TCA13 Association of the British Pharmaceutical Industry

Senedd Cymru | Welsh Parliament

Adolygiad o weithrediad y Cytundeb Masnach a Chydweithredu rhwng y DU a'r UE | UK-EU implementation review of the Trade and Cooperation Agreement

Ymateb gan: Cymdeithas Diwydiant Fferyllol Prydain | Evidence from: Association of the British Pharmaceutical Industry

ABPI Submission

ABPI Submission: Welsh Parliament / Senedd Cymru Consultation on UK-EU implementation review of the Trade and Cooperation Agreement

Att: Culture, Communications, Welsh Language, Sport and International Relations Committee; Climate Change, Environment and Infrastructure Committee; Economy, Trade and Rural Affairs Committee; and Legislation, Justice and Constitution Committee.

About the Association of the British Pharmaceutical Industry

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes which invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world.

In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs. Find out more at abpi.org.uk.

Contact: Jakob Strandgaard | International Policy Manager, ABPI | [redacted]

Summary

Key points:

- The dedicated Medicinal Products Working Group is a key channel for the EU and UK to continue dialogue on important issues for our sector. We encourage both sides to use this as a mechanism to identify and resolve trade barriers for the sector.
- However, given the scope of such groups is on implementation of the existing Trade and Co-operation Agreement, the EU and the UK should not limit their bilateral cooperation on such an important area and should continue to explore opportunities for further collaboration in the interest of patient access to medicines and vaccines.
- We would welcome support from the Senedd, particularly the Economy, Trade and Rural Affairs Committee, to keep these issues on the agenda to identify what more can be done to ease EU-UK trade, deliver on the UK's ambitions for a thriving life sciences sector, and ensure patients have access to the medicines and vaccines that they need.
- The UK is currently lacking a mutual recognition agreement (MRA) with the EU on batch testing of medicines for safety and quality, as this was not reached as part of the post-Brexit trade deal. The UK is currently unilaterally recognising EU tests, but this is not reciprocated. We have urged the UK government to put this on the agenda with the EU, and would welcome any additional support that devolved administrations can bring to bear, particularly given the support that such an agreement could provide to Welsh medicines manufacturers and exporters.

Introduction

The Association of the British Pharmaceutical Industry represents innovative pharmaceutical companies operating in the UK: our membership includes both British companies and foreign multi-nationals that are researching, developing, manufacturing, or supplying medicines in the UK.

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 based in more than 3,000 research and manufacturing sites across all four UK nations. Alongside other investment, this delivers £17.6 billion in direct GVA[i] to the UK economy and supports 126,000 high-skilled jobs[ii] across the country. Critically, medicinal and pharmaceutical products are the third largest goods exporting sector in the UK, at £26.1 billion in 2023.[iii]

We welcome the UK Government's recent Industrial Strategy Green Paper, and its identification of the life science sector as a key growth sector. The Welsh life science sector will play a pivotal part in meeting this ambition and supporting UK economic growth. Welsh life sciences companies employ more than 12,000 people and generate £2.5 billion in turnover across 270 sites.[iv] Wales is particularly strong in attracting MedTech jobs, with 13% of the UK workforce located in one of the devolved nations.[v] And there is potential for Welsh growth. 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 16,000 jobs in Wales over the same time period.[vi]

Our industry is international by its nature, intrinsically linked across borders through regional supply chains which ensure efficient and resilient access to innovative products. We welcome the UK Government's commitment to use bilateral and multilateral negotiations as an opportunity to remove redundant or duplicative requirements UK medicines face when accessing markets overseas and make the most of opportunities presented by our high regulatory standards to minimise regulatory trade barriers.

We believe UK trade and international policy can catalyse a race to the top, enshrining quality standards in manufacturing and intellectual property in future trade agreements and building mature relationships with like-minded countries. There are a number of European opportunities that we believe the UK – and Welsh – governments can capitalise on to meet this shared ambition.

Experiences of the EU-UK Trade and Cooperation Agreement (TCA)

The TCA provides a solid base for EU-UK trade for our industry and includes a dedicated medicines annex, commitments to co-operate on areas of regulation and maintenance of current IP frameworks, co-operation on health security, and customs and Rules of Origin (RoO) that facilitate movement of goods.

Medicines have always been treated as important by both sides in the negotiations, and pharmaceutical companies have invested time and resource to ensure continued supply. In Northern Ireland, legislative changes bought forward when the Windsor Framework was

agreed returned us to a “whole UK” medicines market. Companies are now adapting or reverting supply chains to meet this new settlement, and we welcome the long-term certainty this provides.

The EU exported £18.1 billion/ €17.2 billion worth of medicinal and pharmaceutical goods to the UK in 2023. The EU region is the top supplier of medicines into the UK, particularly Belgium, Germany, and Netherlands. The UK exported £9.7 billion/ €8.2 billion to the EU during the same time period, making the UK the third biggest source of medicine imports to the EU behind the United States and Switzerland.[1]

As a member of the Domestic Advisory Group (DAG) to the UK, the ABPI is continuing to support the UK Government to monitor emerging and ongoing issues related to trade and customs. We continue to collaborate with Welsh Government officials to ensure that we are sharing, where appropriate, all information pertinent to the ecosystem in Wales.

The TCA establishes a dedicated Medicinal Products Working Group which met for the first time earlier in 2024. We believe this is a key channel for the EU and UK to continue dialogue on important issues for our sector and would encourage both sides to use this as a mechanism to identify and resolve trade barriers for the sector. However, given the scope of such groups is on implementation of the existing TCA, the EU and the UK should not limit their bilateral cooperation on such an important area and should continue to explore opportunities for further collaboration in the interest of patient access to medicines and vaccines.

We would welcome support from the Senedd and particularly the Economy, Trade and Rural Affairs Committee to keep these issues on the agenda as we look ahead to what more can be done to ease EU-UK trade, deliver on the UK’s ambitions for a thriving life sciences sector, and ensure patients have access to the medicines and vaccines that they need.

Mutually recognising medicine quality tests between the UK and EU

Ensuring resilience of supply chains for medicines and medical goods is a priority for both the UK Government and European Commission, and the first objective of the TCA’s Medicinal Product’s Annex is to “facilitate the availability of medicines in each Party’s territory”. This goal is also reflected in wider strategies by each Party; as neighbours and partners facing shared challenges, including to supply chains, reinforcing this is critical.

When a medicine is manufactured it must be tested for safety and quality. Countries with equivalent high standards and regulatory checks often agree a “mutual recognition agreement” (MRA) on these batch tests, so that they do not have to be repeated when the product moves across a border.

When the UK was a member of the European Medicines Agency there was no need for such an agreement, but it was not reached as part of the post-Brexit trade deal. The UK is currently unilaterally recognising EU tests, but this is not reciprocated. We have urged the UK Government to put this on the agenda with the EU, and would welcome any additional support that devolved administrations can bring to bear, particularly given the support that such an agreement could provide to Welsh medicines manufacturers and exporters.

The EU and the UK separately have agreed such MRAs with Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the United States, and it is arbitrary that one is not in place between the UK and the EU. Such an agreement would benefit both sides by:

- Improving ability to supply patients: both the UK and EU have discussed the importance of safeguarding supply for critical goods such as medicines. They both have strategies which include working with international partners to find agreements that would make supply chains more resilient and tackle shortages. This is one such area they should be prioritising and would be of particular importance for critical and high-demand medicines, as well as medicines with limited shelf-lives.
- Saving time and money: almost half (46%) of all medicines and pharmaceutical products exported from the UK go to the EU. Reducing the cost of duplicating a batch test on a product exported from the UK into the EU could save businesses £1,500 per batch.
- Diversifying supply to like-minded partners in Europe: Removing the need for UK medicines to undergo additional, unnecessary testing before export to the EU would ensure diversified supply in Europe. This would also provide more straightforward access to the whole European market, supporting investment into building or expanding manufacturing sites when companies factor in the costs of exports.

Contact and publication details

- Contact: Jakob Strandgaard, International Policy Manager, ABPI. [redacted]
- This evidence is submitted on behalf of an organisation, the Association of British Pharmaceutical Industries (ABPI).
- It is confirmed that the submitted name can be published alongside the evidence.
- It is confirmed that the Committees do not need to treat this information as confidential.

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[i] Office for National Statistics, 'Regional gross value added (balanced) by industry: all ITL regions', 2021, available at www.ons.gov.uk/economy/grossvalueaddedgva/datasets/nominalandrealregionalgrossvalueaddedbalancedbyindustry

[ii] Office for National Statistics, 'Industry census data 2021', available at https://www.ons.gov.uk/census/census2021dictionary/variablesbytopic/labourmarketvariablescensus2021/industrycurrent

[iii] Office for National Statistics, 'Trade in goods: country-by-commodity exports', 2024, available at http://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/datasets/uktradecountrybycommodityexports

[iv] Bioscience and health technology sector statistics 2020 - GOV.UK

[v] Life sciences - what's next for this top UK sector: a Board of Trade paper (web version) - GOV.UK

[vi] PwC & ABPI, 'Life sciences superpower: growing the leading global hub in the UK', June 2022, available at www.abpi.org.uk/r-d-manufacturing/building-a-thriving-environment-for-medicine-discovery/life-sciences-superpower-growing-the-leading-global-hub-in-the-uk