Cancer Research UK response to the Health and Social Care Committee (Commons) evidence session: Impact of a no-deal Brexit on health and social care

Introduction

1. Cancer Research UK (CRUK) is the largest charitable funder of cancer research in the world. In 2017/18 we invested £423 million in research to improve the prevention, diagnosis and treatment of cancer. We are the only charity funding research into all 200 types of cancer and we receive no Government funding, depending on the public for support.

2. In the 1970s, 1 in 4 people survived their cancer for ten years or more. Today, thanks to research, 2 in 4 people survive. CRUK’s ambition is to accelerate progress so that 3 in 4 people survive their cancer by 2034. This is even more important given the increasing incidence of cancer, which will grow from 350,000 a year in 2015 to over 500,000 by 2035 across the UK.

3. We welcome the Government’s fresh ambition to radically improve early diagnosis of cancer. Reaching the ambition of 75% of patients being diagnosed at stage one or two by 2028 is a significant challenge but will improve the prospects for thousands of patients if achieved. This target, and our own ambition to accelerate progress, relies on the UK’s world leading environment for science and research – an environment which would be put at risk by the UK leaving the European Union without a deal.

4. We are concerned that a no-deal Brexit would undermine the UK’s position as a global leader in the life sciences. A disorderly exit would harm clinical research, affect access to life-saving medicines for patients, and put at risk the UK’s ability to attract global scientific talent.

The impact of a no-deal Brexit on research and patients

5. Clinical trials. More than a quarter of the trials funded by CRUK involve at least one other EU country. These trials are vital to ensure the most innovative treatments benefit patients in the UK and worldwide. International collaboration is especially important for rare and childhood cancers, where there often aren’t sufficient numbers of patients in any one country to make evidence meaningful. A harmonised regulatory system underpins effective cross-national collaboration on clinical trials with other EU countries. Between 2004 and 2016 over 4,800 trials were run in collaboration between the UK and at least one other EU country¹.

6. The Government has confirmed that, in the event of a no-deal Brexit, the UK would continue to operate under the auspices of the EU Clinical Trials Directive (2001/20/EC). However, according to the European Commission’s notice to stakeholders, UK-based Sponsors of cross-national clinical trials would require legal representation in an EU member state². Making these changes would be a considerable burden, and a potentially a prohibitively costly step for smaller, non-commercial Sponsors.

7. The Clinical Trials Directive will be replaced by the forthcoming EU Clinical Trial Regulation (536/2014) (CTR). We welcome the UK Government’s commitment to align as closely as possible

---

with the CTR when it comes into force. However, access to the underpinning portal and
database (which will streamline submissions, co-ordinate assessments and help communication
between participants) is subject to negotiations with the EU. In the absence of a comprehensive
agreement with the EU, it is very unlikely the UK would have access to this digital infrastructure,
reducing the efficacy in set-up and patient safety reporting of future UK-EU trials. Ultimately,
this would put at risk the UK’s ability to continue to collaborate effectively with long-standing
European partners on trials. Such a situation would undermine our world-leading status in areas
such as paediatric oncology.

8. **Access to medicines.** The European Medicines Agency (EMA) centrally organises the
authorisation and monitoring of medicines across the EU. Through this system, the EMA covers
an area responsible for 25% of global pharmaceutical sales, while the UK on its own accounts for
just 3%\(^3\). In a no-deal scenario, the UK would be outside this system and risks being deprioritised
by pharmaceutical companies bringing new drugs to market. Switzerland’s independent
medicines regulator has been found to approve medicines around five months later than the
EMA\(^4\).

9. Any delay in accessing new life-saving medicines reaching UK patients would be unacceptable.
The Government’s no-deal notices pragmatically explore the opportunities for the Medicines
and Healthcare products Regulatory Authority (MHRA) to take a parallel approach to medicines
licensing after Brexit, for example through recognition of Committee for Medicinal Products for
Human Use (CHMP) opinion for marketing authorisation applications submitted prior to exit day.
It is far from certain, however, that this approach would avoid delays to the newest medicines
reaching patients. We continue to believe that the best outcome for patients would be a deal
which ensures the EMA’s licensing decisions continue to apply in the UK, and where the MHRA
continues to play a significant role in those decisions.

10. The Withdrawal Agreement currently precludes the MHRA from working on EMA medicines
assessments during the Implementation Period. This is of concern, and CRUK are working to
understand how, and when, this capability could be regained. In a no-deal scenario, however, it
is likely this situation would be more permanent. This risks undermining the leading status of UK
science and leaving a sizable gap in EMA capabilities. Between 2008 and 2016 the MHRA acted
as the lead assessor on at least 20% of centralised EMA medicines approval processes and
provided data in about 50% of all decentralised medicine approval procedures\(^5\). Indeed, the EMA
has already scaled back its operations in anticipation of losing MHRA capacity and expertise
during the Implementation Period\(^6\).

11. We welcome the pragmatism shown by Government and the pharmaceutical industry to date in
working together to ensure continuity of supply of medicines to patients, including plans to
stockpile some medicines. This will be crucial in protecting immediate supplies of life-saving

---

\(^3\) BMI Research. Pharmaceutical sales, USDbn, 2015


medicines for cancer patients in the event of a no-deal Brexit. However, this is not a long-term solution and it is unclear whether stockpiling to cover a six-week period will be sufficient. Government must be clear how it intends to prevent longer-term disruption to the supply of medicines if no deal is agreed with the EU.

12. In addition, many novel medicines cannot be stockpiled due to short lifespans, and investigational medicinal products (IMPs), products for use in clinical trials, are not covered under the terms of the Government’s Medicines Supply Contingency Planning Programme. The Supply of Investigational Medicinal Products technical notice simply states that organisations should consider their supply chains and make contingency arrangements, without further detail. Given that clinical trials cannot operate without access to these products, Government should clarify as a matter of urgency how it intends to safeguard access to these products in the case of a no-deal Brexit.

13. Researcher mobility. The ability of researchers to easily move and collaborate across borders underpins the UK’s world-leading research environment. 72% of UK-based researchers spent time at non-UK institutions between 1996 and 2015. At CRUK, half of our PhD researchers are not originally from the UK, with more than a third (35%) from the EEA. We welcome the Government’s guarantee on the rights of EU citizens currently living in the UK even in the event of a no-deal Brexit and await further detail. It is important for the international research community that the EU reciprocates this move.

14. In the event of a no-deal Brexit, it is unclear how short-term mobility between the UK and EU27 would be affected. Given the importance of cross-border working for researchers, including conferences, teaching and shared projects – such as the vital clinical trials described above - we are concerned there would be significant immediate disruption to the collaborative research environment.

15. A no-deal Brexit would mean the UK moving to a new immigration system on the 30 March 2019, and no bespoke deal with the EU on researcher mobility. This system would have to be in place by 30 March 2019 to avoid disruption to UK science, which would prove demanding given the timescale. Should a new system not be ready, it is likely the current non-EEA system would be applied.

16. A roll-out of the current non-EEA system across the board would be detrimental to science, research and innovation in the UK. This system is expensive for the researchers we fund and resource-intensive for the employers who recruit these researchers (such as research institutes and universities). It also uses salary as a proxy for skill, which penalises skilled but relatively lower paid laboratory technicians, who are vital for the UK’s life-saving research.

How effectively we consider the Government is planning for such an outcome

---

18. CRUK acknowledges that the Government’s recently published no-deal notices are pragmatic and are pleased that the concerns of the research community are clearly being considered. Nonetheless, a no-deal Brexit is clearly the worst outcome for cancer patients and research in both the UK and EU27. It is essential that we can continue to work with international partners to drive forward progress on improving outcomes for cancer patients. The priority now is for both the UK and EU to reach a deal that safeguards the interests of patients and research.