TTIP is a negotiation that addresses a broad range of bilateral trade and investment policies, as well as global issues of common interest. It promises to boost economic growth on both sides of the Atlantic.

**OUR POINT OF VIEW**

Lilly welcomes the decision to launch TTIP negotiations.

**What's needed and why?**

TTIP should set ambitious standards for pharmaceuticals in the fields of regulatory harmonisation, intellectual property protection and enforcement, and market access in order to:

1. **Ensure rapid access for patients to innovative new medicines**
2. **Support a European pharmaceutical industry which directly provides over 700,000 highly skilled jobs**
3. **Be an appropriate benchmark for future trade agreements with other countries**

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**OUR WORK IN EUROPE**

- Lilly has doubled annual R&D investments in Europe over the past 10 years to over €450 million and we now employ around 9,000 people across the region.
- We have two major research sites in Europe, in the UK and Spain, in addition to an extensive manufacturing network.
- Approximately one third of our worldwide clinical trials take place in Europe, a total investment of nearly €125 million per annum.
- Our European manufacturing sites are important exporters to other parts of the world. For instance, our Spanish site exports to over 120 countries worldwide and 92% of our Fegersheim (France) site production is exported to over 100 countries on five continents.
- Lilly’s research centre in the UK is home to many of our pioneering innovations, and is a centre of excellence in neuroscience. There are currently over 600 people working on the site, with over 45 nationalities working across more than 30 disciplines.

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**ABOUT LILLY**

- A heritage of more than 135 years, with headquarters located in Indianapolis, U.S.A.
- 10th largest pharmaceutical company in the world.
- Approximately 38,000 employees worldwide.
- Clinical research conducted in more than 55 countries.
- Research and development facilities located in 8 countries.
- Manufacturing plants located in 13 countries.
- Products marketed in 125 countries.
- Our medicines treat diabetes, cancer, schizophrenia, depression, bipolar disorder, attention deficit hyperactivity disorder and other life-threatening and life-changing illnesses.

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**GET CONNECTED**

Website: [www.lilly-europe.eu](http://www.lilly-europe.eu) // Blog: [www.lillypad.eu](http://www.lillypad.eu)

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WHAT ARE OUR PRIORITY ISSUES?

REGULATORY HARMONISATION

Focus additional harmonisation between the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) will reduce unnecessary duplication and pave the way for the development of global standards.

Key objectives:
- Increased collaboration
- Mutual recognition of inspections: Recognise each other’s Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections. The FDA and EMA have already taken steps to coordinate inspections which assess compliance with GMP and GCP. TTIP should go one step further by removing the need for duplicate inspections.
- Parallel scientific advice: Expand the current programme to cover all medicines, enabling companies to simultaneously pursue applications in both the EU and US and to conduct clinical trials based on a common approach.
- Quality by Design: Expand the current pilot programme to allow for the parallel evaluation of relevant development and manufacturing quality components submitted to both EMA and FDA. This would provide for better deployment of resources, potentially improving patient access to medicines and helping prevent shortages.

Additional collaboration through the International Conference on Harmonisation (ICH):
- Endorse the work of ICH and agree priority areas of focus.

BETTER INTELLECTUAL PROPERTY PROTECTION AND ENFORCEMENT

A once in a generation opportunity for the EU and US to set aligned high standards for intellectual property (IP) protection and enforcement. This will contribute to incentivising the development of innovative medicines that meet patients’ needs.

Key objectives:
- Increased alignment
- Regulatory data protection: Converge to the highest standards (i.e. 8+2+1 years for small molecules and 12 years for biologics). This would provide greater alignment and business predictability, and will ensure that the EU and the US continue to lead the world in support of pharmaceutical innovation.
- Patent enforcement systems: Allow for early resolution of patent disputes before an infringing product is launched on the market.
- Patent ®©™

Additional collaboration through the International Conference on Harmonisation (ICH):
- Endorse the work of ICH and agree priority areas of focus.

ENSURED MARKET ACCESS

Pricing and reimbursement systems that reflect the value of the research and development process help create a stable and predictable environment. This will enable innovation to flourish and the biopharmaceutical industry to continue to bring new medicines to patients.

Key objectives:
- Agreed principles on pricing and reimbursement
- The cost of developing a new medicine has escalate dramatically from about €600m in 2001 to €1bn today*.
- All aspects of the biopharmaceutical industry – including R&D, manufacturing and sales and marketing – are intertwined. A negative approach towards one element could damage the EU’s overall attractiveness for global investors. Without a supportive and collaborative environment, biopharmaceutical innovation may shift overseas to more competitive environments.
- Market access is critical for ensuring that patients rapidly gain access to new treatments, as well as for helping companies more rapidly recoup their investment in research and maintain direct and indirect employment. TTIP is an opportunity to include a Pharmaceutical Annex similar to that in the EU-Korea and US-Korea trade agreements, covering agreed principles for pricing and reimbursement.