



Lilly Manifesto for Europe

ACCELERATING ACCESS AND INNOVATION

Lilly is a medicines company. **For more than 145 years, Lilly has developed a constant stream of innovative medicines to make patients' lives better.** We won't stop now. Today, Lilly scientists are searching for the next wave of medicines for cancer, autoimmune diseases, Alzheimer's, and cardiometabolic conditions including diabetes, obesity, and heart disease, among others.

Heading towards the June 2024 European Parliament elections, and a series of national elections, **Lilly invites candidates to endorse a Europe that invests in health and biomedical advances.**

To welcome innovation, there must be a single conversation that joins up industrial policy for growth and considers the true value of medicines for the benefit of Europe's economy and, most importantly, its people. To achieve this, we call for policies and pragmatic solutions that seek to accelerate access to innovative medicines for patients across Europe, improving health outcomes and health system sustainability, and to make Europe a **globally competitive hub** for biopharmaceutical research & development (including clinical trials), regulatory approvals, and manufacturing.

LILLY'S POLICY ASKS

1. Ensure new medicines reach patients faster and more widely.

Europe needs to create a more **globally competitive regulatory framework**, including improving end to end processes for clinical trials and market authorisations. **Faster and simplified regulatory processes** could reverse the ongoing decline in the EU's share of global clinical trials, **through to speeding access for patients across Europe as rapidly and as equitably as possible.** When appropriately resourced and inclusive to health technology developers, the EU Health Technology Assessment (HTA) regulation should enable faster national HTAs to avoid patient access delays. It is important authorities meet the pace of innovation and avoid duplication of the EU Joint Clinical Assessment at Member State level. Member States should ensure pricing systems recognize the full value of medicines, reflecting outcomes for patients and for the broader health system and society.

- Lilly has c.110,000 people in **clinical trials** globally and **supports national streamlining for faster clinical trials enrolment** to reverse Europe's relative decline.
- Lilly is **dedicated to applying for market authorizations in Europe expeditiously.**
- Lilly is **committed to filing for pricing and reimbursement across EU27 as soon as possible** and no later than two years from the EU central market authorisation, where national systems allow.
- Lilly is engaged in working with Member States to **accelerate patient access.**
- Lilly supports a life-science industrial strategy to **enhance EU global competitiveness.**

2. Improve patient outcomes and health system sustainability by tackling non-communicable diseases (NCDs).

Europe urgently needs a **comprehensive strategy to tackle NCDs including obesity, diabetes and Alzheimer's disease.** Such a strategy should establish a framework for early detection and diagnosis to tackle disease early and provide the right treatment at the right time. Addressing existing policy barriers to NCDs care can improve access to more effective, innovative treatments and prevent costly complications. This approach can **enable economic growth, reduce societal costs, and strengthen healthcare system resilience.**

- It is estimated that the number of **diabetes-related premature deaths** recorded in Europe was 1.1 million through 2021, equivalent to filling three jumbo jets every single day.¹
- **NCDs associated with obesity** are among the most pressing public health challenges of our time, reducing the GDP by 3,3% in OECD/EU27 countries every year. Obesity puts people at an increased risk for more than 200 complications,² with several complications ranking among the leading causes of mortality globally, including type 2 diabetes, cardiovascular diseases, and certain cancers.³
- **Alzheimer's disease (AD)** is a progressive, neurodegenerative disease, with a devastating impact on patients, their families, and the wider society. Europe must endorse the creation of an Alzheimer's disease diagnostic pathway that enables early detection, accurate diagnosis, and results in better patient outcomes.

LILLY'S POLICY ASKS

3. Boost the competitive innovation ecosystem to increase investments by maintaining current intellectual property (IP) incentives.

Boost the competitive innovation system to increase investments by maintaining current intellectual property (IP) incentives to attract new investments in European biopharmaceutical R&D and manufacturing. **Strong and predictable IP incentives** are the foundation for creating new medicines for patients and help sustain a rich life sciences community. Over time, innovative medicines become the generics and biosimilars of tomorrow, improving health and saving system resources to reinvest in the next wave of medicines.

- Lilly invests **27.3% of revenue back into research**.
- **23.9%** of our **employees are engaged in R&D** activities.
- Lilly investments into high risk areas such as Alzheimer's disease, where we have **sustained 35 years research**, and other difficult and slow-progressing diseases depends on the certainty of strong and predictable IP incentives.

4. Support the resilient supply of medicines through open trade and sustainable environmental policies that maintain the discovery of, and access to, innovative medicines.

Our most important goal is to provide a **safe and reliable supply of our medicines to the people who rely on them**. Lilly is embarking on a European expansion and every investment into manufacturing capacity renews our commitment to patients today – and to those who may need our medicines tomorrow. Making medicines requires the use of valuable resources including energy, water, and raw materials. Sustainability is a key consideration in the design of our new manufacturing facilities. A proportionate approach to ESG (Environmental, Social and Governance) and chemicals sustainability policies needs to strike a balance between environmental goals and the practicalities of changing manufacturing platforms for medicines that have critical product lifecycles.

- **Our manufacturing expansion encompasses important investments** with a new location in Alzey, Germany, alongside strategic investments in Sesto, Italy; Fegersheim, France; and Limerick, Ireland.
- **Existing international alliances** can strengthen Europe's supply chain resilience, building on geographic diversity and opening trade flows to avoid disruptions. An average Lilly product, from raw materials through to production, may use about 800 different ingredients, components, and materials that are procured globally from approximately 150 vendors. Policies that mandate wholesale changes to global supply chains (e.g., location, sourcing, or inventory) will distort the security and reliability of supply.
- Lilly has a **longstanding commitment to sustainability and respecting the local environment**. Our ESG report can be found at [esg.lilly.com](https://www.lilly.com/esg).
- We need to align **jobs and skills strategies** with an industrial policy that supports R&D and manufacturing investments in Europe. Sustaining a vibrant talent pool in science, technology, engineering, and mathematics (STEM) is vital as we reach new milestones with new technologies and advanced therapeutic medicinal products (ATMPs), with a quarter of Lilly's pipeline in cell & gene therapies.

1. https://idf.org/europe/media/uploads/sites/2/2023/06/IDF-Europe_Type-2-Diabetes.-A-preventable-catastrophe.pdf
2. Deborah Born et al., What is clinically relevant weight loss for your patients and how it can be achieved? A narrative review, *Postgraduate Medicine*, vol. 134, no 2, pp. 359 – 375
3. <https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghs-leading-causes-of-death>