

# Protecting the health of citizens and patients across the UK and EU: Priorities for a future relationship

In 2016, the UK voted to leave the EU. Since then, the government has been working to deliver the referendum result and leave with a negotiated deal. The latest Withdrawal Agreement has now been tabled, a welcome step towards an agreed deal. The Brexit Health Alliance (BHA) looks forward to moving into a second phase of negotiations and transition period.

This briefing sets out the BHA's priority areas for negotiations on the future relationship between the UK and EU, in order to protect the health and wellbeing of citizens and patients across the region.

## Key points

- The BHA welcomes the broad aims of the deal, as they support the key interests of patients in the UK and EU. However, refining the future relationship in the second phase of negotiations will be critical to safeguard patients and the UK's health and care sector.
- The BHA believes that a close cooperative relationship with the EU across trade in medicines and medical devices, health security and research is the best way to keep patients safe and continue to offer an excellent level of health and care services.
- For this continued, close cooperative relationship to be possible, rapid agreement across the following areas is required:
  - cooperation to align regulations and customs arrangements that maintain availability of safe medicines and medical devices for patients and population health
  - preservation of reciprocal healthcare arrangements to ensure simple and safe access to healthcare for UK and EU citizens travelling in the region
  - full UK participation in European research, so that UK patients continue to benefit from the latest developments in treatment and innovation
  - making continued collaboration and data sharing on health security a priority in the negotiations to protect citizens across Europe from threats that know no borders.

# Summary

While recognising that the EU has limited competence in health – and that health will never be a stand-alone topic in the Brexit negotiations – the BHA continues to argue that negotiations on the future relationship between the UK and EU should prioritise protecting the health and wellbeing of citizens and patients across the region. This entails factoring healthcare concerns into agreement on cross-cutting issues such as citizens' rights, health security and supply chains of medicines and medical devices.

The recently published revised Withdrawal Agreement<sup>1</sup> and Political Declaration<sup>2</sup> only go so far in providing assurance around these outcomes. As with the previous versions, there continues to be broad aims set out around regulatory and customs collaboration, cooperation of UK authorities with EU agencies, exploration of UK participation in EU programmes in areas such as science and innovation, and cooperation on health security matters.

However, whereas we are recommending close regulatory and customs cooperation – to safeguard the health and wellbeing of citizens and patients as well as the UK's health and care sector – the starting point for the future relationship, as currently described, is one of divergent regulation.

We believe that crucial, early agreement needs to be reached on the following areas in this second phase:

1. **Maintaining customs cooperation on medical devices and medicines**, recognising the substantial scale of trade between the UK and the EU. Commitment is also needed on **UK agencies' participation in the European Medicines Agency** and other regulatory networks and databases, to maintain maximum regulatory alignment.
2. **Preservation of reciprocal healthcare arrangements** and social security coordination.
3. **Maximum levels of participation in European research**, including UK association with Horizon Europe and full researcher mobility; alignment on pre-competitive research regulation, including the fullest UK cooperation on clinical trials; and participation in European Reference Networks.
4. **Seeking to make health security a priority in the negotiations**, recognising that health threats do not respect borders.

The BHA remains committed to working with the UK government and organisations across Europe to achieve the agreements above. See the table below for further detail on specific areas we are seeking early agreement on.

## Recommendations at a glance

The vision for the future relationship between UK and EU	Current Withdrawal Agreement and Political Declaration position	What is required to achieve the vision?
Regulatory alignment for patients and population health ...to maintain availability of safe medicines and medical devices for patients and population health.	Broad aims were set out in the Political Declaration around a free trade area for regulatory and customs cooperation, with no tariffs or restrictions, comprehensive partnership, and cooperation of UK authorities with EU agencies.	Build on the Political Declaration's aims to achieve full cooperation across the complex regulatory systems that facilitate trade, supply chains and manage safety of products, through: <b>1.</b> Continued regulatory and customs cooperation for medicines and healthcare products – zero tariffs and alignment of regulatory standards to avoid replication of marketing authorisations, border inspections, etc. <b>2.</b> Continued active participation within the European regulatory network and European Medicines Agency.
Preservation of reciprocal healthcare arrangements ...to ensure simple and safe access to healthcare for UK and EU citizens travelling in the region.	The Withdrawal Agreement points to maintenance of positive cross-cutting elements, such as citizens' rights. The Political Declaration has a further stated aim to consider addressing social security coordination in the light of future movement of persons.	Build on the Political Declaration's aims to achieve: <b>1.</b> Appropriate, affordable access to reciprocal healthcare for UK and EU patients, by preserving or mirroring current arrangements. <b>2.</b> Coordination of social security payments and systems. <b>3.</b> Minimal burden for health providers required to handle new, complex admin and funding processes.
Maximum collaboration in research and innovation ...so UK patients continue to benefit from the latest developments in treatment and innovation.	The Political Declaration made an important commitment to explore UK participation in EU programmes in areas including science and innovation.	Solidify the commitments in the Political Declaration with a model for positive future cooperation for research and innovation, including: <b>1.</b> A stand-alone agreement on science and research for UK participation in Horizon Europe and European Reference Networks. <b>2.</b> Continued cooperation and full alignment between the UK and EU on clinical trials. <b>3.</b> Free exchange of research and innovation personnel.
Robust coordination mechanisms on public health and wellbeing ...to protect the health security of citizens across Europe and the UK from threats that know no borders.	There is commitment in the Political Declaration for the UK to be able to work with European partners to protect citizens' health and maintain effective and swift data sharing vital for law enforcement.	Build on the Political Declaration commitments through: <b>1.</b> Prioritising health security in negotiations. <b>2.</b> A strong health security partnership for cross-border threats, including close collaboration with the Health Security Committee and other bodies. <b>3.</b> Alignment with regulatory and health and safety standards to avoid duplication and delay. <b>4.</b> Continued health security data exchanges and collaboration to protect citizens from unsafe medicines, infectious diseases and other hazards.

# Priorities for a future relationship:

## Our recommendations

The BHA\* does not take any stance on the merits or otherwise of Brexit. Our aim is to protect the interests of patients across Europe in this process and to make sure that the UK's health and care sector is in the strongest possible position once the UK leaves the EU. To this end, we are seeking agreement on the following areas:

- regulatory alignment for the benefit of patients and population health
- preservation of reciprocal healthcare arrangements
- maximum collaboration in research and innovation
- robust coordination mechanisms on public health and wellbeing.

### Regulatory alignment and customs cooperation

The BHA is clear that future cooperation in medicines and medical devices is in the interests of both the UK and EU. The regulation of medicines and medical technologies is managed by EU-wide systems, facilitating trade under the single market. This means that products are regulated to make sure that they are safe before they can be placed on the EU market. They are also closely monitored after being placed on the market to ensure continued safety.

Regulatory arrangements for medicines and medical devices are complex, and changes to this regime may have an impact on supplies across Europe now and in the future. A deal between the UK and the EU that does not address future cooperation on medicines and medical technologies regulation would certainly put the health of patients across Europe at risk.

During the second phase of the negotiations, the BHA believes that arrangements for the regulation of medicines and medical devices should be addressed as a matter of urgency. We believe that a future agreement should build on the aims set out in the Political Declaration, which include:

- the development of an ambitious, wide-ranging and balanced economic partnership, which will be comprehensive, encompassing a Free Trade Agreement, as well as wider sectoral cooperation where it is in the mutual interest of both parties
- a free trade area with deep regulatory and customs cooperation and a Free Trade Agreement ensuring no tariffs, fees, charges or quantitative restrictions across all sectors with appropriate and modern accompanying rules of origin
- exploring the possibility of cooperation and active participation of UK authorities with EU agencies such as the European Medicines Agency (EMA).

\*BHA members: Academy of Medical Royal Colleges, Association of Medical Research Charities, Association of British HealthTech Industries, Association of the British Pharmaceutical Industry, Association of UK University Hospitals, BioIndustry Association, Faculty of Public Health, Medical Schools Council, National Voices, NHS Confederation (including the Independent Healthcare Providers Network, Mental Health Network, NHS Clinical Commissioners and NHS Employers), NHS Providers, Northern Ireland Confederation for Health and Social Care, Richmond Group of Charities, Scottish NHS Chief Executive Group, Welsh NHS Confederation.

**To ensure that patients in the UK and EU can continue to access medicines and medical technologies, the BHA makes the following recommendations:**

1. Active participation should continue within the European regulatory network and EMA. The BHA would prefer the UK to have a similar status to EEA countries with the ability to lead on assessment.
2. Patient safety and public health should be explicitly guaranteed in any agreement and secured by aligning the UK as much as possible with the EU's regulation of medicines and medical devices.
3. Regulatory and customs cooperation should continue for all medicines and healthcare products – zero tariffs on goods and alignment of regulatory standards. This would recognise the complex, integrated and often 'just-in-time' supply chains which exist between the UK and EU.

### **Preservation of reciprocal healthcare arrangements**

The future relationship between the UK and EU should build on the current Political Declaration's aim to "consider addressing social security coordination in the light of future movement of persons".

**As part of EU-UK trade negotiations, we make the following recommendations:**

1. The EU and UK should ensure that the positive cross-cutting elements in the current Withdrawal Agreement are not lost. The UK has shown willingness in this area through its no-deal assurances, a positive starting point for negotiations.
2. Clear, appropriate and affordable access to reciprocal healthcare for both UK and EU patients and their families, preferably by preserving (or mirroring) current arrangements, which should cover:
  - travellers/short-term visitors
  - non-citizen residents, whether working or not
  - patients travelling specifically to receive agreed healthcare across the UK/EU border
  - UK citizens travelling across internal EU borders to receive healthcare or moving residence from one EU state to another.
3. To minimise the burden for both UK and EU health providers if they are required to handle new, more complex administrative and funding processes, should current arrangements be discontinued.

### **Maximum collaboration in research and innovation**

Patients will suffer unless there is partnership on science and research between the EU and UK after Brexit. Patients currently benefit enormously from the current close collaboration between medical researchers who investigate, develop and test new treatments on an EU-wide basis.

The BHA is calling for a positive cooperation model for research and innovation between the UK and the EU, continued cooperation on clinical trials and a straightforward and welcoming UK migration system to attract researchers, innovators and their families.

**In pursuit of a stand-alone agreement on science and research, we recommend the following:**

1. UK involvement in and funding of EU-funding programmes, which supports health research, innovation networks and clinical trials.
2. Associate membership of Horizon Europe as part of a system which allows UK-based academics to lead, design and participate in EU-wide collaborations.
3. Continued UK participation in, and funding for European Reference Networks for rare and complex diseases, to benefit patients in the whole of Europe.

**For continued cooperation and full alignment between the UK and EU on clinical trials, we make the following recommendations:**

1. Inclusion of clinical trials in negotiations on the future UK–EU research and innovation relationship, and full UK participation in the EU clinical trials system on a similar basis to member states. This will mean continued access for patients across the UK and EU to opportunities for innovative treatments by taking part in clinical research.
2. Following the welcome commitment from the UK government to implement the new EU Clinical Trials Regulation (CTR) when it comes into force, the UK should seek to have access to the single EU clinical trials portal and database, alongside being part of relevant regulatory processes.
3. Agreement between the UK and EU on close future collaboration to minimise the burden on researchers, continue to provide access to the widest pool of patients, and allow Europe to use its collective expertise to be an attractive and competitive region to conduct clinical research. UK divergence from the CTR could lead to additional complexity when setting up multinational trials, including potential delays to trial set-up and completion.
4. Continued alignment with EU Data Protection laws, vital to ensuring cross-border data sharing for medical research.

**A future relationship should support the free exchange of research and innovation personnel. This requires a migration system as recommended below:**

1. A system that builds on the commitment set out in the Political Declaration to develop “appropriate arrangements” for the recognition of professional qualifications. A future framework should facilitate the mutual recognition of qualifications and enable healthcare professionals and researchers to practise and meet continuing competence criteria after the UK leaves the EU.
2. A system that builds on the UK government’s announcements for fast-track visas to attract world-leading scientists to provide a simple and welcoming migration experience with minimum barriers for all medical researchers, and health and care staff. The delivery of innovative treatments is dependent on the wider NHS being able to effectively deliver care. However, the workforce is currently under considerable strain and, as EEA nationals make up a significant proportion,<sup>3</sup> we need a holistic migration approach that allows the system to function as a whole.

3. A system that explores continued access to Erasmus and ensures that European students are able to access globally competitive universities in the UK and retains them in the job market post-education, which is vital for UK and European science.

### Robust coordination mechanisms on public health and wellbeing

The health security of citizens across Europe, including the UK, needs to be protected from threats that know no borders; tackling these health risks effectively requires joined-up policies and action. The Political Declaration recognises that effective and swift data sharing is vital for effective law enforcement. The BHA believes the same priority must be given for health security protection.

The BHA believes that the UK and EU should continue to cooperate in matters of health security – building on the commitment made in the current Political Declaration – in three areas where the UK is currently involved in a range of EU-wide mechanisms to:

- exchange information and early warnings about health threats, such as communicable diseases, illegal drugs or unsafe medicines, ensuring maximum preparedness to tackle them
- ensure that food and other materials transported across borders, for example medicines, transplant organs or blood, meets high safety standards
- set and enforce high standards relating to (among other things) reducing antimicrobial resistance, animal welfare and farming, and environmental policies.

### **To maintain the health security of UK and EU citizens, we make the following recommendations:**

1. Both parties should prioritise health security in the negotiations, reserving the right of UK and devolved governments to regulate in the interests of public health and safety.
2. A strong health security partnership which facilitates coordination between the UK and EU in dealing with serious cross-border health threats, such as pandemics, infectious diseases safety of medicines (pharmacovigilance) and contamination of the food chain. Ideally, this would be through continued access to the European Centre for Disease Prevention and Control (ECDC) and other relevant EU agencies, systems and databases.
3. The BHA wishes to see continued close collaboration with the Health Security Committee and to maintain the UK's relationship with ECDC post Brexit, ideally with full member status, recognising this may require some flexibility and revisions to the current ECDC legislative framework.
4. Alignment with current and future EU regulatory and health and safety standards relating to, for example, food, medicines, transplant organs, animal welfare and the environment, to avoid the need for replication of inspections and non-tariff barriers at the UK/EU border.
5. Continued collaboration to protect citizens from unsafe medicines and seek exchange of safety information between the Medicines and Healthcare products Regulatory Agency and the EMA as a priority.

**To maintain data exchanges for the purpose of health security, we recommend the following:**

1. The UK government should seek to ensure all UK pharmacovigilance organisations continue to be members of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance.
2. The UK government should seek to maintain membership of all the major EU pharmacovigilance systems and databases, including the European Databank on Medical Devices. The following systems have been noted as being of importance in tackling cross-border health threats:
  - the European Centre for Disease Prevention and Control (ECDC)
  - the Early Warning Response System (EWRS)
  - the European Surveillance System (TESSy)
  - the Epidemic Intelligence Information System (EPIS)
  - the Threat Tracking Tool (TTT)
  - the Field Epidemiology (EPIET) and Public Health Microbiology (EUPHEM) fellowships
  - EU Health Security Committee
  - EudraVigilance
  - IMI alert system for exchanging information about unsafe health professionals.



## Next steps

The Brexit transition period begins once the Withdrawal Agreement Bill is ratified and ends by default in December 2020. This period represents the opportunity to define the UK's future relationship with the EU, our largest trade and collaboration partner.

The BHA argues that time is of the essence and that health should be made one of the top priorities in the UK's negotiating mandate. The health community should have a seat at the table, alongside business, in the development of trade policy and negotiations. This would not only bring certainty to citizens, but also ensure that the UK remains a great place to work and live and does not lose out on global opportunities. The short timescales currently envisaged to agree a future trade deal with the EU present a challenge, and a significant risk that the safety and health of patients and citizens could be overlooked during negotiations.

## Further information

The Brexit Health Alliance has produced a number of briefings on the potential impact of Brexit:

### [Patient access to medical research](#)

This briefing sets out how patients across Europe have benefited from pan-European collaboration on medical research, outlines what is at stake if this collaboration is set back and what UK and EU decision makers can do to mitigate the risks.

### [Access to medicines and medical technologies](#)

This briefing explores how UK and EU citizens could be affected by the disruption in trade post Brexit, as well as the impact of a lack of cooperation in the regulation of medicines and devices between the EU and the UK post Brexit.

### [Reciprocal healthcare](#)

This briefing outlines how the current reciprocal arrangements work, the progress made so far in Brexit negotiations and the implications of a possible no-deal or bad deal for both patients and healthcare providers.

### [Protecting the public's health across Europe after Brexit](#)

This joint briefing from the BHA and the Faculty of Public Health, a member of the Alliance, sets out how people across Europe currently benefit from the close collaboration between the UK and EU on public health, and proposes solutions to maintain and improve a high level of public health protection after the UK leaves the EU.

# References

1. Gov.uk (19 October 2019), [Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community](#), [online], accessed 21 October 2019.
2. Gov.uk (19 October 2019), [Political Declaration setting out the framework for the future relationship between the European Union and the United Kingdom](#), [online], accessed 21 October 2019.
3. Dolton P, Nguyen D, Castellanos M, Rolfe H (2018), [Brexit and the health and social care workforce in the UK](#), National Institute for Economic and Social Research, [online], accessed 21 October 2019.

## The Brexit Health Alliance

The Brexit Health Alliance was established to make sure that the interests of those who use health services, as well as healthcare commissioners and providers, educators, researchers and the healthcare industry are reflected in the Brexit negotiations.

For further information about the work of the Brexit Health Alliance, please visit:  
[www.nhsconfed.org/BrexitHealthAlliance](http://www.nhsconfed.org/BrexitHealthAlliance)

## Brexit Health Alliance members

Co-chairs: Niall Dickson CBE, Sir Hugh Taylor

Secretary: Kate Ling

Members: Academy of Medical Royal Colleges, Association of Medical Research Charities, Association of British Healthcare Industries, Association of the British Pharmaceutical Industry, Association of UK University Hospitals, BioIndustry Association, Faculty of Public Health, Medical Schools Council, National Voices, NHS Confederation (including the Independent Healthcare Providers Network, Mental Health Network, NHS Clinical Commissioners and NHS Employers), NHS Providers, Northern Ireland Confederation for Health and Social Care, Richmond Group of Charities, Scottish NHS Chief Executive Group, Welsh NHS Confederation.