abpi
Bringing medicines to *life*

Creating trade policy for a life sciences superpower

March 2021

Contents

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Executive summary

#1
biotech cluster in Europe

2,000+
UK patent applications in the past 10 years

£23bn+
exported to patients across the world

Global
life sciences hub

The UK is a life sciences superpower. Its exceptional strength in the research and production of world-class medicines and vaccines has developed over many decades out of a strong science base, open approach to foreign investment in pharmaceuticals, a skilled manufacturing workforce, and robust culture of protecting innovation through intellectual property (IP) rights. Its regulators are recognised as among the most experienced and sophisticated in the world.

This ecosystem enables the UK pharmaceutical sector to thrive as a major exporter of life-saving medicines to patients across the globe. Over £23 billion worth of medicinal and pharmaceutical products were exported around the world in 2019.[1] This figure is over double the £11.4 billion worth of branded medicines procured by NHS England in the same year, illustrating the scale and importance of UK pharmaceuticals as a fundamentally export-oriented sector.[2]

As well as exporting vital medical goods, the UK also exports life science ideas – licensing treatments for production, converting its own IP into manufactured medicines in markets around the world, and shaping debates about the present and future of medicines regulation and pharmaceutical innovation.

The sector's strength is already recognised in the Life Sciences Industrial Strategy, where the Government has laid out its vision for transforming the UK into a global life sciences hub. Outside of the EU, the UK needs a trade policy that aligns with this goal and is fully customised to its unique features: enabling the sector to pull in the imports, talent, and capital it needs for world-class science and manufacturing, and ensuring it can export UK pharmaceutical innovation easily and compete fairly in export markets.

As pharmaceutical products make up the largest proportion of UK life science exports, this report focuses on how the UK's trade policy should support the growth of the UK innovative pharmaceutical industry, as part of its aspiration to become a life sciences superpower.

Executive summary

A trade policy for the pharmaceutical sector can and should encompass all these aspects in a single strategic vision that supports the Government's broader industrial policy and public service priorities. This vision can then inform a consistent UK approach to Free Trade Agreements (FTAs) and wider trade policy.

To achieve the Government's ambition for the UK to thrive as a life sciences superpower, the Association of the British Pharmaceutical Industry (ABPI) believes the Government should establish three core pillars for its trade policy for pharmaceuticals.

Summary of ABPI recommendations: three pillars for a strategic UK trade policy for the pharmaceutical sector

Protect & promote UK scientific innovation

- Develop an 'IP diplomacy' strategy to promote UK standards in export markets.
- Ensure that preferential trading partners commit to a clear baseline of best practice for IP that reflects current UK standards, to make sure the value of UK scientific innovation is fairly recognised and rewarded overseas.
- Ensure that pricing and reimbursement processes are fair, transparent and do not discriminate against UK companies.

Increase regulatory coherence & pioneer new pathways

- Leverage the UK's acknowledged credibility as a medicines regulator and producer of innovative pharmaceutical policy to encourage all countries to regulate medicines to the highest international standards.
- Develop and deepen formal channels of cooperation on medicines regulation to remove duplicative processes that cause unnecessary costs and delays.
- Work collaboratively with regulatory peers to pioneer new thinking behind novel regulatory pathways.

Streamline the pharmaceutical supply chain

- Ensure the full elimination of tariffs on medicines and pharmaceutical inputs, accompanied by simple rules of origin to encourage and to support UK pharmaceutical manufacturing.

1. The foundations of a trade policy for the UK pharmaceutical sector

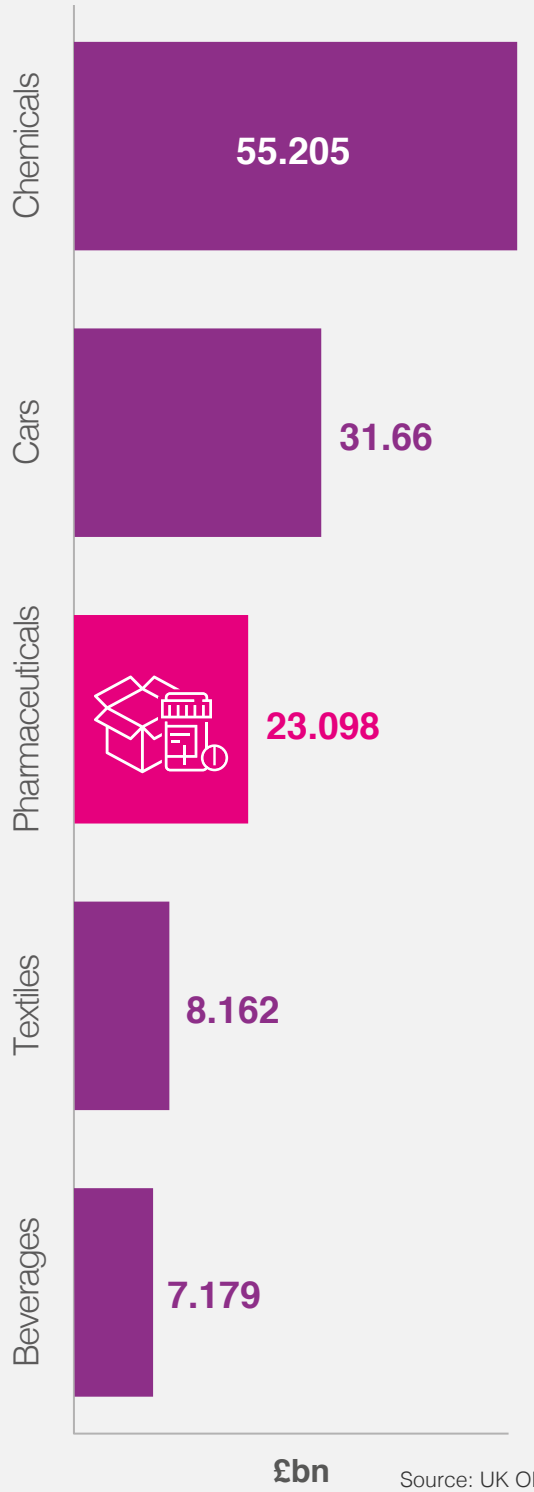
The pharmaceutical sector is a major source of UK exports. Medicinal and pharmaceutical products are the UK's third largest category of goods exports after chemicals and cars, accounting for 6.3% of total goods exports and generating £23 billion in exports in 2019 (Fig 1).[3]

The sector's IP also generates significant value in export markets, as pharmaceutical companies license their innovations to ensure medicines can be sold in markets around the world.

The sector's success is underpinned by policy choices both at home and abroad. In the UK's export markets, policy decisions affect how pharmaceutical innovation is valued, protected, and regulated for patient safety and market approval. Domestically, some of the most important choices are those which support the UK as an attractive location for research, development, and manufacturing. The UK is a major recipient of foreign direct investment (FDI) in pharmaceuticals and a global centre for pharmaceutical research and development (R&D). Our robust IP framework and world-class regulators encourage research and investment into the long, complex, and costly process of developing new medicines here in the UK.

As such, the UK pharmaceutical sector has attracted over £11 billion in inward investment over the past two years.[4] The industry invested £4.8 billion into R&D in the UK in 2019 – making it both the leading sector for overall investment in R&D and growth in R&D expenditure.[5] This in turn powers domestic pharmaceutical manufacturing, with a highly skilled and highly productive workforce in more than 850 research and manufacturing sites across the UK.[6]

Figure 1. UK goods exports 2019 selected finished commodities



Source: UK ONS

The UK's top 20 export markets for pharmaceutical products in 2019

£mn

£23098
World

Key sources of APIs and other manufacturing inputs: EU, US, China, India, Switzerland.

Germany	**£2430**
Belgium	**£784**
Netherlands	**£1560**
France	**£977**
Spain	**£652**
Ireland	**£1206**
Italy	**£434**

£510 Canada

£5970 United States

£125 Mexico

£425 Switzerland

£9199 EU

£295 Russia

£186 Israel

£314 Saudi Arabia

£182 UAE

£1571 China

£202 South Korea

£758 Japan

£178 Brazil

£555 Australia

Key frameworks for UK pharmaceutical exports

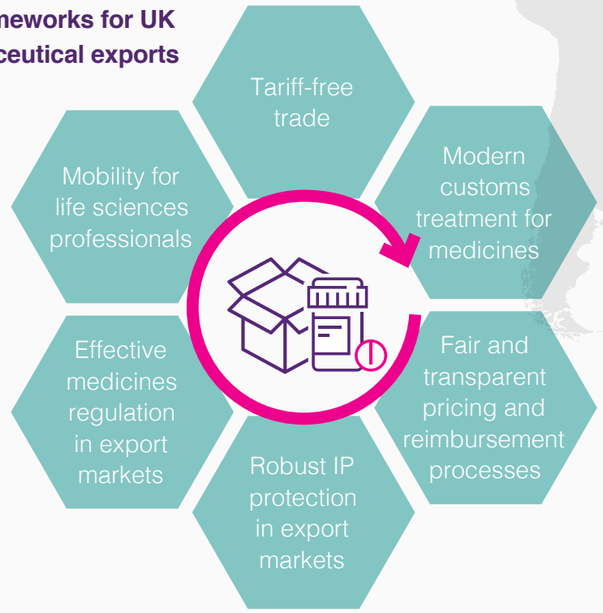
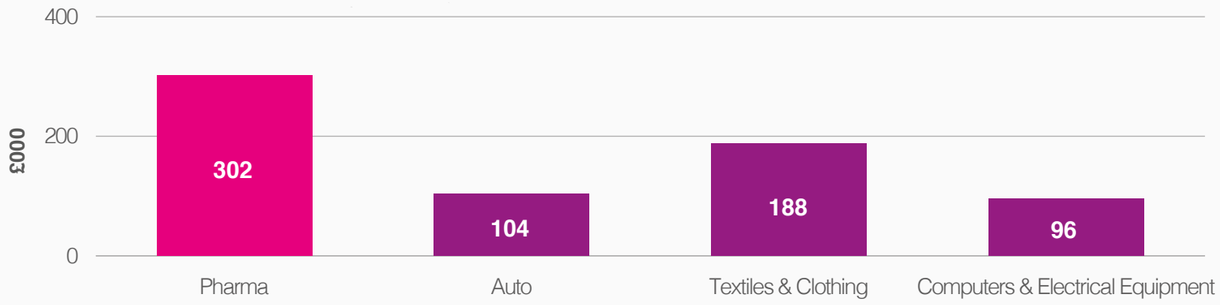


Fig 2. High-productivity workers underpin pharmaceutical exports



GVA per manufacturing worker, selected sectors 2019

Source: UK ONS

The three pillars of a trade policy for the UK pharmaceutical sector

A strategic trade policy for the UK pharmaceutical sector has the power to translate domestic capability into export strength, making a vital contribution to every stage of the innovation, production, and distribution chain. The following three key pillars are at the heart of the ABPI's vision for a strategic trade policy that contributes to securing the UK's status as a life sciences superpower:

1. Protect and promote UK scientific innovation

Pharmaceutical innovation is uniquely capital-intensive in the product development phase, requiring large investments in R&D for each medicine produced. This should be supported by:

- Strong IP frameworks in the UK and export markets that ensure a fair return on development costs, allow for fair competition and a level playing field in partner trade markets.
- Pricing and reimbursement processes that are fair, transparent, do not discriminate against UK companies and appropriately value UK innovation in export markets.

This approach will ensure that the value of UK scientific innovation is not undercut in export markets and provides pharmaceutical companies with the certainty needed to continue investing in the high-risk process of medicines development. This will in turn support the position of the UK as a global hub for life sciences, boosting inward investment and creating highly skilled and productive jobs across the country.

2. Increase regulatory coherence & pioneer new pathways

Regulatory frameworks for medicines shape the way they are made, authorised, and distributed. These frameworks should be supported by:

- Building on the acknowledged credibility of the UK's Medicines and Healthcare products Regulatory Agency (MHRA) as a world-leading medicines regulator, to promote the highest international regulatory standards: through formal cooperation agreements, regulatory dialogues and via international fora.
- Fostering greater international regulatory coherence to remove duplicative processes that cause unnecessary costs and delays.
- Collaboration with regulatory peers to pioneer and shape visionary thinking on novel regulatory pathways, in areas such as gene therapy, tissue-engineered medicines, and artificial intelligence (AI).

Increased regulatory coherence can support UK exports by removing duplicative processes that cause unnecessary costs and delays, and help to align important regulatory approaches as they emerge. This supports the UK's public service priorities by allowing regulators and companies to focus on getting medicines and vaccines to the people who need them, in no way limiting UK governments' freedom to define the policies of the NHS.

The UK pharmaceutical sector attracted

£11bn+

investment over the past two years

3. Streamline the pharmaceutical supply chain

Streamlined supply chains avoid duplicative requirements during the manufacturing and export of vital medicines. This should be supported by:

- Tariff-free access to key export markets.
- A UK market that is open for the import of raw materials for research and manufacturing, which underpins UK exports.
- Simple and transparent customs processes for pharmaceuticals and other health technologies.
- Proportionate trade responses to public health emergencies, avoiding counterproductive restrictions on imports and exports.

Improving the efficiency of manufacturing and supply chains makes it easier for UK companies to export their goods around the world and ensures that medicines are developed at a competitive cost. This allows companies to manufacture at scale and helps to deliver the best possible treatments and value to health systems like the NHS.

The trade policy toolkit

The ABPI sees four basic tools available to promote and champion a trade policy for the UK pharmaceutical sector.

A strategy built around these pillars, utilising these tools can reinforce the role of the UK as a global platform for developing, manufacturing, and exporting world-class pharmaceuticals. The next three sections of this ABPI report set out a strategic vision for UK trade policy for each of these pillars.

FTA negotiations

FTAs are a vital way of aligning and locking in common high standards in the UK and with any trading partner. They can provide a joint commitment to robust IP protection, tariff liberalisation, openness to investment and effective medicines regulation by binding best practice in both markets, which enhances the value of export markets.

Regulatory diplomacy

As a highly regulated sector, the conditions of medicines regulation in export markets are a key determinant of UK export success. Strong links between UK regulators and their peers can support convergence in regulatory practice, aligning approaches to emerging regulatory questions and formally recognising UK 'gold-standard' approaches, or those similar in partner countries, in a way that reduces duplicative processes for exporters.

The WTO framework

The WTO framework has a number of elements specifically targeted to trade in pharmaceuticals that urgently need updating to reflect technological change and medical advancement – such as the WTO Pharmaceutical Tariff Elimination Agreement. The UK can and should advocate for these changes and encourage adoption of, and adherence to, important international rules on public procurement, technical regulation of pharmaceuticals, and IP.

Unilateral policy in the UK

There are a range of choices the UK can make for its own framework that will support its performance as a life sciences superpower. Outside of the EU, the UK can set its general external tariff at the appropriate level to ensure competitive costs for manufacturing inputs and continue to enhance its robust framework for protecting IP to enable timely patient access to new medicines in the world.

2. Promoting and protecting scientific innovation

Many modern export sectors are highly-innovative, but few require the level of scientific innovation that is needed to discover and develop a life-transforming medicine. This can entail years of research and significant investment in lengthy clinical trials that have high rates of failure.

For every 10,000 compounds that are tested, for instance, only one or two will successfully pass all stages of R&D and clinical trials to become marketable medicines.[7] As such, the ultimate cost of a medicine is not simply the cost of manufacturing it, but the huge cost of discovery and development.

> **The UK IP framework is one of the most robust in the world and forms the bedrock of our industry's innovation.**

This is why the UK has always sought to ensure that patients have broad access to innovative treatments while providing strong IP rights to support our sector's investment in R&D. The complex and risky process of developing medicines and vaccines needs the incentive of knowing that successful innovation will not be imitated without a period in which it can be appropriately rewarded. IP protection enables pharmaceutical companies to both recoup their initial costs and continue investing in the high-risk process of medicines development. Crucially, this does not mean the NHS pays higher prices for access to our sector's innovative treatments. In fact, the UK has one of the most rigorous systems in the world to make sure the NHS gets value for money.

The UK IP framework is one of the most robust in the world and forms the bedrock of our industry's innovation. In part, it reflects the culture of scientific innovation and internationalism that has long been encouraged in the UK. The UK should be proud of the fundamentals of this framework and the simple aim of UK trade policy should be to promote these standards and explore opportunities for mutual enhancement in a way that supports innovation, development, and timely patient access to medicines.

Central to the UK life sciences IP framework are periods of exclusive rights to market a particular product. These are provided by the patent system and other complementary mechanisms which 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 at home. This reduces the opportunity to export our innovative products and detracts from the overall value of our sector's exports, which ultimately disincentivises UK companies from investing in the high-risk process of medicines development.

Recommendation

The IP provisions in UK FTAs should reflect current UK standards in order to avoid cutting-edge UK innovation being undervalued in overseas markets. Anyone seeking to sign a trade agreement with the UK should be willing to sign up to these existing UK standards of protection as a condition of preferential trade.

This will not only boost the immediate value and opportunity for UK pharmaceutical exports, but will sustain future investment in scientific innovation here in the UK. This in turn supports the cultivation of a skilled manufacturing and commercial life sciences workforce in every region of the country.

Patent term extension or equivalent[8]

Patents are at the heart of protecting and encouraging cutting-edge innovation in life sciences. The basic life of a patent is generally 20 years, and this term is set from the moment a patent is applied for.

In the UK, 'Supplementary Protection Certificates' (SPCs) are available for pharmaceutical products to reflect the fact that a material part of the life of a patent can be used up during development (pre-clinical activities and clinical trials) and obtaining the authorisation required to market a product. This process often takes between eight to 12 years and means that by the time a medicine can be sold, and manufacturers rewarded for the value of their innovation, a large amount of the patent term will have expired.

The SPC provides up to an additional five years of protection upon patent expiry, to compensate for the time taken to secure marketing authorisation. Some, but not all, other countries have a similar mechanism in place to extend patent rights, although the period of extension can be calculated in different ways and in some cases the scope of protection is narrowly applied (Fig 3).

Fig 3. Patent term extension (PTE) in countries engaged in trade negotiations with the UK

Country	Maximum length	Scope
UK	**5 years**	**Available for all basic patents**
US	5 years	Available for all basic patents
Australia	5 years	Not available for all basic patents
New Zealand	2 years	

Recommendation

A core component of the UK's future trade policy should be encouraging and ensuring that trading partners introduce and implement PTE for all types of basic pharmaceutical patents with compensatory protection for developmental delays, with a term and scope consistent with the current UK standard. This will ensure that our scientific innovation is fairly valued in overseas markets, safeguarding the value of UK exports.

Regulatory data protection

The data required to prove that an innovative medicine is safe, effective, and to subsequently gain marketing authorisation is extensive and very costly to produce.

Companies seeking to obtain approval for generic or biosimilar medicines do not have to produce such data, and instead, essentially use a simplified marketing authorisation procedure under which they only have to prove their product is similar to that of the innovator. The generic company relies on, and is able to benefit from, the extensive investment and efforts of the innovator.

To protect the value of the innovator's investment and incentivise pharmaceutical innovation, the UK prevents the simplified marketing authorisation procedure from taking place for 10 years[9] from the UK approval of the innovator medicine.

Regulatory data protection (RDP) is distinct from, but complementary to, patent protection. It usually runs alongside the patent protection term and does not extend the period of exclusivity that patents and SPCs provide. It is important as an 'insurance policy' in cases where there is inadequate patent protection.[10]

RDP is especially important for biological medicines that use material derived from living organisms, such as a protein or other substances produced in the body. Compared to traditional pharmaceuticals, biologics are more structurally complex and are often not adequately covered by patents. RDP helps provide some protection for companies developing innovative biologic products where patents do not.

Globally, where it exists at all, the term and scope of RDP varies between jurisdictions (Fig 4). For the term of protection, the highest standards that exist globally are 12 years of RDP for biological preparations and 10 years for small molecule medicines starting from the date of marketing approval.[11]

Recommendation

Ensuring that at a minimum, trading partners introduce and implement RDP in line with current UK standards should be a key part of any future UK trade agreement.

This will ensure that pharmaceutical companies continue to invest in pharmaceutical R&D and manufacturing in the UK. This approach will not affect the price the NHS pays for medicines.

Fig 4. RDP in countries engaged in trade negotiations with the UK

Country	Biological medicines	Small molecule medicines
UK	**10 (+1)**	**10 (+1)**
US	12	5 (+3)[12]
Australia	5	5
New Zealand	5	5

Pricing and reimbursement

The UK Government and pharmaceutical industry share a common goal to ensure that patients globally have timely access to UK innovation.

However, the ABPI also acknowledges the affordability challenges faced by many healthcare systems and therefore advocates for FTAs to promote the use of non-discriminatory pricing and access solutions to ensure that innovation is appropriately valued by a fair, efficient, and transparent process. This process should sustain the incentives for future medical innovation while recognising concerns about the affordability of innovative medicines.

In many markets, governments are by far the single largest buyer of medicines or they set policies for the reimbursement of medical costs that, for example, dictate the price of medicines or whether they can be purchased by public healthcare systems at all. The pricing and reimbursement policies of some governments can lack transparency in terms of the process behind decision-making and/or contain a bias towards domestic producers, the latter of which has the potential to present non-tariff barriers in export markets. These barriers directly impact the economic value of exports and impose unfair terms for innovative UK pharmaceutical exporters.

Recommendation

The UK should ensure that the pricing and reimbursement processes applied to pharmaceutical innovation by trading partners comply with international standards, and do not discriminate against UK companies. This ensures that UK scientific innovation receives a fair return on development, manufacturing, and commercialisation costs.

The trade policy toolkit for promoting and protecting UK scientific innovation

FTA negotiations

FTAs should aim to 'lock in' a high baseline of IP protection as close as possible to the UK's own standards as a condition of preferential trade. They should guarantee the provision of extended patent protection to compensate for medicines development and approval time and RDP, ideally for the time provided in UK law.

Regulatory diplomacy

'IP diplomacy' should be a core part of the UK's international regulatory and standards strategy in global fora. This should include active promotion of UK IP standards and engagement by UK embassies in key export markets.

The WTO framework

The WTO TRIPS framework confirms the most basic rights to IP protection in the global economy. The UK should be a firm defender of the 'TRIPS baseline' while seeking to build on it through FTAs and regulatory diplomacy. In addition, an important group of WTO members have used the WTO Government Procurement Agreement (GPA) to make binding commitments to ensure a level of fairness and non-discrimination between local and foreign suppliers in the procurement of medicines.

Unilateral policy

The UK should preserve its commitment to strong IP protection to ensure it remains a global example.

3. Medicines regulation and policy

Medicines are rightly one of the most heavily regulated products in the world. Pharmaceutical products are closely monitored in the UK for safety, requiring authorisation for marketing, manufacturing, distribution, and packaging. The UK's high regulatory standards ensure that innovative treatments reach patients in a safe and timely manner.

Promoting the highest international standards for medicines regulation

The UK's MHRA is one of the world's most respected medicines regulators. It is renowned for its rigorous assessment standards and dedication to patient safety.

Now no longer part of the European medicines regulatory network, the MHRA can seek to use its influence to promote its 'gold-standard' regulatory frameworks and develop innovative practices as new technologies are introduced. This can be achieved alongside or independently from FTAs through formal cooperation agreements, regulatory dialogues and via international fora.

The COVID-19 pandemic has highlighted that robust, reliable, and consistent regulatory standards are critical for maintaining public trust in medicine safety. Expeditious authorisation processes are equally vital to ensure timely patient access to new medicines and vaccines. By maintaining these high regulatory standards, a strategic trade policy for the UK pharmaceutical sector can minimise frictions and barriers to the cross-border flow of medicines through cooperation and, where possible, convergence and mutual recognition of regulatory systems.

Increasing regulatory coherence

Different countries regulate medicines in different ways. This adds considerable complexity to the process of developing a marketable medicine.

It can also mean that companies face duplicative requirements in areas such as inspection of manufacturing sites and obtaining batch testing certificates, causing unnecessary costs and delays. These non-tariff barriers are often less visible than taxes or duties applied to goods that are traded across borders, but their impact is the same: they create barriers to trade that companies spend time and money having to navigate. This ultimately increases the time that patients and health systems must wait for access to new medicines.

Increased regulatory coherence can reduce all three of these burdensome factors – time, cost, and complexity – and can be achieved by ensuring the UK's high standards are promoted around the world and formally recognised through mutual recognition agreements (MRAs). MRAs involve UK partners agreeing to recognise good UK practice in their own regulatory assessments and vice versa. This has a material impact on reducing non-tariff barriers for pharmaceutical companies by removing duplicate requirements and minimising border paperwork. This ultimately enables faster patient access to medicines and allows resources to be focused on advancing innovation and getting medicines and vaccines to the people who need them.

Pioneer new thinking behind regulatory pathways for emerging technologies

The MHRA is renowned for its role in setting new regulatory pathways for emerging treatments and technologies. These range from regulatory frameworks for the development of advanced therapeutic medicinal products (ATMPs), which are ground-breaking medicines made from genes, tissues, or cells to regulatory decision-making based on 'Real World data' (RWD), which relates to observational data gathered in experimental settings.

Establishing dialogues on emerging fields between the MHRA and its regulatory peers is necessary to ensure that medicines regulation keeps pace with the fast-moving and innovative nature of the pharmaceutical industry. It will also allow the UK to promote its own standards as best practice in a way that minimises divergence from our major trading partners, allowing UK innovation to be protected in export markets and reach patients across the world.

To support its status as a life sciences superpower, the ABPI believes the UK should continue to pioneer regulatory pathways in the following areas:

- The development and authorisation of ATMPs, such as gene therapy and tissue-engineered medicines.
- The development of standards and ethical principles for the application of digital technologies in R&D, including AI and machine learning.
- Environmental and sustainability standards, especially relating to the use of plastics in pharmaceutical packaging and manufacturing.
- Data-sharing and security standards for medicines, especially to facilitate the cross-border transfers of clinical trial data under conditions of robust data security for consideration by third-party regulators.
- The use of RWD and evidence in regulatory decision-making.

Recommendation

The UK should pursue opportunities for regulatory cooperation with key trading partners as part of its trade agenda to secure the position of the MHRA as a gold-standard medicines regulator at the forefront of developing new and innovative regulatory pathways.

A forward-looking regulatory diplomacy strategy will help to align important regulatory approaches as they emerge, ensuring the UK remains at the forefront of advancing emerging technologies. It will also enable the UK to remain a competitive destination for life sciences investment in R&D and manufacturing, supporting the creation of highly skilled and productive jobs across the country.

The trade policy toolkit for medicines regulation and policy

FTA negotiations

UK FTAs should aim to capture elements of medicines regulatory cooperation in binding commitments to follow shared best practice. Pre-existing MRAs should be incorporated into FTAs to give them a strong rooting in FTA governance frameworks.

Regulatory diplomacy

Regulatory diplomacy should focus on leveraging the UK's acknowledged credibility as a medicines regulator and producer of pharmaceutical policy. In particular, the UK should seek to use cooperation frameworks to:

- Prevent unhelpful divergence in medicines regulation.
- Pioneer innovative regulatory pathways in areas of emerging technology, such as ATMPs, AI, machine learning, sustainability standards and the use of RWD.

Where appropriate, this cooperation should be codified in memoranda of understanding (MOU) or MRAs that reduce the need for duplicative processes such as manufacturing site inspections and batch testing for imports.

Unilateral policy

Outside of the EU, the UK can explore regulatory changes to increase pharmaceutical innovation. Innovations from the COVID-19 pandemic, such as new data dashboards and telemedicine, can be consolidated in the longer term to support a sector that is more readily able to embrace emerging health technologies. This approach will contribute not only to the strength and competitiveness of our sector, but the overall resilience of our healthcare system in the years to come.

4. The pharmaceutical supply chain

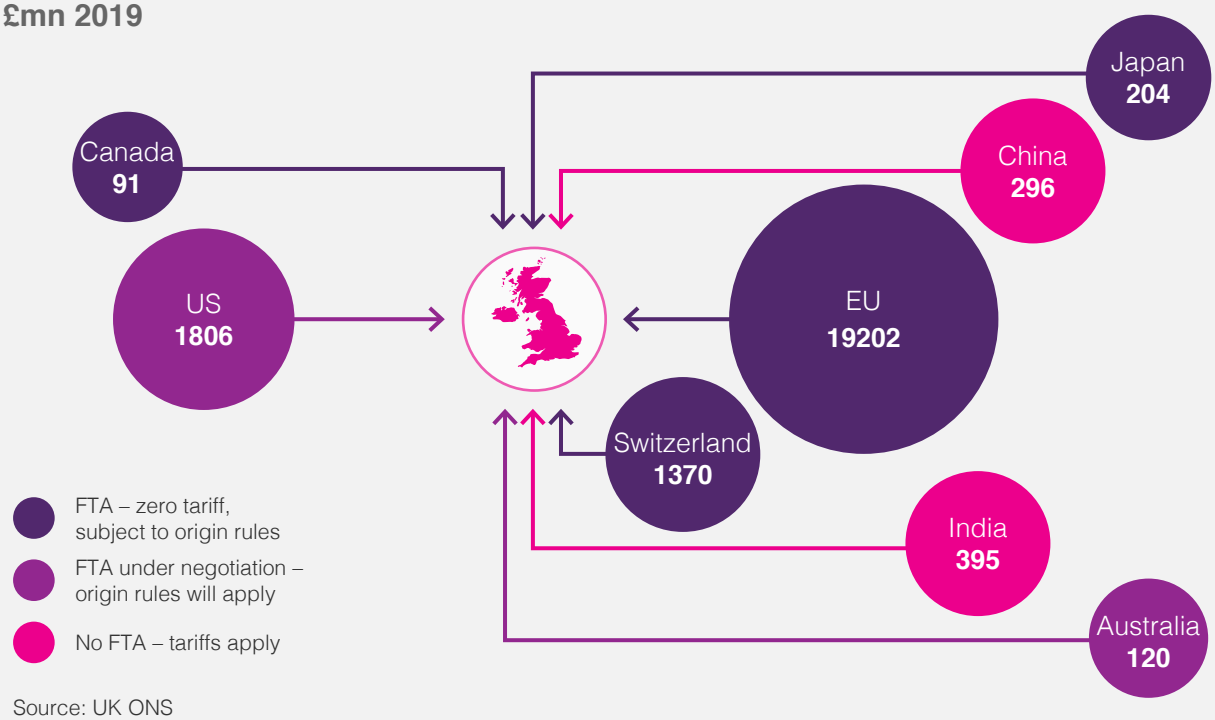
The UK pharmaceutical sector supplies a global market, using imported pharmaceutical inputs from around the world for manufacturing and transformation. Over decades, companies have carefully built robust supply chains to ensure patients in the UK and around the world have ongoing access to medicines.

The truly global nature of the pharmaceutical supply chain means that at-the-border costs and bureaucratic burdens have a material impact on the ability of UK pharmaceutical companies to produce medicines. Addressing these should be an important part of a trade policy for the UK pharmaceutical sector, ensuring a reliable and resilient supply of medicines for patients everywhere.

The COVID-19 pandemic has underscored the importance of supply chain reliability. Although the crisis has prompted policymakers to look closely at the question of dependence on imported medicines and inputs, the story of the pharmaceutical sector has been one of incredibly resilient supply. Our well-established global supply chains have made it possible for the industry to meet the exponential increase in global demand for certain classes of medicines required for the COVID-19 response. As such, strengthening and diversifying global supply chains is key to ensuring future supply resilience for medicines.

Even outside of times of crisis, there will always be a need to rely on cross-border trade of manufacturing inputs and finished products to ensure continuity of medicine supply to patients across the world. Global supply chains ensure that medicines are developed efficiently and that companies can manufacture at the scale needed to provide the volumes required to serve all patients across the world. This helps to deliver the best possible value to health systems like the NHS, and provides industry with the flexibility to respond to surges in demand.

Fig 5. Key UK import partners for pharmaceuticals
£mn 2019



Source: UK ONS

Tariff elimination

Tariffs impose a direct cost on trade in medicines and pharmaceutical ingredients, as well as R&D.

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 US, Canada, Australia, Japan, Norway, and Switzerland). However, the list of APIs covered in the agreement was last updated over a decade ago and is now substantially out of date, unable to keep up with the industry's scientific and technological development. This is especially problematic for small and medium-sized enterprises (SMEs) who produce APIs that are integral to the supply chain. The failure to update this list means that more than 600 innovative new APIs developed over the last decade continue to be taxed when traded across borders.

For non-signatory countries, tariffs on medical products vary between jurisdictions. Finished medicines, APIs, intermediates and starting materials can all be subject to tariffs.[13] 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. They can be eliminated through FTA negotiations, which provide an opportunity for the UK to secure zero-tariff trade on all finished medicines and materials used in the research, development, and production of pharmaceuticals.

Recommendation

The UK must ensure that all FTAs eliminate tariffs on medicines and pharmaceutical inputs, and should be a leading voice at the WTO in advancing the case for liberalising trade in pharmaceuticals more widely. This enables pharmaceutical companies to avoid unnecessary costs when moving goods across borders and to develop medicines in the most efficient way, delivering the best possible value to health systems like the NHS.

Rules of origin

In any UK FTA, companies will have to meet rules of origins 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 SMEs that make up 82% 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.[14] 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.

Outside of the EU, the UK can and should also redefine its proof of origin process and requirements. The current EUR1 process creates a heavy burden on exporters who are required to apply for a certificate of origin on a shipment-by-shipment basis. This creates a bureaucratic and financial burden for companies that has the potential to discourage exports. A certificate of origin process similar to the US, whereby a self-certified certificate issued by the exporter/supplier is valid for a one-year period, would reduce complexity and make the export process significantly more accessible for SMEs.

Customs protocols for pharmaceuticals

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.

Recommendation

The UK should review its approach to origin requirements and customs protocols to ensure that rules make commercial sense and are easy for small companies to implement. A common approach to rules of origin should be adopted for all UK FTAs.

This approach will greatly improve the efficiency of manufacturing and supply chains, making it easier for UK companies to export their goods around the world. This is especially the case for SMEs who can grow their business and employee base through serving export markets, making a valuable contribution to the UK economy.

SMEs make up

82%

of our industry

The trade policy toolkit for the pharmaceutical supply chain

FTA negotiations

All UK FTA negotiations should ensure the full elimination of all tariffs on medicines and pharmaceutical inputs, accompanied by simple, flexible rules of origin that reflect the realities of UK pharmaceutical supply chains.

The WTO framework

Having previously been a signatory as part of the EU, the UK has committed to acceding the WTO Pharmaceuticals Tariff Elimination Agreement as an independent trading nation. It should be a leading voice in calling for the update and expansion of the Agreement's list of products, especially post-2010 APIs and intermediates. The UK should also promote the WTO as a forum to advance the case for liberalising trade in medical goods more widely, through initiatives such as the WTO Trade and Health Initiative that seeks to remove tariffs and avoid export restrictions on COVID-critical products.

Unilateral policy

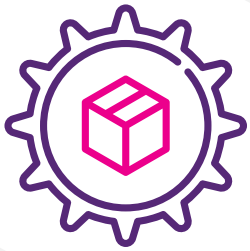
While tariff liberalisation should be pursued through FTAs and at the WTO where possible, the UK should keep all its most-favoured nation (MFN) tariffs on pharmaceuticals and inputs under regular review and reduce them in line with its domestic needs. The policy priority should be securing inputs at a cost that supports pharmaceutical manufacturing and UK patient outcomes.

The UK should review its approach to origin requirements to allow for one-year multiple shipment self-certification for reputable traders.

Recommendations

A life sciences superpower: 3 key benefits for the UK

- Companies will continue to invest in pharmaceutical R&D and manufacturing in the UK, creating highly skilled and productive jobs across the entire country.
- The removal of tariff and non-tariff barriers will boost high-value UK exports.
- Streamlined supply chains and regulatory practices support the UK's public service priorities by helping to deliver the best possible treatments and value to the NHS.



A strategic trade policy for the UK pharmaceutical sector: a summary of ABPI recommendations

UK scientific innovation

- Develop an 'IP diplomacy' strategy to promote UK standards in export markets.
- Ensure that preferential trading partners commit to a clear baseline of best practice for IP that reflects current UK standards.
- Ensure that pricing and reimbursement processes are fair, transparent and do not discriminate against UK companies.

Medicines regulation and policy

- Encourage all countries to regulate medicines to the highest international standards.
- Develop and deepen formal channels of cooperation on medicines regulation to remove duplicative processes.
- Work collaboratively with regulatory peers to pioneer new thinking behind novel regulatory pathways.

The pharmaceutical supply chain

- Ensure the full elimination of all tariffs on finished medicines and raw materials.
- Adopt a simplified, common approach to origin requirements and customs protocols for all UK FTAs.

No FTA commitments should in any way limit the UK's freedom to define the policy of the NHS as it wishes, in line with its existing international commitments to non-discrimination.

Glossary

APIs	Active pharmaceutical ingredients are the biologically active ingredients used as raw material to make pharmaceuticals.
ATMPs	Advanced therapeutic medicinal products are medicines based on genes, tissues, or cells.
FDI	Foreign direct investment refers to investment made by a foreign firm, individual or entity in the UK.
FTAs	Free trade agreements are legally binding treaties that establish the conditions of preferential trade between trading partners.
GMP	Good manufacturing practice is a system for ensuring that products are consistently produced according to quality standards.
IP	Intellectual property is an intangible asset most commonly categorised under copyrights, patents, trademarks, and trade secrets.
MFN	Most-Favoured Nation rates are the tariffs that countries impose on imports from other members of the WTO, unless the country is part of a preferential trade agreement.
MHRA	Medicines and Healthcare products Regulatory Agency.
MOU	Memoranda of understanding are agreements that express a shared commitment or common line of action that can be used to support regulatory dialogues.
MRAs	Mutual recognition agreements allow parties to recognise the results of regulators and competent authorities in each other's jurisdiction, reducing the need for duplicative regulatory assessments.
PTE	Patent term extension restores a portion of the patent term that is lost during the development and authorisation process of a pharmaceutical.
RDP	Regulatory data protection prevents the simplified marketing authorisation procedure for generics or biosimilars from taking place for a defined period.
RWD	Real World data is observational data gathered in experimental settings.
SMEs	Small and medium-sized enterprises are generally categorised as firms with fewer than 250 employees, according to the UK definition.
SPCs	Supplementary Protection Certificates are the form of patent term extension used in the UK that effectively extend patent rights.
WTO	World Trade Organization is an intergovernmental organization that is concerned with the regulation of international trade between nations.

References

1. Trade and Investment Core Statistics Book (DIT, 2021).
2. This figure refers to the NHS spend on branded medicines. The figure for export sales refers to both branded and generic medicines. Aggregate net sales and payment information (DHSC, 2020).
3. Trade and Investment Core Statistics Book (DIT, 2021).
4. FDI data by sector (FDI Markets, 2021).
5. Pharmaceutical R&D increased by £306 million (6.9%) from 2018 to 2019. Business enterprise research and development, UK: 2019 (ONS, 2020).
6. Bioscience and health technology sector statistics 2019 (Office for Life Sciences, 2020).
7. Drug development: the journey of a medicine from lab to shelf (The Pharmaceutical Journal, 2015).
8. In the UK, supplementary protection certificates (SPCs) effectively extend patent rights.
9. This can be extended to 11 years where, in the course of the first eight years, a new authorisation is obtained for new therapeutic indications bringing a significant clinical benefit in comparison with existing therapies.
10. For example, where patents are held to be invalid in legal proceedings or a medicine's development time is unusually long.
11. The 10 (+1) RDP regime provides potential extension to a maximum of 11 years of protection should, in the course of the first eight years, a new authorisation be obtained for new therapeutic indications bringing a significant clinical benefit in comparison with existing therapies. This extension is for both the initial indication and the new indication.
12. The 5 (+3) RDP regime is only available for the new therapeutic indication.
13. 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.
14. Bioscience and health technology sector statistics 2019 (Office for Life Sciences, 2020).

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