Briefing: European regulatory system for medicines
September 2018

Introduction and overview

What: This briefing outlines Cancer Research UK’s position on amendment NC17 to the Trade Bill. The amendment would make it a Brexit negotiating objective of the UK Government to seek full UK participation in the European regulatory system for medicines (ERSM) after exiting the EU.

Why: 1 in 2 people born since 1960 will be diagnosed with some form of cancer in their lifetime. Research and the resulting medicines have helped see survival double over the past forty years, so now around half of people survive their cancer. Cancer Research UK (CRUK) want to accelerate that progress so 3 in 4 people survive their cancer by 2034.

We need: For this to happen, we must ensure timely access to life-saving medicines after Brexit. Cancer Research UK want Government to:

1. Prioritise agreeing a close working relationship with the European Medicines Agency (EMA) which safeguards timely patient access to life-saving medicines.

2. Reach an agreement with the EU which would allow the MHRA to act as a Lead Authority on EMA assessments of new medicines

3. Provide further clarity on the Government’s plans to negotiate access for the UK to the portal and database which accompany the incoming EU Clinical Trial Regulation (CTR)

1. CLOSE RELATIONSHIP WITH EMA – Timely access to life-saving drugs

- The EMA’s processes for authorising and monitoring medicines allow national medicines regulatory authorities to cooperate, meaning faster patient access to new medicines. Without an agreement to fully participate in this system, authorisation and monitoring could be disrupted and patient access to new medicines could be delayed.

- While the EMA covers an area responsible for 25% of global pharmaceutical sales, the UK accounts for just 3%. Outside the ERSM, the UK risks being deprioritised by pharmaceutical companies bringing new drugs to market. For example, Switzerland’s independent medicines regulator has been found to approve medicines around five months later than the EMA.

- Any delay in life-saving medicines reaching UK patients would be unacceptable. In the light of discussions of stockpiling medicines, it is imperative Government seeks an agreement which would allow EMA marketing authorisation decisions to continue to apply to the UK.

2. ABILITY TO LEAD APPROVALS – Protecting patients and UK science prestige

- A recent decision by the EMA confirmed that the MHRA will not be able to act as Lead Authority on marketing authorisation applications for new drugs during the transition period.

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• Without the ability to act as a lead assessor there could be significant ramifications for patients around Europe, given the loss of the MHRA’s expertise. 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.iii

• An end to contributions from the MHRA could undermine the UK’s world-leading science environment. The MHRA’s leading role in the ERSM to date is a credit to UK science, and their expertise is enhanced by the ability to frequently lead assessments within the ERSM.

• CRUK urge the Government to seek an agreement with the EU which would allow the MHRA to act as a Lead Authority on EMA assessments of new medicines, and to influence the shape of the ERSM.

3. ALIGNMENT ON CLINICAL TRIALS – Rare and childhood cancers

• Running clinical trials across borders enhances our ability to develop new treatments that benefit patients in the UK and across the world. It also gives patients vital access to the most innovative new treatments. This is especially true for rare and paediatric cancers, where there often aren’t sufficient patients in one country for research.

• Between 2004 and 2016, 4,800 trials were run in collaboration between the UK and at least one other EU nation.iv

• The UK has agreed to align with the forthcoming EU Clinical Trials Regulation (CTR). But to fully benefit from alignment, it is essential that access to the associated portal and database, currently being set up by the EMA, is negotiated.

• CRUK would welcome further clarity on the Government’s plans to negotiate access for the UK to the accompanying EU portal and database, as well as clarity on the ability for UK researchers to continue to lead clinical trials with EU nations. UK academics have expressed concerns over the inability to lead on clinical trials, including the impacts on reputation and funding prospects.

Further information

1. For further information on this briefing, please email publicaffairs@cancer.org.uk

References

1 BMI Research, Pharmaceutical sales, USDbn, 2015

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