

ABPI Cymru Wales

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Bringing medicines to *life*
Dod a meddyginiaeth i *fywyd*

Cymru | Wales

David Rees AM
Chair of the External Affairs and Additional Legislation Committee
National Assembly for Wales
Pierhead Street
Cardiff, CF99 1NA

15th August 2018

Dear *MR REES,*

Thank you for the opportunity to comment further on Wales' preparedness for exiting the European Union in relation to medicines. As you noted in your letter, this is done amid ongoing negotiation between the UK Government and the European Union (EU), and the continued uncertainty about the eventual outcome. Any comment below should be seen in this light.

You have particularly requested our views on:

- the preparedness of the healthcare and medicines sector in Wales for the UK's departure from the EU;
- how the Welsh Government is leading efforts to prepare the Welsh healthcare and medicines sector for the UK's departure from EU, including contingency planning for a 'no deal'; and
- any other issues you would wish to bring to the attention of the External Affairs Committee.

We have outlined these below, under your headings. I hope that this is useful.

The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. We represent companies who supply more than 80% of all branded medicines used by the NHS and who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome disease.



Preparedness of the healthcare and medicines sector in Wales for the UK's departure from the EU

Since the day of the referendum result, the ABPI has been working with companies to understand the impact of the UK leaving the EU on the supply of medicines to patients. The priority for the pharmaceutical industry is to make sure patients across the whole of the UK and the EU experience no disruption to getting the medicines they need. Every month, 45 million patient packs of medicine move from the UK to the EU27, with 37 million packs moving in the other direction¹.

The ABPI has been supporting companies to make all necessary preparations and have advised companies to prepare for all possible outcomes from the Article 50 negotiations, including the UK leaving the UK without a deal from March 2019. This includes underlining the importance of evaluating supply lines for individual products, particularly for products with complex supply lines and those with temperature control requirements, short shelf lives.

Each company is preparing in the best way possible that reflects their individual circumstances. For some companies, this means duplicating processes in both the UK and the EU to ensure that medicines can be made available in both the EU and the UK.

The ABPI has also been taking an approach of working closely with the UK Government, through both the UK EU Life Sciences Steering Group, and specific working groups on medicine supply, to prepare for the UK's exit from the European Union.

We have also carried out specific activity in Wales, working closely with our members and colleagues across the sector. This has included providing updates on discussions at a UK-level, when this has been appropriate. We have proactively participated in the *Welsh NHS Confederation Policy Forum Brexit Sub-Group*, which provided a briefing to Assembly Members in July 2018 (available from: <https://www.nhsconfed.org/media-centre/2018/07/impact-of-brexit-on-the-welsh-health-and-social-care-system>).

The ABPI's position continues to be that regulatory cooperation is essential in order to ensure that UK and EU patients have access to medicines and clinical research, and that the UK remains a leading force in life sciences. This is the best way to ensure that patients in the UK and Wales are able to continue to access the medicines they need after the UK's exit from the EU.

How Welsh Government is leading efforts to prepare the Welsh healthcare and medicines sector for the UK's departure from EU, including contingency planning for a 'no deal'

ABPI Cymru Wales has met with the Welsh Government Health Department to discuss the issues facing the pharmaceutical industry as a result of the UK's departure from the EU. Our discussions included a very short discussion on supply chain issues - the outcome of which was that this was an issue that would need to be handled on a pan-UK basis, and covered a range of subjects that have the potential to adversely affect the work of our members.

We would encourage the Welsh Government to reach out to the UK Government's Department for Health and Social Care (DHSC) and the other Devolved Administrations, so

¹ *EFPIA Brexit Survey*, <https://www.efpia.eu/media/288531/brexit-survey-outcome-08112017.pdf>



that contingency planning and delivery for the continued supply of medicines across the UK is co-ordinated and aligned.

Any other issues you would wish to bring to the attention of the External Affairs Committee

The draft Withdrawal Agreement sets out the terms of the implementation period that will operate between March 2019 and December 2020². Agreement on the terms of the implementation period is dependent on agreement between the UK and EU on the overall Withdrawal Agreement. The terms of the draft Agreement indicate that the UK would have a very limited role in the European Medicines Agency (EMA) during the implementation period.

Article 123 indicates that ‘the UK shall not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union’ and that the UK may only ‘upon invitation, exceptionally attend meetings or parts of meetings or the committees’ in the event that a number of conditions are fulfilled.

The ABPI are seeking for a future relationship between the UK and the EU which is based on closer collaboration than that described in the draft Withdrawal Agreement. It is essential that the future relationship between the UK and the EU regarding medicines regulation is closer than that described for the implementation period.

I hope that the above is useful. Please do not hesitate to contact me if I can provide any further information or clarification.

Best Regards,

Dr Richard Greville
ABPI Director Wales and Supply Chain

² *Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,*
https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf