Securing the best Brexit deal for EU patients and Life Sciences

The EU has a world-leading Life Sciences sector. At its heart is a biopharmaceutical industry which makes medicines that help people live longer, healthier lives. The industry directly supports 745,000 jobs, and invests tens of billions into R&D each year.

745,000 jobs are directly supported by the biopharmaceutical industry in the EU[1]

The UK has played a critical role: decades of close co-operation and shared expertise in scientific research, medicines regulation, intellectual property (IP), and recruitment of highly-skilled individuals have enabled the Life Sciences sector to thrive across the EU.

€35 billion invested in R&D by the biopharmaceutical sector in 2016[2]

As the UK leaves the EU, a smooth transition is critical to delivering certainty for patients and workers, preventing interruption to the medicines supply chain, and preventing the collaboration that makes pharmaceutical innovation possible from being stifled.

Lilly is one of the world's largest pharmaceutical companies, with R&D and manufacturing sites across Europe, including in the UK.

Lilly employs **11,900** people in Europe including **2,500** staff across 3 UK sites[3]

LILLY'S VISION FOR BREXIT NEGOTIATIONS

To ensure certainty for patients, for Lilly's Life Sciences business across Europe, and to secure the best Brexit deal for EU Life Sciences, Lilly believes that policymakers should:

Provide immediate-term certainty to patients, people working across the EU and UK, and companies by:

- Committing to transitional arrangements that ensure continuity of medicines supply to patients across Europe.
- Providing swift assurances to EU nationals working in the UK today, and UK nationals working in the EU, and enabling highly skilled specialist workers to continue to move between the UK and EU.
- Agreeing an approach to the European Medicines Agency relocation to Amsterdam that maintains stringent safety standards and prevents any delay to patient access to medicines.

Achieve continued close EU-UK cooperation to support biopharmaceutical innovation:

- Retain the UK's role in EU-wide regulatory systems for human and veterinary medicines.
- Allow tariff-free trade and low administrative costs of trade between the UK and the EU.
- Ensure the EU can benefit from continued UK participation in EU science and research programmes.

Lilly

Provide immediate-term certainty to patients, people working across the EU and UK, and companies

Although the long-term relationship between the EU and the UK will not be known until negotiations are complete, some important steps can and should be taken now to provide immediate certainty.

Commit to transitional arrangements that ensure continuity of medicines supply to patients across Europe.

It is in the interest of both the EU and the UK to avoid a 'cliff-edge' and agree appropriate transitional arrangements that take effect if the future EU-UK trading relationship is not finalised by the time the UK looks set to leave the EU in March 2019. Transitional arrangements must protect current research, manufacturing and regulatory arrangements and – above all – must prevent any interruption to the supply of medicines to patients across the EU and the UK. Every month, 45 million patient packs of medicine are supplied from the UK to the EU, with 37 million patient packs supplied from the EU to the UK.

The UK attracts the **3rd** and **5th** largest spend in pharmaceutical R&D and manufacturing in the EU respectively[4]

Providing swift assurances to EU nationals working in the UK today, and UK nationals working in the EU, and enabling highly skilled specialist workers to continue to move between the UK and EU.

Discovering, developing and manufacturing medicines is a global endeavour, with biopharmaceutical companies relying upon access to the best talent from around the world. In the EU, many people move between Member States to support the success of the Life Sciences sector. For example, 12% of workers at Lilly's UK R&D site are EU nationals. With Brexit calling the long-term status of EU nationals working in the UK, and UK nationals in the EU into question, both sides must provide assurances that these people will be able to continue to work in their respective countries after the UK leaves the EU.

12% of workers at Lilly's UK R&D site are EU nationals[5]

Agreeing an approach to the European Medicines Agency relocation to Amsterdam that maintains stringent safety standards and prevents any delay to patient access to medicines.

The EMA headquarters will move from its current location in London to Amsterdam and the transition must not impact the EMA's ability to carry out its key functions. A smooth and timely transition must ensure the process of regulating medicines will not be interrupted and, critically, that patient safety is not put at risk. Key considerations include staff retention, IT systems, procurement and the scale of the UK's current contribution.

36,000 expert visits to the EMA must be facilitated on an annual basis[6]

Achieve continued close EU-UK cooperation to support biopharmaceutical innovation

In the long-term, the best outcomes from the Brexit negotiations for public health and jobs will be secured through agreeing continued close EU-UK cooperation on medicines.

Retain the UK's role in EU regulatory systems for human and veterinary medicines.

The close and consistent medicines regulatory co-operation that exist for the UK and EU have benefited patients and industry in recent decades. The UK's Medicines and Healthcare Regulatory Agency (MHRA) is a major contributor to the work of the EMA, with 21% of EMA cases having the MHRA as scientific advice co-ordinator. A common system for medicines licensing, clinical trials, data privacy and pharmacovigilance is in the interests of public health and jobs and should be maintained after the UK leaves the EU, and must operate within a co-operation agreement that keeps the UK in the scope of the EMA.

21% of European Medicines Agency cases had MHRA as scientific advice co-ordinator in 2016[7]

Allow tariff-free trade and low administrative costs of trade between the UK and the EU.

The UK and EU have a deep trading relationship when it comes to Life Sciences. 44% of the UK's £29.5bn life sciences exports went to the EU in 2015. To support a thriving European industrial ecosystem, an effective, unencumbered medicines supply chain is vital. This rests on an ambitious and comprehensive UK EU Free Trade Agreement, with tariff-free trading and minimal customs and administrative charges on pharmaceutical products and ingredients.

44% of the UK's £29.5bn Life Sciences exports went to the EU in 2015[8]

Ensure the EU can benefit from continued UK participation in EU science and research programmes.

The Life Sciences sector benefits from the Innovative Medicines Initiative (IMI) and Horizon 2020 schemes, including indirect benefit from the positive effects on UK academia. Lilly is the 10th largest industry contributor to the IMI. To ensure continued positive effects of R&D collaboration, the UK should continue to participate in EU-wide science funding schemes by remaining part of the European research area.

Lilly is the **10th** largest industry contributor to the Innovative Medicines Initiative[9]

Lilly in Europe

Number of staff: approximately 11,800
Approximately 900 people in R&D
Our Global Services group employs over 1,200 in Europe

Manufacturing employs over 3,000 people across 5 sites in Europe

35% of Lilly's global manufacturing staff are based in Europe

Works with over 12,000 vendors across Europe represents approximately €1.7 B in spending

European manufacturing sites are important exporters to other parts of the world

Major research sites in Europe.

Erl Wood research site (UK) is Lilly's largest research operation outside of the US

Nearly €600m in European based R&D funding in 2016

146 active clinical trials globally
103 active trials in Europe with more than 60,000 patients enrolled over 3,800 sites

25% sales reinvested into research and development globally

Founded on May 10, 1876 in Indianapolis, Indiana, U.S.
Lilly established in Europe in 1934 (UK)

Seeking new breakthrough therapies in areas including: Alzheimer's, Autoimmune diseases, Diabetes, Oncology, Pain

Pioneering medical breakthroughs include the first commercially available human insulin and the polio vaccine

Across the globe and here in Europe, Lilly has developed productive alliances and partnerships that advance our capacity to develop innovative medicines at lower costs

Innovative Medicines Initiative (IMI):

- 10th biggest contributor to IMI
- Committed to 49 projects since the beginning
- Total in-kind contributions of €43 M
- Diabetes and Neuroscience (Neurodegeneration) projects represent approximately 60% of Lilly's contributions.
- Lilly also participates in oncology projects and other non-therapeutic area projects

Elanco Animal Health increased European presence in 2014 with major acquisitions

References

1 European Federation of Pharmaceutical Industries and Associations (EFPIA): The Pharmaceutical Industry in figures: key data 2017
2 European Federation of Pharmaceutical Industries and Associations (EFPIA): The Pharmaceutical Industry in figures: key data 2017.
3 Lilly data on file (as at June 2017)
4 European Federation of Pharmaceutical Industries and Associations (EFPIA): The Pharmaceutical Industry in figures: key data 2017
5 Lilly data on file (as at April 2017)
6 Open Letter from the Pharmaceutical Industry Heads of Research and EFPIA on the Relocation of the European Medicines Agency
7 UK Department for Business, Energy and Industrial Strategy – Life Sciences Indicators, April 2017
8 Association of the British Pharmaceutical Industry (ABPI): Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU (Sept 2016)
9 European Federation of Pharmaceutical Industries and Associations (EFPIA) data on file (as at June 2017).

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