-evaluate their supply chains and growing challenges that Chinese biopharmaceutical firms encounter in accessing the US market. Interestingly, this is pushing China to shift its focus to the Southeast Asia region to alleviate US-induced supply chain pressures.[29]
- A national security regulatory regime focused on protecting sensitive personal data and government-related data from "countries of concern", including China, notably through a February

[22] Over the past decade, China's biopharma R&D grew 400-fold and the market value of biotech firms surged 100-fold between 2016 to 2021 (https://www.csis.org/analysis/understanding-national-security-commission-emerging-biotechnology-report)

[23] https://www.ft.com/content/f76c2e6b-dcc4-4e2c-a007-b53330226a5f

[24] https://www.nature.com/articles/d41586-024-03522-y#:~:text=The%20goals%20include%20establishing%20up,synthetic%20biology%20and%20gene%20editing.

[25] Survey results from 124 unique biopharma and biotech companies as well as pre-clinical companies and companies with products in clinical development. More than two-thirds (68%) of these companies are small, emerging companies with fewer than 250 employees.

[26] https://clarivate.com/academia-government/lp/chinas-research-landscape/

[27] Citeline

[28] For a summary, see for ex: https://sanctionsnews.bakermckenzie.com/the-biosecure-act-potential-implications-for-biotechnology-collaborations-with-chinese-companies/

[29] https://carnegieendowment.org/research/2025/01/biopharmaceuticals-rising-chinas-strategic-pivot-to-southeast-asia-amid-great-power-tech-competition?lang=en&center=china

28, 2024 Executive Order on "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern"[30] and the final rules implementing it. US persons will be categorically prohibited from engaging in certain transactions that may result in foreign access to bulk US sensitive personal data and government-related data, as well as certain transactions being "restricted", requiring security measures to be implemented. The rules may restrict or prohibit the transfer of data from clinical trials to China, where this data is linked to US citizen participating in the clinical trial. Given China's position as a growing hub for data analysis, this will have consequences for biopharmaceutical companies.

- Policies are also raising uncertainty about whether it will make it harder to source assets from China through licensing deals. On February 21, 2025 the Trump administration issued a memorandum titled "America First Investment Policy".[31] It emphasises national and economic security and aims to restrict both inbound and outbound investments related to "foreign adversaries" in strategic industries. This includes also biotech and healthcare among the sectors it seeks to cover.[32] In a potential enhancement of an interagency enforcement group "Committee on Foreign Investment in the United States (CFIUS)", the Trump administration is directing the US government to use "all necessary legal instruments" to restrict China-based entities from investing in certain strategic sectors, including healthcare.

A report published on 8 April 2025 by a US congressional commission (National Security Commission on Emerging Biotechnology) urges funding to unlock more private capital into biotech R&D, including in health, given China's growing biotech leadership and biotech's role in national security. The report warns that "There will be a ChatGPT moment for biotechnology, and if China gets there first, no matter how fast we run, we will never catch up.[33]" The US' intensifying tensions with China risk triggering more protectionist measures, driven by a national security rationale. With the size of China's pharmaceutical market playing a growing role in attracting investments by multinational companies, a stronger push towards delinking would generate significant costs for businesses. For Europe, in a scenario of escalation between the US and China, efforts to remain a relevant location for biopharmaceutical investment will need to be substantial as both countries will double down on attracting investment.

Opportunities

Today's new, rapidly unfolding geopolitical rulebook brings increased uncertainty for the sector in the US. Paradoxically, the shifting geopolitical landscape could become a catalyst for Europe to assert global leadership through a predictable, science-driven and innovation-friendly environment for biopharma innovation. There are several opportunities for Europe.

EU leadership in science and global health

Science: Biopharma's competitiveness is closely tied to high-skilled talent and the broader health ecosystem. Different forms of public-private partnerships in key areas of relevance for basic research and R&D, a dynamic infrastructure and highly skilled workforce to attract clinical trials, global health

[30] https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf

[31] https://www.whitehouse.gov/presidential-actions/2025/02/america-first-investment-policy/

[32] https://www.fiercepharma.com/pharma/trump-america-first-investment-policy-raises-uncertainty-booming-field-us-china-biotech

33 https://www.csis.org/analysis/understanding-national-security-commission-emerging-biotechnology-report

initiatives that involve the private sector, for example to expand immunization globally, are all examples of interaction of the pharmaceutical sector with the broader ecosystem. There have recently been several announcements of the US halting of public grants for research. Illustrative among these are CDC plans to cancel $11.4 billion in funds for the pandemic response,[34] cuts to cancer research funding programmes[35] and the likelihood of cuts to research with mRNA technology for areas such as prevention and treatment of infectious diseases and cancer, with scientists reportedly being advised by the US National Institutes of Health (NIH) to remove references to mRNA technology from grant applications, as reported in the FT.[36]

Global health: In recent announcements and decisions, the US is substantially scaling down its role in global development aid, including for health-related programs,[37] bilateral partnerships with third countries, for example, by March 10, 2025 83% of USAID programmes had been terminated.[38]

While it is too early to assess the full impact of these policies and, as decisions are still pending, a reduction of federal research funding by the NIH and other agencies will reduce the US' attractiveness for science, investment and talent, with knock-on effects on the whole biotech ecosystem. Here, the EU has an opportunity to step up. Stronger EU leadership in global health partnerships and research that promotes smart finance and integration of cutting-edge technology globally, that boosts its attractiveness for scientific research within the EU, and maintains a high-trust regulatory system can have significant spillover effects for its leadership in health innovation. The challenge will be to create an ecosystem to concentrate on scientific excellence and talent in the EU, for example through dynamic and competitive biotech hubs.

Biotech and biopharma as strategic security assets: Pharmaceutical supply chains and global security are interconnected, highlighted by the COVID-19 pandemic. The Critical Medicines Act proposal aims to integrate pharmaceuticals into a policy framework that combines industrial strategy with security. Before its publication, ten member states urged the Commission[39] to align the Act with the US Defense Production Act, which treats pharmaceutical supply as a national security issue and prioritizes government orders for essential drugs during crises. The security aspects of biotech and biopharmaceuticals are becoming more significant[40], with NATO's 2024 strategy promoting the responsible use of biotechnology and artificial intelligence in its international strategy on biotechnology and human performance augmentation (HPA) technologies.[41] Increased focus on economic and national security should drive biosecurity research in the EU.

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[34] https://www.nature.com/articles/d41586-025-00954-y

[35] https://www.statnews.com/2025/03/24/trump-cancer-research-funding-cuts-patients-researchers-worried/

[36] https://www.ft.com/content/70654d6d-48ad-45be-8a10-dcd1a75ffc5e?accessToken=zwAAAZXSDM09kc9wZU1tSK1FvtOKENzRp1_8Xg.MEYCIQCaiD8Mmc97wXNexb3U_ooF-mqo8XMwQXRYA8BlRDI10QIhAKzHa39V3B_wptYuM1Wt4Z6NonLJbLDJyAtyBNS042-O&segmentId=e95a9ae7-622c-6235-5f87-51e412b47e97&shareType=enterprise&shareId=215da7ca-339c-4d7e-850e-fa7c34515565

[37] https://www.nytimes.com/2025/03/26/health/usaid-cuts-gavi-bird-flu.html

[38] EPRS, At a Glance – Cuts in US Development Assistance, March 2025

39 Europe's dangerous medicine dependency is the Achilles heel of its defence strategy, 09/03/2025; published in Euronews

40 The Strategic Imperative of Biotechnology, CSIS, 27 September 2024; https://www.csis.org/blogs/strategic-technologies-blog/strategic-imperative-biotechnology-implications-us-national

41 Summary of NATO's Biotechnology and Human Enhancement Technologies Strategy, 12 April 2024; https://www.nato.int/cps/ra/natohq/official_texts_224669.htm

Implications and ways forward for Europe

The current uncertainty raises challenges for multinational companies, smaller biotechs and their investors, compounded by the biopharmaceutical sector's inherent high-risk nature. They will impact strategies in out-licensing, in diversification and scaling up of supply chains and in location and size of manufacturing investment, among others.

The US' position as a leading market for the sector[42] gives it leverage. Its policies on tariffs and taxes are aimed at increasing pressure on US-headquartered companies to reshore biomanufacturing capacity to the US. Several major US-headquartered biopharma companies recently announced manufacturing investment plans in the US, though longer lead-times will mean that they will materialise only in the medium to longer term (4-6 years for a greenfield biologics plant on average). As recently reported in the Wall Street Journal, initiatives might also be introduced to encourage firms to report profits in the US and/or stricter US tax policies that will oblige pharmaceutical companies to report more profits at home.[43] European-headquartered firms remain more exposed in terms of their relatively weaker manufacturing presence in the US[44]. Industry has warned of a risk of "exodus" of companies to the US[45].

Europe is a major exporter of pharmaceuticals to the US. During the whole 2002-2023 period, the EU ran a trade surplus with the United States, peaking at €54 billion in 2022, in addition to the US remaining strategically dependent on essential goods imports for critical medicines.[46] From the EU member states, Germany, Belgium and Ireland rank among the leading exporters of pharmaceuticals to the US. For Germany, for example, around 23% out of the total pharmaceutical exports went to the USA[47]. If tariffs are applied, a unified EU position and strategy will be essential.

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[42] United States is projected to generate the highest revenue, with US$660.04bn in 2025, whereas the projected revenue in the Pharmaceuticals market in Europe is expected to reach US$204.56bn in 2025, all figures from Statista. See also EFPIA, The Pharmaceutical industry in Figures: in 2023 North America accounted for 53.3% of world pharmaceutical sales, compared with 22.7% for Europe.

43 Trump's Tariffs Could Blow Up Big Pharma's Tax Shelter, WSJ, 02 April 2025, https://www.wsj.com/health/pharma/how-trumps-tariffs-could-upend-pharmas-overseas-tax-strategy-5b8ca758

44 Will Trump's tariffs turbocharge foreign investment in America?, The Economist, 17 March 2025 ;https://www.economist.com/business/2025/03/17/will-trumps-tariffs-turbocharge-foreign-investment-in-america

45 EFPIA press release, 08.04.25 ; https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/pharma-ceos-alert-president-von-der-leyen-to-risk-of-exodus-to-the-us/

46 The EU's Art of the Deal, 19 December 2024; https://institutdelors.eu/wp-content/uploads/2025/01/20241219_EUs_Art_of_the_Deal_Arthur_Leichthammer_Elvire_Fabry.pdf

47 Handelsverflechtungen: Welche Industrien US-Zölle besonders hart treffen, VFA, 2025; https://www.vfa.de/de/wirtschaft-standort/handel-internationale-beziehungen/macroscope-handelsverflechtungen-us-zoelle

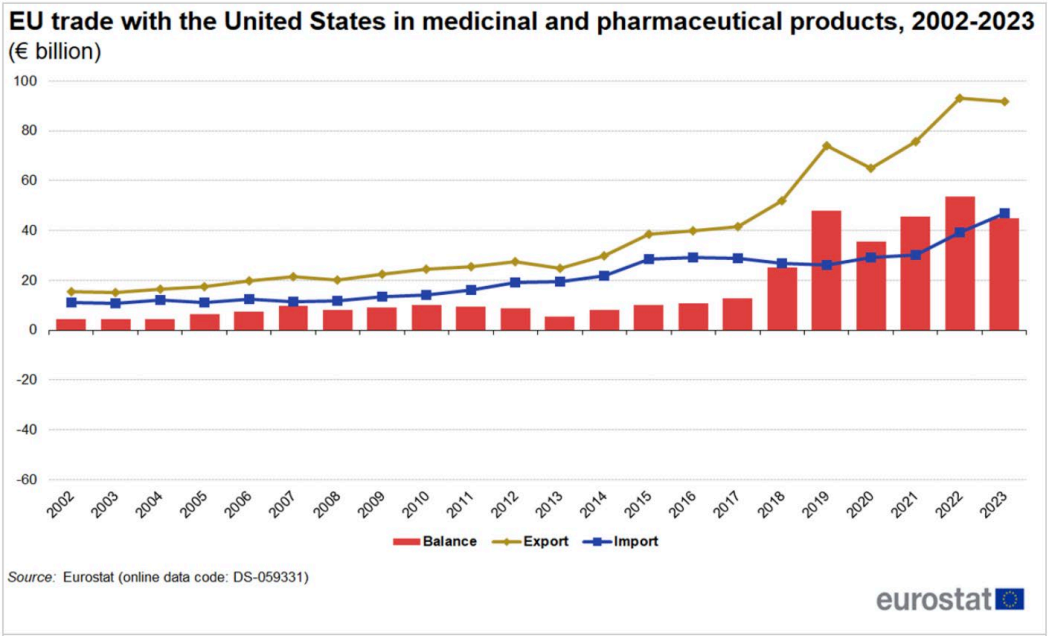

Figure 4: EU trade with the United States in medicinal and pharmaceutical products, 2002-2023 (€ billion)

The EU should focus on strengthening key building blocks in the biopharmaceutical value chain. It will require joined-up coordination at the EU level, aligning national policies more systematically with the EU's competitiveness objectives, achieving greater scale and complementarity of efforts. This should build on existing strengths and leverage the consequences of US policies.

Four areas should play a prominent role in EU action: Helping biotech startups scale in Europe and leverage the EU's excellence in science, strengthening the Clinical Trials Ecosystem, securing Europe's leadership in pharmaceutical biomanufacturing and investing in health as a central driver for long-term economic and security strategy.

Helping biotech startups scale in Europe and leverage the EU's excellence in science

Emerging biopharma companies now drive over two-thirds of the global R&D pipeline, generating 67% of the R&D pipeline in 2022; in 2002 it was 33%.[48] With many companies under a steep "patent cliff" that will put pressure on margins, funding ever more complex and costly R&D means that companies seek efficiency and cost minimisation.[49] Many are shifting to external growth strategies and relying on an ecosystem of smaller biotechs to strengthen pipelines. Since 2018, more than 70% of new molecular entity revenues have come from externally sourced products. Of these products, roughly 45% were sourced before launch.[50] With biopharmaceuticals being a high-risk, high reward sector, with a high attrition rate (most drug development not resulting in product approval), access to risk finance, such as venture capital (VC), is of critical importance.

[48] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2023
[49] https://www.bcg.com/publications/2025/patent-cliff-threatens-biopharmaceutical-revenue
[50] https://www.mckinsey.com/industries/life-sciences/our-insights/external-innovation-biopharma-dealmaking-to-boost-r-and-d-productivity

A recent EIB report[51] highlights that securing equity finance makes firms 13 percentage points more likely to innovate across all high-tech sectors, including the health sector, particularly for startups and scale-ups with risky breakthrough ideas and technologies. The EU Startup and Scaleup Strategy's recent public consultation confirms that Europe needs easier access to funding, reduced red tape, and stronger support for infrastructure and startup ecosystems.

- But in Europe, scale-up success is too often stifled by fragmented markets and scarce late-stage funding. US firms continue to dominate biotech capital flows, bolstered by mature venture ecosystems and coordinated public investment. Europe has excellent science, but the high level of scientific output does not translate sufficiently into innovation when measured by biotech patents. The US is leading (39% of total biotech patents in 2020), followed by the EU with an 18% share and China is advancing quickly.[52] Draghi's report highlights the financing gap for the pharma sector in Europe, with an environment characterized by lower access to risk finance,[53] notably venture finance in EU vs US, which continues to lag in the early and late stages, particularly missing larger-sized investors with late-stage deals. Larger capital markets are key to mobilising large-scale and higher-risk finance for innovation. Recent examples of more substantial funds, such as the launch of a €165m initiative that includes major global pharmaceutical companies with US headquarters,[54] could signal a more positive trend. To bridge Europe's investment gap, as highlighted in the Draghi report, it must unlock private investment by increasing the firepower of the European Investment Fund and InvestEU for high-risk, late-stage financing and addressing the small size of deals through European Investment Bank support for late-stage growth capital.
- Reducing fragmentation in venture capital flows and the planned Savings and Investment Union should boost capital for the biopharma sector.
- Addressing fragmentation of public R&D spending, simplifying access to public R&D funding and identifying areas of strength in science to map strategic priorities in biopharmaceutical research for investment by both public and private actors, for example, ageing research and advancing integration of AI into R&D given its potential for increasing R&D productivity. The European Competitiveness Fund could play an important role here and steer it towards strategic science priorities (e.g. ageing, AI-driven R&D).

This should also benefit the growth of AI in the health sector. The increase in AI-enabled drug discovery is fueling the global market of AI in biotech, driven by advanced data analysis, precision medicine, and faster drug development needs. Global artificial intelligence in drug discovery market is expected to expand by nearly 30% annually from 2024 to 2030.[55]

The EU should also capitalise on recent shifts in the US, where federal research funding is being cut across key health areas. Many US scientists reportedly eye relocation, with a Nature poll[56] indicating that 75% of US-based scientists are considering emigrating. A letter signed by at least 10 member states

[51] Innovation, Integration and Simplification in Europe, European Investment Bank, 2025

[52] https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/global-landscape-biotech-innovation-state-play-2024-03-20_en

[53] in 2021-2022 US biotech companies received USD 62.5 billion in venture finance, compared with the USD 11.2 billion received by European companies (Draghi, 2024)

[54] https://sofinnovapartners.com/news/Sofinnova%20Partners%20exceeds%20target%20with%20€165M%20biotech%20acceleration%20fund,%20Europe's%20largest,%20with%20strong%20Pharma%20support

[55] https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-drug-discovery-market

[56] https://www.nature.com/articles/d41586-025-00938-y?utm_source=semafor

addressed to the Commissioner for Research and Innovation, Ekaterina Zaharieva, ask that the EU step up funding to attract talent. Europe has a window of opportunity to attract top talent. But the EU will be in competition with other parts of the world to benefit from a 'brain gain', and needs to create the right incentives, infrastructure, simplified rules and procedures,[57] and resources. The National Institutes of Health (NIH) alone dedicates around $47 billion to biomedical research each year. The next Multiannual Financial Framework should drive a much better pooling of efforts.

The fast-advancing field of health biotech, which integrates AI and other cutting-edge technologies, requires dynamic and adaptive regulation. The reform of the pharmaceutical regulatory framework[58] should be concluded as soon as possible and should be strongly focused on creating a globally competitive regulatory framework. The sector also needs clarity and predictability in rules governing use of AI in R&D and clarification in the implementation of the European Health Data System.

Finally, Europe should think big and develop the European equivalent of the US DARPA, a fully independent and sufficiently resourced European Innovation agency. This idea is far from new and has more recently been highlighted in the Draghi report, but it is taking on a different dimension, given the technology race in several critical areas besides biopharma (e.g. AI, quantum etc), and the connection between these and their application in defence. At the same time, DARPA's principles on which it built its success should be well understood and adapted to the EU context to become genuinely applicable in the EU.[59]

Strengthening the clinical trials ecosystem

Clinical trials are a cornerstone of biopharmaceutical innovation. With emerging biopharma companies playing an increasingly important role in initiating clinical trials, accounting for 59% of trial launches in 2021,[60] boosting Europe's biotech start-ups and scale ups must go hand in hand with boosting Europe's attractiveness for clinical trials.

The need to make drug development more efficient and less costly is becoming increasingly pressing given global competition and pressures on pharma prices, and the rising costs of developing a new medicine.[61] Lowering the costs of clinical trials is an important part of this effort, with scientific and technical progress in both biotech and AI offering opportunities. Promising early-phase success rates of AI-discovered molecules point to potentially substantial R&D efficiency gains, with machine learning helping to predict the outcome of a drug compound in the discovery phase.

A challenging economic environment and increased geopolitical uncertainty will further compound the trend to derisk pipeline bets. Between 2019 and 2023, the volume of partnerships at the discovery and

[57] https://polish-presidency.consilium.europa.eu/media/r5fa13v5/warsaw-declaration_final.pdf
[58] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en
[59] https://www.project-syndicate.org/commentary/european-darpa-could-boost-innovation-if-implemented-correctly-by-lars-fr-lund-and-fiona-murray-1-2024-10
[60] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation
[61] For example, Deloitte estimated in 2023 the average cost of developing a new medicine among the top 20 global biopharma companies rose by 15% from the previous year – by $298m to $2.3bn.

preclinical research stages shrank by a CAGR of 9% and 4% per year, respectively,[62] and investors are looking at more mature assets with strong clinical data for novel approaches targeting therapeutic areas of interest. China's growing number of biotech companies are becoming serious contenders to European and US companies, with China's clinical trial processes, combined with a large patient pool, strengthening its ability to run drug discovery and development quickly and at lower cost and fuelling a rise of assets. In 2020, less than 5% of large pharmaceutical transactions worth $50 million or more upfront involved China. By 2024, this was nearly 30%, as recently reported.[63] [64]

The EU's decreasing share of global clinical trials is concerning and weakens its position in the value chain. Research conducted by IQVIA[65] shows that there are now 60,000 fewer clinical trial places available to patients. The EU Clinical Trials Regulation (CTR) seeks to harmonize processes, making multi-country applications easier. However, research by IQVIA shows that despite the ambition for harmonized standards and common regulatory procedures, capacity and motivation for national implementation of the CTR are inconsistent, hampered by a slow and fragmented ecosystem.

Denmark and Spain have seen growth in clinical trials, demonstrating that attractive investment and policy measures are crucial for generating private sector investment. Spain has risen to a top position in global rankings for clinical trials through focusing on speed and costs. It offers tax credits and a relatively speedy regulatory process to reduce the lag from the start of a drug trial to approval.[66] Investors also point to comparable science quality at a cheaper price than Spain's rivals. It has conducted a proactive implementation of the CTR through cross-stakeholder coordination, investment in key clinical trial sites, and collaboration between commercial and non-commercial entities.

Europe would also benefit from introducing stronger incentives to conducting clinical trials in Europe. For example, in its position of April 2024 on the Commission proposal to reform the core EU pharmaceutical legislation, the European Parliament adopted an incentive of an additional 6 months of regulatory data protection if the innovator conducts *"a significant share"* of research and development (including preclinical and clinical studies) within the EU in part at least in collaboration with public entities. Finally, industry is also advocating for a new multi-stakeholder initiative to advance cross-border trials to enable patients to have better and earlier access to trials.[67]

Securing Europe's leadership in pharmaceutical biomanufacturing

Biomanufacturing, including the production of vaccines, contributes positively to Europe's trade balance, and is an area in which Europe still has a strong position globally[68]. Most active pharmaceutical

[62] https://www.mckinsey.com/industries/life-sciences/our-insights/external-innovation-biopharma-dealmaking-to-boost-r-and-d-productivity

[63] based on a report by investment bank Stifel, see also: https://www.wsj.com/health/pharma/the-drug-industry-is-having-its-own-deepseek-moment-68589d70

[64] Rapid trials prompt deals rush for Chinese 'super me-too' drugs, 6 February 2025, Financial Times; https://www.ft.com/content/f76c2e6b-dcc4-4e2c-a007-b53330226a5f

[65] Assessing the clinical trials ecosystem in Europe, October 2024, EFPIA

[66] How Spain became big pharma's new hotspot in Europe, 2 April 2025, Bloomberg; https://www.bloomberg.com/news/articles/2025-04-02/how-spain-attracted-investment-from-pharma-giants-astrazeneca-novartis-roche

[67] Breaking down barriers: making cross-border access to clinical trials a reality, 8 July 2024, EFPIA

[68] Biomanufacturing: Europe's Industrial Future, EuropaBio, 2024; see also: https://www.biomedeurope.org/wp-content/uploads/2024/09/Life_Science_Attractiveness_-_2023_November_22_Final_Final_LR2.pdf

ingredients for innovative medicines production in the EU are sourced from within the EU itself (77%).[69] Several EU member states, such as Germany, France, and Ireland are important hubs for biologics production. Growing demand for biosimilars and biologics and the shift towards targeted treatments for complex and chronic diseases are likely to further boost this sector.

In biomanufacturing, supply chains are more vertically integrated and have more production steps centralised in one location to make them easier to control. This involves highly specialised production facilities and complex, multistep processes that complicates supplier switching. In addition, biologics starting materials often have a high degree of complexity with each of these starting and raw materials comprising *other* raw materials. The raw materials can be difficult to source consistently, necessitating strategies like multisourcing to mitigate risks. For these reasons, for manufacturing biologics and vaccines shifting supply chains is complex and time-intensive.

ATMP value chains, for example, are highly interconnected. Attracting early research translated into therapies requires an innovation-oriented ecosystem, in which companies can be sure to achieve an appropriate return on investment, while acting as a magnet for attracting manufacturing, because for ATMPs "the process is the product". Location of clinical trial sites and commercial sales of first cell therapies are often similar.[70]

Understanding the particularities of biomanufacturing within this broader context and elements that impact it is essential to develop policies that will secure its continued strength in Europe. Price dynamics in Europe risk leading to similar trends, as could be observed in the field of small molecule 'critical medicines', especially as China and India are reaching the standards required for exporting biopharmaceuticals and continue to benefit from governmental support strategies.

The EU's Clean Industrial Deal[71] and Critical Medicines Act should provide a blueprint of measures that can most appropriately attract biomanufacturing investment in the EU. The Trump administration recently rescinded the US Executive Orders for Biotechnology and Biomanufacturing,[72] which had been put in place to boost biomanufacturing capacity, and increased awareness of biotech and biomanufacturing as a security issue also in Europe. Coherent supply chain derisking strategies and adaptability will be essential in navigating geopolitical tensions. To ensure supply chain resilience, the EU should pursue its intended strategy of building partnerships with third countries and boosting different actors of the value chain within the EU. The EU IPCEI logic of spill-over effect of new suppliers and services, benefiting smaller firms and enhancing regional industrial capabilities, should be brought into play in a strategy of support for Europe's biomanufacturing ecosystem of manufacturers and specialised suppliers.

[69] Draghi, 2024

70Factors affecting the location of biopharmaceutical investments and implications for European policy priorities, 3 October 2022, CRA ; https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf

71 The Clean Industrial Deal, 26 February 2025, COM(2025) 85 final

[72] Fact Sheet : President Donald J. Trump rescinds additional harmful Biden Executive Actions, 14 March 2025, The White House ; https://www.whitehouse.gov/fact-sheets/2025/03/fact-sheet-president-donald-j-trump-rescinds-additional-harmful-biden-executive-actions/#:☒:text=Removing%20Biden%27s%20directive%20to%20prioritize,the%20guise%20of%20environmental%20policy

Investment in health as a central driver for long-term economic and security strategy

Europe's public healthcare systems enable access to quality healthcare for their citizen.[73] They are important steering instruments through the role that they play in pharmaceutical access policies and pricing and reimbursement decisions, and through generating health data that advance research and healthcare delivery. To maintain the competitiveness of its biopharmaceutical sector, Europe must focus not only on supply-side incentives.

With the decision on pricing and reimbursement of pharmaceuticals falling within the remit of national authorities, member states have a key role to play through enabling rapid and effective access of treatments to patients that need them. Europe's fragmented access environment and access delays are driven by a variety of factors, most of which are specific to the national context. Delays raise legitimate concerns over equity of access to patients in all EU member states, creating unpredictability for manufacturers, and reduce the incentive to launch in all markets. Proposals by the European Commission put forward within the framework of the revision of the pharmaceutical legislation of incentivising companies to launch a new medicine in all markets by tying the regulatory data protection period to obtaining reimbursement in all EU member states have proven divisive. For industry, the way forward lies in tailored solutions for specific issues, countries, and products.[74]

Companies and investors in the biopharmaceutical sector need to manage various uncertainties, including scientific, regulatory, and financial and supply chain risks, alongside those linked to payer decisions and market access. Net present value analysis is typically used in investment evaluations, weighing projected revenues against development costs and other factors. The access frameworks in countries and access projections play an important role in this analysis[75]. Uncertainty due to market access and pricing challenges impact investors' valuations. The EU's HTA Regulation, which sought to reduce the fragmentation of national HTA processes through bringing one part of the process to the European level, and thereby addressing access delays, will require companies to incorporate the joint clinical assessment into their business development decisions. This includes late-stage acquisitions or in-licensing agreements, where an asset's clinical studies with selection of comparators and patient populations may already have been set without considering preferences of the EU's Health Technology Assessment bodies.

Another attempt at Europeanising the equity of access issue now comes in the form of calls for joint procurement, formally included in the critical medicines act. However, that political ambition has yet to be translated into faster, sustainable access, with joint procurement contracts that provide attractive propositions for manufacturers.

The reality is that finding European solutions to patient access delays for new biopharmaceuticals remains challenging. The geopolitical environment and policy initiatives by the US, China and other competitors to the EU will further erode Europe's fragile place as a launch region. The US remains the leading market for pharmaceuticals, enabling faster commercialization of new therapies compared to the EU. Europe is unlikely to remain an attractive market for biopharmaceuticals if the ecosystem for

73https://pmc.ncbi.nlm.nih.gov/articles/PMC7773202/#:~:text=The%20attainment%20of%20UHC%20is,and%20control%20of%20emerging%20diseases.

74 https://efpia.eu/news-events/the-efpia-view/efpia-news/new-data-from-efpia-reveals-multiple-factors-leading-to-unequal-access-to-medicines-for-patients-across-europe/

75 https://becarispublishing.com/doi/epdf/10.57264/cer-2025-0036

access is not substantially improved in terms of speed, predictability and reward for value. Given Europe's publicly funded healthcare systems, any policy efforts to adjust and reverse projected trends must also integrate budgetary and fiscal policies.

Indeed, the mutually reinforcing trends of demographic ageing, the health impact of climate change, the rise of chronic diseases, health security and economic growth call for an in-depth understanding of fiscal policies as powerful steering instruments and of appropriate methodologies that can more accurately reflect the positive impact of spending in health. Health spending should be calculated as an asset, i.e. an investment with future benefits (health, economic, security, etc.) and by taking into account the full range of fiscal revenues generated, including by the biopharmaceutical sector itself.

As highlighted in Draghi's report, the trade-offs between stimulating innovation, ensuring fiscal sustainability, and maintaining patient access must be acknowledged and integrated into policymaking. Given the EU's need for competitiveness and innovation, as well as social cohesion and prosperity, finding the right trade-offs will enable public healthcare systems to achieve these objectives.

Conclusion

The interplay between these four pillars—innovation, clinical trials, biomanufacturing, and health investment—reveals the complexity of strengthening Europe's biopharmaceutical competitiveness in today's geopolitical environment. These pillars cannot be addressed in isolation; they form an interconnected system where progress in one area reinforces advancement in others. For instance, a stronger biotech ecosystem attracts clinical trials, which in turn support biomanufacturing investments, all underpinned by a fiscal approach that recognizes healthcare spending as strategic investment rather than a mere cost.

The US is redefining its biotech strategy through the lens of national security and derisking. China is investing aggressively in biomanufacturing and biotech, with early-stage science being increasingly outsourced to China. The tensions between the US and China are reshaping global supply chains, research partnerships, and investment flows in ways that present both significant challenges and strategic opportunities for Europe. Between these two poles, Europe risks becoming a bystander unless it puts biopharma at the core of its competitiveness and industrial policy agenda.

Europe stands at a critical juncture in the global biopharmaceutical landscape. The window of opportunity created by US policy shifts—including research funding cuts, global health disengagement, and increasing protectionism—provides Europe with opportunities to fully leverage its assets: its market size, its science, talent and scientific freedom, its innovative companies, its openness to global partnerships, its exports strength and a model of healthcare that other regions envy. By systematically addressing the four pillars outlined in this paper, Europe can turn geopolitical pressures to its advantage.

Europe's biopharmaceutical sector embodies the tensions between the continent's industrial ambitions and its social model. Resolving these tensions productively means recognizing healthcare spending not merely as a cost to contain, but as an investment in future resilience, innovation, and economic strength. What it needs now is scale, speed, and political will to overcome long-standing barriers between member states, between public and private sectors, and between industrial and health policies, and move towards unprecedented coordination between EU institutions and member states that aligns

national health policies with EU-level industrial and innovation strategies. The alternative—fragmented approaches and hesitant investment—risks permanent relegation to secondary status in this critical sector.