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Rt Hon Stephen Crabb MP
Chair - Welsh Affairs Committee
House of Commons
London, SW1A 0AA

19th February 2021

Dear Mr Crabb,

The UK-EU Trade Deal and Border Arrangements

Thank you for your letter and for the opportunity to input into the Welsh Affairs Select Committee's work into '*The UK-EU Trade Deal and Border Arrangements'*.

I have laid out our answers to the specific questions from the Committee below, as well as some further context on the impact of the Trade and Cooperation Agreement on the branded pharmaceutical sector.

1. What have been the implications of the UK/EU Trade and Cooperation Agreement for the pharmaceutical sector in Wales and the rest of the UK?

We have always said that a deal is in the best interest of patients in the UK and the EU. This means ongoing collaboration in key areas including scientific research and cooperation in areas like medicines safety. During the negotiation period, the pharmaceutical industry in both the UK and EU consistently advocated for a deal and were pleased that one was reached in late December.

ABPI members prepared extensively for the end of transition and this included stockpiling medicines, preparing alternate supply routes and duplicating manufacturing processes. This work, undertaken at significant expense, was designed to mitigate any supply issues and ensure patients across the UK continue to access the lifesaving medicines they rely upon.

ABPI is not aware of any major disruption to medicines supply in the UK or Wales following the end of the transition period. Importantly, the deal does not negatively impact the supply of COVID-19 vaccines from the EU to the UK.

However, given the significant changes in customs and border arrangements there are issues which will require action in both the short and long term. Importantly the deal does not include a Mutual Recognition Agreement on batch testing regulatory standards between the EU and the UK, and there are still immediate and outstanding issues to resolve on the Northern Ireland Protocol.

The lack of an MRA on batch testing regulatory standards between the EU and the UK presents a future risk to the availability of medicines to UK patients and the attractiveness of the UK as a global life sciences hub outside of the European Union.

Batch testing is the process of confirming that every batch of medicine has the correct composition, with Qualified Person certification and release the evidence which ensures it meets the correct standards for use. Currently, the MHRA maintains a list of countries where the UK will accept their batch testing, QP certification and release and this will include the EU for a limited time. Following the failure to agree an MRA in December, the EU is currently mandating batch testing on pharmaceutical products which move from the UK to the EU.

In jurisdictions such as the EU and the UK, with very high standards of regulation, the need for repeated testing is an unnecessary duplicative requirement that complicates the supply chain and can delay the batch of medicine reaching patients for an average of 6 weeks and costs £1,500 per batch.

Currently our members are being asked to prepare to complete this duplication in two settings: from 2022 for medicines imported from GB into NI; and from 2023 for medicines imported from the EU to GB. We are appreciative of the UK Government's championing of this issue during the EU trade negotiations and are aware that the EU rejected an MRA. As a result, and in the absence of an MRA, the industry is asking for the UK Government to amend current UK Guidance, so that the UK continues to recognise EU and EEA batch testing beyond the 31st of December 2022.

Failure to reach an agreement or extend the UK exemption on batch testing could cause issues for the sector and patients. Notwithstanding the difficulty in scaling up UK batch testing, future issues could include a reduction in the number of medicines available to UK patients, wasted company resources on duplicative processes that could be deployed to R&D efforts, and finally an unnecessary diversion of finite MHRA regulatory resources.

Beyond batch testing, the industry also requires further guidance on the supply of medicines to Northern Ireland. Whilst industry is pleased with the pragmatic phased-in approach to implementing the Northern Ireland protocol, there are still significant uncertainties to overcome before the phase-in period ends on the 31st of December 2021.

Failure to resolve issues around supply could result in patients in Northern Ireland receiving a narrower choice of medicines, similar to other small, self-contained markets such as the Republic of Ireland, Cyprus or Malta.

Throughout the transition period, the ABPI has communicated our members concerns on issues associated with the need for regulatory import requirements and the future of the Falsified Medicines Directive in Northern Ireland to the UK Government. Unfortunately, and despite the deal agreed in December, these issues are still outstanding and whilst the industry was pleased that a phase-in period for the Northern Ireland protocol was agreed and provided a practical stop gap.

However, we support the view expressed by Michael Gove MP to the Vice-President of the European Commission, Maroš Šefčovič, which called for an extension to the current phase-in period until the 1st of January 2023 whilst a long-term approach is developed that will ensure no barriers of any kind to the movement of medicines into Northern Ireland.

To allow time for these discussions to take place, it would also be helpful to seek an agreement with the EU to retain the customs easements currently in place for medicines travelling from GB to NI, which are currently set to expire in April.

2. Are you aware of the pharmaceutical company mentioned by Ian Price and of the alleged difficulties they have experienced in exporting goods to the EU? [If so] What discussions have you had with the firm and the UK and Welsh governments to explore potential remedies to their problem?

We're not familiar with the case that was mentioned and have not received any examples from our members that they are facing similar problems.

As previously referenced, ABPI members prepared extensively for the end of transition to ensure that supplies of medicines continued uninterrupted but require action to be taken on the issues of batch testing and further guidance on supplying Northern Ireland.

3. Are you aware of other firms who have been unable to export/import consignments to/from the EU and/or are considering relocating business operations to the EU?

No ABPI members have made us aware of being unable to import or export consignments to or from the UK. However, as outlined above, there are concerns that need to be addressed to secure the uninterrupted flow of medicines in the future and to ensure business to not feel the need to relocate operations outside of the UK.

We hope that this response covers all aspects of your questions fully. However, if we can at any time provide further information or clarification to assist the Committee in its work, please do not hesitate to get in touch.

Best Regards

Dr Richard Greville
Director, ABPI Cymru Wales and Distribution Supply Chain