British American Business

Open for Business

What a transatlantic trade and investment agreement means to the UK life sciences sector

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and Development

"Owen Mumford started life as a surgical instrument business over 60 years ago. John Mumford and Ivan Owen, with the help of Ivan's father, first set up shop in a small garage in Woodstock, near Oxford. Since then, the company has been at the forefront of medical device innovation.

Successful expansion has led to the company employing over 700 people. We sometimes refer to ourselves as the largest company in Oxfordshire no one has heard of! Despite the local anonymity, our Safety Lancing and Drug Delivery products are used around the world.

Over 80% of our products are exported. We have long established sales offices in the USA, UK, France and Germany, with more recent expansion into Latin America through our Mexico office and Asia Pacific through our Malaysia office."

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*This leaflet was published following the event **'What a transatlantic trade and investment agreement means to the UK life sciences sector'**, organised on **24th September 2015** in **Oxford**. It was the first time business, government and the NHS came together to discuss the issues. The event explored the UK-US trade and investment dimension in the life sciences sector and the changes and benefits a transatlantic trade and investment partnership (TTIP) agreement could bring to business in the region.*

Panellists: Joseph T. Burke, Trade, Investment and Energy Officer, Economic Section, US Embassy in London, Peter Nolan, Chief Business Officer, Oxford BioMedica, Dr Shawn Manning, Managing Director and Founder of Akesios Associates, David Henig, Department of Business, Innovation & Skills; Kate Ling, Senior European Policy Manager, NHS European Office and Thomas Thorp, Senior Director Corporate Affairs and Market Access, Lilly UK. The panel was chaired by Larry Stone, president, Group Public & Government Affairs, BT, and Co-Chair of BAB Policy Group.

The UK life sciences sector

The UK has a flourishing life science sector. Comprised of pharmaceuticals, diagnostics, medical devices and high technology industries, it is a key driver for employment, innovation & growth. Across the UK the sector boasts nearly 5,000 companies (including non-manufacturing and service companies)[1], employing an estimated 183,000 people[2].

The life sciences sector is important to entire regions in the UK. Berkshire, Buckinghamshire, Oxfordshire, Milton Keynes and Bedfordshire, for example, are home to 550 health care companies involved in clinical care, life sciences and medical research, education and training, innovation and informatics[3].

The transatlantic trade and investment partnership (TTIP) agreement currently being negotiated between the EU and the US has the potential to benefit the broader UK life sciences and healthcare sectors, including businesses, research institutes, hospitals, workers and patients alike.

The UK/US trade and investment dimension

With 6% of global market sales the sector and an annual turnover of £56bn[4], it is the largest life sciences sector in Europe[5]. From large global pharmaceutical companies such as Lilly, to small & medium sized enterprises (SMEs), such as Oxford BioMedica, the UK is home to a wealth of creativity and innovation. The US is the largest individual market accounting for 23% of exports[6].

The pharmaceutical industry is the UK's most research intensive sector, accounting for £4.1bn in R&D spending[7]. Between them, the EU & US account for more than 75% of global R&D spending, sustaining 1.5 million jobs[8].

Barriers to trade and investment

Membership of the European Union and its single market has led to a harmonisation of legislation and intellectual property processes. An ambitious and comprehensive TTIP agreement could see similar benefits for the transatlantic location. Current issues life sciences companies when trading across the Atlantic include:

- Regulatory divergences – TTIP could help to reduce unnecessary duplication and create harmonized processes, such as inspections of sites to ensure good manufacturing practices (GMP). These inspections are currently duplicative, time-consuming, and expensive, and could be reduced if regulators agree to recognize each-others' inspection reports.
- Approval Process – At present companies producing medical devices need to comply with separate US and EU approval processes. This delays the time it takes for products to reach the market.

What a transatlantic trade & investment partnership means to the UK life sciences sector

TTIP offers an opportunity to improve how UK life sciences companies, sell and grow in the US market.

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[1] UK Government: Office of Life Sciences
[2] UKTI (2015): Inward Investment Report 2014 - 2015
[3] OAHSN (2015): Oxford & the Thames Valley: A favoured location for inward life science investment
[4] HM Government (2013): Strength and Opportunity 2013
[5] JLL (2014): Life Sciences Cluster Report
[6] UK Government (2012): UK Trade Performance Markets & Sectors
[7] Ibid footnote 6
[8] EFPIA (2014): TTIP: The benefits for patients, healthcare, sciences & business
[9] European Commission: Letter from EU Trade Commissioner, Cecilia Malmstrom to Lord Livingston

What TTIP will not do is change the way in which EU Member States regulate public health services. It will remain for the UK government to run the NHS. TTIP will not force national governments to open public services to competition or outsource to private providers. It will also not prevent member states from bringing back previously outsourced services back into the public sector. The decisions on how to run public services will remain with national governments[9].

A greater alignment between the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) would, however, reduce red tape and foster faster patient's access to innovative medicines.

TTIP will contain a specific 'SME Chapter' that will include among other things, including a recommendation for a central hub with all necessary information on exporting to the US. Reducing regulatory duplication can have a significant positive impact on all companies, but SMEs stand to gain the most. Through addressing regulatory divergences such as mutual recognition of Good Manufacturing Practices (GMP) TTIP could help to reduce duplicative site inspections. As the cost of inspections has a proportionally larger impact on SMEs, they stand to gain most from this.

By stimulating transatlantic investment in life sciences and encouraging greater research cooperation TTIP could help ensure the UK remains at the front of scientific discovery and improve healthcare outcomes for patients across the UK.

Owen Mumford continued

"The harmonised regulatory framework for devices across the EU means that once approved, products can be marketed EU wide without further work. While one or two country specific requirements remain, trade is free of barriers within the EU.

Trade barriers between the US and EU are not really too significant – there has always been a mutual recognition that access to safe and effective technology to help healthcare professionals on both sides of the Atlantic to treat patients is in our mutual interest.

Oxford Science Park

However, the regulatory frameworks in the EU and US are markedly different in form and requirement. This means, for example, that products can be classified differently, require different evidence to support their approval, and require different notification processes for changes and updates. The result is that completely separate regulatory filings are required for the US and EU.

The US market is critical to Owen Mumford's business, working as we do with many of the USA's top pharmaceutical companies, retail pharmacy chains and hospitals. We have seen that it is important to have a significant presence in the US market to support our sales as this improves trade relationships. Local knowledge is important when trading in any market.

If TTIP negotiations were able to make progress in reducing the additional burden this places on our business, for example by harmonising the data pack to be submitted and/or agreeing the classification of devices, then this would be very helpful. We are optimistic some progress can be made. Given the current differences however, questions remain as to the extent to which this can be achieved."

The UK government is keen for industry to provide further evidence of the barriers it faces when trading and investing with the US. Please get in touch at **ttip.team@bis.gsi.gov.uk**. For any further information, please contact our partners represented on the back cover and click on links provided in box *(on soft copy)*

British American Business

BritishAmerican Business is the leading transatlantic business organisation, dedicated to helping companies build their business on both sides of the Atlantic. It incorporates the American Chamber of Commerce (UK) and the British-American Chamber of Commerce (USA), which merged in 2000 to create a single, pre-eminent transatlantic organisation under the BAB brand. We represent a pragmatic, creative and conscientious British-American business community and we are a driving force for a pro-growth transatlantic economic zone.

Open for Business is a series of industry specific events with the objective to explore the changes and opportunities that a successful and comprehensive trade and investment partnership (TTIP) agreement can bring to UK sectors, in particular in regards to the scope and sector-specific content of the agreement. This initiative aims to build a nation-wide sector case for TTIP and UK-US trade and investment in general that will contribute to the debate in the UK and beyond.

- UK Government: TTIP
- EFPIA: TTIP Life Sciences Leaflet
- European Commission: Position on Pharmaceuticals
- European Commission: Fact Sheet Pharmaceuticals
- European Commission: Fact Sheet Medical Devices
- NHS European Office: TTIP – separating myth from fact
- European Commission: Protecting Public Services in TTIP

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