BIA policy submission

29 August 2025

UK BioIndustry Association

Business & Trade Committee inquiry - UK trade with the US, India and EU

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.[1] 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)[2].

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 due to their size. These features make the sector relatively unique and require special consideration as government is entering into trade deals with key markets.

[1] DSIT, DHSC, OLS: Bioscience and health technology sector statistics 2021 to 2022. (2023)

[2] ONS: Business enterprise research and development, UK: 2022. (2024)

Please also see the BIA's response to the UK Trade Strategy[3], which outlines industry's perspective on the best way to support and protect UK businesses in international contexts whilst facilitating trade to drive growth.

Summary

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, among other trade policies, enable UK companies to access global markets for partnerships and export.

With 53.3% and 22.7% of market share respectively[4], the North American and European markets are the key focus 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. Whilst India is not yet a priority launch market, its rapidly expanding middle class and growing industrial base makes it an important country for UK life sciences, as a producer of medicines and a source of talent.

As such, effective and balanced trade agreements between these countries are essential for the resilience and growth of the UK sector, and must facilitate an environment that is conducive to the life sciences. Evaluation of the success of these agreements requires clear strategic objectives, as well as commitment from government that outcomes will be effectively implemented and enforced.

Areas of particular interest to the life sciences are:

- **Tariffs**. Trade tariffs will hold back the growth of UK life sciences, particularly our burgeoning manufacturing businesses. We should therefore prioritise tariff elimination in FTAs and international relationships.
- **Regulation**. International regulatory cooperation is necessary to facilitate trade and growth. However, in many areas of regulation – such as the batch testing of medicines – alignment or mutual recognition is no longer in place. Addressing these barriers is essential for company growth, while upholding UK pro-innovation regulatory frameworks.
- **Intellectual property**. Strong and enforceable IP protections are fundamental to life sciences innovation and investment. Trade agreements must include IP commitments that safeguard UK research, enable collaboration, and ensure that innovative companies can scale and compete globally.

[3] BIA: BIA response to UK Trade Deal (2025)

[4] Efpia: The pharmaceutical industry in figures. (2024)

- **Innovation & R&D.** A global ecosystem that promotes innovation and supports R&D is essential for the life sciences. Trade agreements must also promote innovation, facilitate cross-border R&D partnerships, and support investment into the life sciences. Reduced participation in programmes such as Horizon Europe has already limited opportunities for UK companies and steps must be taken to prevent this from happening again.

These are the key themes in trade agreements relevant to life sciences and biotech, but such agreements are multifaceted. In addition to the above themes, Parliament should judge agreements on how well they align with and support the Industrial Strategy and sector plans.

The India FTA includes provisions on tariffs, government procurement, regulatory cooperation, and IP. While the EU and US deals are yet to be finalised, they have the potential to strengthen market access, improve regulatory alignment, and create international structures that allow the life sciences to flourish.

Regardless of the current stage of each agreement, much remains to be seen. The overall efficacy of these agreements will depend on the implementation and enforcement of each commitment, and will require constant monitoring from government to ensure they remain on track, particularly in those areas outlined above that are of most importance – and therefore represent the biggest potential risk and opportunity – for the life sciences.

Responses to consultation questions

Strategic Assessment

1. Do the agreements represent a good deal for the UK?

Overall

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[5] will particularly benefit

[5] BIA: Deep Biotech: Disruptive innovation for global good (2023)

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. Trade agreements with those markets are therefore an important tool for growth.

As the details of the US and EU trade deals are not finalised, we comment below on important aspects both trade deals *should* address in order to benefit the UK's life sciences sector.

India

The India FTA includes several positive announcements that can benefit the life sciences sector. These include reduced tariffs on medical devices and elements of the wider life sciences supply chain, bilateral regulatory cooperation, preferential treatment for UK businesses under India's government procurement regime, targeted SME support, and the establishment of an Innovation Working Group.
However, we are disappointed that more was not achieved to support innovators in the IP chapter. The UK is an innovation economy, and life sciences is one of the most R&D and innovation intensive sectors in the UK. The FTA contains a large IP chapter, but it does not commit India to raising its IP standards to those of the UK, both in terms of innovation incentives that enable greater return on investment, and enhanced enforcement procedures. We do however welcome the recognition of voluntary licensing mechanisms, which may include technology transfer on mutually agreed terms, which will enable greater collaboration between the UK and India's life sciences and health sectors whilst protecting IP essential to UK companies' success.

The chapter will need to be cemented through detailed implementation plans and robust enforcement activities so that IP-rich businesses in the UK life sciences sector can collaborate and innovate in and with Indian partners. Progress should be monitored, with continuous input from life sciences companies.

EU

The EU remains one of the UK's most important partners in life sciences, providing key markets for trade, investment, and collaboration. A major bottleneck to accessing the European market is the lack of a mutual recognition agreement for medicine batch testing. Under the current arrangements between the EU and UK, each batch of manufactured medicines must be tested and released in the UK, and then re-tested upon entry to the EU. The UK does not require this of EU-produced medicines imported into the UK, putting their manufacturers at a competitive advantage. A mutual recognition agreement would provide critical support to therapy developers,

in-house manufacturers, contract research organisations (CROs), and contract development and manufacturing organisations (CDMOs) operating within the UK to drive investment in this government-defined growth sector.

All of the TCA (trade and cooperation agreement) commitments to intensify cooperation on health security, establish special dialogues on mobility and professional qualifications, and strengthen enforcement of competition are positive steps. In particular, steps to create a Common Sanitary and Phytosanitary (SPS) Area would reduce trade frictions on plant and animal produce by substantial amounts, saving bureaucracy and cost while ensuring biosecurity, as long as the UK's pro-innovation agenda and advancements in areas such as precision breeding are upheld. All these steps collectively form the foundation of the UK's ambition to be a global leader in life sciences innovation, supported by complementary initiatives such as our association to Horizon Europe, which will help maintain vital international research collaboration.

US

The US is the pre-eminent economy and market for life sciences, accounting for a majority of global healthcare spending and investment in innovation. It is vital for the UK to enter trade agreements, including Free Trade Agreements (FTAs), with key markets such as the US. We therefore welcome the Government's prioritising negotiations with the US Administration. Talks have largely focused on tariffs, which would hold back the growth of UK life sciences, particularly our burgeoning manufacturing businesses, if introduced. The UK should prioritise tariff elimination in FTAs and international relationships with the US and all other nations. With this in mind, the BIA welcomes the commitment from government to negotiate a reduction in applied tariff rates with the US on a preferential basis on a range of originating goods of the UK in sectors of importance to the UK, as well as the intention to promptly negotiate significantly preferential treatment outcomes on pharmaceuticals and pharmaceutical ingredients.We also welcome the commitment to improve the environment for pharmaceutical companies in the UK.

Research and regulatory cooperation are critical to ensuring that UK life sciences companies can innovate and compete globally. The UK and US have previously discussed the establishment of a formal Science and Technology Agreement, which would have provided a valuable framework for collaboration in R&D and regulatory alignment. However, this was not part of the UK-US deal earlier this year. We therefore call on government to prioritise this in negotiations, making sure that cross-border scientific partnerships, mutual recognition of regulatory standards, and innovation support form a central part of the UK–US economic relationship.

It is difficult to assess the impact on the sector, without more detail and defined lines of accountability.

2. To what extent has the Government achieved its stated negotiating objectives?

Clear and consistent negotiating objectives are an important factor both when establishing the bounds of a trade agreement, and when evaluating its success. While the government has stated publicly that the objective of the US agreement will be to avoid significant tariffs and deepen the economic relationship between the UK and US[6], more could be done to define, and publish, these negotiating objectives across the board. Of course, each trade agreement must navigate highly specific intercountry dynamics, which will be reflected in varied approaches and differing priorities. However, consistent overarching objectives would anchor each agreement back to a broader strategy, and allow for a more direct evaluation of success. As it stands, a lack of clear, publicly accessible objectives or wider context makes it difficult to assess whether a given agreement is successful, and how it contributes towards the overall trade strategy.

Future trade agreements with the US and EU should support the UK's Industrial Strategy objectives and the delivery of the Sector Plans, which should formally be part of any negotiating objectives.

3. How should Parliament judge the success of these agreements over the coming years?

General

The overall success of the agreements should be judged against their abilities to drive forward the goals of the Industrial Strategy, and the Life Sciences and Digital & Technologies Sector Plans, which are all relevant to life sciences and biotech (the latter Plan including engineering biology). They should strategically align with the Plan's core themes and international sections. Most importantly, all elements of a trade deal should be judged on how they promote innovation, which is a core tenet of the Industrial Strategy.

[6] DBT, Statement by the Trade Secretary on US Tariffs. 2025.

Metrics such as FDI, exports, and R&D investments are important indicators to measure the success of trade deals. In addition, the elimination of tariffs, better regulatory cooperation, supportive services for start-ups and SMEs, and industry trade missions can be used to measure the benefits that the trade deals deliver to the sector.

The content of the agreements themselves will also have a distinct bearing on whether they are considered to be a success from the perspective of the UK life sciences sector.

For example, products developed and sold by our members tend to be highly regulated. 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. Such regulatory cooperation is particularly important with key markets in the EU and US.

There **is a significant amount that is missing from current arrangements that could be improved upon in future agreements. However, there are number of priorities that, if addressed, could have the biggest impact. They are as followed:**

EU

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.

Desirable outcomes on UK/EU medicines regulation

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[7], 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.

A successful EU trade deal should therefore result in improvements on medicines regulation that benefit UK life sciences business.

In addition, a successful EU trade deal must not undermine the UK's progress in its pro-innovation regulation agenda of life sciences and engineering biology, and in particular the UK's leading precision breeding regulatory framework as part of any renewed SPS agreement.

US

Similarly, while the complete text of the US–UK trade agreement remains to be published, the governments' initial pledges suggest a heavy emphasis on regulatory alignment in issues relevant to the life sciences sector. Specifically, the two countries are eager to progress ongoing Mutual Recognition Agreements (MRAs) and expand agreements across industrial goods as well as stepping towards a services regulation structure. This would lay the groundwork for prospective regulatory alignment in the future, particularly in areas such as medical devices, diagnostics, and other regulated products.

Encouragingly, there are initial commitments to deepen economic integration in crucial sectors, through government policy, licensing arrangements, and private sector involvement. Additionally, preliminary talks have referenced an intention to establish high-standard commitments to the enforcement and protection of intellectual property rights, a priority goal for UK life science innovators seeking international partnerships.

[7] Statistics on UK-EU Trade, Research Briefing, House of Commons Library, May 2023

India

With agreement reached on the India FTA, its success can be judged throughout the implementation phase and beyond. The India FTA features a large IP chapter, including patents. 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.

To ensure success, the UK must ensure the commitments and provisions on IP, and in particular patents, are actioned, upheld and improved upon, and properly enforced, including through period review and through engagement with life sciences SMEs.

Economic Impact

5. What is likely to be the impact of the agreements on: b) UK producers, including SMEs and key sectors

General

The UK life sciences sector is a global sector, with operations, supply chains and R&D operating across borders. UK life sciences companies will benefit from trade deals with the US and EU where they streamline regulation and market access, drive FDI, support life sciences SMEs to export, allow for the movement of world-class talent, and overall enhance practical support to help the sector engage, compete, and collaborate internationally, upholding the UK's high standards and rules. Overall, we anticipate all trade deals to be of benefit to the UK life sciences sector and SMEs due to their aim for better cooperation. However, the above-mentioned concerns need to be eased, and the UK's pro-innovation agenda must not be undermined, e.g. through an unfavourable SPS agreement or the introduction of tariffs.

India

While the impacts of the agreement are yet to be determined post implementation, the India FTA is promising to have a positive impact on the UK's life sciences sector. We welcome the focus of the agreement to benefit SMEs, which make up the vast majority of businesses in the sector. The provisions outlining to work cooperatively to identify and address barriers to SMEs' access to international markets; considerations of the needs of SMEs when formulating new laws and

regulations; assessing the effect of globalisation on SMEs; and examining issues related to SMEs' access to financing, technology, and support for innovation, are therefore expected to be of particular benefit to the life sciences sector[8]. The deal may also increase R&D and scale-up partnerships between both countries, particularly given India's CRO and manufacturing capabilities, enabled by the deal's IP licensing commitments.

However, as the deal did not include innovation incentives, innovative UK SMEs with products on the market and large life science companies will face pricing pressures and competition from generics companies in the Indian market, which will reduce revenues. Emerging UK businesses need to be protected from IP boundary pushing by such competitors through enforceable safeguards.

c) UK workers and consumers?

Life sciences is a global industry, and innovation requires new ideas and diverse points of view. Beyond domestic talent, many companies complement their domestic expertise with non-UK employees that bring a diversity of skills, creativity, and perspectives, allowing them to compete in a global marketplace. In fact, 25% of those working within the sector are born outside the UK[9]. Therefore, continued support for global talent is essential for the success of the sector.

The trade agreement between the UK and India already commits to ensuring that the visa process remains transparent, and that no unnecessary government obstacles interfere with travel between the two countries for professionals. It is important that similar agreements are reached for both the EU and the US, as not doing so would negatively impact UK workers, and UK life sciences at large.

[8] UK-India FTA, Chapter 19 (2025).

[9] BIA, ABPI, ABHI, SIP Life sciences 2035 developing the skills of future growth. (2025)

Standards and Safeguards

6. Do you believe the three agreements adequately safeguard UK standards in labour rights, environmental protection, consumer protection and food standards?

The trade negotiations between the EU and UK include a commitment to a renewed Sanitary and Phytosanitary (SPS) agreement to ease trade in agri-food products. For the life sciences and biotech industry at large, the prospect of an agreement on SPS is welcomed. Regulatory alignment means that goods can flow more easily to and from the UK and the EU. Some of our members have reported challenges with importing animal derived products under the Border Target Operating Model (BTOM) which set out the UK's approach to security controls on imports of SPS goods, animal and plant products imported from the EU post Brexit. Entering alignment with the EU would facilitate the import of key reagents which are essential to the running of many biotechnology companies.

However, for innovative companies working on agricultural biotechnology, the prospect of dynamic alignment with the EU poses a risk, as this may jeopardise the UK's progressive regulatory framework for precision bred organisms (PBOs). The UK's current PBO regulations are more advanced than the EU's, which do not currently distinguish between genetically modified organisms (GMOs) and PBOs.

As the UK negotiates the SPS agreement, we must ensure that precision breeding is carved out as an exception to any dynamic alignment, in order to preserve the UK's pro-innovation regulatory framework for precision breeding.

Furthermore, the India trade deal commits the UK to agree to an ambitious and robust SPS chapter, with the aim to facilitate trade while ensuring the protection of human, animal and plant life and health. We welcome the commitment that there will be nothing in the agreement that will compromise the UK's high food safety and biosecurity standards, and that the UK will protect its regulatory autonomy to set our own independent standards. The comprehensive SPS chapter should be considered in lieu of the UK's negotiation of a potential new EU SPS agreement, upholding the UK's pro-innovation regulation agenda across both.

Engagement and Transparency

7. How well has the Government communicated its progress in negotiations – and how much has it listened to stakeholders during those negotiations?

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 Responsible Innovation Advisory Panel, and various Department for Business and Trade (DBT) fora. We value these mutually-beneficial relationships and, through partnership working with Government, have achieved significant policy outcomes that have benefited UK growth. However, the use of non-disclosure agreements (NDAs) and confidentiality agreements used by DBT when discussing trade policy can prove problematic for trade associations, hindering interactions between government officials and association members. Such agreements should only be used in the most necessary circumstances.

For these negotiations specifically, the BIA appreciates the delicate nature of the conversations, and the need for discretion. However, the lack of transparency or clarity regarding the strategic objectives of the negotiations in general, makes it very difficult to both understand what government hopes to achieve, and to gauge whether it has been successful. Crucially, sector insights from industry experts and trade associations are vital and should be a prominent part of setting negotiating objectives, and implementation. More clarity around this at the fore would allow us to engage earlier in the process, and share sector perspectives and requirements at a stage that is more amenable to adjustment, for example through industry roundtables and working groups.

8. How should the Government best engage with stakeholders to implement the UK-India FTA to maximise its potential?

Working in close partnership with industry and via trade associations

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) has until recently only spanned 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 of three Secretaries of State, it will be much easier to work effectively and collaboratively with OLS and other departments to support the sector internationally and attract inward investment.

On a similarly positive note, DBT has established groups to enable industry to understand, anticipate and respond to UK and other countries' initiatives, regualtory changes and new legislation that stems from trade deals. This is a significant and welcome step to better engagement. By providing a structured and regular platform for dialogue, it will enable life sciences companies to share insights, highlight challenges, and contribute to shaping policy and regulatory approaches more effectively.

India

The Innovation chapter of the India FTA seeks to bolster support for innovation in the UK and India, including by fostering opportunities for innovation-intensive industries, such as the life sciences sector, and encouraging trade in innovative products and services. It will establish an Innovation Working Group, which will allow the UK and India to enhance existing collaboration, research, and development.

The Innovation Working Group should engage closely with innovators in the life sciences sector, and particular industry innovators, including SMEs and startups, when it comes to assessing future regulatory approaches, supply chain resilience, and the commercialisation of new technologies, all of which are important elements of the life sciences sector. The views of innovators, including via trade associations, should be sought by the Group in between its annual meetings, where relevant.

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