

BREXIT

Consequences for UK and EU-27 patients

Briefing by Genetic Alliance UK, September 2017

Impact on EU patients

Key message: The consequences of Brexit are likely to affect all patients in Europe to some degree. Without action Brexit will cause a reduction in EU capacity in four key areas.

Biomedical research:

Technopolis Group (May 2017), co-funded by The Academy of Medical Sciences, Arthritis Research UK, the Association of Medical Research Charities, the British Heart Foundation, Cancer Research UK, the Medical Research Council, MQ: Transforming Mental Health and Wellcome, produced a report examining the contribution that UK Biomedical research makes to the European Union. Link: wellcome.ac.uk/sites/default/files/impact-collaboration-value-uk-medical-research-to-eu-science-health.pdf

This report shows that the UK makes key contributions in five areas:

1. Contributions to advisory bodies, networks and policies that underpin research across the EU and its member states
2. Participation in pan-EU clinical trials, providing notable leadership for rare disease and paediatric clinical trials
3. Coordination and hosting of some of Europe's unique large-scale infrastructures for medical research
4. Development of new therapies and medical technologies that benefit EU patients, backed by a thriving pharmaceutical and biotechnology sector
5. Training early career researchers from across the EU to develop their skills and launch their research careers

One of the elements in which the UK participates in pan-EU clinical trials is through the provision of scientific advice regarding clinical trials. Under the incoming Clinical Trial Regulation, the Medicines and Healthcare products Regulatory Authority (MHRA) was expected to be a key regulator for the single portal approach.

The UK is one of a handful of EU nations at the forefront of exploring the potential of genomic medicine. The degree to which the benefits and learning from this activity will be available to the EU-27 will depend on how arrangements for sharing data are settled.

Key message: Maintaining a means for research collaboration between the EU-27 and the UK will benefit EU and UK patients with respect to volume and quality of research outputs and participation opportunities.

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Regulation of medicines:

The UK national medicines and clinical trials regulator, the MHRA, is a leading regulator at the European Medicines Agency (EMA). As per the centralised procedure, the appointment of the Rapporteur and Co-Rapporteur for individual dossiers is made on the basis of criteria that ensure that scientific opinions are made objectively using the best available expertise in the European Economic Area (EEA). *The Medicines and Healthcare products Regulatory Agency have over 30 years of knowledge as lead regulator on over 3,500 medicines on the EU market and currently lead between 20% and 35% of the EMA's licensing and vigilance work.* (MHRA and EMA figures.) This skew is due to the regulatory expertise and capacity of MHRA. A significant proportion of oversight of medical devices for the EU also takes place within the five UK notified bodies overseen by the MHRA.

The EMA announced in April that work has started on preparing for the scenario that the UK cannot participate in regulatory activity following Brexit. It is important to recognise that this is scenario planning – this does not prejudice the outcome of negotiations. There are however, no other scenarios being planned for, other than the current scenario and status quo. It is an achievable challenge to bridge the 20% capacity gap (although it is worth noting that on 27 September the EMA published a statement that it would take 2/3 years to reach full operational capacity after relocation due to concerns over staff retention caused by relocation), but bridging the knowledge gap may be more difficult. Whether this results in a lowering of quality of regulation in the EU, or in the tightening of regulatory attitudes towards innovation, remains to be seen. It is hard to argue that there will not be opportunity costs relating to this capacity drive and to the physical move of the EMA.

The opportunity costs are likely to affect the innovative approaches that the EMA is exploring with partners more than its core statutory duties. These would include examination of opportunities to link health technology assessment processes with market authorisation processes, accelerated assessments of innovative medicines for indications with high unmet need, and the expansion of evidence bases for regulatory decision making to better include patient voice.

Key message: The UK's continuing involvement in regulation of medicines in Europe - as offered by the UK Government in the "Collaboration on science and innovation" position paper and the 4 July FT letter: "*UK is fully committed to continuing the close working relationship with our European partners, in the interests of public health and safety*" - **would benefit all European patients by maintaining capacity and capability to regulate medicines in innovative areas.**

'Innovation aware' legislative influence:

The UK has a positive, future facing attitude to research and treatment innovation. When it comes to national competencies such as the regulation of reproductive choice and innovative reproductive techniques the UK is a world leader. This 'innovation aware' approach is delivered by the UK to Europe through its roles in the European Council and in the European Parliament. The current balance of views in Europe has seen innovation relevant legislation such as the General Data Protection Regulation, the In Vitro Diagnostics Regulation, the Clinical Trials Regulation, and less recently the Advanced Therapies Medicinal Products Regulation pass with compromises and close calls.

The UK is not the only nation of the EU with this approach; however with its population and influence in the Parliament and the Council, its loss could lead to a shift in the landscape for the development of this kind of policy in the EU.

Many of the bodies through which UK-based scientists can inform the EU will persist through European academic networks, as will the voice of UK patients through European patient organisations.

Key message: A shift in attitude and influence on biomedical and ethical issues in the European Union could reduce 'innovation friendly' regulation within the European Union. Engagement and advocacy will be key tools to mitigate this risk.

Clinical expertise:

The UK is one of six nations with close to complete membership of the European Reference Networks set up under the Cross-Border Healthcare Directive. There is a UK member of 22 of the 24 current European Reference Networks, and UK institutions have a leadership role in a quarter of them. 105 of the 945 healthcare professionals registered are from the UK.

Key message: There is significant clinical expertise in the UK. Excluding the UK from the European Reference Network initiative will reduce quality within the programme with adverse consequences for both the UK and the EU-27.

Impact on UK patients

There is more uncertainty for the outcome of Brexit for UK patients. This is because we do not know what infrastructure, agreements, regulation etc. will be created to replace EU counterparts, if this proves necessary. For all of the four domains listed as risks to EU patients above, risk applies to UK patients too, though the degree of risk will depend on the terms of the deal.

Biomedical research:

Without an agreement on continuation of the Clinical Trials Regulation – UK patients may not be able to participate in clinical trials that are happening within the EU. The UK may become a less desirable place to run clinical trials if it is more challenging to link with clinical trials in Europe.

Regulation of medicines:

Though UK patients have the MHRA, they could end up trading quality of regulation for access to new treatments. If the UK does not link with the European regulatory environment, and we do not share (or better participate in) the European Marketing Authorisations from the EMA, then companies are likely to choose to launch in the UK after other major markets have been dealt with. This could lead to crucial delays in access to novel treatments.

'Innovation aware' legislative influence:

There may be tools (such as academic networks) to allow the UK to maintain some of its influence over the EU's attitude to innovation and innovative techniques. However, the risk remains that if the UK does manage to achieve a link with the EU regulatory structure, it may find itself a passenger in a regulatory environment with a drift towards conservative approaches.

If therapies that involve somatic genome editing become possible, the EU may take a conservative approach to these technologies. Of course, this might present the UK with an opportunity, but we need to be careful to ensure the terms of a deal would permit this.

Clinical expertise:

Of course the UK clinical community stands to benefit a great deal from EU expertise, it will be important to try to maintain networks as much as possible.

Negative feedback

When we link some of the potentially adverse outcomes for the UK, there is a negative feedback cycle that can exacerbate some of these problems.

- Issues with the regulatory process would lead to a reduction in modern comparator medicines available in the UK
- Fewer comparators, less potential for collaborative research and/or reduction in clinical expertise, would lead to a reduction in clinical trials in the UK
- Fewer clinical trials would lead to a reduction in expertise in the UK

All of these factors would deter bioindustry investment in the UK, which would fuel the negative spiral. However a strong life sciences sector is a major target for the UK Government, there are key elements of the Brexit settlement that might make this target unreachable.

Key message: acid test for success of the Brexit negotiations for EU/UK patients

Whatever the terms of the negotiations and the resulting arrangements, EU and UK patients will be looking for two things:

- Timely access to innovative therapies
- Unreduced opportunity to participate in clinical trials

If these are not achieved, patients on both sides will have a bad deal.