

# BIA submission: UK Trade Strategy

## About the BIA and our members

The BIA is the voice of the UK's innovative life science and biotech industry, and our mission is to enable and connect the UK ecosystem so that businesses can start, grow, and deliver world-changing innovation. The BIA has a diverse membership, counting over 600 members including start-ups, scale-ups and established global companies, as well as universities, research centres, and investors.

Life science is a growing sector of the future that poses a unique opportunity. The UK life sciences industry employs over 300,000 people, with around two-thirds of these jobs outside London and the South East. There are 6,850 life sciences businesses, 75% of which are SMEs, and combined they generate a turnover of £108.1bn.<sup>1</sup> The average GVA per employee is over twice the UK average at £104,000 and the sector consistently invests more in R&D than any other (£9 billion in 2022).<sup>2</sup>

BIA primarily represents innovative start-ups and scale-ups. Due to the long R&D timelines, high risk and cutting-edge nature of life sciences and biotech, the sector is more dependent on venture capital than almost all others. Businesses must raise multiple, successive rounds of venture capital, with the total amount needing to be raised to develop a single new medicine ranging from about £1 billion. During this time, they will not be generating revenue and will be loss-making. Moreover, investing in life sciences is a highly specialised activity, and the UK has relatively few established investors compared to the US or even our European competitors. The sector is also a highly global one, with overseas markets, especially the US, the primary target from day one for businesses. These features make the sector relatively unique and require special consideration when government is developing its policies and strategies to support the sector.

## An over-arching comment on DBT's approach to partnership working with industry

The BIA is a strong established and trusted partner of the UK government. We bring valuable experience of mission delivery as former members of the COVID Vaccine Taskforce, as well as partnership working through the Life Sciences Council, the Biosecurity Council, and various Department for Business and Trade (DBT) fora. We value these mutually-beneficial relationships and, through partnership working with DBT, have achieved significant policy outcomes that have benefitted UK growth.

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<sup>1</sup> [DSIT, DHSC, OLS: Bioscience and health technology sector statistics 2021 to 2022. \(2023\)](#)

<sup>2</sup> [ONS: Business enterprise research and development, UK: 2022. \(2024\)](#)

We are grateful for the Department's international advocacy for our sector, and particularly its continued efforts to uphold strong IP rights that our members depend on, including across multilateral negotiations and international agreements. The importance of our strong mutual partnership has most recently been exemplified by joint efforts to prevent unrealistic requirements being imposed on the UK sector that could have had devastating consequences, through the Convention on Biological Diversity's recent decision on Digital Sequence Information.

However, the use of non-disclosure agreements (NDAs) and confidentiality agreements can prove problematic for trade associations, hindering interactions between government officials and association members. DBT's use of these agreements is particularly draconian, something we do not experience with other departments. We strongly urge DBT to take the new trade strategy as an opportunity to reassess the use of NDAs and confidentiality agreements, which should be eliminated in all but the most necessary circumstances.

## Responses to consultation questions

### Key points

- With 53.3% and 22.7% of market share respectively<sup>3</sup>, the North American and European markets are the key focus for the UK's life sciences and biotech sector, meaning the trade strategy should prioritise relationships and deals with these markets.

Government should:

- Continue to develop a "concierge" offer to provide fully joined up government support to capture inward and domestic life sciences investments.
- Ensure all government teams and agencies involved in supporting life sciences trade and investment are upskilled in the business models of innovative industries, and processes, programme eligibility requirements and KPIs are designed with these business models in mind.
- Expand support for trade missions and tailor to life sciences start-ups and scale-ups.
- Prioritise tariff reduction in trade agreements and update the WTO Pharmaceuticals Tariff Elimination Agreement.
- Promote regulatory cooperation in FTAs but also pursue bilateral or multilateral partnerships, ensuring the UK has a strong and leading voice.
- Coordinate and cooperate across government to support life sciences trade and investment. This is vital, as the sector is impacted by myriad international agendas, the responsibility for which is spread across Whitehall.

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<sup>3</sup> [Efpia: The pharmaceutical industry in figures. \(2024\)](#)

- DBT should not use confidentiality agreements as standard in its interactions with industry
- Place championing innovators at the heart of the trade strategy

## **1. How can we facilitate trade for businesses and provide practical tools to support them to drive growth through trade now and in the future?**

### **Inward and domestic investment support**

The UK is in a global competition for highly mobile and valuable life sciences investments. This has intensified post-COVID, as governments around the world have seen the necessity of a domestic life sciences R&D and manufacturing base. Such opportunities can come from foreign companies looking where to locate their next investment, and from our growing domestic life sciences sector, which has many scaling companies making significant investments in new R&D and manufacturing facilities, with great economic growth benefits for the UK.

In recent years, the UK government has built a strong “concierge” offer for investors, supporting them through the process of investing in the UK with good link up across Whitehall, including DBT, the Office for Investment and the Office for Life Sciences, DBT. This service should continue to be expanded, as it’s important this is offered to domestic and foreign companies alike, to secure investments in the UK.

It is still very hard for companies, particularly smaller ones, who often do not know who to speak within government and must navigate national and local government systems alone. This makes the UK less attractive by raising unnecessary barriers to investment, and often making the investment in the UK feel like more of a risk. Despite the new opportunity of manufacturing investment for high value sectors, opportunities within the UK for manufacturing are often lost to countries like Ireland, Singapore and the US. These countries have very established concierge approaches to investment. The potential investors meet with key stakeholders from the area and have an account manager to help with whatever their particular needs are, such as land availability, planning permissions and energy grid connections. Account managers ensure the investor will have access to skills required to manufacture and market the product, and arrangements are often made for quality and manufacturing experts to meet with the clients. Competitive fiscal offers, such as grants or special tax rates are also offered regularly. The government has taken significant, welcome steps in recent years to put these offers in place, and to better link up teams and agencies across government to secure investments. A continued focus on this through strategy and resourcing is needed.

All agencies involved in the delivery of these services also need to be upskilled in the business models of the innovation economy. Too many government processes, programme eligibility requirements and key performance indicators are predicated on traditional business and accounting models. These are not fit for purpose regarding the support of high-growth, R&D intensive, innovative businesses – many of which are pre-revenue, loss-making, by venture capital, and often many years from turning a profit. Nonetheless, it is businesses like these that are creating new industries, generating jobs, and moving society forward through innovation.

## **Trade missions**

Government-facilitated trade missions provide excellent opportunities for UK businesses to build relationships with potential partners overseas. This is especially true for Small and Medium Enterprises (SMEs) that do not have the resources or name recognition to open such doors themselves. Not all missions need focus on trade in the traditional buying and selling sense. In today's global innovation-led economy, building new R&D partnerships, finding new equity investors, or meeting potential business partners all contribute to a company's ability to succeed. Delegations and UK representation at conferences – as well as worldwide representation at UK conferences – can play a key role in the facilitation of these objectives.

Work should be done to increase these opportunities for connection wherever possible. For example, the collaboration between the BIA, DBT, and SynBioBeta to take 12 companies to the conference in San Francisco was highly successful, and further collaborations should be considered. In addition, the costs of exhibiting for SMEs and startups can be prohibitively expensive, so government funding for those companies in most need should be considered, so that promising young companies are able to build traction, connect with investors, and set the stage for future trade.

## **Tariffs**

To facilitate trade and provide tools for growth, it is vital for the UK to enter trade agreements, including Free Trade Agreements (FTAs), with key markets such as the US and Asia. However, trade tariffs will hold back the growth of UK life sciences, particularly our burgeoning manufacturing businesses. The UK should prioritise tariff elimination in FTAs and international relationships.

The BIA has long advocated for the UK government to work with other World Trade Organisation (WTO) members, to update the Pharmaceuticals Tariff Elimination Agreement to reflect scientific advancements and introduce an ongoing update mechanism. The WTO Pharmaceuticals Tariff Elimination Agreement is the key non-binding agreement between key pharmaceutical producing countries to reduce duties to zero on certain pharmaceutical products. The agreement covers finished pharmaceutical products and specified active pharmaceutical ingredients (APIs) and intermediaries (biologic products are also typically included).

The agreement needs a significant update to the specified list of APIs and intermediaries that qualify for zero percent duties. Despite our ask there has been no movement on this at the WTO, nor has the UK sought to put it on the WTO agenda. This agreement has not been updated in since 2010 and a significant number of new APIs and intermediaries are now not included. As a result, innovative pharmaceuticals products manufactured in the UK could be at risk of being subject to tariffs in the years ahead.

## **2. How can we build the right partnerships internationally through trade mechanisms to promote growth?**

The UK's life sciences sector is truly global. R&D, business, and investment partnerships between trusted international partners are a regular occurrence and critical to the functioning of the sector. International diplomacy and regulatory cooperation enable UK companies to access global markets for partnerships and export.

The US and the EU are key markets for the UK's life sciences and biotech sector, in terms of attracting the right talent into businesses, accessing investment, and for launching innovative products. The UK's deep biotech subsector<sup>4</sup> will particularly benefit from access to the US, Japanese, and European markets, all of which have a renewed focus on creating incentives for pulling through biosolutions for a sustainable bioeconomy.

### **Regulatory cooperation**

Products developed and sold by our members tend to be highly regulated, generally at a national level. Moreover, many products are at the cutting-edge of science and technology, meaning regulatory frameworks are not always as clear or appropriate as they could be. Addressing these both nationally and internationally is therefore critical for innovative companies' growth, and thus UK economic growth.

Given the global nature of our sector, international regulatory cooperation is necessary to facilitate trade and growth. However, the UK's departure from the EU has hampered collaboration where – in many areas of regulation – alignment or mutual recognition is no longer in place. Moreover, rising geopolitical tensions, national security, and foreign policy changes in major global economies bring real risk of trade disruption in the years to come, as regulation is used to meet new objectives.

FTAs are one way regulatory cooperation can be achieved but bilateral or multilateral partnerships can be equally effective if the UK has a strong and leading voice.

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<sup>4</sup> [BIA: Deep Biotech: Disruptive innovation for global good \(2023\)](#)

The MHRA has long been recognised as a world-leading regulator, and during the pandemic it demonstrated its capacity to act in an agile manner to enable rapid patient access to safe and effective treatments. However, following the agency’s transformation resulting from the UK leaving the EU, capacity issues at the MHRA – which regulates medicines and medical devices in the UK – have caused delays across a range of services, including clinical trial and marketing authorisation applications and scientific advice meetings. Businesses are also hampered by duplication resulting from the UK’s departure from the European regulatory system. Batch testing of medicines produced in the UK for export to Europe is one such example. The UK accepts products from the EU, without the need for repeated batch testing, but this is not reciprocated. Approximately 50% of all UK pharmaceutical exports reach the EU<sup>5</sup>, so a Mutual Recognition Agreement for batch testing between the UK and EU would save considerable time and money, as well as encouraging growth via trade.

The MHRA’s International Recognition Procedure (IRP), introduced in January 2024, enables the UK to grant UK marketing authorisations to medicines approved by other trusted regulators. It has the potential to support faster patient access to new medicines, while ensuring the MHRA’s resources are targeted to support innovation. To supplement this development, collaboration with EU should be explored to allow UK access to EudraVigilance in the context of pharmacovigilance and patient safety. However, the BIA does not support UK/MHRA involvement in work-sharing with the EU/EMA or coordinated assessment of clinical trial and marketing authorisation applications.

### **Partnership working across government and with industry**

The life sciences sector is supported and impacted by the activities of many Whitehall departments, so coordination and cooperation across government to support life sciences trade and investment is vital.

The Office for Life Sciences (OLS) only spans the Department of Health and Social Care (DHSC) and the Department of Science, Innovation, and Technology (DSIT). In the past this has meant that DBT has had a different operating environment with ideology at its political core. Now, with a united political team, it will be much easier to work effectively and collaboratively with OLS and other departments to support the sector internationally and attract inward investment. Our members operate in a highly globalised ecosystem and that is heavily impacted by international rules, many determined in trade agreements and at international institutions such as the WHO, WTO and WIPO – all overseen by different departments. Coordination with the departments responsible is therefore key and should be addressed in the new Trade Strategy.

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<sup>5</sup> [Statistics on UK-EU Trade, Research Briefing, House of Commons Library, May 2023](#)

Equally, working in partnership with industry is critical to the operation of an effective trade strategy, and trade associations are an effective way to do this. The BIA is a strong, established, and trusted partner of the UK government. We will bring you valuable experience of mission delivery as former members of the COVID Vaccine Taskforce, and partnership working through the Life Sciences Council, the Biosecurity Council, and many other fora. We also have international links with sister trade associations that provide another route for intel gathering and influence in international negotiations.

However, the use of non-disclosure agreements (NDAs) and confidentiality agreements can hinder interactions for trade associations with government officials and association members. DBT has a particularly draconian use of these agreements, which we do not experience with other departments. Their use should be eliminated in all but the most necessary cases.

### **3. How should the UK operate in the international context to support and protect businesses?**

#### **Championing innovators**

The UK is a world-leader in research and innovation, and the Industrial Strategy rightly recognises that knowledge-intensive sectors like life sciences are the drivers of future economic growth. Championing innovators internationally is therefore in the UK's interest and should be at the core of the new trade strategy.

Upholding the UK's strong intellectual property (IP) regime is crucial to both the support and protection of innovative UK life sciences businesses at home and abroad, as it allows them to predictably protect and enforce the IP rights on which they depend.

It is important that any future trade deals do not weaken the UK's strong IP regime. Protecting IP is essential for life sciences companies, most of whom are SMEs focused on research and development (R&D). The majority of technologies and advanced therapies these companies work on are not yet licensed or available to patients. Any threat to the IP rights of these companies risks their viability and may affect their ability to deliver the technologies, therapies, and treatments of the future. The UK's commitment to our world-leading IP regime must therefore extend internationally as a key consideration in ongoing and future Free Trade Agreements (FTAs), as well as related multilateral agreements such as on pandemic preparedness and others conducted through WHO, WTO, WIPO and other multilateral bodies.

The UK must support negotiating partners in their efforts to bolster their IP regimes, and create certainty that UK businesses can predictably enforce their IP rights. Indeed, there is an opportunity through trade for the UK to encourage the strengthening of IP regimes around the

world, and for the UK to borrow from those countries with strong IP regimes to strengthen its own. This could include extending exclusivity periods or increasing what is considered patent-eligible subject matter. As such, the UK Government – through the Intellectual Property Office and beyond – should continue its efforts to strengthen IP regimes around the world, sharing knowledge and supporting capacity building of regime functions. It should also continue to learn from strong regimes and work through WIPO to aid the flow and exchange of knowledge.

Regulatory divergence and convergence in key markets territories, particularly where innovative technologies are concerned – including genomics, engineering biology, precision medicine and AI – needs to be carefully monitored, assessed, and addressed. This will enable innovative UK businesses to expand into new markets with minimised regulatory and trade burdens, and allow UK life science companies to collaborate effectively with international partners. Where the UK can see advantage in taking a lead in new regulatory freedoms or approaches, it can create a competitive advantage that UK companies can benefit from (e.g. Genetic Technologies (Precision Breeding)). Any trade strategy should open doors to strengthening collaboration at an international level to promote this convergence of global standards, knowledge sharing, and addressing of common challenges. This could be delivered outside of trade deals through multilateral coalitions and international agreements, including confidentiality arrangements and mutual recognition agreements.

Lastly, the UK should showcase its strengths in life sciences internationally to help businesses access new markets and reach new partners, while ensuring it's identifiable by those partners. This can be achieved through Memorandums of Understanding between strategic partners and through trade missions, particularly with harder-to-access international partners.

**For further information about the contents of this submission, please contact Martin Turner, Director of Policy and External Affairs, via [mturner@bioindustry.org](mailto:mturner@bioindustry.org)**