About the ABPI

1.1 The ABPI exists to make all four nations of 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.

1.2 In Scotland, our members support over 17,000 jobs and exports of manufactured pharmaceutical products were worth over £462 million to the Scottish economy in 2018. Overall, the industry supports a total of £2.5 billion worth of industrial output and is Scotland’s second most productive sector.

1.3 Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Our voluntary agreement with government ensures that spending on branded medicines, across all four nations of the UK, can only grow by 2% per annum with anything over this repaid. In 2019/20 this agreement is forecast to deliver over £70m back to NHS Scotland\(^1\).

1.4 Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK and ABPI Scotland provides the secretariat services to the Scottish Parliament Cross-Party Group on Life Sciences.

1.5 The ABPI welcomes the opportunity to submit this evidence to the Scottish Parliament Culture, Tourism, Europe and External Affairs Committee inquiry on the Negotiation of the Future Relationship between the European Union and the UK Government.

1.6 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\(^2\).

Securing Medicines for Patients in the UK and EU

2.0 Industry trade bodies ABPI and EFPIA (The European Federation of Pharmaceutical Industries and Associations) have always been clear that, despite
preparing for all outcomes, getting a comprehensive trade deal is the best outcome for the UK and EU.

2.1 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.

2.2 Companies were already working at capacity and have done everything in their power to prepare for a future UK-EU relationship that has yet to be agreed. However, there remain a number of critical unanswered questions and unpublished guidance hampering companies’ ability to plan for January 1st, 2021.

2.3 With little over two months until the end of the Transition Period, potential border disruption and uncertainty over the arrangements that will be in place from January 2021, means that threats to medicines supply are again on the horizon.

2.4 However, unlike 2019 where industry prepared for a potential ‘no deal’, there is an additional pressure due to COVID-19 and the added uncertainty regarding how the Northern Ireland Protocol will be interpreted and implemented, and what this will mean for our companies’ medicines supply chains.

2.5 As the end of the transition approaches it is essential that the Scottish Government and, where appropriate, the Scottish Parliament work with all relevant bodies to prepare businesses for the inevitable changes industry need to make and the challenges they may face.

2.6 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 urges both sides to conclude a deal that covers the essential areas of:

- medicine supply;
- patient safety;
- science, research, and people;
- and customs.

2.7 Should a holistic agreement not be possible in the remaining time, we call 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;
- Agreeing to a one-year ‘phase in’ of the Northern Ireland Protocol with respect to medicines, starting from the point when there is agreement on its interpretation, without leaving a void until that time.

2.8 Regarding rules of origin regulations, whilst most finished pharmaceutical products are not subject to tariffs under WTO terms, active ingredients (APIs) and other unfinished intermediaries used to manufacture medicines can be. The introduction of
even small tariffs on essential supply chain components would increase the cost of production and reduce the attractiveness of the UK and Scotland for manufacturing. As a result, we recommend the UK and EU:

- Guarantee tariff liberalisation for all finished medicines, APIs and intermediates used in the manufacturing of medicine, research and clinical trials;
- Establish rules of origin requirement simplified and based on common, defined chemical and pharmaceutical processing activities, similar to those agreed in EU and Canada.

Preparing for the end of transition

3.0 The sector, the Scottish Government and the UK Government 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, with several areas of guidance still required by industry.

3.1 Industry has received part of this guidance through a letter from Steve Oldfield, Chief Commercial Officer of the Department of Health and Social Care. The letter outlines DHSC plans for this multi-layered approach, confirming key aspects of the UK Government and industry responsibilities for the end of the transition period. The letter confirms that the multi-layered model includes: the need for rerouting away from the ‘short straights'; UK 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).

3.2 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 have welcomed the important detail 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. However, ABPI members still require further information on a series of issues and are working with Government to secure much needed clarity.

3.3 Most notably, how the Northern Ireland Protocol will operate in practice regarding medicines, including how medicines will be moved between countries in the UK and where medicines can be manufactured and how they can be packaged under the Protocol. This is of particular importance to Scotland, as more than 80% of all medicines suppling Northern Ireland travel through the Stranraer crossing.

3.4 The ABPI will continue to seek additional details from the UK Government in this area and recently called upon them and the EU to agree a one-year ‘phase in’ of the
Northern Ireland Protocol with respect to medicines, starting from the point when there is agreement on its interpretation.

Research, Skills and People

4.0 Europe is a global leader in Life Sciences R&D, with EU research and innovation framework programmes, such as Horizon Europe, helping to drive world-leading research and support international collaboration.

4.1 For the past 40 years, the four nations of the UK have 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 2016. Ranked 1st out of 28 Member States on participation in Horizon 2020 (between 2014 and 2016), the UK has also been a huge beneficiary from EU framework programmes.

4.2 Scotland’s research community has benefitted from EU research programmes which include Horizon Europe and its predecessors. Since 2014, Scottish researchers have received 711m Euros of funding which represents around 11% of the total awarded to the UK. Therefore, leaving the EU will have a significant impact on the research community in Scotland and details on future funding routes is required.

4.3 Clinical research is an important component of the industry footprint in Scotland and our members spend millions of pounds each year on clinical trials. Whilst the successful collaboration of our triple helix (academia, industry and NHS) is key to attracting studies, so too is the ability to link internationally and take part in multi-centre trials and this should be safeguarded despite leaving the EU.

4.4 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.

4.5 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

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3 Scottish Government statistics, [June 2020](#)
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:

- 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.

4.6 The ABPI recognises the positive impact EU migrants have made to Scotland’s health and life science industries as well as the demographic challenges posed by our exit from the EU.

4.7 The ABPI believes that for the UK to retain its position as a global hub for life sciences the movement of high-skilled talented people is vital.

4.8 We recognise and welcome that the UK Government and EU have made it clear that they will protect the rights of citizens working in each territory. The UK’s intent to develop a new immigration system to allow for the best and brightest scientists from the EU and the rest of the world to travel to, and work in, the UK is also welcomed, but we require more detail as to how this will work in practice.

4.9 To support a continuation of essential business operations, the ABPI has called on the UK Government to agree to maintain mutual recognition of professional qualifications. This means employees with relevant qualifications from the other jurisdiction will continue to be able to perform their job as they can today, based on their existing qualification.

The future

5.0 The Scottish Government has recognised the importance of the life sciences sector and have included it as one of their nine growth sectors. Since 2010 the sector has achieved, on average, year-on-year growth of 10 per cent and has contributed £2.4 billion in gross value added. Life sciences, of which the pharmaceutical industry is a core component, contributes around a fifth of Scotland’s business enterprise research and development spend and is a major contributor to our exports. Given the strength of the sector it is important that our new relationship with the EU enables this growth to continue and that new trade deals continue to support the long-term health of the pharmaceutical industry.

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

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 our 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.

5.1 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.

5.2 To avoid this, our industry would appreciate greater clarity on how to ensure the UK has a single, coherent trade strategy, which is approved by all governments and nations of the UK.

5.3 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.

5.4 Finally, 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 to 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.