Brexit Health Alliance written response to Science and Technology Select Committee Inquiry on Brexit science and innovation summit

About the Brexit Health Alliance
Bringing together the NHS, medical research, industry, patients and public health organisations, the Brexit Health Alliance aims to safeguard the interests of patients and the healthcare and research they rely on during the Brexit negotiations.

Summary
As phase II of the negotiations are being planned by both the United Kingdom (UK) and the European Union (EU), the Brexit Health Alliance has called for issues with the potential to negatively impact on patients to be prioritised and urgently resolved.

Regulation of medicines and medical technologies and medical research

- Patients must be ensured speedy access to new medical innovations; experience no disruption in the supply of medicines and treatments; and, crucially, patient safety must not be compromised. This can be achieved through the close regulatory cooperation between the EU and UK that has been proposed by the UK government.
- Patients must be able to continue to participate in vital pan-EU clinical trials. It is vital that the UK not only aligns with the new EU Clinical Trials Regulation, but also negotiates continued participation in the EU-wide clinical trials portal which underpins the approval and supervision of clinical trials in Europe.
- Pragmatic solutions should be sought to allow patients to benefit from the UK's participation in EU systems such as data sharing networks, pharmacovigilance and the new clinical trials infrastructures.
- There should be an implementation period beyond the end of March 2019 to adequately reflect the time needed to ensure relevant customs, trade and regulatory procedures are in place.

Access to EU research funding

- UK patients, the public, researchers and organisations can take part in pan-European research and innovation networks and clinical trials and that these can be supported by UK involvement in EU funding programmes such as Horizon 2020 (and its successors) and the EU Health Programme.

Reciprocal healthcare for patients who need care across the UK/EU border after Brexit:

- NHS hospitals and clinicians must be able to continue to participate and lead European Reference Networks for rare and complex conditions, for the benefit of rare disease patients across Europe.

Migration

- The UK must have a migration policy that attracts, retains and supports exchange and movement of individuals who contribute to the advancement of medical science and research.

European health community recommendations, including on health research

- The joint statement by the European health community (December 2017) sets out a vision on how the Brexit negotiations can work in the best interest of patients across Europe, which resonates with the vision proposed by the UK government's Future Partnership Paper on Science and Technology.

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For the Brexit Health Alliance, protecting and enhancing medical science and research in the UK has the aim of achieving better outcomes for patients. There are many areas within the remit of phase II negotiations that could ultimately impact patients and their ability to benefit from the advances of medical science and research.

***1. Regulation of medicines and medical technologies and medical research*:**

- **Patients must be ensured speedy access to new medical innovations; experience no disruption in the supply of medicines and treatments; and, crucially, patient safety must not be compromised. This can be achieved through the close regulatory cooperation between the EU and UK that has been proposed by the UK government, and by the Brexit Health Alliance.**
- **Patients must be able to continue to participate in vital pan-EU clinical trials. It is vital that the UK not only aligns with the new EU Regulation on clinical trials, but also negotiates continued participation in the EU-wide clinical trials portal which underpins the approval and supervision of clinical trials in Europe.**
- **Pragmatic solutions should be sought to allow patients to benefit from the UK's participation in EU systems such as data sharing networks, pharmacovigilance and the new clinical trials infrastructures.**
- **The Brexit Health Alliance is calling for an implementation period beyond the two years of Article 50 negotiation to adequately reflect the time needed to ensure relevant customs, trade and regulatory procedures are in place.**

1.1 Our recent briefing on Brexit and the impact on patient access to medicines and medical technologies highlights the impact Brexit could have on patient access to medicines and medical technologies. Decades of cooperation and harmonisation of standards on medicines have led to frictionless trade and supply of goods and products across the EU's single market and customs union. The EU market currently represents 25% percent of global pharmaceutical sales market, compared to the UK's 3 % share. This means that the European market attracts new technologies and investments and this has an impact on R&D conducted in the region.

1.2 Furthermore, EU regulatory frameworks for medical research – spanning from clinical trials to data protection to the use of animals in research – help build consistent research standards between countries. Working within the same regulatory framework as EU partners opens up opportunities to collaborate and affords opportunities to work on a larger scale. Shared frameworks can facilitate the exchange of ideas, research samples and data. This can be particularly important for research into rare disease populations where multi-nation, multi-centre studies are the only way to access the number of patients needed for robust research.

1.3 Taken together, between 6,000 and 8,000 rare diseases affect the daily lives of around 30 million people in the EU. The EU Orphan Drugs Regulation (2000) has increased R&D of medicines for rare diseases and attracted investment from pharmaceutical companies. From 2000-2015, 1,469 orphan designations and 103 marketing authorisations have been granted and rare diseases remain an ongoing priority for EU research funds.

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1.4 Since the introduction of the EU Paediatric Regulation, from 2006-2015, the number of children due to be included in registered trials jumped 6,000 per cent, meaning significant growth in research about children funded by the European pharmaceutical industry. Research that can ask 79 million European children to join studies will identify successful medicines more quickly than research that asks 11 million UK children to join studies. The EU is also a source of funding for multinational trials and infrastructure in paediatric medicine. During the 2006- 2013 period, 19 pan-European research projects aimed at generating data about off-patent medicines in support of achieving market authorisation received EU funding. All these trials had UK involvement thanks to access to EU funds. British children will share the benefits of these trials with children in other countries.

1.5 With regards to regulation of clinical trials, the implementation of the EU Clinical Trials Regulation (CTR), has been delayed. Given that the CTR may not come into force until after the UK has withdrawn from the EU, the implications of this delay on the regulation of trials in the UK need to be considered.

1.6 It is not only a question of the UK aligning with European legislation, it will also be necessary for the UK to negotiate access to the critical infrastructure and networks at European level to allow that participation. This means:

- for close cooperation between the pharmaceuticals and European Medicines Agency and pharmacovigilance networks.
- for medical technologies, being able to not only ensure alignment with the new EU medical devices regulations, but also ensuring that UK notified bodies and MHRA can continue to be recognised by the EU.
- for clinical trials, not only applying the new EU regulation on Clinical Trials to UK law, but also ensuring access to the clinical trial portal and database which will be the tools for approval and supervision of clinical trials across the EU.
- for data protection, not only remaining aligned with the new EU General Data Protection Regulation, but also seeking an 'adequacy' decision from the European Commission, facilitating smooth transfer of personal data from the EU to the UK and vice-versa.

2. Access to EU research funding

- **UK patients, the public, researchers and organisations must be able to take part in pan-European research and innovation networks and clinical trials. These should continue to be supported by UK involvement in EU funding programmes such as Horizon 2020 (and its successors) and the EU Health Programme.**

2.1 EU funding programmes for research and innovation have supported and boosted collaborations between researchers in the UK and across the EU. The UK received €8.8 billion of EU science funding between 2008 and 2013. UK organisations have received €3.2 billion since 2014 through Horizon 2020, €420 million of this coming from the health strand of the programme. The formation of strategic partnerships is vital to the progression of medical research. The UK's access to EU funding programmes is about more than just financial benefit; the collaborative opportunities that are afforded are crucial.

2.2 The UK has also benefitted from the collaborative research partnership between the European Union and the European pharmaceutical industry, receiving €302.8 million from the Innovative Medicines

2.3 A number of leading UK medical research charities are listed as participants or coordinators across Horizon 2020 projects and as partners in one of the 71 Innovative Medicines Initiative projects.

2.4 EU funding programmes and schemes facilitate research into rare diseases to a greater extent than national equivalents; co-ordination of the much larger pan-EU population allows engagement of a sufficient cohort of both researchers with appropriate expertise and patients able to participate in research.

2.5 It is critical to maintain an environment for medical research that enables innovative collaborative research across the UK and the EU for maximum patient benefit to be achieved in Article 50 negotiations. This should include a special focus on research for rare diseases and special populations to ensure continued close collaboration with EU partners on rare diseases.

2.5 We welcome the UK- EU joint report from the conclusion of the first phase of that confirmed that the UK will continue to participate in EU programmes that run until 2020, including Horizon 2020. But it is vital that the UK achieves continued involvement in EU funding programmes and schemes beyond H2020 including Framework Programme 9, currently in development.

3. Reciprocal cross-border healthcare for future post- Brexit flows of patients:
NHS hospitals and clinicians must be able to continue to participate and lead European Reference Networks for rare and complex conditions, for the benefit of rare disease patients across Europe

3.1 European Reference Networks are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.

3.2 During the Brexit Health Alliance's campaign on reciprocal healthcare healthcare rights, we called for straightforward and appropriate access to reciprocal healthcare for both UK and EU patients, preferably by preserving current arrangements. We welcome the agreement reached in the UK- EU joint report in December 2017 on EU citizens' rights. However, to ensure collaboration in European Reference Networks post Brexit, there needs to be an agreement reached on patient rights and reciprocal healthcare for post Brexit flows.

3.3 Our campaign put a focus on a number of case studies from UK clinicians who coordinate ERNs and the important role ERNS play in better diagnosis and treatment of patients and also pan-European research and innovation (for example clinical trials and rare disease registries).

Brexit Health Alliance

Supporting healthcare as the UK leaves the EU

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4. Migration

The UK must have a migration policy that attracts, retains and supports the exchange and movement of individuals who contribute to the advancement of medical science and research.

4.1 Science and research are intrinsically collaborative and international: global mobility is a key feature of the UK medical research community. There is global competition for high-quality research talent and expertise. Exiting the EU offers an opportunity to develop a migration policy that helps to attract global scientific talent at all professional levels to work here and add value to medical research, patients, and the UK as a whole.

4.2 The health sector has an integral role to play in the success of the UK economy and should be seen as a partner able to support the delivery of the Government's Industrial Strategy and Life Sciences Strategy – not solely as a beneficiary of successful strategies.

4.3 We welcome the clarification gained on rights for EEA nationals already living in the UK and rights of UK nationals in the EEA at the conclusion of the first phase of negotiations. However, we remain concerned that uncertainty about the UK's future migration system is damaging the UK's reputation and attractiveness as a place to conduct research and urge the Government to ensure that these guarantees are embedded in law as soon as possible.

4.4 In order for the UK to remain an attractive destination for health researchers, scientists and clinicians, we urgently need a simple immigration framework that attracts and retains valued individuals within the UK life sciences and health community. The system must be fair, transparent and efficient, and sufficiently flexible to allow for the UK's changing skills needs and research priorities in the years ahead. A rigid policy focused on access to the UK being aligned to one characteristic only such as skill level, pay, or region will not be sufficiently flexible to deliver the desired outcome.

5. European health community recommendations, including on health research.

The joint statement by the European health community (December 2017) sets out a vision on how the Brexit negotiations, can work in the best interest of patients across Europe -including on health research

5.1 We would like to highlight to the Committee a statement from the European health community on Brexit (European network organisations representing patients, research organisations, industry and public health organisations). This presents a vision for the future relationship between the EU and the UK which would preserve medical research and patient safety. We believe it is in line with the vision laid down by the Government's Future Partnership Paper.