2024 - 2029

Innovating for a Healthier Future

Online version available at
www.pfizereupolicy.eu

From left to right: Andrea Chiarello, Charles Faid, Coralie Delettre, Yordan Aleksandrov, Riccardo Rovera

Although the European Union has limited competencies in the field of health policy, a wide range of internal market, freedom of mobility, digital and wider consumer policies impact the way in which healthcare and medicines are developed and become available to European citizens.

During the 2019-2024 EU legislative mandate, EU health policy gained increasing importance as the global COVID-19 pandemic forced millions of Europeans into lockdowns and claimed countless lives. This unexpected, devastating crisis contributed to creating political support for a 'European Health Union' and stronger competence for EU institutions to tackle cross-border health threats.

We at Pfizer are proud to have been a trusted partner of the EU and its Member States in responding to the pandemic. With the same determination and spirit of collaboration demonstrated during the COVID-19 pandemic, we are now looking forward to engaging with EU policymakers in the 2024-2029 legislature and share our know-how, best practices and recommendations for a more competitive, healthier and more resilient Europe.

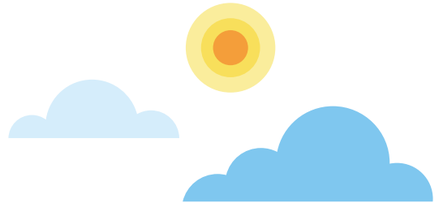
Health ranks as a top priority in citizens' inquiries regarding EU policy. As policymakers recognise the strategic role of the life sciences sector for the health of European citizens as well as the economy, it will be crucial to jointly advance forward-looking policies that preserve our industry's ability to innovate and deliver breakthroughs that change patients' lives.

By way of introductions, we are glad to share with you this booklet outlining our perspectives on the key EU themes which are foreseen to remain at the top of the EU health policy agenda for the next five years.

We are always pleased to provide you with further information and assistance wherever possible and are available to meet with you at your convenience. Please do not hesitate to get in touch.

Your sincerely,

Andrea Chiarello
Head of Pfizer EU Government Affairs



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Pfizer in Europe - Ensuring Resilience and Innovation in Patient Supply

- We help provide medicines and vaccines to more than **600 million patients in over 180 countries.**
- Pfizer's ability to meet patient needs in Europe and around the globe depends on **a stable, pro-innovation policy environment** and the ability to maintain a **supply chain that is both flexible and resilient.**
- We operate one of the most sophisticated supply chain systems in the industry, with:
  - 35+ Pfizer-owned sites
  - 300+ suppliers globally
- Pfizer continues to make progress on our **Environmental, Social and Governance (ESG) strategy** and we aim to achieve the **voluntary net zero standard by 2040.**[i]

With a presence here since the 1950's, Europe is home to:

OVER
14,000
COLLEAGUES
working in
manufacturing

16
MANUFACTURING,
SUPPLY AND R&D SITES

Our sites here produce active pharmaceutical ingredients (APIs) and finished medicines, ranging from small molecules, to sterile injectable hospital products, vaccines and biologics.

Pfizer has invested significantly in our workforce and operations across Europe.

This is driven by multiple imperatives, including:

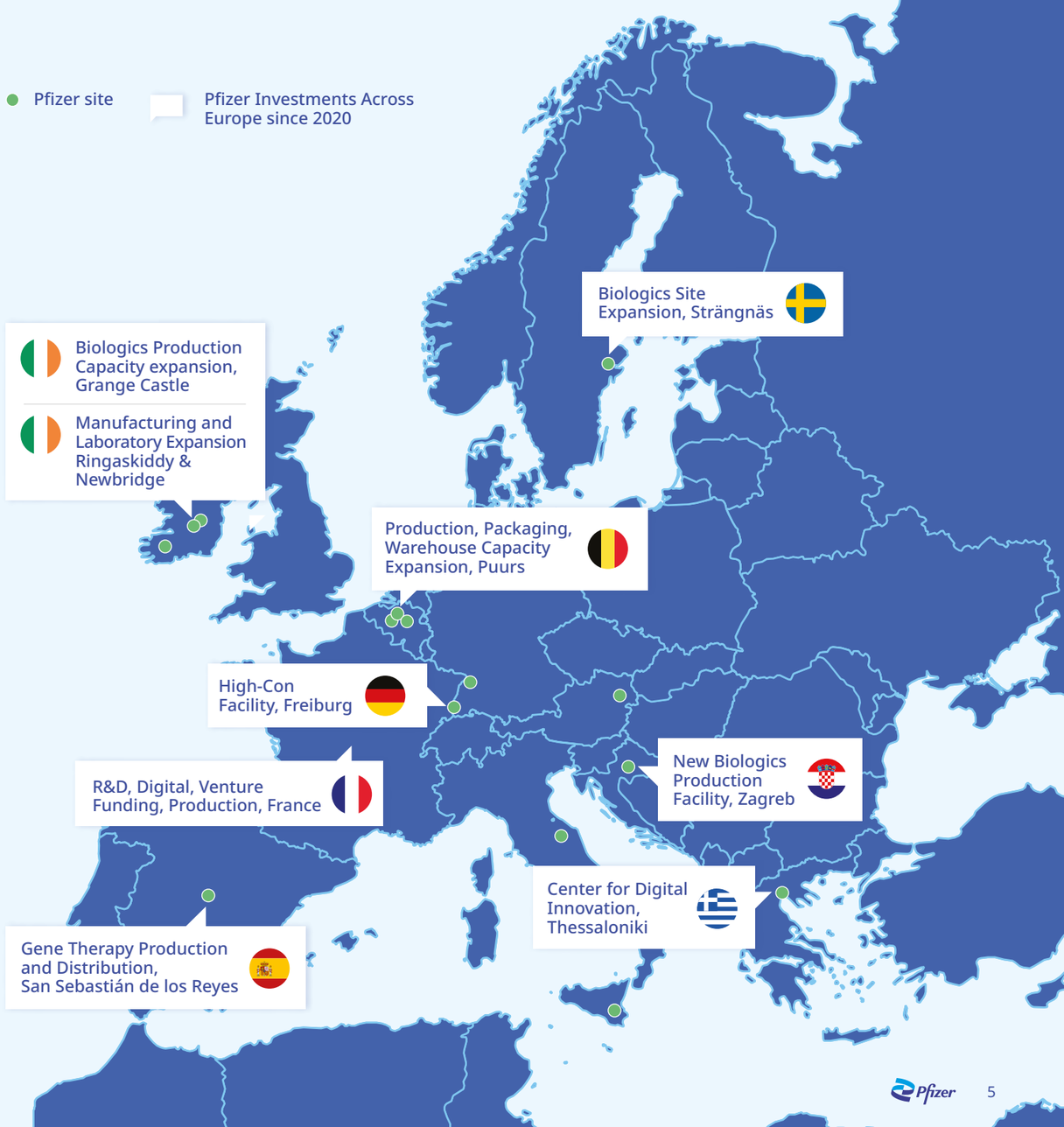
- **Manufacturing scale-up** to respond to the COVID-19 pandemic.
- Ensuring **best-in-class logistics** to meet patient demand across Europe and globally.
- **Increasing production capacity** and **technical capabilities** for today's and tomorrow's medicines.
- Maintaining a **cutting edge in R&D and digital innovation.**
- Finding innovative ways to **minimise our impact on the environment.**

Pfizer Logistics Centers in Europe made
908,000 SHIPMENTS
Annually to customers across the continent

Our sites in europe handle
97% OF PFIZER MEDICINES SOLD HERE

76% OF THE APIS IN OUR PATENTED MEDICINES COME FROM EUROPE[ii]

This information is intended to support policy discussions with policy stakeholders. Information correct as of February 2024.
i For more information on ESG, please see: https://www.pfizereupolicy.eu/ sites/default/files/Pfizer_ESG-Commitment_Infographic_FINAL_0.pdf
ii Statistics on customer shipments do not include UK. API sourcing statistics: 76% from Europe, 19% from the US and 5% from Asia.



Incentivising pharmaceutical innovation which reaches patients

Pharmaceutical innovation doesn't happen by accident. It requires the thoughtful implementation of an interconnected set of pro-innovation policies that enable companies to take on enormous risks and allocate the vast resources associated with the development of new medicines.

Driving pharmaceutical innovation

Incentives and rewards are the foundation on which innovation is built: they encourage and protect innovation and drive Research and Development (R&D). They also support the European knowledge based economy, contributing to the creation of wealth and jobs[1], and help strengthen Europe's competitiveness in global trade, making the region an attractive investment location for the most innovative industries.

In recent years, the EU has been eclipsed by the US as a world leader in medical innovation and faces increasingly intense competition for life science investment from China, other parts of Asia, Switzerland, and the UK.[2] The revision of the EU's general pharmaceutical legislation and the EU patent package proposals are the two key dossiers that will determine how incentives will be addressed.

What does progress look like?

Fostering an innovative R&D ecosystem through EU legislative files, including the EU Pharmaceutical[3] and Patent[4] packages, while ensuring a strong and competitive industry that can deliver innovation to patients in Europe and globally.

Dig deeper

Industry position and key messages on the EU Pharma Package and Patent Package, EFPIA, available at www.efpia.eu

[1] Pfizer alone employs over 14 000 colleagues working in manufacturing in Europe.

[2] Where innovation happens, matters, EFPIA blog on the revision of the EU pharmaceutical legislation

[3] Reform of the EU pharmaceutical legislation, European Commission

[4] Intellectual property: harmonized EU patent rules boost innovation, investment and competitiveness in the Single Market, European Commission

Delivering health equity and improved medicines access across Europe

Healthcare innovation is only of value if it reaches patients in a timely and equitable manner. This presents a challenge in the European Union, with significant differences in time to access between Western and Central and Eastern European countries. In some Member States, access is up to ten times longer than in others. This is unacceptable.

It is imperative to develop a shared understanding of the barriers that delay or undermine patients' ability to obtain necessary healthcare services and treatments. Once the root causes of these access issues are identified, companies, authorities and other stakeholders need to work in partnership to address them.

What does progress look like?

To ensure access for patients, there must be closer collaboration between health authorities, EU institutions and industry to explore innovative access agreements and value-based healthcare, understanding that healthcare investment is fundamental to improve patient outcomes.

Dig deeper

Root causes of access delays in Europe and the industry's commitment to address them, available at www.efpia.eu:

1. Patients W.A.I.T. Indicator 2023 Survey, EFPIA and IQVIA, June 2024
2. The root causes of unavailability of innovative medicines and delay in access: Shortening the wait, EFPIA and Charles River Associates, June 2024
3. Addressing Patient Access Inequalities in Europe, EFPIA, March 2022

Supporting the digital revolution in healthcare

Digital innovation plays a pivotal role in connecting healthcare systems, facilitating data exchange, and promoting personalised medical solutions, ultimately contributing to improved health delivery for patients across Europe.

Realising the potential of the European Health Data Space

In today's healthcare landscape, integrating data and digital technologies is critical. Leveraging patient data and embracing digital solutions enables healthcare companies to enhance treatment outcomes, streamline delivery, and empower patients. The European Health Data Space (EHDS)[5] will change the way health data is classified, stored, managed and shared —accelerating digitalisation across Europe. Data is at the core of digital transformation, and now is the pivotal moment to create a resilient digital ecosystem which can allow digital transformation to yield its full potential. This requires that the public and private sectors develop new ways of working together.

At Pfizer, we are thrilled to be part of this new ecosystem and we look forward to collaborating with public and private partners to advance research for the benefit of patients.

What does progress look like?

Building and supporting the active use of an agile and responsive digital ecosystem which fosters innovation and keeps patients at the centre.

Dig deeper

Position Paper on the European Health Data Space, EFPIA, available at www.efpia.eu

Maximising the promise of AI in healthcare

We are witnessing a paradigm shift that transcends traditional boundaries. Artificial intelligence (AI) is not just another tool but a key player in enhancing R&D in healthcare. From refining diagnostic accuracy to speeding up drug discovery and clinical trials, AI sets the stage for a healthcare revolution. To address this, Pfizer has developed our own Responsible AI Principles[6], a set of policies and controls that allow the company to harness the power of AI ethically and responsibly.

[5] Regulation on the European Health Data Space, EU Parliament

[6] Policy Position on Artificial Intelligence, Pfizer

What does progress look like?

- Supporting the implementation of new legislative frameworks, including sector specific guidance, while keeping patients' needs at the forefront.
- Fostering collaboration between industry stakeholders and policymakers for crafting effective and adaptable legislations that promote innovation while safeguarding ethical standards.

Dig deeper

Statement on the use of AI in the medicinal product lifecycle in the context of the AI Act, EFPIA, April 2024, available at www.efpia.eu

Policy Position on Artificial Intelligence, Pfizer, available at www.pfizer.com

Building resilient and sustainable trade through EU located manufacturing and supply

Discovering and developing life-saving medical innovations is only part of the puzzle. Being able to produce, deliver and deploy them is fundamental to life sciences industry's work to support patients in Europe and globally. This requires pro-innovation rules, cutting-edge production and open global supply chains.

The role of trade policy in driving resilience and innovation

Global trade is a major driver for jobs and growth in Europe and nowhere is this more evident than in the innovative pharmaceutical sector. Despite an often challenging environent in Europe and increasing geopolitical challenges, exports of medicines and vaccines continue to be a source of economic resilience for the EU. In 2022, pharmaceutical exports from Europe totalled €287 billion, accounting for just over 11% of all EU exports.[7] This depends on a pro-innovation environment in Europe and an open, predictable, rules-based global trading system to help ensure that patients around the world can access our medicines.

What does progress look like?

Supporting resilience and innovation in life sciences by defending open trade and global supply chains, underpinned by a rules-based trading system, innovation-driven international agreements with key trading partners and effective enforcement.

Dig deeper

Support Open and Ambitious Trade Policies, Pfizer, available at www.pfizereupolicy.eu

The policy case for a Trade in Healthcare Agreement, Global Counsel, available at www.global-counsel.com

Manufacturing, Trade and Equitable Global Access to COVID-19 Vaccines and Therapeutics, Pfizer, available at www.pfizer.com

Benefiting from fit-for-purpose supply chains

Pfizer and the research-based pharmaceutical industry are committed to supplying the right medicines for each patient that needs them; we therefore support coordinated efforts in the EU to improve the resilience of supply chains[8] and reduce the risk of shortages.[9]

Given the complexity of issues at play, there is no single solution to shortages, but policies should be risk-based, proportionate and data-driven. Dialogue between companies and authorities, optimized use of demand data, strategic management of inventory and strengthening regulatory cooperation are all key to having a positive impact.

Looking ahead, the shared goal of tackling medicines shortages depends on close collaboration between industry, regulators, healthcare providers and others.

[7] International trade in medicinal and pharmaceutical products, Eurostat

[8] Pfizer operates one of the most sophisticated supply chain systems in the industry with 35+ Pfizer owned sites and 300+ suppliers globally.

[9] Medicines Shortages EFPIA Call for Action, EFPIA

What does progress look like?

Shortage prevention policies should be risk-based and proportionate, focused on easily accessible and improved demand data which enables flexible allocation of inventory. EU legislation, including the EU Pharma Package, supported by non-legislative activities should reflect this, and there should be stronger co-ordination between EU and national level actions on shortages.

Dig deeper

Pfizer in Europe: Resilience and Innovation in Patient Supply, Pfizer, available at www.pfizereupolicy.eu

Medicine Shortages: EFPIA Proposal for Action, EFPIA, available at www.efpia.eu

Safeguarding Competitive Pharmaceutical Manufacturing in Europe

Europe strives for greater strategic autonomy. The life sciences industry is a key contributor to this goal.[10] Prerequisites for continued life-science investment and manufacturing in Europe include a strong infrastructure for health, open and competitive markets, a favourable regulatory environment, support for R&D, and a predictable legal and governance environment.[11]

The EU Green Deal and Climate Policy address legitimate concerns and should not only be applauded, but supported. Pfizer is doing its part by adapting operations to achieve voluntary net-zero standard by 2040.[12] However, some Green Deal implementation measures can heavily compromise competitiveness goals and the industry's ability to manufacture in Europe. For example, the proposed restriction of PFAS[13] risks making medicines R&D and manufacturing of medicines in Europe impossible.[14] Reconciling environmental targets with competitiveness and reaching autonomy goals aiming to reduce reliance on countries outside of the EU will enable taking the existing pharmaceutical industry environmental health and safety activities to the next level, and make environmental sustainability an engine, rather than an obstacle, of competitiveness and innovation in Europe.

What does progress look like?

Enacting science, evidence, and risk-based environmental sustainability measures and chemicals restrictions that balance legitimate environmental sustainability concerns with continuity of R&D, manufacturing, and access to medicines in Europe. Chemicals restrictions dossiers include, or at least maintain, derogations for medicines, medicines R&D and production, based on the level of risk and exposure, until appropriate and feasible alternatives are found.

Dig deeper

Delivering treatments to patients: The medicines manufacturing journey, EFPIA, available at www.efpia.eu

EFPIA signs the Antwerp Declaration calling for a European Industrial Deal that can drive the region's competitiveness and resilience EFPIA, March 2024, available at www.efpia.eu

[10] Pfizer has 16 manufacturing, supply and R&D sites in Europe

[11] Healthy Markets for Health Investments: Policy Considerations from the Private Sector, US Chamber of Commerce

[12] Our ESG Commitments, Pfizer

[13] ECHA publishes PFAS restriction proposal, European Chemicals Agency

[14] Evidence shows more than 600 essential medicines at risk, and manufacturing in Europe will 'grind to a halt' if wide-ranging chemical ban is implemented, EFPIA blog

Integrating environmentally sustainable policies

Pfizer is actively integrating environmentally sustainable practices in its European and global operations. To address concerns related to climate change, Pfizer is embracing eco-friendly approaches and sustainable sourcing as part of broader Environmental, Social, and Governance (ESG) efforts. We are aiming to achieve the Voluntary Net-Zero Standard by 2040 and, as a company, we have set ambitious short and long-term goals in the ESG realm. For example, we aim to source 80% of electricity from renewables by 2025, and 100% by 2030.[15]

[15] Our ESG Commitments, Pfizer

[16] Net-Zero Industry Act, European Commission

What does progress look like?

Sustainable practices should be adopted across the whole supply chain. As Pfizer, we are continuously supporting our suppliers in their ESG ambitions. EU policymakers should use evidence, science and risk-based approaches to foster the industry's green ambitions, in the same spirit as the Net-Zero Industry Act.[16]

Dig deeper

Our ESG Commitment, Pfizer, available at www.pfizereupolicy.eu

2023 Impact Report, Pfizer, available at www.pfizer.com

Industrial policy and what it means for the healthcare sector

Industrial policy, if designed and implemented strategically, can be a key driver of sustainable growth and high-quality employment in the EU. It can also support the competitiveness of the European industrial ecosystem.

The innovative pharmaceutical industry is a strategic sector for Europe

In 2023, life sciences companies spent over €40 billion in research and development in Europe, employed around 865,000 people directly, with about three times more indirectly.[17] More importantly, patients worldwide depend on Europe as a key source of medicines. For Pfizer, this means helping provide medicines and vaccines to more than 600 million patients in over 180 countries, including in Europe.

Industrial policy has taken center stage in the recent political debate, including with the March 2024 European Commission's biotechnology and biomanufacturing strategy[18]; the European Council's call for a "new competitiveness deal"[19] in April; and the Council Conclusions on 'A competitive European industry driving our green, digital and resilient future' adopted in May.[20] These official statements are a strong signal that competitiveness and industrial policy should take a prominent position in the 2024-2029 legislative term. This is a positive, and necessary, step forward: despite our sector's industrial footprint, Europe has been falling behind global competitors in the last 25 years, particularly in R&D, with lower investment, fewer clinical trials and longer approval times for new medicines.

[17] The Pharmaceutical Industry in Figures, EFPIA, 2023

[18] Press Release, Commission takes action to boost biotechnology and biomanufacturing in the EU, European Commission

[19] Conclusions from the Special meeting of the European Council (17 and 18 April 2024)

[20] A competitive European industry driving our green, digital and resilient future, Council Conclusions, May 2024

What does progress look like?

- Develop more effective policies and framework conditions to stimulate innovation and make Europe a world leader in pharmaceutical R&D;
- Build a holistic policy agenda that drives EU competitiveness, including by considering health as an investment;
- Support flexible and resilient supply chains by advancing strategic international partnerships.

Dig deeper

2024 European Commission's biotechnology and biomanufacturing strategy

Conclusions from the Special meeting of the European Council (17 and 18 April 2024)

A competitive European industry driving our green, digital and resilient future, Council Conclusions, May 2024

A Competitiveness Strategy for European Life Sciences, EFPIA, June 2024

Online version available at:

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Visit our website to learn more about our team and vision.

www.pfizereupolicy.eu