

**Cancer Research UK response to the Health Committee (Commons) inquiry: ‘Brexit – medicines, medical devices and substances of human origin inquiry’
October 2017**

1. Cancer Research UK (CRUK) is the world’s largest independent cancer charity dedicated to saving lives through research. It supports research into all aspects of cancer and this is achieved through the work of over 4,000 scientists, doctors and nurses. In 2016/17, we spent £432 million on research in institutes, hospitals and universities across the UK. We receive no funding from the Government for our research and are dependent on fundraising with the public. Cancer Research UK wants to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.
2. We welcome the committee’s inquiry on ensuring certainty for patients, the NHS and the UK’s life sciences industry as the UK leaves the EU. It is vital that patients and research are prioritised in Brexit negotiations. Our response builds on our previous response to the Health Select Committee inquiry on “Brexit and health and social care”ⁱ. We have grouped and reordered the committee’s questions where appropriate for our response.
3. **Key messages:**
 - a. The UK must seek regulatory alignment with the EU in the following areas:
 - i. EU Clinical Trials Regulation (CTR): greater clarity is needed on plans to ensure the UK aligns with the CTR post-Brexit, particularly as this will not fall in the remit of the EU (Withdrawal) Bill. Alignment with the CTR will better support clinical research in the UK and is crucial for patients with rare and childhood cancers where pan-European studies are needed. Specifically, we need to understand the mechanism for the UK access to the EU portal and database – key parts of the new regulation.
 - ii. EMA drugs licensing: The UK should explore an agreement with the EU to ensure we can continue to take part in the EMA’s centralised procedure for drugs licensing. Any future drug licensing system must not exacerbate delays in access to the most innovative treatments for patients in the UK and across the EU.
 - b. The Home Office must design a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality. The research workforce is fundamental to our ability to understand disease and develop new treatments and interventions for patients.

What are the key considerations that arise for companies, healthcare services and regulatory bodies in the UK as a result of the UK’s withdrawal from the EU? Focusing on patients and the public, what needs to be done to ensure that any adverse impact is minimised or eliminated, and that opportunities to enhance services are maximised?

What are the implications for medical research and development, including for the timely patient access to new medicines, technologies and other relevant medical innovations developed within or outside the U.K? How can any adverse consequences be avoided or mitigated and any potential opportunities be enhanced?

4. We welcome the Government position paper on science and Brexitⁱⁱⁱⁱ. It is reassuring that emphasis is placed on continuing close collaboration for medical research. We are particularly pleased that our priorities are reflected in the paper, as well as in the Life

Sciences Industrial Strategy^{iv}. Now, more detail is needed on how these priorities will be taken forward in negotiations and in domestic policy.

5. Earlier this year CRUK, alongside other funders, published a report '*The impact of collaboration: the value of UK medical research to EU science and health*^v'. This report identified key areas where the UK has made significant contributions to the EU. The following are of most relevance to this inquiry and have helped to shape our priorities:
 - Participation in pan-EU clinical trials, providing notable leadership for rare disease and paediatric clinical trials.
 - Development of new therapies and medical technologies that benefit EU patients, backed by a thriving pharmaceutical and biotechnology sector.
6. It is imperative the UK remains a world-leader in health and research post-Brexit. Patients and research must therefore be at the heart of Brexit negotiations. To achieve this, we believe the following should be prioritised.

Ensuring an aligned and optimal regulatory environment for clinical trials

7. As the UK exits the EU, it's vital that cancer patients have timely access to clinical trial opportunities. CRUK supports over 250 clinical trials across the UK, recruiting around 25,000 patients each year. Of the 200 trials CRUK directly funds, more than a quarter (28%) involve patients from at least one other EU country^{vi}.
8. The current EU Clinical Trials Directive (CTD) is due to be replaced by the new EU Clinical Trial Regulation (CTR). The UK played a pivotal role in the development of the CTR and CRUK believes it is a positive step forward in regulation of clinical research. For example, it will harmonise the assessment and supervision process for all clinical trials via a central EU portal and database, currently being set up by the European Medicines Agency (EMA). Ultimately, alignment with the CTR will better support clinical research in the UK and facilitate pan-EU trials
9. Pan-EU or international approaches to trials are particularly crucial for paediatric and rare cancers. Collaborating across borders enables enough participants to make evidence from trials meaningful. The UK has led or participated in the largest number of pan-EU clinical trials for these types of disease^{vii}. Researchers are also increasingly stratifying patients according to the genetic profile of their cancer, reducing the number of eligible patients in a single country.
10. Due to technical difficulties, implementation of the CTR has been delayed until the end of 2019, meaning the Regulation will not be covered by the EU (Withdrawal) Bill^{viii}. Alignment with the CTR will therefore be subject to negotiation on the UK's future relationship with the EU.
11. Our concern is that if the CTR is implemented before alignment is agreed, the UK could become a 'sovereign regulator' and the current framework of UK laws will remain in use. This would leave the UK behind and without access to a harmonised regulatory system, significantly impacting on our ability to do clinical research and lead world-class studies.
12. We welcome UK Government plans to seek regulatory alignment with the EU to protect public health and safety^x. We support their ambition to put patients at the heart of regulation, provide long-term stability and ensure the UK is a leader in medical innovation.

But greater clarity is needed about how the UK will be able to align with the CTR so patients across Europe are able to benefit from taking part in UK-EU clinical trials.

- 13. As a priority, the Government should provide greater clarity on plans to ensure UK alignment with the EU Clinical Trial Regulation when we leave the EU. Specifically, we need to understand the mechanism for the UK access to the EU portal and database – key parts of the new regulation.**

Ensuring the UK is an attractive market for companies to launch innovative treatments

14. Cancer drugs play a crucial role in many patients' treatment. It is vital that we avoid creating further delays in access to medicines by diverging from the EMA's centralised licensing process post-Brexit. Such a divergence could lead the UK to become a lower priority market: the EMA covers an area responsible for 25% of global sales, whereas the UK accounts for just 3%^{xi}.
15. The MHRA is recognised as one of the leading national authorities in its field^{xii}. Between 2008 and 2016^{xiii}, the MHRA acted as Scientific Advice Coordinator in at least 20% of centralised EMA medicine approval procedures and provided data in about 50% of medicine approval procedures.
16. The MHRA has also been instrumental in pharmacovigilance and designing the regulatory environment across the EU for clinical trials, ultimately driving patient safety and faster access to new medicines for patients across Europe^{xiv}. This was referenced in a joint letter by UK and EU industry leaders^{xv}. The MHRA has also made its desire to stay involved clear, in a statement immediately following the Brexit vote^{xvi}.
17. Our preferred option would therefore be for the UK Government to seek an agreement with the EMA, which would allow EMA decisions to apply in the UK, and would allow the MHRA's continued participation in decision-making and shaping the regulatory environment. This would help ensure that the UK remains an attractive launch market for pharmaceutical companies bringing drugs to market, and therefore that UK patients are able to access innovative medicines quickly.
18. Crucially, continuity would also benefit patients across Europe, by maintaining expert input into decision-making and regulation, and ensuring the process is not delayed. This has been referenced by EFPIA, the membership body for the European pharmaceutical industry, who have argued that a break in regulatory continuity would represent 'an unacceptable risk to patient health'^{xvii}.
19. We recognise and support the UK Government's commitment to maintaining swift patient access to medicines in the recent position paper on Science and Innovation^{xviii}. But we would welcome further detail on the specific nature of the desired future relationship with the EMA.
- 20. The UK should explore an agreement with the EU to ensure we can continue to take part in the EMA's centralised procedure for drugs licensing. Any future drug licensing system must not exacerbate delays in access to the most innovative treatments for patients in the UK and across the EU.**

Ensuring we have a skilled science workforce

21. Researchers are at the heart of breakthroughs that benefit cancer patients in the UK, in Europe and worldwide. Our top priority is to ensure the Government designs a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.
22. CRUK funds postgraduate students and researchers from an international pool to ensure that we are working with the very best minds to conduct the highest quality research. 46% of our PhD students and half of our research fellows are from outside of the UK^{xix}. The flow of talent globally is an essential part of the research environment and international movement is a feature of most researchers' careers and professional development. 72% of UK-based researchers spent time at non-UK institutions between 1996 and 2012^{xx}.
23. In consultation with our research community we have developed a detailed position on researcher mobility to ensure the UK remains an attractive place to undertake research^{xxi}. In summary, our recommendations cover:
 - **The status of EEA nationals in the UK** – the Home Office should clarify the position of existing EEA residents in the UK and UK nationals in the EEA by:
 - Setting the specific cut-off date for when EEA residents will no longer be entitled to stay to the date the UK actually leaves the EU
 - Setting a minimal cost of application
 - Transferring those currently with permanent residency permits automatically to settled status.
 - Developing effective systems to process these applications
 - Ensuring their interpretation of EEA nationals' continuous residence is not affected by periods spent abroad for study or research.
 - **The current non-EEA immigration system** - the Home Office should make efforts to implement solutions and recommendations in the current non-EEA system:
 - CRUK's fellowships should continue to be fast tracked for Tier 1 through the Royal Society
 - Continued exemptions and priority for PhD-level roles in the Tier 2 route.
 - There should be no increase of Immigration Skills Charge for the research workforce for Tier 2
 - Any changes to salary thresholds should not negatively impact charitable research funders' budgets
 - **The UK's future immigration system – the top priority for CRUK is to ensure that the Government designs an immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.** A future immigration system should include the following features:
 - Mechanisms to recruit international staff with minimal costs, delay and uncertainty
 - The most effective measure of skill and benefit of migrants coming to the UK
 - Policies to enable partners and dependents of the research workforce to live, work and use public services in the UK
 - Support to ensure that international students in the UK are able to take up firm job offers

- Flexibility to enable extensive short- and medium-term movement of the research workforce
 - Dependencies between skills development and international research workforce
 - Mechanisms to support non-UK research group leaders to bring members of their research group with them when they move to the UK
 - Ability for Home Office to capture and publish more detailed migration statistics to inform future immigration policy development
24. The Home Office should not simply roll out the current non-EEA immigration system for EEA nationals. This is particularly an issue for roles below PhD-level which there are no exemptions for in the current non-EEA system. This includes technical roles as well as roles involved in the running of our clinical trials
25. **The Home Office must design a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.**

How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?

26. It is not currently clear what the nature of these new arrangements that will impact on patients and research will be post-29 March 2019. Therefore, we are not in a position to estimate a suitable timeline for transition at this stage. However, we do believe a transition period would help ensure patient safety is protected.
27. In addition, the current landscape in terms of the Brexit negotiations is very complex. For example, the implications of the delay in implementing the CTR are not yet fully understood, and this is just one piece of regulation. A huge amount of work is still needed and therefore a transition period would be sensible.
28. The EMA has indicated that their activities will be impacted by their relocation. This includes a reduction in, and delayed timelines for, their activities. Putting in place transition arrangements for their relocation may help reduce the impact of their relocation on their work.

What arrangements are needed to ensure the safe, effective and timely supply of medical radioisotopes over the short, medium and long-term?

29. Radioisotopes are important in diagnosing and treating cancer. The UK's future affiliation to the Euratom treaty – a treaty that establishes the free trade of nuclear material across the EU as well as the safeguarding of particular nuclear materials – remains unclear.
30. Leaving Euratom should not impact on safeguarding of medical radioisotopes as these are not classified as "special fissile material". However, our understanding is that leaving Euratom could impact on the UK's ability to access medical radioisotopes, as their free trade is covered by Euratom.
31. The UK imports these medical radioisotopes from within the EU and globally, mainly from France, Holland and the Czech Republic. It is vital that cancer patients in the UK are still able

to access these materials after we leave the EU. Because of their short half-life they degrade quickly and cannot be stockpiled.

32. We would endorse other calls to ensure there is not a “cliff edge” after Brexit, and advocate continued access to these materials and, if necessary, transitional arrangements. The uncertainty around the UK’s future involvement in the Euratom Treaty is another example of the care needed to make sure patients are prioritised in Brexit negotiations

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References

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- ^{iv} For more detail of CRUK’s position on the Life Sciences Industrial Strategy, see our response to the HoL Science and Technology Committee response: <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/lords-life-sciences-and-the-industrial-strategy/written/70483.pdf>
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- ^{xx} Elsevier, International comparative performance of the UK research base, 2013
- ^{xxi} Cancer Research UK position on researcher mobility (2017) <http://www.cancerresearchuk.org/about-us/we-develop-policy/our-policy-on-supporting-science/our-policy-on-researcher-mobility>