

Senedd Cymru
Y Pwyllgor Materion Allanol a
Deddfwriaeth Ychwanegol
Ymadael â'r Undeb Ewropeaidd:
Paratoadau yng Nghymru ar gyfer
diwedd y cyfnod pontio
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Ymateb gan Cymdeithas Diwydiant
Fferyllo Prydain

Welsh Parliament
External Affairs and Additional
Legislation Committee
Exiting the European Union:
Preparedness in Wales for the end of
the transition period

Evidence from The Association of the
British Pharmaceutical Industry

Introduction

1. The ABPI exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future. Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Governments and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK. Life sciences companies are critical for the health of our population, and the success of our economy. Operating across 860 sites in the UK, the pharmaceutical industry invests more than any other sector in R&D in the UK, to the value of £4.5 billion in 2018¹.
2. The sector employs 63,000 people across the UK, with 24,000 dedicated to R&D¹, and is six times more productive than the UK average manufacturers, at £330,000 GVA². It is a critical stabilising sector in a recession hit economy and remains central to any long-term economic recovery centred on innovation, productivity and high-skilled, quality jobs.
3. The EU remains the UK's closest and largest trading partner for pharmaceutical products. In 2019, 40.3% of UK's pharmaceutical exports went to the EU at a value of £9.37bn and 80.9% of the UK's pharmaceutical imports were from the EU.³
4. The ABPI welcomes the opportunity to submit this evidence to the Welsh Parliament External Affairs and Additional Legislation Committee's inquiry on Exiting the European Union: Preparedness in Wales for the end of the transition period. We have focused our response on the questions most relevant to our members and life

¹ ONS, Business enterprise research and development, UK: 2018 (21 November 2019) Available at:

<https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/business-enterpriseresearchanddevelopment/2018>

² ABPI, '2020 Manifesto for Medicine: Making the UK the best place in the world to research, develop and use the medicine of the future', 2019.

Available at: <https://www.abpi.org.uk/media/7695/abpi-2020-manifesto-for-medicine.pdf> ³ ABPI analysis of ONS UK trade in goods country-by-commodity data for 2019 (Released April 2020)

science sector, with particular focus on the role of Welsh Government and Welsh Parliament.

Welsh Government action to prepare Wales for the end of the transition period - What the EU, UK and Welsh Governments do to ensure the uninterrupted supply of medicines at the end of the transition period?

5. Governments and pharmaceutical companies across Europe have rightly been focused on responding to COVID-19. This has been an especially challenging time for our members who have been working around the clock to ensure supply chains continue to be robust in the face of global disruption and unprecedented demands, under worldwide lockdown conditions.

6. Companies were already working at capacity before the pandemic hit and have done what they can to prepare for an unknown future UK-EU relationship. Yet, there remain several critical but unanswered questions hampering our members' ability to plan for January 1st, 2021. As the end of the transition approaches it is essential that the Welsh Government and, where appropriate, the Welsh Parliament work with all relevant Welsh and UK bodies to prepare businesses for the inevitable changes they face.

7. With little over four months until the end of the Transition Period, the forecast border disruption and uncertainty of the arrangements that will be in place from January 2021, means that threats to medicines supply are again on the horizon. This time, however, there are additional challenges due to COVID-19, normal winter pressures on the NHS and the added uncertainty about how the Northern Ireland Protocol will be interpreted and implemented.

8. We have asked that both sides in the negotiations agree and implement practical policy solutions as a matter of urgent priority, so our members can ensure continued, uninterrupted supply of their medicines. The ABPI recognises the challenge in securing an ambitious and comprehensive trade agreement in the very limited time left before the end of the Transition Period, but has urged both sides to conclude a deal that covers the essential areas of: medicine supply; patient safety; science, research, and people; and customs.

9. Should a holistic agreement not be possible in the remaining time we have called upon both sides to reach an agreement that will ensure uninterrupted supply of medicines to patients in the UK and the EU. Specifically, this will be achieved by:

- Agreeing a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice, including batch testing
- Ensuring that companies from across the UK can provide a seamless supply of medicines to patients in Northern Ireland from the end of the Transition Period

Ensuring the best future for research in Wales

10. Wales has a clinical research culture, which spans the NHS, academia and industry; with Health and Care Research Wales (HCW) reporting that in 2018-19, 212 commercially sponsored studies were undertaken across the country³. Some HCW initiatives have helped to streamline the processes for undertaking studies, helping Wales become an increasingly attractive proposition to industry⁴. Most recently, research in response to the COVID-19 pandemic has been undertaken in Wales, including the recruitment of patients into the Oxford University/AstraZeneca vaccine trial^{5,6}. Whilst we have world-leading institutions^{7,8}, at the heart of their success is participation in multi-centre, often initial studies.

11. The UK and EU have been discussing Union Programmes for research and science as part of their negotiations. It is encouraging that both sides have committed to the principle of UK participation.

12. In addition to funding, the EU framework programmes provide practical vehicles to foster collaboration in R&D, establishing international research consortia which share data, access to talent, access to patients and access to research and clinical trial databases. Participants in Horizon 2020 came from over 130 countries, with nearly 350,000 researchers supported across global institutes and 1 in 5 publications based on academia-private sector collaborations⁹.

13. For the past 40 years, the UK has played a crucial role in shaping the EU research and innovation framework programmes, driving world-leading research, supporting international collaboration, and sharing technical expertise. Furthermore, with the largest therapeutic pipeline in Europe, the UK has been a significant contributor to Europe's scientific output, conducting almost 20% of the total research work within EU health programmes between 2007 and 2016¹⁰. Ranked 1st out of 28 Member States on participation in Horizon 2020 (between 2014 and 2016)¹¹, the UK has also been a huge beneficiary from EU framework programmes.

14. The EU research and innovation framework programmes (such as Horizon 2020) and various research consortia (such as European Reference Networks), have provided collaborative platforms, which have been key to the joint success of

³ Health and Care Research Wales Annual Report - <https://www.healthandcareresearch.gov.wales/news/annual-report/showcases-extensive-partnership-and-collaboration/>

⁴ Health and Care Research Wales - https://www.healthandcareresearch.gov.wales/uploads/industry/Research_in_Wales-ouroffer-to-the-life-sciences-sector.pdf

⁵ <https://www.healthandcareresearch.gov.wales/covid-19-research/>

⁶ <https://abuhb.nhs.wales/news/news/wales-to-play-major-role-in-national-trial-for-covid-19-vaccine/> ⁸ <https://www.wwic.wales/>

⁷ <http://brain.wales/>

⁸ <https://www.walescancerresearchcentre.org/wcrc/>

⁹ EU Commission. Key findings from the 2020 interim evaluation. 2017. Available from:

https://ec.europa.eu/research/evaluations/pdf/brochure_interim_evaluation_horizon_2020_key_findings.pdf

¹⁰ Cancer Research UK. The impact of collaboration: the value of UK medical research to EU science and health [Internet]. 2017. Available from: https://www.cancerresearchuk.org/sites/default/files/uk_and_eu_research_full_report_v6.pdf

¹¹ EU Commission. Horizon 2020 in full swing - Three years on [Internet]. Horizon 2020 -European Commission. 2018. Available from: <https://ec.europa.eu/programmes/horizon2020/en/news/horizon-2020-full-swing-three-years>

the UK and EU, in research and innovation – this has been one of the key non-financial benefits of participation in the EU research framework programmes. Continued collaboration is therefore essential in supporting both the UK and EU's research and innovation agendas.

15. The ABPI strongly supports the Government's commitment to consider participation in EU programmes such as Horizon Europe and believe it is the best way to ensure continued R&D in Wales. However, the ABPI believes that the UK should not only look to secure continued participation but also seek to secure influence in EU research programmes.

16. Involvement of a non-member state in the EU's strategic research agenda is not new. For example, Israel is an Associated Country participant in Horizon 2020 which means it can influence and contribute to the strategic research agenda, through joint committees, which evaluate and review implementation of Israel's association agreement and the implementation activities of Horizon 2020¹². Although we would like the UK to have greater involvement in programmes such as Horizon 2020, the relationship with Israel does set a precedent for establishing a similar arrangement for the UK.

17. Earlier this year, the Wellcome Trust published a post-Brexit agreement for research and innovation, which proposes how an agreement between the UK and EU might be achieved:

- UK association to Horizon Europe as a core part of a research and innovation agreement
- A shift away from the historical GDP-based financial formula for the UK to agree terms
- Precedent to provide the UK with an appropriate degree of influence over the Horizon Europe programme
- The exchange of research workers and their direct families as an essential part of any research and innovation agreement
- An agreed backstop mechanism for the sharing of personal data

18. The ABPI welcomed this agreement and since has signed a letter from the Life Sciences sector, stating that Horizon Europe association should be a core part of the future relationship between the EU and the UK for research, underpinning valuable scientific partnerships that have been built up over many years. The sector calls on both sides to continue these negotiations with fresh energy, a spirit of compromise, and a focus on what is needed for the success of the programme. To that end, there are several solutions to some of the sticking points in Horizon Europe discussions:

¹² Wellcome Trust. A post-Brexit agreement for research and innovation. 2020. Available from: <https://wellcome.ac.uk/sites/default/files/a-post-brexit-agreement-for-science-bruegel-wellcome-january-2020.pdf>

- Demonstrating commitment to the programme
- Ensuring a fair financial contribution through a 'two-way' correction mechanism
- Accepting EU oversight of the use of programme funds
- Agreeing to introduce reciprocal mobility arrangements to support the programme
- Clarifying that the results of research can be exploited beyond the EU

Preparedness of key economic sectors in Wales - What the pharmaceutical sector in Wales must do to prepare for the end of transition?

19. The life sciences sector and Governments across the UK worked collaboratively to prepare for the potential of a no deal EU Exit in 2019, implementing a multi-layered approach, to achieve a high level of readiness for medicines and medical products. A similar collaborative approach is needed to prepare for a possible non-negotiated outcome.

20. Part of this guidance was received through a letter from the UK Government Department of Health and Social Care (DHSC)¹³. The letter outlined their plans for a similar multilayered approach and confirmed key aspects of UK Government and industry responsibilities for the end of the transition period. The letter confirmed that the multilayered model includes:

- the need for rerouting away from the 'short straights',
- a Government Secured Freight Capacity and Express freight service,
- DHSC engagement with companies to help prepare 'trader readiness', and
- encouragement for 6-week stockpiles on UK soil, not over normal business levels, where possible

21. Despite this guidance, several areas remain outstanding and are urgently sought by our industry. It is particularly important in regulations on licencing, clinical trials and pharmacovigilance. Previous guidance was issued in advance of the March and October 2019 deadlines and similar guidance from the DHSC is required.

¹³ <https://www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020>

22. The MHRA has recently published information for pharmaceutical companies preparing for the end of the EU transition period. The guidance provides some information on how to operate from 1 January 2021, including on licensing of medicines and devices, clinical trials, exporting active substances for medicines, importing medicines and investigational medicinal products, pharmacovigilance procedures and new IT systems. Companies has welcomed the important detail included in this guidance which will support them in planning for the end of the transition period. Whilst the guidance is largely similar to the Brexit 'no deal' guidance published in 2019 (which was withdrawn as a deal was secured), there are some additions relating to the added complexity of the Northern Ireland protocol and a more time-restricted acceptance of EU batch testing and release.

23. The ABPI will continue to seek more engagement with the UK Government in these areas.

The implications for preparedness arising from the negotiation of UK international agreements, including the UK-EU future relationship agreement (or agreements), other significant free trade agreements (e.g. UK-USA, UK-Japan, UK-Australia, UK-New Zealand etc.)

24. The trade negotiations between the UK and the EU, USA, Japan and others provides the opportunity to build on the mutual strengths of thriving life sciences sectors, and remove trade barriers, encouraging ABPI member companies to research, develop and manufacture medicines, in the UK.

25. The ABPI strongly believe that the UK's approach to the negotiations should be guided by three overarching objectives:

- Through its independent trade agenda, the UK cements itself as a global leader in life science innovation and increases its international influence in shaping life sciences policy and improving the lives of patients.
- The UK aims to promote and uphold high standards of IP rights by ensuring that trading partners afford UK life science innovators at least the same level of protection that all life science innovators receive in the UK
- The UK works with other countries which have leading medicine regulatory agencies to pioneer the thinking behind new regulatory pathways and standards that can evolve to account for new technologies

26. Negotiating multiple trade agreements in parallel can be complex and the pharmaceutical industry notes that the UK is currently attempting to negotiate multiple deals simultaneously and at a fast pace. There is therefore a risk that the

UK agrees to provisions with different trading partners that are in contradiction to each other and increase the requirement and complexity of compliance for businesses operating in and exporting from the UK.

27. To avoid this, our industry would appreciate greater clarity on how departments across governments are linked up to help ensure the UK has a single, coherent trade strategy and approach, which is co-produced by all countries of the UK.

28. Now that we have left the EU, the UK has an opportunity to capitalise on its strong domestic life sciences sector and enhance its pro-innovation policies, cementing itself as a global leader in this area by pursuing and agreeing gold standard IP provisions in deals with other partners. With respect to the EU negotiations, we have asked that the UK and the EU ensure that their current IP frameworks remain the minimum accepted standard.

29. Secondly, on medicine regulation, given the current complete alignment of regulatory standards between the UK and EU, the industry's main priority for the UK's trade agenda is for the EU-UK negotiations to seek to maintain their current high level of regulatory compatibility and to secure streamlined processes and procedures between the EU and the UK in the interest of patient safety. This still allows for the UK and other partners work together to develop thinking on the international standards for the medicines of the future, while still allowing for close regulatory compatibility with the EU.

Working with you

30. ABPI Cymru Wales are keen to support this work, by use of virtual meetings and written briefings. We can establish bespoke briefing sessions on any aspect of this paper, expanding upon the content in this briefing, and addressing your questions for the sector.

31. If you would like to set up a virtual meeting briefing session, please email jferris@abpi.org.uk or call 029 20 454297.