

**Cancer Research UK response to the Scottish Parliament Health and Sport Committee inquiry:
‘Impact of leaving the European Union on health and social care in Scotland’
January 2018**

1. Cancer Research UK (CRUK) is the world’s largest independent cancer charity dedicated to saving lives through research. We support 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 – including over £34 million in Scotland at our two research centres in Glasgow and Edinburgh. We receive no funding from any Government for our research and are dependent on fundraising with the public. Our ambition is 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 into what impact leaving the European Union will have on health and social care in Scotland. It is vital that patients and research are prioritised in Brexit negotiations now that the negotiations over the UK’s exit from the EU have advanced to the second phase. Our priorities focus on the ability for the UK to collaborate with the EU post-Brexit and therefore on powers reserved for Westminster. However, there is a clear role for Scottish Government in safeguarding the interests of patients and research in Scotland.
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 in Scotland and across the UK with rare and childhood cancers where pan-European studies may be 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. European Medicines Agency (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.

- 1) How could the potential risks of Brexit for health and social care in Scotland be mitigated?
- 2) How could the potential benefits of Brexit for health and social care in Scotland be realised?
- 3) In what ways could future trade agreements impact on health and social care in Scotland?

1. We welcome the UK Government position paper on science and Brexitⁱⁱⁱ. It is reassuring that emphasis is placed on continuing close collaboration for medical research and we are pleased that our priorities are reflected in the paper. We also welcome the Scottish Government highlighting the importance of “maintaining strong relationships with other EU countries, including the free movement of world-class researchers” to research in Scotland in *Scotland’s Place in Europe*ⁱⁱⁱ and throughout the Brexit negotiations. Now, more detail is

needed from the UK Government on how these priorities will be taken forward in negotiations and in domestic policy.

2. 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*^{iv}'. 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:
 - The UK's participation in pan-EU clinical trials, providing notable leadership for rare disease and paediatric clinical trials. There were over 4,800 UK-EU clinical trials between 2004 and 2016, and the UK has led or participated in the largest number of pan-EU trials for rare disease and paediatric treatments.
 - The UK's development of new therapies and medical technologies that benefit EU patients, backed by a thriving pharmaceutical and biotechnology sector. Around 25% of the world's top 100 prescription medicines were discovered and developed in the UK.
 - The UK's training of early career researchers from across the EU, to develop their skills and launch their research careers. Around 16,000 students from other EU countries are registered on UK biomedical courses.
3. 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

4. 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^v.
5. 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
6. 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^{vi}. Researchers are also increasingly stratifying patients according to the genetic profile of their cancer, reducing the number of eligible patients in a single country. Therefore, to get sufficient clinical trial data to inform interventions, multi-country trials may become increasingly important for all types of disease.
7. 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^{vii}. Alignment with the CTR will therefore be subject to negotiation on the UK's future relationship with the EU.

8. Any delay in aligning with the EU CTR could leave the UK behind, without access to a harmonised regulatory system. This could significantly impact our ability to do clinical research and lead world-class studies. It is crucial that an agreement is made before the EU CTR is implemented.
9. We welcome UK Government plans to seek regulatory alignment with the EU to protect public health and safety^{ix}. 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.
10. **We're asking the Scottish Government to support our calls for the UK Government to provide greater clarity on plans to ensure UK adoption and 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^x.**

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

11. Cancer drugs play a crucial role in many patients' treatment. Before drugs come to national bodies like the Scottish Medicines Consortium for decisions about whether to be routinely prescribed to patients, they first need to be licensed. In the EU, licensing is primarily carried out through a centralised procedure, led by the European Medicines Agency (EMA). 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}.
12. The Medicines & Healthcare products Regulatory Agency (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.
13. 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}.
14. 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.
15. 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 European Federation of Pharmaceutical Industries and Associations (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}.

16. 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.
17. **The Scottish Government should call on the UK Government to explore an agreement with the EU to ensure the UK 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^{xix}.**

Ensuring we have a skilled science workforce

18. The research workforce is at the heart of breakthroughs that benefit cancer patients in Scotland, the rest of the UK, in Europe and worldwide. Our top priority is to ensure the UK 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.
19. 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. Half of our PhD students and 46% of our research fellows are from outside of the UK^{xx}. 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^{xxi}.

Case Study - The Cancer Research UK Beatson Institute, Glasgow

As one of Cancer Research UK’s core-funded institutes, the Beatson carries out a programme of world-class science directed at understanding key aspects of cancer cell behaviour, and tries to translate these discoveries into new therapies and diagnostic and prognostic tools to help cancer patients. To participate in world-class science, the Beatson must attract world-class talent. This includes many researchers from the EU and further afield:

- Over 30 nationalities are currently represented at the Beatson.
- Over half the Beatson’s graduate students and 45% of its post-doctoral scientists are from non-UK EU countries
- None of the Beatson’s junior group leaders are UK citizens.
- Overall, almost 70% of the Beatson’s research scientists are non-UK citizens.

20. 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^{xxii}. In summary, our recommendations cover:

The status of EEA nationals in the UK and UK nationals in the EEA.

- We are pleased there have already been reassurances on:
 - 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
 - Transferring those currently with permanent residency permits automatically to settled status.
- We still need further clarity on:
 - Setting a minimal cost of application

- 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 UK 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

21. 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.

22. The Scottish Government should call on the UK Government to design a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality^{xiii}.

ⁱ HM Government, Collaboration on science and Innovation: A future partnership paper (2017) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/642542/Science_and_innovation_paper.pdf

ⁱⁱ CRUK response Government paper: Collaboration on science and Innovation: A future partnership paper (2017) <http://www.cancerresearchuk.org/about-us/cancer-news/news-report/2017-09-06-government-sets-out-aims-for-science-post-brexit>

ⁱⁱⁱ Scottish Government (2016) <http://www.gov.scot/Resource/0051/00512073.pdf>

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- ^{iv} Technopolis Group (2017). The Impact of Collaboration: the value of UK medical research to EU science and health. <http://www.cancerresearchuk.org/about-us/we-develop-policy/we-work-with-government/exiting-the-eu/uk-and-eu-research>
- ^v Statistics from CRUK's internal databases and include clinical trials from our Clinical Research Committee, New Agents Committee and Centre for Drug Development.
- ^{vi} Technopolis Group (2017). The Impact of Collaboration: the value of UK medical research to EU science and health. <http://www.cancerresearchuk.org/about-us/we-develop-policy/we-work-with-government/exiting-the-eu/uk-and-eu-research>
- ^{vii} EMA Management Board: highlights of October 2017 meeting http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2017/10/WC500236190.pdf
- ^{viii} Letter from Robin Walker (DExEU) to Norman Lamb (Chair of Commons Science and Technology Select Committee) (September 2017) <http://www.parliament.uk/documents/commons-committees/science-technology/170921-Robin-Walker-to-Norman-Lamb-DExEU%20letter.pdf>
- ^{ix} The UK wants to continue to work with the EU on medicines, Jeremy Hunt and Greg Clark joint letter, Financial Times (July, 2017) <https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b?mhq5j=e5>
- ^x Cancer Research UK position on the EU Clinical Trial Regulation http://www.cancerresearchuk.org/sites/default/files/dec2017_cruk_policy_statement_eu_clinical_trial_regulation.pdf
- ^{xi} BMI Research, Pharmaceutical sales, USDbn, 2015
- ^{xii} All-Party Parliamentary Group on Global Health (2015). The UK's contribution to health globally: benefiting the country and the world, June 2015. Available at: <http://bit.ly/1aLMjeu> (Accessed September 2017)
- ^{xiii} Ibid.
- ^{xiv} Varnai, P., Rentel, M., Davé, A. De Scalzi, M., Timmerman, W., Rosemberg-Montes, C. and Simmonds, P. (2017). The impact of collaboration: the value of UK medical research to EU science and health. Technopolis Group, 2017. Available at: <http://bit.ly/2z2emce> (Accessed October 2017)
- ^{xv} Cranz, H., Moll, N., Brennan, J., van den Hoven, A., Thompson, M., Smith, W., Bates, S. and Smith, J. (2017) Joint trade association letter on Brexit. *European Federation of Pharmaceutical Industries and Associations*, July 2016. Available at: <http://bit.ly/2wuHKln> (Accessed September 2017)
- ^{xvi} MHRA, 2016. MHRA and making a success of Brexit. MHRA, June 2016. Available at: <http://bit.ly/29UYmM2> (Accessed October 2017).
- ^{xvii} Kuiper, E. (2017) [online] Patients must be central in any decision on the EMA's new home. EFPIA, July 2017. Available at: <http://bit.ly/2sGNTed> (Accessed October 2017)
- ^{xviii} HM Government (2017) Collaboration on science and innovation: a future partnership paper. Available at: <http://bit.ly/2xNVqLf> (Accessed September 2017)
- ^{xix} Cancer Research UK position on Brexit and drug licensing (2017) http://www.cancerresearchuk.org/sites/default/files/cruk_policy_statement_on_brexit_and_drug_licensing_final.pdf
- ^{xx} This is from internal data collected by our Research and Innovation Directorate.
- ^{xxi} Elsevier, International comparative performance of the UK research base, 2013
- ^{xxii} 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>
- ^{xxiii} 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>