Health Committee: Brexit – medicines, medical devices and substances of human origin inquiry

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Submission from the Wellcome Trust

30 October 2017

Key points

- Continued harmonisation with the European Union on regulation in the life sciences is important to support collaboration on research and trade in medicines with the UK. Actions are needed in several areas of legislation, and the UK must:
    - Implement the **Clinical Trials Regulation** and negotiate continued access to the EU-wide systems, including IT infrastructure, to ensure alignment with the EU on clinical trials.
    - Implement the **General Data Protection Regulation** and negotiate agreements with the EU and other countries to ensure the continued free movement of personal data for research.
    - Negotiate alignment on **medicines licensing** to ensure straightforward access to the EU pharmaceutical market to minimise the impact on patients.

- A 'no deal' scenario would risk significant negative impact on patients and research in the life sciences. A transition arrangement, such as temporary European Economic Area (EEA) membership, is needed to provide stability and certainty for the life sciences sector.

- After Brexit, it is vital that the UK maintains a world-leading regulatory environment that is pragmatic and proportionate, protects patients and the public, adapts quickly to emerging research and technologies, collaborates globally, and takes a coordinated whole-system approach to regulation.

Introduction

1. Good regulation creates a supportive environment for health research by protecting people and by building public trust. The UK life sciences sector currently benefits from science-led, risk-proportionate regulation, which is reinforced by robust regulators who have earned the public's confidence and global prestige. With this foundation, the UK has flourished as an environment for emerging research areas and technologies, such as new IVF techniques to avoid mitochondrial disease.

2. Harmonised regulatory frameworks between the UK and the EU are an important component of this environment; they have reduced the bureaucratic burden on trade and research, making it easier to collaborate, conducts trials and share resources across borders. Cross-border collaborations are flourishing and UK researchers most

frequently partner EU colleagues, compared to researchers in other countries[1,2], leading to mutual benefits[3].

3. Following the referendum, we have identified key pieces of legislation for life-sciences research and considered the benefits and risks of diverging or continuing to harmonise with the EU. On balance, continued harmonisation is preferred to facilitate the continuation of strong collaborative links. In the following sections we discuss the priorities for life sciences regulation, and highlight instances where copying EU to UK law through the EU (Withdrawal) Bill will be necessary but not sufficient to ensure harmonisation.

Preferred outcomes

EU Clinical Trials Regulation (EU CTR)

Recommendation: implement the CTR and negotiate continued access to EU-wide systems, including IT infrastructure, to ensure alignment with the EU on clinical trials.

4. Regulation of clinical trials is harmonised across the EU so that trials can be run to mutually agreed rules and standards in all Member States, reducing the resources needed to comply. This enables those running clinical trials to recruit from large pools of participants and deliver more robust conclusions. This is particularly important for research into rare diseases, where single nations often have insufficient patients for a trial.

5. Underpinned by this harmonised framework, the UK is globally competitive for clinical trials – ranking first for early-stage Phase I trials in Europe, and second for Phase II and III trials[4]. The UK has about a 25-30% share in the total number of trials ongoing in the EU[5].

6. A new EU Clinical Trials Regulation (CTR) will replace the current Directive. The Regulation is widely considered to be an improvement on the existing Directive and will streamline the operation of multi-country trials through greater harmonisation. Implementation has been postponed from 2018 until 2019 following delays in the development of essential IT infrastructure.

7. If the UK does not harmonise with the Directive, and later to the Regulation, it will impose an additional resource burden on researchers setting up and running multi-country trials in the UK, as they would have to apply different rules at different sites. Under the Regulation, a single application will allow researchers to operate a trial across more than one Member State. However, if the UK is not part of this system, multi-national trials will need to secure separate approvals in the UK and EU. Since around a half of all trials running in the UK also have sites in the EU[6], this would create significant additional work for trial sponsors.

[1] In 2015, 60% of the UK's internationally co-authored papers were with EU partners, which represent an increasing share. www.royalsociety.org/~/media/policy/projects/eu-uk-funding/phase-2/EU-role-in-international-research-collaboration-and-researcher-mobility.pdf
[2] A survey of Fellows and grant recipients of the National Academies showed that Europe was the most likely source of international collaborators (87% of responses). acmedsci.ac.uk/file-download/96518966
[3] Collaborative research papers between the UK and EU26 members boost the citation scores for both partners, taking scores to twice the world average. www.cancerresearchuk.org/sites/default/files/uk_and_eu_research_full_report_v6.pdf
[4] www.abpi.org.uk/our-work/library/industry/Documents/Open_for_innovation_ABPI_Sourcebook_2016.pdf
[5] Personal correspondence
[6] Personal correspondence

8. The UK's relatively small population might not be sufficient to run large trials, or those for rare diseases, in the UK alone. The UK has a population of ~66 million, compared to the current EU28 which has a population of ~512 million, and a US population of ~323 million. Isolating the UK from a larger system would therefore make the UK a much less attractive destination for cutting-edge clinical research, with UK patients missing out on trials of innovative treatments.

9. Moving away from harmonisation and reduced collaboration would also be detrimental to the EU as the UK is a leader in clinical trials. EU patients benefit by taking part in UK trials, which includes the second largest number of pan-EU trials for rare disease and paediatric treatment[7]. At present, the EU benefits from the UK's clinical trials expertise, which was important in shaping the new Regulation.

10. Rt Hon Robin Walker, Parliamentary Under Secretary of State at the Department for Exiting the European Union, has given assurance that the UK is committed to a close partnership with the EU on clinical trials[8], which we welcome. To deliver this Government must implement the CTR. This would likely require specific legislation as the Regulation will take effect after we leave the EU and is not therefore included in the EU (Withdrawal) Bill.

11. However, implementing the CTR alone will not be sufficient to ensure harmonisation; the UK will need to negotiate continued participation in EU-wide systems. Critically, this must include access to the clinical trials portal, the IT infrastructure which will underpin the single application process across the EU.

General Data Protection Regulation (GDPR)

Recommendation: implement the GDPR and negotiate agreements with the EU and other countries to ensure the continued free movement of personal data for research.

12. The UK is a world leader in genomics and research using health data, both of which rely on international collaboration and sharing data across borders. To maintain this position, it is important that there can be straightforward exchange of personal data with the EU and other countries after Brexit.

13. Across the EU, the sharing of personal data is governed by the GDPR, which will come into force in May 2018. The UK Government and wider life sciences sector successfully shaped the development of the GDPR, to make it work for the benefit of UK health research.

14. There are a number of options in EU law to allow the sharing of personal data with a third country. The most straightforward of these is for the UK framework to be considered 'adequate' by the EU. If adequacy or an equivalent is not achieved, there will be significant risks and additional burdens to data sharing, making the UK a less attractive partner for research.

15. We welcome the Government's recognition of the importance of negotiating free exchange of personal data, and retaining a data protection regime consistent with the EU[9]. It is important that this outcome is achieved in negotiations. The Data Protection

[7] http://www.cancerresearchuk.org/sites/default/files/main_report_v8.pdf
[8] http://www.parliament.uk/documents/commons-committees/science-technology/170921-Robin-Walker-to-Norman-Lamb-DExEU%20letter.pdf
[9] https://www.gov.uk/government/publications/the-exchange-and-protection-of-personal-data-a-future-partnership-paper

Bill, currently before Parliament, must maintain the provisions of the GDPR, with care taken to avoid provisions that might reduce the chance of securing an agreement with the EU.

16. EU data law also defines how we share personal data with nations outside the EU including the US and Canada. Personal data can be exchanged between the EU and countries with specific agreements or considered 'adequate' by the EU. Following Brexit, the UK will not be covered by these agreements and will need its own arrangements with these countries. Government must therefore simultaneously make progress on arrangements to share data with other third countries, in order to participate seamlessly in global flows of personal data.

Medicines licensing

Recommendation: align medicines licensing to ensure straightforward access to the EU pharmaceutical market

17. As a member of the EU, the UK is part of a bloc with a 25% share of global pharmaceutical sales – standing alone we represent only 3%[10]. Smaller countries that are outside a wider approval system typically see medicines reach the market later. For example, Switzerland and Canada, which have sovereign regulators, typically see medicines reach the market six months after the EU[11]. If the UK is to remain an attractive market place for innovative new medicines, the hurdle arising from being a having a small pharmaceutical share must be overcome.

18. Rt Hon Jeremy Hunt, Secretary of State for Health, and Rt Hon Greg Clark, Secretary of State for Business, Energy and Industrial Strategy, have recognised the importance of this issue, and committed to working with the EU on medicines regulation[12]. We welcome this commitment, but the UK and EU will now need to work together to swiftly reach a deal that protects the health of patients across Europe.

19. Licensing of Advanced Therapy Medicinal Products (ATMPs), including some cell and gene therapies, are also regulated under EU legislation as an extension to traditional medicinal products. Alignment is particularly important in this area because advanced therapies are mostly targeted at rare diseases, where there are likely to be small number of cases in a single country and being part of a large market is more important.

Importance of transition arrangements and impact of no deal

20. Current uncertainty around life sciences regulation after Brexit is undermining the sector's confidence and is already impacting on research and innovation planning. Clarity on the nature of a transition arrangement, such as temporary European Economic Area (EEA) membership, is needed to provide certainty as soon as possible. This would provide time for the negotiation of a bespoke deal that would meet the needs the life sciences sector.

[10] www.abpi.org.uk/our-work/library/industry/Documents/UK-EU-Steering-Group-Report.pdf
[11] http://thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)31926-8.pdf
[12] https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b

21. A catastrophic ‘no deal’ scenario must be avoided. A disorderly exit from the EU would create uncertainty around the current regulatory cooperation, including for the numerous critical elements described above.

Wider approach to regulation to maximise benefits for science and patients

Recommendation: ensure world-leading regulation, underpinned by a whole-system approach, to deliver benefits to patients safely and swiftly.

22. Following Brexit, the UK will need to work hard to continue to be a competitive destination for research and innovation. Regulation is a central component of this offer, and effective regulation requires a whole-system approach. Innovative technologies may rely on multiple regulations, which need to work in together seamlessly. With the scale of legislative changes involved in delivering Brexit, it is critical that there is coherent oversight, with careful consideration given to interactions between regulations, including areas already under UK control.

23. The UK must create an environment that uses regulation to support emerging technologies and innovative interventions. The UK must build on its strong track record in regulating cutting-edge and potentially controversial research areas, such as new IVF techniques to avoid mitochondrial disease. To deliver sustainable regulatory change underpinned by public trust, pragmatic and joined-up regulation needs to be combined with meaningful dialogue between researchers, regulators, the public and media.

24. With several internationally respected regulators, including the MHRA, the UK must make the most of its ability to contribute to global regulatory convergence, and in particular to advocate for principles that are important to the UK, such as risk proportionality. UK regulators must continue to embrace this role and have the resource and support to fulfil this effectively.