Brexit Health
Alliance

Supporting healthcare as the UK leaves the EU

Pandemic ready?

How post-Brexit negotiations could affect our ability to manage another coronavirus

The outcome of the post-Brexit negotiations between the UK and EU could affect our ability in future to manage pandemics. To protect public health and wellbeing across the UK and the EU, the Brexit Health Alliance is campaigning to ensure that the UK can continue to:

- **Participate in key EU data-sharing platforms and alert systems** to exchange information and early warnings about health threats.

- **Import and export the medicines and medical devices that we need**, such as ventilators and personal protective equipment, so that they reach patients as quickly as possible. This relies on the minimum of delay caused by tariffs and regulatory barriers, and requires the UK and EU to reach agreement on shared standards, such as manufacturing and inspection, so goods can be licensed for rapid release onto the UK market, or vice-versa.

- **Participate fully in research and testing of new treatments, including clinical trials**, so that patients can benefit as soon as these become available. This requires agreement on meeting the rules governing these trials, including use of and access to patient data and information sharing portals for researchers and clinicians.

- **Recruit and retain the researchers and clinicians we need to staff our services**. People's decisions to come to and stay in the UK will be affected by the agreement reached between the UK and EU on future entitlement of EU citizens and their families to healthcare and social security benefits such as pensions.

Introduction

The COVID-19 pandemic has changed everything. Before, the implications of the UK's exit from the EU for protecting the British (and European) public from cross-border health threats such as infectious diseases was a side issue that scarcely featured in discussions of the future UK/EU relationship. Now, COVID-19 has thrust this issue into the limelight so that it can no longer be ignored.

COVID-19 has demonstrated the importance of resilient international supply chains for medicines and medical goods such as personal protective equipment, and the value of collaboration in the fight against public health emergencies.

The outcome of the post-Brexit negotiations between the UK and EU will affect our ability in future to manage pandemics. There is no time to lose. The clock is ticking towards the end of the post-Brexit transition period on 31 December 2020 and a decision must be made by 1 July about whether or not this deadline will be extended. If the deadline is not extended, the NHS and the rest of the UK will have less than six months to prepare for the impact of the new deal, or no deal at all. Health and care services and businesses need to know as soon as possible what will change and what they will need to do to ensure service continuity.

In this briefing, the Brexit Health Alliance (BHA) explains what's at stake and what needs to be done to ensure that the UK is as prepared as it can be to safeguard the nation's health after leaving the EU.

Brexit Health Alliance

Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

2

Pandemic preparedness: the current situation and potential future

The UK/EU negotiations on their future relationship

Before leaving the European Union on 31 January 2020, the UK and EU concluded a legally binding withdrawal agreement that covers the lifetime rights of UK and EU citizens who currently reside and/or work across UK/EU borders, the financial settlement between the UK and EU, and the Northern Ireland Protocol on avoiding a hard border on the island of Ireland. They also agreed a political declaration setting out the principles underpinning their future relationship and indicating their intentions.

Since the publication of the withdrawal agreement and political declaration, the EU and the UK have published more detailed negotiating texts and statements. There are high-level references to potential cooperation on matters relating to health. For example, the EU, in their negotiating mandate[1] and draft legal text,[2] repeat the statement in the political declaration that: 'The parties should co-operate in matters of health security in line with existing union arrangements with third countries. The parties will aim to co-operate in international fora on prevention, detection, preparation for and response to established and emerging threats to health security in a consistent manner.'

As an exceptional measure, the EU has additionally proposed that the UK could request temporary access to the EU's Early Warning Response System (EWRS) in emergencies, in case of an outbreak such as COVID-19, deemed a serious cross-border threat to the European region.

They also hold out the possibility of 'participation in union programmes in areas such as science and innovation.'

> UK Parliamentary Select Committees have highlighted 'the general omission...of health as a regulatory floor' in the EU and UK negotiating positions and the need for a broader reflection on the treatment of health and healthcare systems in international trade negotiations.
>
> **UK Parliament's European Scrutiny Committee Report,** 6 May 2020

Similarly, in its approach to negotiations[3] and negotiating texts[4] the UK says it is 'open to exploring co-operation between the UK and EU in other specific and narrowly defined areas where this is in the interest of both sides, for example on matters of health security.'

However, the Brexit Health Alliance believes this is far from comprehensive. We have voiced our concern that many issues relating specifically to health are notable by their absence and are in danger of being overlooked by both sides

> Health and public health systems are at the top of the political agenda in the UK and the EU27 and likely to remain there for the duration of the negotiations, along with a much greater public awareness of how regulatory standards (for example, on medical devices such as ventilators), trade in essential goods (such as personal protection equipment) and mobility of workers (in the health and social care sector) affect how these systems are able to respond to a pandemic.
>
> **UK Parliament's European Scrutiny Committee Report,** 6 May 2020

Pandemic preparedness planning and response across Europe – the current situation

The planning, funding, organisation and running of health services is an area of national competence, which is why the EU nation states took their own decisions and approaches in response to the COVID-19 pandemic. The pandemic has demonstrated that in emergencies, member states resort to measures within the boundaries of a nation state.[5] Nevertheless, at EU level there are numerous ways in which the member states work together to identify and deal with cross-border health threats.

Health ministers of the EU member states meet regularly in the EU Health Security Committee. The European Union runs organisations and networks such as the European Centre for Disease Prevention and Control (ECDC) and the Early Warning and Response System (EWRS), which aim to coordinate preparedness, planning and response to health threats across the EU. Now that the UK has left the EU, a question mark hangs over whether participation will continue, and if so, to what extent.

Third countries Canada, China, Israel and the US have bilateral agreements with the ECDC to facilitate limited information sharing, but not full access – a model which the UK, as a third country, could follow.

Worldwide and European pandemic preparedness planning and response

The international response to major outbreaks of infectious disease is coordinated by the World Health Organisation (WHO). All members of WHO have an obligation under its International Health Regulations (IHR) to notify WHO of events that may constitute a public health emergency of international concern.

After Brexit, the UK will continue to participate in WHO's system, but only EU and EEA (European Economic Area) member states will have access to ECDC/ EWRS. ECDC routinely monitors a wider range of diseases and conditions than are notifiable under IHR,[6] and aims to help EU member states work in a coordinated and complementary way.

Additionally, the freedom of movement for goods and persons within the EU single market enables the EU Health Security Committee to take urgent coordinated action, such as emergency approval of pandemic medicines and joint public procurement across the EU.

Opinions as to the effectiveness of ECDC in emergency situations vary. By their own estimate, during the 2014 Ebola outbreak, the EU's coordinated response helped ensure that the number of cases in the EU/EEA was limited to eight in total.[7,8] However, not until after WHO had declared a global pandemic on 11 March did the EU member states set up the European Commission advisory panel on COVID-19 and approve the creation of a strategic EU medical stockpile.[9]

Clinical trials and rapid access to new drugs

The UK has been clear it will no longer be a member of the European Medicines Agency (EMA), the EU body responsible for overseeing clinical trials for new vaccines and medicines and deciding on marketing authorisations that apply across the EU. It is likely that the UK's independent medicines regulator, MHRA, will instead create its own rapid marketing authorisation mechanism, possibly co-operating with other global regulators to participate in a more powerful market than the UK alone.

Clinical trials data and marketing authorisations from the UK may not satisfy the EMA in future. This has sparked fears that some pharmaceutical companies may opt to base clinical trials in the EU, or in third countries that apply EU-compliant standards, so as to ensure they obtain marketing approval through the EMA for the EU market. They may prioritise the EU's single market over the UK's far smaller market, as already happens with Switzerland and Canada.[10]

After the end of the transition period on 31 December 2020, the UK will be outside the EU's rapid authorisation (via the EMA) and emergency bulk buying mechanisms for pandemic vaccines and medicines for treatment. Additionally, unless agreed as part of the future relationship, UK participation in EU-funded multinational clinical trials and research collaborations, including those on COVID-19, may not continue.[11]

Border controls and flows of products and people

Currently the UK, as part of the EU single market, has benefited from free movement of EU/UK citizens and goods in both directions across the UK/EU border. After the end of the transition period, new arrangements will be in place that will involve checks either at or behind borders on people (immigration control), phytosanitary checks on animals and foodstuffs, and checks to ensure that other products comply with regulatory standards. During periods of heightened vigilance such as pandemics, measures such as health checks on people at external and internal EU borders, as well as requirements for quarantine upon arrival, have the potential to seriously disrupt supply, maintenance and distribution of healthcare products. A future UK/EU agreement needs to address these issues to ensure the minimum of delay in supplies reaching patients and the uninterrupted maintenance of vital machinery and equipment.

Brexit Health Alliance

Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

5

What's at stake for UK pandemic planning in post-Brexit negotiations

The EU has announced a range of initiatives to help EU member states cope better with the COVID-19 pandemic. These initiatives are available to the UK until the end of the transition period on 31 December 2020.

However, the following programmes will not be available to the UK after the end of transition period unless specifically agreed in the UK/EU future relationship agreement:

Medical supplies

Access to the RescEU stockpile of equipment, such as ventilators and protective masks. Under the EU's Civil Protection Mechanism, one or two countries procure and host goods that are 90 per cent funded by the EU, on behalf of all participating countries. The goods are then distributed by the EU's Emergency Response Coordination Centre, which was set up to respond to natural or man-made disasters such as floods, earthquakes and pandemics. Non-EU countries such as Turkey, North Macedonia, Montenegro, Norway and Iceland participate, so the UK could potentially negotiate access.

Promoting research for a COVID-19 vaccine

The European Commission has been active in supporting research and innovation to tackle the COVID-19 outbreak. Six of the 18 research projects funded by the EU's Horizon 2020 research programme involve UK partners, and 140 teams across Europe are working to help find a vaccine to fight COVID-19. UK collaboration from 2021 onwards in EU research programmes will depend upon the future relationship agreement.

One of the 18 projects recently selected to receive €48.2 million of funding from Horizon 2020 to develop diagnostics, treatments, vaccines and preparedness actions in the fight against the COVID-19 epidemic, is already delivering positive results. Bringing together public and private organisations from Ireland, Italy, the United Kingdom and China, the HG nCoV19 test project has developed a new rapid point-of-care diagnostic to detect viral infection that gives accurate and reliable results in 30 minutes. HiberGene, the Irish company coordinating the project, has obtained approval to put it on the market. The EU support to this specific project amounts to €930.000.

European Commission, 20 May 2020

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Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

6

Joint procurement of supplies

All EU member states and EEA countries, along with the UK, Albania, Montenegro, North Macedonia, Norway, Serbia, Kosovo and Bosnia and Herzegovina, are part of the Joint Procurement Agreement, which includes access to procurement schemes to bulk buy personal protective equipment, ventilators, laboratory equipment and ICU medicines. The UK has signed the legal agreement to allow it to participate but did not join the first three schemes.[12]

However, according to Matt Hancock, Secretary of State for Health and Social Care, the delay in the equipment actually being delivered meant that 'the impact on our ability to deliver PPE is zero.' This view was corroborated by evidence from industry experts[13] to the UK Parliament's International Trade Committee on 23 April, that being part of a wider procurement scheme such as the EU's, would not have made a difference to delivery of PPE due to the shortage of worldwide supply/reliance on global supply chains.

The UK has now joined the latest EU procurement round, which will initially involve therapeutic treatments.

Peer support for clinicians

The EC has launched the COVID-19 Clinical Management Support System to provide an online platform for clinicians across Europe to exchange with peers on the management and possible treatment of severe or complex COVID-19 cases.

Joint repatriation flights

The EU has funded 75 per cent of the costs of bringing EU citizens, including some UK citizens, back to Europe.

Protecting jobs

The EU is making €37 billion available from existing EU structural funds to EU countries in 2020 through the Coronavirus Response Investment Initiative. This is not new money, but existing unspent funding that can be drawn upon and diverted under rule relaxations to deal with the impact of COVID-19. The UK Parliament's European Scrutiny Committee, in its report issued on 1 April 2020 noted: 'Under the Withdrawal Agreement, the UK remains eligible to be awarded EU funds until the end of 2020. However, the government has not made clear if it will seek to make use of the €555 million (£509 million) of funding the Commission has proposed to make available for COVID-19-related projects specifically, nor how it intends to spend all or part of the additional €2.4 billion of unallocated structural fund allocation for 2020 the UK has left.'[14]

EU Solidarity Fund to cover health emergencies

Up to €800 million will be made available this year via the EU Solidarity Fund, to fight the COVID-19 pandemic. Individual EU member states have to apply for grants and applications are considered on a case by case basis, so while technically eligible until the end of 2020 the UK is not expected to apply.

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Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

7

Key asks

The Brexit Health Alliance's key asks from the UK/EU negotiations:

- **Public health** – Continued close coordination between the UK and EU on public health and wellbeing. Participation in key EU data-sharing platforms and alert systems to exchange information and early warnings about health threats to ensure maximum preparedness to tackle them.

- **Patient safety** – Collaborative regulatory frameworks to continue for medicines and medical technologies across the UK and EU, so that patients are assured of high safety standards and public health and wellbeing are protected.

- **Access to medicines and medical devices** – Continued cooperation in import and export of medicines and medical technologies for frictionless trade of health products across UK/EU borders and rapid patient access to new treatments.

- **Citizens' rights to treatment** – UK and EU citizens to continue to benefit from rights to healthcare in any of the EU member states, ensuring simple and safe access to treatment when working, living or travelling at local, affordable cost.

- **Furthering medical research** – Continued participation in a Europe-wide system that encourages cooperation, innovation and research to continually improve patients' options for treatment. Continued UK/EU collaboration is vital to retain Europe's reputation as an attractive destination for cutting-edge research.

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Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

8

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Brexit Health Alliance

Pandemic ready? How post-Brexit negotiations could affect our ability to manage another coronavirus

9

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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.

The alliance includes members from across the devolved administrations and as such its work applies across the whole of the UK, including where health is a devolved matter.

For further information about the work of the Brexit Health Alliance, please visit: 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 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 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