The impact of Brexit on patients and public health should be prioritised in second phase of negotiations

Eleven organisations representing patients across the UK and Europe have today, 13 March, warned EU negotiators of the risk of drugs getting stuck at borders, regulatory systems for medicines splintering and potential breakthrough research collaborations being forced to stall.

In a letter to Brexit negotiators Michel Barnier and David Davis, the organisations make a plea to both sides of the negotiations not to forget about patients.

Ahead of the European Council meeting on 22 March where the guidelines for the negotiation of phase 2 will be agreed, the organisations are urging negotiators to consider a set of priorities to ensure there are no negative affects on patients, no matter what deal is achieved. The proposals have been put forward in order to safeguard the interests of patients and make sure that worst-case scenarios don’t happen.

The signatories to the letter, who include the heads of the Association of Medical Research Charities and the European Patients’ Forum, cite the future of European clinical research as being particularly important. For some patients, particularly those with a rare or less common disease, working together across nations is the only way that sufficient expertise and patient numbers can be brought together to progress research. It’s vital that patients across the EU can continue to take part in pioneering clinical trials.

As the next phase of negotiations start, organisations with patients at the heart of their work have identified four priorities to make sure no patient loses out, no matter what their country of residency:

1. Achieve close cooperation on medicines regulation to ensure safety and early access to innovative new treatments
2. Don’t let trade agreements restrict the supply of medicines and medical devices
3. Make sure patients across the EU can access Europe-wide clinical trials – this type of multi-nation collaboration is key to research
4. Ensure a smooth transition to deliver changes as seamlessly as possible.

Talking about why organisations across the whole of Europe have got together to take this unprecedented step, Aisling Burnand MBE, Chief Executive of the Association of Medical Research Charities (AMRC) said:

"By working in partnership, the EU and the UK have together achieved many research breakthroughs and developed pioneering systems of medicines regulation that have saved and improved countless lives. As the second phase of Brexit negotiations begins, it is vital that the concerns of patients are addressed
with urgency. By taking health care and research into consideration, Brexit negotiators have the opportunity to ensure that no patient, whichever country they live in, faces unnecessary delays in accessing existing as well as new and better treatments. Fishing and aviation have been identified as key areas of consideration ahead of discussions on the UK-EU relationship; we now urge negotiators to work together to make sure patients are front and centre of the second phase of talks.”

Susanne Logstrup, Director of the European Heart Network said:

"I think it is safe to say that neither the almost 49 million people who live with cardiovascular disease in the EU, nor their families and carers, would expect or want Brexit to jeopardise the current cutting-edge collaborative research, or the availability and price of life-saving medicines. We trust that our political leaders will not allow 40 years of progress in health and medicine to get de-railed.”

Derick Mitchell, Chief Executive of the Irish Platform for Patient Organisations, Science & Industry, said:

"The impact of Brexit on patients both in the UK and across the EU is significant and has not been sufficiently considered in negotiations to date. Any future regulatory alignment between the EU and UK must ensure sufficient and timely supply of medicines and medical devices. It must not exacerbate delays in access to the most innovative treatments for patients. In the interests of patients and public health, patient voices should be heard loud and clear by negotiators on both sides.”

Roisin Foster, Executive Board Member, Association of European Cancer Leagues, said:

"We are deeply concerned about the threat posed by Brexit to cancer patients – in their future access to new treatments, their inclusion in drug trials and the potential impact on the transfer of knowledge that ensures optimum treatment. Given that this year alone 3.9 million people will be diagnosed with cancer across the European Union and over 1.9 million will die from the disease, we sincerely hope that Mr Barnier and Mr Davis will give a clear commitment to ensuring protection for cancer research and access to treatment in the forthcoming negotiations, planning and implementation of Brexit.”
Mr. Michel Barnier  
Chief Negotiator Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU  
European Commission  
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1049 Brussels, Belgium

Rt. Hon David Davis MP  
Secretary of State Department for Exiting the European Union  
9 Downing Street  
SW1A 2AG London

Brussels and London, 13 March 2018

Dear Mr Barnier and Dear Mr Davis,

We are writing to you as a group of organisations that support and represent the interests of European patients to urge you to ensure that patient safety and access to medicines are prioritised in the second phase of negotiations to determine the UK’s future relationship with the EU.

We welcomed the positive agreement on reciprocal healthcare achieved at the conclusion of the first phase of negotiations in December 2017. We were reassured that negotiators sought to protect the interests of patients, irrespective of their country of residence. We urge you to ensure that this approach, with the aim to protect those undergoing and seeking treatment, continues into the second phase of negotiations.

In order to achieve this, we have identified a number of priorities that should be included in the second phase of negotiations and addressed as a matter of urgency:

1. **Close cooperation in the regulation of medicines and medical devices**

   Working together pools regulatory expertise across Europe and creates an attractive market for companies to launch new therapies. Millions of patients across the EU benefit from better access to innovative therapies and a high level of product safety as a result of comprehensive EU medicines regulation and shared regulatory systems for medical devices.

   It is vital that close UK-EU cooperation and coordination in the regulation of medicines and medical devices is secured in the future for the benefit of patients and business.

2. **A trade agreement that protects the supply of medicines and medical devices**

   The scale of the trade delivering medicines and medical devices to patients in the UK and the EU is substantial. In the case of medicines, the UK supplies 45 million packs of drugs to Europe every month; whilst 37 million packs travel in the opposite direction. These products
are often manufactured in complex supply chains across Europe where products or components of products cross borders several times.

Nobody should have their health put at risk by a block in the supply of medicines or medical devices. Future trade agreements must, therefore, include provisions to ensure that medicines and devices can continue to cross borders, so UK and EU patients can continue to access them.

3. Continued partnership on medical research to enable innovative research to be conducted across the UK and the EU

There is a long history of partnership in medical research that has not only benefited patients across the UK and the EU, but also those across the world. Collaborative research is more impactful: papers authored by UK and EU partners boost citations, taking scores to twice the world average, while each €1 invested into EU research programmes delivers returns of €11 for society.

By working together, the EU and the UK have achieved many research breakthroughs, particularly for rare disease patients for whom working on a multi-national level is vital to pool expertise and provide access to sufficient numbers of patients.

The aligned clinical trials landscape across the EU means that patients can take part in pioneering pan-EU trials. It is vital that these trials continue and that opportunities for EU and UK patients to take part in them are protected. Specifically, we urge that the UK remains committed to aligning with the forthcoming Clinical Trials Regulation and that negotiations secure collaboration on key underpinning infrastructure including the centralised clinical trials portal.

An environment for medical research that builds on this strong foundation and enables further innovative collaborative medical research across the UK and the EU for maximum patient benefit should be a key objective in future negotiations.

4. A smooth transition to ensure patient safety

A smooth transition will be critical to ensure that the necessary changes are delivered seamlessly, with no impact on the ability of UK or EU patients to access medicines after the UK leaves the EU.

Given the uncertainty in this area, as well as the urgent need to safeguard patient safety and access to medicines, the undersigned organisations urge negotiators to address these issues as soon as possible.

Patient safety and access to medicines must be at the heart of the second phase of negotiations to determine the UK’s new relationship with the EU. We speak with a single voice: there must be no negative impact on patients whatever the deal agreed.

We look forward to hearing from you and would very much welcome the opportunity to set up meetings with your teams to discuss our priorities.

Yours sincerely,

Nicola Bedlington
Secretary General, European Patients’ Forum
Nina Renshaw
Secretary General, European Public Health Alliance

Wendy Yared
Director, Association of European Cancer Leagues

Susanne Logstrup
Director, European Heart Network

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Chief Executive, Cancer Focus Northern Ireland