

Growing Britain's life sciences sector through international and trade policy

November 2024

Contents

Executive summary	2
ntroduction	5
Pillar 1: Promoting high regulatory standards globally that seep patients safe and addressing market access barriers to safeguard supply chains	7
Pillar 2: Safeguarding intellectual property as a output of innovation and economic development	11
Pillar 3: UK leadership in multilateral negotiations and on global health issues	13
Conclusion and recommendations	16
References	18





Executive summary

In a changing international context, the UK needs a new approach to international and trade policy for the life sciences. The sector is strategically important to the domestic economy and global health security and has been rightly identified by the new government as key to delivering its core missions.

Successive governments, including the last Labour Government, have understood the importance and complexity of the pharmaceutical industry, as well as the health and economic value the sector can offer the UK.

This report sets out **three key objectives** for any international and trade strategy that is to support Britain's life sciences sector, and **three key areas of activity needed** to achieve them. In all, we believe these will deliver on the clear missions of the new government to make the UK more prosperous, more secure, and reconnected with the world.

What should the UK aim to achieve?



Greater value of UK pharmaceutical exports supporting UK jobs and economic growth.

How should the UK meet these objectives?



Promoting high regulatory standards globally that keep patients safe and addressing market access barriersto safeguard supply chains.



Improved global health outcomes and better preparedness for the next health emergency.

2.

Safequarding

provisions as a

and economic

development.

intellectual property

foundation of innovation

Resilient global supply chains for critical medicines and medical supplies.

3



UK leadership in multilateral negotiations and on global health issues.

Supporting the government's missions for growth and health

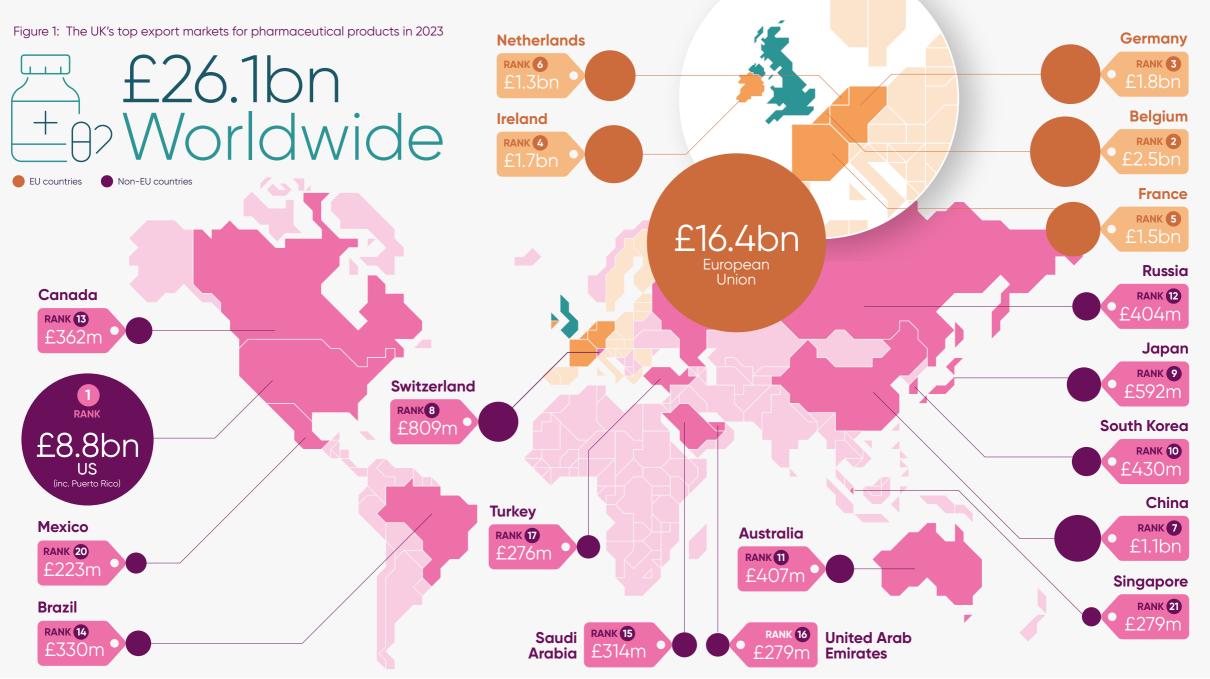
The pharmaceutical industry invests £9 billion a year in UK research and development, which is by far the largest of any sector. In addition, it delivers £17.6 billion in direct gross value added (GVA)¹ to the British economy and supports 126,000 high-skilled jobs² across the country. Critically, ours is the country's third largest goods' exporting sector at £26.1 billion.³

The growth unlocked by an effective life sciences strategy would benefit everyone, everywhere. By removing trade barriers, enshrining reciprocally high regulatory and IP standards with trade partners, and defending the international rules-based order, the UK will attract internationally mobile investment into research, development and manufacturing.

Such investment will provide high-quality jobs and greater capacity to make and export vital medicines and vaccines, also putting the UK in a better position to support international development efforts that meet global health goals, from addressing antimicrobial resistance (AMR) to helping build health capacity in lower- and middle-income countries.

A strong partnership with business is fundamental to delivering the government's growth mission. We strongly encourage engagement with the life sciences sector to make this shared ambition a reality.





mce for National Staustics, Country by continuoury exported of ou



Introduction

The UK life sciences sector is highly innovative, a major contributor to economic growth and an essential partner in achieving global health goals. The production and export of innovative medicines and vaccines is only possible because of the significant investment made by pharmaceutical companies into research, development and manufacturing in the UK.

Since existing the EU, the UK has had to establish a new role on the international stage while creating the conditions domestically to attract and retain investment in key growth sectors. This has happened at a time when competition for global mobile investment has risen, along with geopolitical tensions and protectionism.

With clear missions of the new government to deliver growth and reconnect Britain to the world, we support a review of the UK's international and trade strategy to ensure that it is delivering for the UK economy, UK business – and, most importantly, for patients in the UK and globally. As a sector, we believe that the UK's international strategy should look to achieve three outcomes in line with the government's key missions:

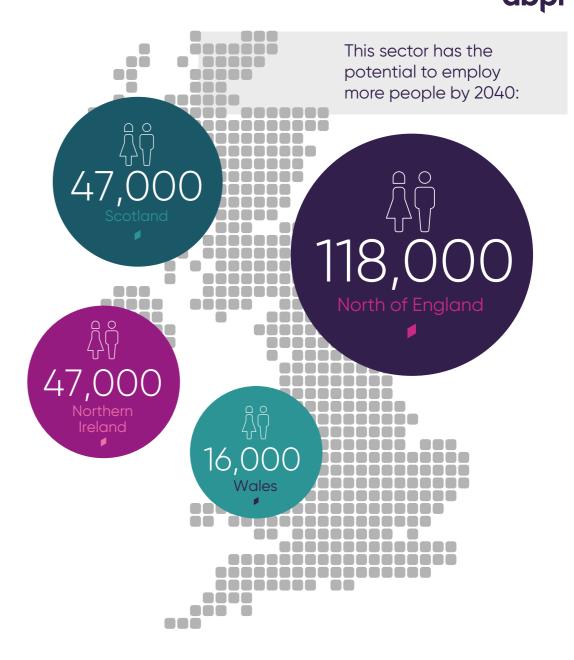
I. Boosting the value of UK pharmaceutical exports to deliver UK jobs and growth

Over the past two years, the UK pharmaceutical sector has attracted over £11 billion in inward investment, powering domestic pharmaceutical manufacturing, with a highly skilled and productive workforce in more than 3,000 research and manufacturing sites across the UK. Alongside other investment, this delivers £17.6 billion in direct GVA⁴ to the British economy and supports 126,000 high-skilled jobs⁵ across the country. Critically, ours is the third largest goods exporting sector in the country at £26.1 billion in 2023.⁶

However, foreign direct investment has fallen significantly year-on-year⁷, and there is a need for the UK to boost its attractiveness. If the UK were to increase its share of global pharmaceutical exports by 4 per cent, it could generate a further £16.3 billion in gross domestic product (GDP) and 85,000 new jobs.

Currently, the sector employs more than 54,000 people across the North of England, for example, with the potential to employ more than 118,000 by 2040. By the same measure, we could see an additional 47,000 jobs in Scotland, 27,000 in Northern Ireland and 16,000 in Wales. The sector also directly generates 1.25 times the economic value of the UK automotive sector and about 2.4 times that of the UK aerospace and oil and gas industries, meaning many of the jobs created by our industry will be among the most productive in Britain.

With the cost of economic inactivity due to ill health estimated in the tens of millions of pounds,⁸ health security delivered through greater supply resilience, pro-innovation trade, and an effective intellectual property framework can support workforce and productivity goals.



2. Improving global health outcomes and preparing for the next health emergency

The COVID-19 pandemic brought into sharp focus the need to ensure the world is prepared for future health emergencies. The international health ecosystem delivered the fastest-ever development and authorisation for a vaccine, in just 326 days. Fewer than six months later, the pharmaceutical industry's monthly production output was close to a billion doses.

However, there are lessons we can learn from this response to better prepare the world for the next health emergency and address underlying health inequalities that result from weak health systems, immature regulatory frameworks and restrictive rules on the movement of health products. It should also provide the incentive for governments and industry to jointly find solutions to incentivise R&D investment in areas that are currently lacking in vaccines or treatments. The UK's credibility as a life science leader should be used to drive this debate and continue work to meet the UN's Sustainable Development Goals (SDGs).

3. Safeguarding global supply resilience of critical medicines and medical supplies

Geopolitical challenges and post-pandemic thinking have only increased the salience of supply chain security concerns. The UK should consider the role that its international and trade policy for life sciences can play in safeguarding continued access to medicines and vaccines for patients at home, as well as through an interconnected network of partner countries, given the inherently global nature of our sector.

The UK pharmaceutical sector supplies a global market, using imported pharmaceutical inputs from around the world for manufacturing and transformation. This can mean that at-the-border costs and bureaucratic burdens have a material impact on the ability of UK pharmaceutical companies to produce medicines. Minimising these should be an important part of a trade policy for the UK pharmaceutical sector, ensuring a reliable and resilient supply of medicines.

Resilient supply chains help to deliver the best possible value to health systems like the NHS and provide industry with the flexibility to respond to surges in demand.

abpi

How we can deliver on this ambition

This report sets out how these outcomes can be achieved through three pillars of activity that we believe should be the basis of an effective international and trade strategy for the life sciences. Together, these form the basis for a clear and coherent approach to some of the biggest challenges facing both the UK and the world today, as well as significant opportunities to further bolster the UK's competitive advantage at a time of intense change domestically and across the world.

The UK should seek to use all of the tools at its disposal to deliver on these ambitions, from high-quality Free Trade Agreements (FTAs) negotiated where there is a strong policy case to do so, to sector-specific agreements such as mutual recognition agreements (MRAs).

The role and importance of international frameworks cannot be overstated for a global sector like the life sciences. The fundamental rules of trade governed by the World Trade Organization (WTO) set minimum standards and the confidence to operate internationally as the life sciences must do, and the World Health Organization (WHO) plays an important role in global health. For the pharmaceutical industry, there are also specific international forums that set regulatory standards for health products.

The UK's longstanding support for these frameworks is recognised by global boardrooms and vital to demonstrate how leadership can attract the investment needed to compete with the G7.

The UK should also consider more creative approaches to delivering international and trade objectives, including brokering regulatory dialogues between like-minded regulators either bilaterally or through convergence mechanisms that enable work-sharing, collaboration and resource sharing. Nor should Britain be afraid to utilise unilateral policies, such as continuing to allow medicine imports from the EU without the need to re-batch test, or reviewing its external tariff schedule, to deliver its objectives.

In all, a robust and competitive national industrial policy, together with a sophisticated international and trade policy, creates a virtuous circle that will ultimately help to deliver the growth the new government wants. The UK should continue to influence debates for fair international treatment of Britain's life sciences firms, while retaining a clear commitment to the strong protections at home that support the UK's competitive advantage globally.



Pillar 1

Promoting high regulatory standards globally that keep patients safe and addressing market access barriers to safeguard supply chains

Regulatory standards for medicines and vaccines are, rightly, some of the most stringent of any industry. To ensure patient safety, product quality and efficacy throughout development, manufacture, distributionand use, medicines must adhere to multiple regulatory requirements. However, due to differing regulatory regimes in different countries, this can lead to duplication when inputs and finished medicinal products cross borders.

Promoting adoption of the UK's trusted international leadership in developing, implementing and championing high regulatory standards that are internationally aligned, would help to bolster supply resilience and keep patients safe across the world.

i. Regulatory standards

The global life sciences supply chain involves multiple regulatory authorities and spans numerous jurisdictions, which can lead to duplication in the necessary supervisory and regulatory oversight activities as inputs and finished medicinal products cross borders.

All life sciences goods placed on the UK market must be authorised in the UK, including those that are imported. Likewise, UK pharmaceutical exports to other countries are subject to similar regulation and standards in export destinations with established regulatory frameworks.

As the Medicines and Healthcare products Regulatory Agency (MHRA) is no longer part of the European medicines regulatory network, it can and should develop its own strategy that signposts areas of existing strength and aspirations for future global leadership. In addition to this, the promotion of 'gold-standard' regulatory frameworks can be achieved alongside or independently from FTAs through formal cooperation agreements, regulatory dialogues and via international fora.

The new government has said it will look to use bilateral and multilateral negotiations as an opportunity to remove redundant or duplicative requirements UK medicines face when accessing markets overseas, and maximise opportunities presented by high regulatory standards to minimise regulatory trade barriers. There is also a case for supporting countries with less developed regulatory regimes to build capacity and expertise up to these standards to fully capitalise on access to the newest products.

By striving for alignment to a single set of high global standards, regulatory agencies can then begin to work to remove duplicative barriers⁹ and thus simplify supply chains for products – building inherent resilience into systems and further establishing an international network of regulatory jurisdictions that guarantee safe and effective medicines.

The UK government should support the development of regulatory standards and capacity, leveraging the UK's credibility in setting and enforcing medicines regulation to shape new rules and support other countries to reach global minimum standards.



abpi

ii. Regulatory cooperation and coherence

Distinct from the drive to improve regulatory standards in all parts of the world, the UK should also be seeking to work with like-minded partners that already have equivalently high standards, charting a pragmatic approach towards, and engaging purposefully with, a global bilateral recognition policy for the development and approval of medicines and medical devices.

Promoting a UK approach to regulatory diplomacy and leadership in which the MHRA's international reach could be coupled with an agile regulatory framework will help unlock increasing international recognition of UK best practice. This can in turn reduce regulatory challenges and encourage further international cohesion and alignment.

Successfully operating such a policy will have the added benefit of helping to shape a level playing field for UK exporters, setting the scene for exportled economic growth through the promotion of internationally-agreed standards that reduce barriers to trade, reduce uncertainty in the domestic investment and operating environments, and reward innovation.

When executed effectively, the benefits of bilateral recognition policy are clear: the UK can realise efficiency savings for domestic industry, ease pressures on regulatory bandwidth, and boost competitiveness through increased export growth and inward investment, all while improving outcomes for patients

The UK is a comparatively small global market for pharmaceuticals, so it is essential that it does not become isolated from wider international dialogues that focus on regulation and the development of international standards, especially for the regulation of new therapies.

iii. Mutual recognition and removal of duplicative trade barriers

In practice, the ambitions for regulatory cooperation can be best met through regulator-regulator dialogues that in turn translate to meaningful agreements, such as mutual recognition agreements (MRAs) that involve the UK and partner countries mutually recognising standards.

Generally, the role of MRAs is not to formally harmonise or align life sciences regulation or technical standards, but to determine areas in which practice among parties is sufficiently similar to produce equivalent outcomes, to the extent that parties are willing to rely on that practice in defined areas as a substitute for their own regulatory actions.

In practice, this means that companies can face duplicative requirements in areas such as inspection of manufacturing sites and obtaining batch testing certificates. However, between those countries that implement the highest regulatory standards domestically, MRAs can be negotiated to enable partners to recognise good UK practice in their own regulatory assessments and vice versa.

The benefits of such agreements will include reduced burden on regulators and businesses by removing duplicative activity and reduced delays and costs associated with exporting and importing medicines – all of which will lead to medicines getting to patients more rapidly, and more resilient supply chains with fewer points of failure in the movement of goods.

MRAs can be agreed as part of or outside free trade agreements (FTAs) and represent a good example of sector-specific deals that can make a meaningful difference to the UK's life sciences industry through the reduction of trade barriers. The UK already has such agreements with



other highly regulated markets including Australia, Canada, Israel, Japan, New Zealand, Switzerland and the US.

The UK government should encourage the deepening of formal channels of cooperation between regulatory agencies including by agreeing and expanding MRAs to further support resilience of supply.

iv. Partnership through international regulatory forums

Many of the standards of tomorrow will not be set in one country, but among groups of like-minded economies, and at the multilateral level (e.g., through bilateral MRAs or regulatory dialogues in emerging areas).

New technologies, from AI to biotechnology, will be increasingly addressed at the WTO and WHO, and will require the government to actively leverage British soft power with traditional partners in Europe and North America, as well as new coalitions across the Commonwealth and Africa, where Britain can be a force for good in building up low-income countries' regulatory capacity.

Regulatory harmonisation between established regulatory authorities through international forums and organisations allows for alignment in technical requirements that can help to break down barriers and pave the way for easier recognition and reliance activity.

Examples where the UK is already engaging in this include Project Orbis, a programme coordinated by the US Food and Drug Administration (FDA) involving Canada, Australia, Switzerland, Singapore and Brazil to review

and approve promising cancer treatments, and the Access Consortium, a programme involving Australia, Canada, Switzerland and Singapore to help secure improved patient access to high-quality, safe and effective medicines.

Identifying opportunities to establish new relationships and deepen existing programmes will deliver a direct benefit to the UK. Greater harmonisation, championed by regulators and supported by wider government approaches to international collaboration on technical manufacturing standards, promotes innovation, furthers patient safety by ensuring that the highest standards are made mainstream, and furthers supply resilience by minimising divergences where this is unnecessary.

The UK government should use its membership of international standards-setting bodies to influence the implementation and creation of future regulatory rules.

V. Eliminating tariffs and simplifying customs and rules of origin

The application of even small tariffs on essential supply chain components increases the cost of medicine production and reduces the attractiveness of the UK for manufacturing. This can in turn reduce patient access to medicines made in the UK.

The case for eliminating these taxes on all components and stages of pharmaceutical trade is therefore compelling and well-established. Pharmaceuticals are in fact one of the few categories of goods with their own liberalisation agreement at the WTO level. The 1995 WTO Pharmaceuticals Tariff Elimination Agreement eliminates tariffs on all finished medicines and some active pharmaceutical ingredients (APIs) for signatory countries (including EU member states, the U.S., Canada, Australia, Japan, Norway, and Switzerland).

For non-signatory countries, tariffs on medical products vary between jurisdictions. Finished medicines, APIs, intermediates and starting materials can all be subject to tariffs.^a These additional taxes and duties are an unnecessary cost for the pharmaceutical industry and divert resources away from investment in the development of essential medicines and vaccines – and getting them to those who need them.

Tariffs on medicines and their components increase manufacturing and import costs, reducing the availability of medicines. Removing tariffs on APIs globally would boost production and diversify medicinal products, benefiting patients with a wider range of options.¹⁰

In any UK FTA, companies will have to meet rules of origin to qualify for preferential tariffs. Medicines are particularly complex products that depend on numerous APIs, intermediates, and globalised production processes. Our industry is constantly innovating and so it is important that mechanisms are in place to ensure that rules of origin reflect this, ensuring the UK's most innovative products can also benefit from preferential tariffs.

For small to medium-sized enterprises (SMEs) that make up 82 per cent of our industry, it is essential that rules are easy to implement so that the administrative cost of exporting does not outweigh the benefit of qualifying for preferential tariffs.¹¹

a For countries that are not signatories of the WTO Pharmaceutical Agreement and have not negotiated an FTA with the UK, a 'Most-Favoured Nation' (MFN) tariff is applicable. MFN tariffs are set independently by countries and are imposed on imports from non-preferential trading partners.

Origin rules must remain robust enough to guarantee an element of local value-added in the UK in all cases, but simple and flexible enough to reflect the global realities of the pharmaceutical supply chain and encourage manufacturing in the UK. The easiest way to achieve this is by basing rules on common, defined chemical and pharmaceutical processing activities that make commercial sense and are easy for customs administrations to verify. A simplified and standardised approach to rules of origin should be adopted for all UK FTAs.

As heavily regulated products, pharmaceuticals are subject to careful monitoring as they cross borders and are placed on local markets. Overly complex and inefficient border processes can cause additional costs, delays and, in some cases, loss of product. As such, these processes should be as simple and expeditious as possible, while still keeping pace with the industry's innovation.

The UK government should consider its domestic approach to tariffs and customs and think strategically about what it is seeking to achieve in bilateral negotiations to support trade in health products.







Pillar 2

Safeguarding intellectual property as a foundation of innovation and economic development

The life sciences sector is highly innovative and highly valuable because of the significant investment made by pharmaceutical companies to research and develop new medicines, vaccines, therapeutics and health technologies. Once discovered, our industry has one mission for its products: getting them to the patients who need them wherever they are.

For every 10,000 compounds that are tested only one or two will successfully pass all stages of R&D and clinical trials to become marketable medicines. As such, the ultimate cost of a medicine is not simply the cost of manufacturing it, but the huge cost of discovery and development, which can take 12 to 15 years and cost up to £2.5 billion.¹² As well as enabling companies to take on the risks and costs of R&D, IP rights enable them to enter vital collaborations, including technology transfer agreements, knowing inventions are protected.

The UK's IP framework is one of the most robust in the world and is the bedrock for our industry's innovation, which is why we have seen continued R&D investment into the UK by private companies. Successive governments have understood that the complex and risky process of developing medicines and vaccines can only occur with the knowledge that successful innovation will not be imitated for a period of time during which the innovator can recoup this investment, which is then used to help fund subsequent innovative advances. Indeed, the Labour Party has said that in government it would strive to ensure reciprocal levels of IP protection in countries with which the UK trades, while maintaining our continued support of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹³

We believe that an international and trade strategy for life sciences should prioritise:

i. Safeguarding the international IP frameworks that support innovation in the UK and across the world

International bodies such as the WTO and the World Intellectual Property Organization (WIPO) set a global baseline of IP rules that countries are required to implement domestically.

At the WTO, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement^b sets a minimum standard of protection for a range of IP rights, including copyright, trademarks, patents and undisclosed information such as test data. The global IP framework that allows pharmaceutical companies to innovate depends on the maintenance of this agreement and continued action to ensure signatories implement the commitments they have made.

WIPO supports 191 member states to develop and implement a balanced IP framework that governs, among other things, technology transfer between publicly funded biomedical research institutions and commercial entities. WIPO plays an important role in dispute resolution, providing an international registration system for industrial designs and trademarks, and an international filing system for patents, which greatly simplify the process of seeking IP protection simultaneously in many countries.



These international rules support innovation across sectors by setting and promoting a baseline of protections that support investment into costly research.

The UK should play an active and vocal role in these institutions to support the preservation of a strong international framework. This is particularly important at a time when anti-IP sentiment is growing.

ii. Improving the value of UK IP exports

Periods of exclusive rights to market a particular product are at the heart of IP frameworks, provided by patent systems and other complementary mechanisms that have been introduced in the UK and many advanced economies to reflect the unique realities of pharmaceutical innovation.

In many countries across the world, the UK's scientific innovation is not given the same level of protection as the UK offers to both domestic and foreign innovators. If we are to increase the value of life sciences exports from the UK and retain the value of British products abroad, then the UK must push for trade partners to have reciprocal levels of protection. Without this reciprocity, the UK does not maximise its life sciences innovation and manufacturing sectors' economic value and contribution, which ultimately has an implication for UK growth and jobs.

It is therefore important that the UK uses its bilateral trade negotiations to seek reciprocally high IP protections. Robust IP protections and enforcement provide our companies with the confidence to invest in R&D knowing that they will have temporary exclusive rights to market any resulting new medicines and vaccines in export markets.

iii. IP diplomacy to support health outcomes and economic development in lower- and middle-income countries

The research-based pharmaceutical industry is a key sector for the future economic growth of many economies, while at the same time a significant contributor to the health and welfare of the billions of people across the globe. A meaningful and effective IP framework has three major benefits for lower- and middle-income countries.

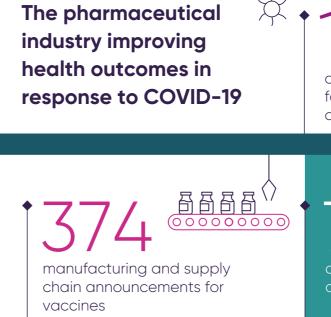
Firstly, a strong and effective IP rights regime supports the development of local innovation ecosystems, allowing local innovators to protect their assets. It also attracts foreign direct investment. This positive economic impact is the reason why China has been moving towards improving its IP framework,¹⁴ particularly as strengthened patent protection significantly impacts the scientific and technological capabilities of developing countries.

Secondly, the pharmaceutical industry improves health outcomes and product access in low- and middle-income countries by licensing medicines and vaccines on a voluntary and mutually agreed basis. These terms support companies to reach partnerships based on trust, prior experience and expertise, all enabled by IP protections that make the underlying innovation possible. The IP also provides confidence to innovators that they can share product designs, manufacturing technologies and know-how with others, including potential competitors, without misappropriation by parties. This was the case in the response to COVID-19, which saw 177 collaborations agreed for the production and commercialisation of treatments, and 374 manufacturing and supply chain announcements for vaccines, 71 per cent of which involved a collaboration. 84 out of the 93 voluntary licensing agreements for COVID-19 treatments were still active in June 2023 – 80 of which were in developing countries.¹⁵

Finally, the launch of an innovative medicine does not only result in an innovator company selling its product into a market. Rather, many of our companies support the training of healthcare professionals to support medicines' administration and build infrastructure required to facilitate delivery and other activities that strengthen the capacity of health systems.

Through its network of IP attachés, the UK government should work with industry to support lower- and middle-income countries in building their own IP systems to achieve better economic growth and health outcomes.





collaborations agreed for the production of treatments

of which involved a collaboration



for COVID-19 treatments were still active in June 2023

of which were in developing countries.





Pillar 3

UK leadership in multilateral negotiations and on global health issues

The COVID-19 pandemic brought into sharp focus the need to ensure the world is prepared for future health emergencies and build resilience in global health systems. There is also an increasing trend towards countries pursuing domestic industrial strategy goals within multilateral forums, at the expense of the frameworks on which the life sciences sector relies.

From international collaborations on science and research to supporting NGOs with their mission to build health capacity in low- and middle-income countries, a truly global view can support Britain's international development goals while enabling domestic economic growth.

i. Championing a 'trade and health' agenda at the WTO

Throughout the COVID-19 pandemic, the need to identify and remove trade barriers that hampered the cross-border flow of essential medical goods was fundamental to the global pandemic response. This included regulatory and production bottlenecks, manufacturing and input constraints, quota-based trade restrictions, and tariff barriers that exposed the logistical complexities associated with vaccine and medicine deployment.

The recent 12th and 13th WTO Ministerial Conferences – the highest decisionmaking body in the WTO – were missed opportunities to address issues concerning supply chain resilience that are integral to the WTO's framework. The UK has the opportunity to take a global leadership role to learn the right lessons from the pandemic, bringing forward a debate on new rules to strengthen the intricate logistical systems that proved vital in delivering lifesaving goods during the pandemic.

The UK has the opportunity to take a leadership role at the WTO to improve the functioning of globalised pharmaceutical supply chains.

This should include strengthening the innovation ecosystem and protecting IP, eliminating tariffs and limiting export restrictions, strengthening supply chains and improving trade facilitation, and enhancing the quality and effectiveness of regulatory policies and procedures.

ii. Safeguarding an innovation ecosystem at the WHO

Together with the direct role the WHO plays in ensuring universal health coverage and protecting people from health emergencies, the international frameworks negotiated by WHO member states play an important role in promoting public health and enabling a rapid research response to pandemic threats.

The COVID-19 pandemic has given renewed energy to proposals for access and benefit-sharing systems (ABS) at the WHO as well as the UN. Debates over a Pathogen Access and Benefit-Sharing (PABS) platform as part of the WHO negotiations are the latest example.¹⁶ Over the past decade, outbreaks such as Ebola have driven debate over how low-and middle-income countries are incentivised to support pathogen-sharing, and their ability to access the new products or IP that result from this R&D.

While decades-old proposals on ABS continue to evolve, the fundamental challenge is the creation of a transactional approach for researchers to access pathogen samples and genetic information, by incentivising countries to share pathogens and genetic information with research 'benefits' as compensation. A transactional approach to pathogen sharing in time-sensitive situations is not compatible with health security objectives.

With proposals under consideration that could involve a variety of parties, including states, industry, and intermediaries, there is a risk that a global PABS system could lead to significant delays to R&D in time-constrained pandemic situations. As seen with existing legal frameworks, even if benefits were pre-agreed, any legal complexity risks undermining a rapid response. Such a system will act as a disincentive for companies, particularly SMEs, to invest in responding to future pandemic threats.

The UK's strength and success in genomic surveillance and the impact of rapid sharing of this for COVID-19 on UK and global health security demonstrates the inherent risks of counterproductive access and benefitsharing mechanisms. Pathogen-sharing needs to be simplified, not made more complex. It is paramount that multiple negotiations and related policy frameworks do not result in distinct, duplicative, or stacked obligations on the biopharmaceutical industry and the UK government alike.

During negotiations, the UK should continue to push for a Pandemic Accord agreement that protects access to pathogens and upholds the ability of companies to pursue transfers of technology on a voluntary basis and under mutually agreed terms.

iii. Responding to the imminent threat of antimicrobial resistance

Antibiotics are the cornerstone of modern medicine, needed to treat common infections and support many routine healthcare procedures and treatments. The number of antimicrobial-resistant bacteria are on the rise. AMR is associated with close to 5 million deaths globally per year¹⁷ and is predicted to be the cause of 10 million deaths per year worldwide by 2050.¹⁸

The UK has played a leading role globally in efforts to develop policies to incentivise R&D for new antimicrobials, including a landmark project in England exploring how to fix a 'broken' market for antimicrobials with a proof-of-concept pilot for two antibiotics for use on the NHS.

Together with national implementation of this work, the UK should work with partners around the world to galvanise global action and share the lessons from the solutions the UK has crafted.

Under the leadership of Dame Sally Davies, the UK Special Envoy on AMR, the UK is already in a good position to take this forward through bilateral and multilateral relationships.





iv. Supporting a development agenda

The UK should rightly be proud of the role it has played in supporting lower- and middle-income countries on health threats, consistent with its commitment to the UN SDGs – in particular, Goal 3 to achieve Universal Health Coverage (UHC). This is an objective that the international pharmaceutical industry supports: beyond pioneering the R&D into new treatments, including for neglected diseases, our industry supports programmes that help get innovative medicines to the people who need them.

Part of this is about helping to build resilient health systems that allow for medicines and vaccines to reach patients, while another is focusing research efforts on diseases that impact communities and patients that have traditionally been neglected. Our industry also plays a role in supporting emergency responses, including humanitarian aid. All of this work is done in collaboration with national governments, multilateral organisations (the WHO, Global Fund, Gavi), research institutions, product development partnerships, community organisations and nongovernmental organisations, which provide the backbone for the delivery of international development aid and support on public health threats. Plans to meet the government's commitment to restore development spending at the level of 0.7 per cent of GDP should consider how to support the key multilateral organisations – critical for the delivery at scale of innovative solutions – to deliver their mission, and how this can be done in a way that also supports a thriving life sciences sector here in the UK.

By using international and development levers the UK government can address health threats and support low- and middle-income countries while also supporting innovative research, development and domestic manufacturing.



Conclusion and recommendations

Ensuring the UK remains an attractive destination to invest by supporting the life sciences sector, including with a strategic view of how to best deploy international and trade policy to further enable manufacturing and exporting from the UK, can help to drive growth and reach the government's clear missions.

If the UK were to increase its share of global pharmaceutical exports by 4 per cent, for example, as both Germany and Ireland have done, it would add £16.3 billion to the national economy.¹⁹

Such value would be added not only in direct revenue for the Exchequer from business performance both exporting more or higher-value products and licensing IP, but also from high-quality manufacturing jobs that typify the life sciences sector. From researchers to advanced production, the life sciences sector is an innovative industry of the future; one that the government has rightly identified for the potential it has to deliver.

Working to remove trade barriers to medicines and vaccines made here, alongside robust IP protections and sophisticated regulatory regimes that can support our products to enter new and existing markets, will boost the value of British exports abroad. By safeguarding the supply of existing products and fostering a thriving ecosystem for the research and development of new medicines, vaccines and therapeutics, such a strategy would secure patient access to medicines here and abroad. The mission of our companies is to make their products as widely available as possible, and the UK can play a pivotal work in supporting access in other parts of the world by encouraging IP frameworks that allow for export, building regulatory capacity and demonstrating best practice.

Policy recommendations – priority actions

Delivering the objectives outlined in this international and trade strategy for the life sciences will require specific actions and positions to be pursued by the UK government as a first step.

1.

Promoting high regulatory standards globally that keep patients safe and addressing market access barriers to safeguard supply chains:

agreeing a mutual recognition agreement with the EU that includes the batch testing of medicines, removing an unnecessary and duplicative barrier for UK exporters

2.

Safeguarding intellectual property as a foundation of innovation and economic development:

- enshrining Labour's commitment to reciprocal levels of IP protection in UK trade partners and support of the TRIPS Agreement into the government's trade strategy
- delivering on the commitment to reciprocal IP protections in all trade agreements the UK secures, including in any FTAs with India or Switzerland

3.

UK leadership in multilateral negotiations and on global health issues:

- Ieading the development of a trade and health agenda at the WTO to reduce barriers and build greater capacity and resilience in the supply of critical medicinal goods to patients across the world
- push for a balanced outcome in WHO Pandemic Accord negotiations that protects access to pathogens and upholds the ability for companies to pursue transfers of technology on a voluntary basis and under mutually agreed terms
- continue to demonstrate the UK's leadership in driving global action in the fight against AMR



abpi

References

- 1 Office for National Statistics, 'Regional gross value added (balanced) by industry: all ITL regions', 2021, available at <u>www.ons.gov.uk/economy/grossvalueaddedgva/datasets/</u> <u>nominalandrealregionalgrossvalueaddedbalancedbyindustry</u>
- 2 Office for National Statistics, 'Industry census data 2021', available at <u>https://www.ons.gov.uk/census/census2021dictionary/variablesbytopic/labourmarketvariablescensus2021/industrycurrent</u>
- 3 Office for National Statistics, 'Trade in goods: country-bycommodity exports', 2024, available at <u>www.ons.gov.uk/</u> <u>economy/nationalaccounts/balanceofpayments/datasets/</u> <u>uktradecountrybycommodityexports</u>
- 4 Office for National Statistics, 'Regional gross value added (balanced) by industry: all ITL regions', 2021, available at <u>www.ons.gov.uk/economy/grossvalueaddedgva/datasets/</u> <u>nominalandrealregionalgrossvalueaddedbalancedbyindustry</u>
- 5 Office for National Statistics, 'Industry census data 2021', available at <u>https://www.ons.gov.uk/census/census2021dictionary/variablesbytopic/labourmarketvariablescensus2021/industrycurrent</u>
- 6 Office for National Statistics, 'Trade in goods: country-bycommodity exports', 2024, available at<u>www.ons.gov.uk/</u> <u>economy/nationalaccounts/balanceofpayments/datasets/</u> <u>uktradecountrybycommodityexports</u>

- 7 Office for Life Sciences, 'Life sciences competitiveness indicators 2024: summary', July 2024, available at <u>www.gov.uk/government/</u> <u>publications/life-sciences-sector-data-2024/life-sciences-</u> <u>competitiveness-indicators-2024-summary</u>
- 8 HM Government, 'National Risk Register', 2023, available at <u>www.gov.uk/</u> <u>government/publications/national-risk-register-2023</u>
- 9 Labour Party, 'A prescription for growth, Labour's plan for the life sciences sector', June 2024, available at <u>https://www.bioindustry.org/ static/6d6bb7a2-d7e5-4abc-bad4ee8fc02c1c17/Labours-plan-forthe-life-science-sector.pdf</u>
- 10 Geneva Network, 'How tariffs impact access to medicines', June 2021, available at <u>https://geneva-network.com/research/how-tariffs-</u> <u>impact-access-to-medicines</u>
- 11 Office for National Statistics, 'Bioscience and health technology sector statistics 2019', available at <u>www.gov.uk/government/statistics/</u> <u>bioscience-and-health-technology-sector-statistics-2019</u>
- 12 Deloitte, 'Seize the digital momentum', January 2023, available at <u>https://blogs.deloitte.co.uk/health/2023/01/seize-the-digital-</u> <u>momentum-measuring-the-return-from-pharmaceutical-innovation.</u> <u>html</u>

- 13 Labour Party, 'A prescription for growth, Labour's plan for the life sciences sector', June 2024, available at <u>https://www.bioindustry.org/</u> <u>static/6d6bb7a2-d7e5-4abc-bad4ee8fc02c1c17/Labours-plan-for-the-</u> <u>life-science-sector.pdf</u>
- 14 Chi, X., Li, M., Sun, H. et al., 'Strategizing intellectual property rights for enhanced innovation: the moderating effects of R&D and FDI in China's regional context', Journal of the Knowledge Economy, 2024 (<u>https://doi.org/10.1007/s13132-024-02133-2</u>)
- 15 Airfinity, 'How different partnership models supported the response against COVID-19', June 2023, available at <u>https://www.ifpma.org/wpcontent/uploads/2023/05/Airfinity_IFPMA_C19TxVx_20230607.pdf</u>
- 16 World Health Organization, 'Proposal for negotiating text of the WHO Pandemic Agreement', October 2023, available at <u>https://apps.who.</u> int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf_
- 17 Antimicrobial Resistance Collaborators, 'Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis', Lancet, 2022, 399(10325), 629–55. (doi: 10.1016/S0140-6736(21)02724-0)
- 18 World Health Organization, 'New report calls for urgent action to avert antimicrobial resistance crisis', Apr 2019, available at <u>www.who.int/</u> <u>news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-</u> <u>antimicrobial-resistance-crisis</u>
- 19 PwC & ABPI, 'Life sciences superpower: growing the leading global hub in the UK', June 2022, available at <u>www.abpi.org.uk/r-d-</u> <u>manufacturing/building-a-thriving-environment-for-medicine-</u> <u>discovery/life-sciences-superpower-growing-the-leading-global-</u> <u>hub-in-the-uk</u>



The Association of the British Pharmaceutical Industry

Dit faccuptat inctus a dolupid mi, qui que restia voloritate vendele cestion perci doluptas acesequas aut minvell oreprore quod ma coratur, temped et expedit untis doluptate verspe con conem iliquam repelluptati unt

