Briefing

Brexit Health Alliance

Supporting healthcare as the UK leaves the EU

Protecting the public's health across Europe after Brexit

The health 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 UK and EU need to reach agreement on the best way of collaborating to fight these public health risks after the UK leaves the European Union.

This briefing 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 Brexit.

The Brexit Health Alliance has identified 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.

The Brexit Health Alliance welcomes the UK government's commitment that:

"We will not allow our high standards of health improvement, health security, food safety and environmental protection to be compromised in any way. Our guarantee of equivalent or higher standards of health protection and health improvement when we have left the EU is unequivocal."[1]

What the Brexit Health Alliance is calling for:

- Both the EU Commission and UK government to prioritise the public's health in negotiations on the future relationship between the UK and the EU.

- A security partnership: strong 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 by continuing access to the European Centre for Disease Prevention and Control and other relevant EU agencies, systems and databases.

- Alignment with current and future EU regulatory and health and safety standards relating to (for example) food, medicines, transplant organs and the environment, to avoid the need for replication of inspections and non-tariff barriers at the UK/EU border.

- The UK government to commit to a high level of human health protection when negotiating future free trade and investment agreements.

We look forward to working with the government to support it in achieving this ambition.

How do patients and the wider public benefit from EU-wide action on public health?

The EU has direct competence in public health[2] as threats are common across all member states. Tackling them benefits from collective action. The EU does not have competence relating to the funding, organisation and provision of health services at member-state level.

The EU has a range of legislation relating to public health, agencies tasked with enforcing the legislation, and programmes encouraging the strengthening of public health across the EU. The main instruments, agencies and programmes are listed in annex A.

There is widespread consensus on the value brought by working together across Europe on health issues, and on what would be lost if this should cease or diminish. **The Brexit Health Alliance urges both the EU Commission and UK government to prioritise the health of citizens by continuing this close and mutually beneficial collaboration**.

Uniting against health threats: infectious diseases, drug addiction, unsafe medicines

Infectious diseases

The Brexit Health Alliance welcomes the government's commitments to health security. In an April 2018 article, the Secretary of State for Health and Social Care commented: "As we've seen over the years with emergencies such as swine flu and Ebola, health transcends global boundaries…improving health security will form an important part of our negotiating position."[3]

The European Centre for Disease Prevention and Control (ECDC) is an EU agency tasked with strengthening Europe's defences against infectious diseases. The agency works in partnership with national health protection bodies such as Public Health England (PHE) to strengthen continent-wide disease surveillance and coordination between national public health agencies during outbreaks and emergencies.

Health protection experts from across Europe have come to regard the ECDC as an important facilitator of professional networking, partnership and collaboration, giving each member state access to a wealth of expertise. The ECDC supports and facilitates 17 networks and consortia of experts from a range of member states. The ECDC aims to enhance capabilities and strengthen capacity for pathogen detection, characterisation and surveillance of specific diseases and antimicrobial resistance.

Examples include the European Antimicrobial Resistance Surveillance Network (EARS-Net), the European Network for STI Surveillance, and the European Influenza Surveillance Network. Citizens across the whole of Europe benefit from a number of ECDC systems, including:

The Early Warning Response System (EWRS)
This surveillance system notifies member states of emerging communicable disease threats and control measures, progression of current epidemics, unusual disease phenomena or new threats from diseases of unknown origin, and proposed mechanisms to prevent and control communicable disease threats, particularly in emergency situations. Access is limited to formally appointed contacts in member states who receive real-time notifications.

The European Surveillance System (TESSy)
TESSy is a unified data collection system comprising all data on communicable diseases provided by member states. Data is analysed and aggregated by ECDC and reports disseminated to member states. Nominated users in member states are granted access to the entire data system.

The Epidemic Intelligence Information System (EPIS)
A web-based communication platform, EPIS allows nominated public health experts to exchange technical information to assess whether current and emerging health threats have a potential impact in the EU.

The Threat Tracking Tool (TTT)
This database of verified events is used to detect and assess emerging communicable disease threats.

The Field Epidemiology (EPIET) and Public Health Microbiology (EUPHEM) fellowships

These two-year fellowship programmes train practitioners from across Europe in either intervention epidemiology or public health microbiology, enabling individuals to access high standards of training with some of the most talented individuals in these fields across Europe. This allows for cross fertilisation of knowledge across Europe and helps build professional networks and collaborations.

EU Health Security Committee

With regards to international health security, the ECDC works within a larger system of European collaboration. The facilitator of this network is the EU Health Security Committee, which functions as an advisory group on health security at European level. It is vital post-Brexit, whether the UK is part of ECDC or not, that the UK remains a part of this committee. Both the UK and EU stand to benefit from its coordinated action on cross-border health threats.

To ensure that citizens in the UK and across the EU continue to benefit from the highest standards of health protection, maintaining the UK's relationship with ECDC post-Brexit presents the best-case scenario, ideally with full member status. (This may require some flexibility and revisions to the current ECDC legislative framework).

The UK has considerable expertise in health protection and is regarded as one of the EU leaders in communicable disease control. Post-Brexit, without a formal relationship with ECDC, social networks and professional relationships may fragment and the ability to tackle infectious diseases is likely to decline.

After Brexit, if an agreement is not reached on continued UK access to ECDC, creating a bespoke relationship with ECDC would be the next preferred option. This would be a long-term project and would require significant investment in system strengthening.

Careful consideration of the UK's post-Brexit relationship with ECDC is needed to protect and enhance the health of the British and wider European public.

Tracking and tackling infectious diseases

Proximity to Europe and high levels of cross-border travel means cases of infectious disease in the UK are regularly imported from Europe, and vice versa. Outbreaks of measles in England and Wales have been repeatedly linked to ongoing outbreaks in countries in eastern Europe,[4, 5] while cases of hepatitis A among men who have sex with men across Europe have been shown to be linked, with 3,813 cases identified to date.[6]

Further diseases regularly emerging in the UK from Europe include legionella, an often severe form of pneumonia, and food-borne sources of infection, such as the multi-country outbreak of salmonella that was linked to Polish eggs in 2017.[7] Just this year a case of multi-drug resistant Neisseria Gonorrhoeae was confirmed in the UK and found to be acquired from South-East Asia.[8]

Drug addiction

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)[9] plays a vital role enabling EU member states, including the UK, to:

- have **timely and strategic intelligence** and risk assessment of the European drugs market and illicit drug flows, and their implications for public health and security

- anticipate, identify and respond at an early stage to new threats and developments through an **early warning and response mechanism**

- adopt and implement **effective and evidence-based interventions**

- build and evaluate national and European **policies and strategies.**

The UK Focal Point on Drugs, based in Public Health England (PHE), provides information to EMCDDA[10] and in return receives intelligence on emerging developments across the EU with European agencies such as Europol and the European Centre for Disease Prevention and Control.

Europol is a key EMCDDA partner within the EU's early warning system on new psychoactive substances,[11] central in detecting new psychoactive drugs, assessing their characteristics and informing recommendations on controls in member states.

> ### The EMCDDA: Drug addiction
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> The EMCDDA has an important role in supporting effective drug strategies in all member states. An alternative framework would need to be developed between the UK and the EU to facilitate shared and agreed approaches to data sharing and drug surveillance.
>
> Risks also arise from exclusion from the EU Drugs Action Plan 2013–16,[12] which depends on work with Europol to improve monitoring of illicit drug supply in Europe and develop indicators on drug markets, drug-related crime and drug supply reduction.

Unsafe medicines

Currently, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has full access to the EU information technology public health network, including EudraVigilance, a centralised European database. This database supports stronger safety monitoring of medicines by reporting and analysing suspected **adverse reactions to medicines** that are authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the EU medicines regulatory network.

If following Brexit the MHRA no longer has access to this system, we can expect delays in the detection of new warning signals in the UK and EU27/EEA of between one and two months. This could also cause delays in the management of new signals (public health threats) of up to five months, based on analysis of experience in Canada, Australia and Switzerland. This would be due to the absence of direct communication between MHRA, EU27/EEA regulatory authorities and other non-EU authorities (for example Food and Drug Administration, United States).[13]

A 'no deal' Brexit would lead to weakened medicine safety systems for patients in both the UK and the EU. The UK currently makes up 36 per cent of the pharmacovigilance referrals made to the EMA, the greatest number of signals of all member states. This expertise would no longer be directly and immediately available to the EU27/EEA. The same is true of the availability of EU27/EEA experience to the UK.

Similarly, for medical devices, together with Germany, the UK manages approximately 65 per cent of all entries into the EU National Competent Authority Report (EU-NCAR), the process whereby competent authorities such as the UK's MHRA disseminate vigilance data.

> ### Unsafe medicines
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> **The Brexit Health Alliance calls for the UK to:**
>
> - seek mutual recognition of pharmacovigilance studies by the Medicines and Healthcare Products Regulatory Agency and the EMA as a priority
>
> - seek to ensure that all UK pharmacovigilance organisations continue to be members of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
>
> - maintain membership of all the major EU pharmacovigilance systems and databases, including the European Databank on Medical Devices (EUDAMED) and EudraVigilance.

These issues were identified in the recent House of Commons Health Select Committee inquiry report *Brexit: medicines, medical devices and substances of human origin*.[14]

Existing EU safeguards (laws and standards) on public health

EU legislation (see annex A) sets high standards for the quality and safety of human cells and tissue. The Brexit Health Alliance supports the continuation of the UK's alignment with these standards in the interests of citizens on both sides of the EU/UK border, but this will depend on the outcome of negotiations.

Contaminated blood products

A shortage of human clotting factors to treat patients with haemophilia in the UK during the 1970s and 1980s resulted in the NHS purchasing blood products from USA companies using paid-for donors, including those at high risk of transmission of blood borne viruses. The result was thousands of patients being treated with contaminated products and over 4,500 patients contracting either HIV or hepatitis C, of whom over 2,000 are thought to have died.

Current EU legislation around quality and safety standards for the transplant of human cells and tissue should ensure that similar tragedies never occur again.[15]

Organ transplants

Between 1 April 2016 and 31 March 2017, six individuals in the Republic of Ireland were able to receive liver transplants not suitable for recipients within the UK from UK donors.[16] Equally over the last decade, 204 organ transplants received by UK citizens were donated in the Republic of Ireland. Harmonised standards for safety and quality of human tissue and cell transplantation across the EU means that donor organs can be exchanged and 'increases the pool of organs available, improving the match between the donor and recipient.'[17]

Food safety, Brexit and Northern Ireland

Owing to its land border with the Republic of Ireland, Northern Ireland is a special case regarding food safety. Food production is central to the economies of both Northern Ireland and the Republic of Ireland. Northern Ireland exports £1.15 billion worth of food to the EU, about 70 per cent of which goes to and through the Republic of Ireland.

If the UK leaves the EU single market and customs union without an agreed alternative, goods including foodstuffs would require inspection at the border to provide public health and safety protection. This would add costs for food business operators and could lead to delays in the food chain, and unsafe food entering the system. Some form of continuing regulatory alignment between Northern Ireland and the Republic of Ireland would avert this outcome.

Public health on the island of Ireland: cross-border initiatives

There are many examples of cross-border collaborations between Northern Ireland and the Republic of Ireland which benefit the health of the public in both jurisdictions. By combining patient populations, staffing and expertise on both sides of the border, it is possible to offer services which are higher quality, more accessible, and economically and operationally viable.

Cooperation and Working Together (CAWT)

This is a partnership organisation between health and social care (HSC) services in Northern Ireland and the Republic of Ireland which facilitates cross-border collaborative working and has been heavily funded from EU programmes.

CAWT first secured £30 million from the EU's INTERREG VA funding programme and delivered 12 strategic programmes, including:

- cross-border acute health services

- alcohol abuse

- eating disorders

- diabetes

- health inequalities

- support for older people.

Eighty per cent of these projects have been mainstreamed after EU funding ceased, demonstrating the significant role CAWT has played in health and social care innovation. More recently, CAWT has so far secured £53 million from the EU INTERREG VA programme to deliver under six project themes by December 2021. This funding has been underwritten by the UK and Republic of Ireland governments until 2021. After the UK has left the EU, scope for obtaining such funding to support future cross-border initiatives is uncertain.

The EU also funds valuable research and development, such as CHITIN (Cross-border Healthcare Intervention Trials in Ireland Network).

Research and development

A target of €175 million was agreed between Northern Ireland and Republic of Ireland governments for cross-border projects funded from Horizon 2020 (H2020), the EU's £80 billion research development and innovation programme. One example is the €8.8 million award for CHITIN, which will support ten cross-border healthcare intervention trials aiming to provide opportunities for people to be included in research trials closer to home, for example in remote communities.

While the UK government has pledged that any applications for research funding submitted before the date the UK leaves the EU will be fully supported, there is anxiety among EU member states about including the UK as a research partner, given the uncertainty of the UK position after Brexit.

Maintaining high standards of protection after Brexit

The EU has confirmed its readiness to work towards a balanced, ambitious and wide-ranging free trade agreement (FTA) with the UK that would address, among other things, sanitary and phytosanitary measures, a framework for voluntary regulatory co-operation, and "global challenges, in particular in the areas of climate change and sustainable development, as well as cross-border pollution, where the Union and the UK should continue close co-operation."[18]

In turn, the UK government has highlighted continued access to EU agencies as a goal in Brexit negotiations. The Prime Minister has stated that: "we will want to make sure our regulators continue to work together…This will be essential for everything from getting new drugs to patients quickly to maintaining financial stability".[19]

We welcome the Secretary of State for Health and Social Care's commitment to **"find an agreement that allows us to maintain the important and mutually beneficial collaboration with Europe on health issues. As the negotiations move forward to agreeing the terms of our future relationship, improving health security will form an important part of our negotiating position."**[20]

As well as securing future relationships, the Prime Minister also stated on 3 March 2018 that: "As we leave the EU we will uphold environmental standards and go further to protect our shared natural heritage. And I fully expect that our standards will remain at least as high as the EU's".[21] Lord O'Shaughnessy, reiterated this pledge on 19 April 2018, declaring: "This government is fully committed to maintaining the highest standards of health protection as we leave the EU".[22]

On Wednesday 16 May 2018, during the third reading of the EU (Withdrawal) Bill in the House of Lords, the government confirmed that the duty to 'Do No Harm', currently enshrined in Article 168 of the Treaty of Lisbon, which makes clear that "a high level of human health protection shall be ensured" in all policies and activities, will continue after the UK leaves the EU.[23]

This new government commitment follows a parliamentary and public campaign by a coalition of 64 health organisations including the Brexit Health Alliance, along with medical royal colleges, faculties and major charities such as Cancer Research UK, Macmillan, Diabetes UK and MIND. The Brexit Health Alliance warmly welcomes the progress made and we look forward to working closely with this and future governments to ensure that this duty is properly understood and observed.

Both the UK and the EU see the mutual benefits of continuing collaboration on public health after the UK's withdrawal from the EU. However, public health and wider health do not feature as a specific topic in the recently published list of topics for discussion on the future framework[24] for the new relationship between the UK and EU.

Health is only one of the many issues being considered when negotiating how much access the UK will retain to various EU agencies and the extent to which the UK will continue to be aligned with a range of EU legislation and regulatory standards after Brexit. The Brexit Health Alliance is concerned that in the overall negotiations, public health may not rank high on the agenda. We are keen to support the UK government and European Commission to realise their ambition to maintain robust and effective collaboration. **We are therefore looking for a commitment from both sides that public health will be prioritised in the negotiations**.

"We must build this country's future outside the EU around a fundamental commitment to further improving the public's health and wellbeing."

Professor John Middleton, President of the Faculty of Public Health

Negotiating healthy free trade and investment agreements

Post-Brexit, the UK will need to negotiate **at least 759 treaties with 168 countries**[25] to maintain current international relationships. The Brexit Health Alliance welcomes the commitment given by government minister Lord Duncan of Springbank during committee stage of the EU Withdrawal Bill, that: "the values and principles which have underpinned our National Health Service for the past 70 years" will "not be traded away with the US or any other trade partner we might have".[26]

It is unclear at present what kind of agreement the UK and EU will reach regarding their future trading relationship. The UK's ability to diverge from current EU-wide trade agreements will depend upon the degree to which the UK remains aligned with EU legislative and regulatory frameworks and has access to participation in EU agencies and collaborations.

There are public health concerns around future trade deals. Most of the economic benefits free trade and investment agreements (FTIAs) deliver come through regulatory harmonisation and elimination of non-tariff barriers. These include standards, regulations and requirements intended to protect consumers, human health, safety and the environment. Harmonising regulations on food safety, toxic chemicals, or labour rights could bring unwanted health outcomes. Trade liberalisation, when applied to tobacco and alcohol, has been associated with adverse health and social consequences. Future FTIAs may challenge the precautionary principle at the heart of the EU and UK's regulatory system.

The Brexit Health Alliance is alarmed that a recent US Foreign Trade Barriers report signals that the US is keen to roll back our food safety and environmental standards.[27] Recent polling shows that 82 per cent of the public would oppose a trade deal[28] negotiated on this basis. We look forward to supporting the government in applying the Article 168 duty to help it determine and interpret the standard by which freedom to trade versus public health is balanced post-Brexit.

> ## "Protecting and improving public health is part of our national DNA and our current and future trading partners will expect us to continue to prioritise health."

Jeremy Hunt, Secretary of State for Health

FTIAs also commonly include investor state dispute settlement (ISDS) clauses. Investment protection in FTIAs consists of standards guaranteeing that governments will uphold principles of treatment that foreign investors can rely upon when deciding to invest. In the case of the (now suspended) Transatlantic Trade and Investment Partnership agreement between the EU and US, the London School of Economics and Political Science cautioned that ISDS could impose meaningful economic costs on the UK, through regular challenges to governmental actions not normally challengeable under UK law. The imprecise wording of investment protection standards could result in the risk of the UK losing arbitration disputes.[29]

ISDS clauses could also impose meaningful political costs on the UK, risking legitimate public policy space through regulatory chill – the abandonment, delay or modification of future preferred regulation in the public interest on account of objections (perceived or real) from investors. Examples of ISDS public health claims include those made by the tobacco industry in opposition to the standardised packaging of tobacco products.

But FTIAs do not have to be like this. Explicit carve-outs of critical goods and services, for example health agreements, can include obligatory standards covering labour, certification and environmental standards.

Food and farming: risks and opportunities

The UK's decision to leave the EU and its Common Agricultural Policy (CAP) will fundamentally impact on how and if British land is farmed, what food is produced and what consumers buy. Future agricultural policies should be underpinned by the aim of achieving clear health outcomes for the whole population. For example, by ensuring provision of affordable fresh fruit, vegetables and protein to all segments of the population. There is an opportunity for government policy to support and encourage production, procurement, provision and consumption of UK-grown foods that support local businesses, human health and the environment.

Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7

Multinational tobacco company Philip Morris International filed an investment arbitration lawsuit claiming compensation from Uruguay, on the grounds that Uruguay's anti-smoking legislation devalued its cigarette trademarks and investments in the country and contravened the bilateral investment treaty between Switzerland and Uruguay (Philip Morris is headquartered in Lausanne.)

Although the claim was eventually rejected, this case demonstrated not only that this kind of action can be used to challenge public health measures, but also that they can provoke regulatory chill discouraging countries from introducing similar legislation for fear of expensive legal action.

After Brexit

In this briefing, the Brexit Health Alliance has set out its concerns and hopes around safeguarding the health of both UK and EU citizens after Brexit. Much has been gained in the past decades by collaborating against health threats across borders, and much would be lost were this to be discontinued.

For this reason, the alliance is seeking reassurance that public health issues will not fall by the wayside in negotiations on the future relationship between the UK and the EU, and that the health of citizens will not be affected in subsequent free trade agreements. The group welcomes wholeheartedly UK government commitments that there will be no diminution in standards of public health protection after the UK leaves the EU.

The Brexit Health Alliance is calling for:

- both the EU Commission and UK Government to prioritise the public's health in the negotiations on the future relationship between the UK and the EU

- a security partnership: strong 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 by continuing access to the European Centre for Disease Prevention and Control and other relevant EU agencies and systems

- alignment with current and future EU regulatory and health and safety standards relating to (for example) food, medicines, transplant organs and the environment, to avoid the need for replication of inspections and non-tariff barriers at the UK/EU border

- the government to commit to a high level of human health protection when negotiating future free trade and investment agreements.

"If the UK no longer had a relationship with the European Centre for Disease Prevention and Control, both UK and European health protection will be weakened due to reducing information exchange, increased risk of failures in surveillance and early warning, and increased risk of poorly informed decision making."

Response by public health expert to Faculty of Public Health survey, March 2018

Annex A

The EU has a range of legislation relating to public health, agencies tasked with enforcing the legislation, and programmes encouraging the strengthening of public health across the EU.

The main agencies are:

- European Centre for **Disease Prevention and Control** (ECDC)

- European **Food Safety** Authority (EFSA)

  – Rapid Alert System for Food and Feed (RASFF)

- **Consumers, Health, Agriculture and Food** Executive Agency (CHAFEA)

- European Agency for **Safety and Health at Work** (OSHA)

- European **Chemicals** Agency (ECHA)

- European Foundation for the **Improvement of Living and Working Conditions** (Eurofound)

- European **Medicines** Agency (EMA)

- European Monitoring Centre for **Drugs and Drug Addiction** (EMCDDA)

Examples of EU public health legislation

- Food safety: **General Food Law Regulation** (Regulation (EC) No 178/2002) includes regulations and directives around food labelling; food composition, contaminants and residue limits; and food production hygiene rules

- Drinking water: **Quality of water intended for human consumption** (EU Directive 98/83/EC)

- Tobacco: **Tobacco advertising and sponsorship** (Directive 2003/33/EC)

- Human tissue: **Quality and safety of blood and blood components** (Directive 2002/98/EC) Transplantation: **Safe human tissues and cells for transplantation** (Directive 2004/23/EC) **Quality and safety of organs intended for transplantation** (Directive 2010/53/EU)

- Air quality: **Ambient Air Quality: Cleaner Air for Europe** (Directive 2008/50 EC) also various regulations on motor vehicle and industry emissions.

- Chemical pollution: **Stockholm Convention**

- Other regulations related to human health include those on waste disposal, transport and port health, occupational health, climate change, medicines and technology.

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Brexit Health Alliance members

This briefing was produced in partnership with the Faculty of Public Health

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