Department for Business Innovation & Skills: Review of the EU Balance of Competences: Research and Development

Response by the Wellcome Trust

August 2013

Key Points

- Effective engagement with the European Union (EU) on issues that affect research and development is vitally important given the increasingly global nature of research. This includes reaching a balance of competences between the EU and member states that is appropriate, proportionate to any risk, and evidence-based.
- Where the EU has a leading role in policy-making, this should be informed by a strong evidence base, use appropriate and timely consultation, alongside adequate transparency and EU-wide harmonisation and implementation.
- The EU should aim to maintain a research and innovation environment which is facilitative of research and globally competitive, whilst maintaining public confidence in the research endeavour.
- It is important that the Department of Business Innovation and Skills works effectively with other government departments to ensure a joined-up approach to engaging with the EU on all issues, including science and innovation, research and development.

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to contribute to this review. We consider engagement with the EU to be of high importance for maintaining UK competitiveness, both within Europe and internationally, and science and innovation must be at the heart of this.

2. As a global charitable foundation and funder of medical research, we consider engagement with the European Union to be an increasingly important part of our advocacy work to secure an optimal environment for biomedical research and translation in the UK and EU. This is particularly important in light of the increasingly multidisciplinary and international nature of research, and the impact of EU legislation on the conduct of research in the UK. Our response focuses on those areas identified in the review which have direct relevance to the Trust's work, or otherwise impact on our activities. We recently submitted evidence to the Review of the Balance of Competences for Health and have mirrored many of the points made in that response herein.

IMPACT ON THE NATIONAL INTEREST

3. Active engagement with the EU is beneficial to the UK and encourages a strong environment for research and innovation. Effective engagement with the EU on issues of health and biomedical science is vitally important given the increasingly global nature of

research. Please see Boxes 1 and 2 for case studies on Animals in Research and Clinical Trials, which highlight both the positive and negative impact of EU legislation on UK research and development.

Where has EU action had a positive impact for the UK on research, technological development, innovation or space? What evidence is there for this? Has EU action encouraged national action in any areas?

EU Regulation

4. **Rare Diseases:** Working in a pan-European and international manner has certain benefits that are more applicable to certain research areas; one such area is when tackling rare diseases. Harmonisation and data sharing are ultimately necessary to compare, combine, and make the best use of results, especially when using the information globally. For rare diseases, harmonised requirements for approvals are particularly important when the patient population is spread across Europe. The International Rare Disease Research Consortium (IRDiRC) is very important in this aspect.

5. **Data Protection:** There are other important areas of the EU's competence that impact on research. For example, the use of personal data concerning health for research is governed by European Data Protection legislation. Negotiations are currently underway on a Data Protection Regulation that would replace the current Data Protection Directive. The new Regulation will have a significant impact on health and social research. We welcome the provisions to support health research in the Commission's proposal for a Data Protection Regulation, which strikes an appropriate balance between protecting the rights and interests of individuals and facilitating scientific research for public good. Despite the positive provisions, we have concerns that the parliamentary amendments could jeopardise the Directive's effectiveness at supporting health research, these concerns are discussed further in paragraph 17.

EU Infrastructure

6. The UK's involvement in the EU has allowed for participation in European Strategy Forum on Research Infrastructures (ESFRI) projects such as ELIXIR, the pan-European infrastructure for biological information, and the European Molecular Biology Laboratory including the European Bioinformatics Institute (EBI) at Hinxton, Cambridge, which is a very effective collaboration for enabling data sharing across Europe. Through the EU, the UK has been able to partner with member states and allow access to cutting edge facilities for fundamental research such as the Institut Laue-Langevin (ILL) in France. Maintaining an effective EU that invests in science and innovation for long term growth is key, especially given recent economic conditions.

7. The Framework Programmes (FP) highlight the benefit of collaborative research and provide value to the UK's prosperity in research in development. The EU platforms benefit from economies of scale and help with knowledge exchange between sectors by acting as a central hub that improves efficiency. We welcome research excellence being a requirement for EU funding, such as through the European Research Council (ERC), and feel this is particularly suited for driving forward research and development in the EU and also nurturing the UK's strengths.

Where has EU action had a negative impact for the UK in these fields? What evidence is there for this? Has EU action prevented potentially useful national action in any areas?

8. **European Physical Agents Directive:** An example of EU legislative action which threatened to have a negative impact was the original 2004 European Physical Agents (Electromagnetic Fields) Directive, which suffered from a lack of adequate consultation and engagement with researchers and the medical profession. The original legislation, if implemented, would have had the effect of dramatically restricting the use of MRI for research and clinical diagnosis, although the EC responded to these concerns when they were raised by a group of radiologists, research organisations and funders, including the Wellcome Trust. A revised version of the Directive containing an exemption for MRI has now been published and approved by the European Parliament, avoiding these potential negative impacts.

What benefits or difficulties has the objective of a European research area (ERA) delivered for the UK?

9. We welcome the principles outlined by the ERA but feel it is poorly defined and hard to identify, at this stage, the tangible benefits or impacts to UK research and development. We welcome the principle of the ERA to aid mobility within the EU of researchers, but feel that in practice, different pay-scales will be detrimental in this endeavour.

How has the EU sought to coordinate the policy instruments at its disposal across different policy areas to create an enabling environment for researchers and innovators? How successful has this been?

10. While the EU has become better at coordinating policy across different areas, as illustrated by some of the examples above, we feel there is still room for improvement. Engagement with Europe is not always straightforward because it is often difficult to find the right information around specific policy proposals. Similarly, it is also often difficult to find the right contacts within the EU structure, although there are numerous networks and interest groups within the EU, such as Science Europe and the Federation of European Academies of Medicine (FEAM), which are highly effective at raising concerns and communicating them back into the development process. The appointment of Ann Glover as the Chief Scientific Adviser to the EC has also been welcomed and we have had several constructive discussions with her since she took on this role; we would hope that the post of the CSA will be maintained by the next Commissioner and will be adequately supported and resourced in order to ensure it has maximum impact.

Box 1: Case Study on Animals in Research

Proposals to revise the Directive on the Protection of Animals Used for Experimental and other Scientific Purposes were first discussed in 2004. The revised directive which was not adopted until 2010 highlighted some of the common issues associated with EU legislation.

The transposing of the Directive into the Animals Scientific Procedure Act 1986 has provided both positive and negative outcomes for the UK. We accept that the legislation was essential to raise standards across Europe for animal welfare and we are pleased that this should allow for easier importing and exporting of animals for the UK. We are however concerned that the EU standard is lower than the previous UK requirements and over time, the UK's high welfare standards could be eroded.

Training has been another area of concern regarding the Directive's implementation into national law. Guidance from the EU regarding the 'EU standard' has been lacking which has created a situation, in the UK, where transposition of the legislation has occurred without the Home Office being able to issue guidance regarding severity assessments. This process could have been improved if there had been effective consideration of timescales, allowing full guidance from the EU to be available prior to transposition, to ensure that all member states are enforcing the same rules. Suitable timescales could have avoided the current levels of uncertainty within the research community and the concerns that the Directive will be implemented differently across Member States. We feel that these lessons could be applied across the EU to ensure a more effective legislative process.

Positively, the process of developing the EU Directive has resulted in a detailed review of policies and procedures in the UK legislation and has in some places improved processes.

Box 2: Case Study on Clinical Trials

One area of particular importance to us is European legislation of clinical trials. The primary avenue by which we have engaged with the EU in this area is through influencing the original Clinical Trials Directive of 2001, and its subsequent revision in the form of the Clinical Trials Regulation, which is now passing through the European Parliament. Effective European legislation on clinical trials is important given the global nature of research, to ensure that the EU provides a competitive environment for the increasing numbers of multi-national trials that are now taking place.

There have been several changes to EU legislation that have negatively impacted UK research and development; this has been primarily down to ineffective engagement with stakeholders during the development stages. An example of this is the 2001 Clinical Trials Directive, which was highly criticised for its 'one size fits all' nature and led to an increased burden on academic researchers, leading to a drop in clinical trials conducted in the UK. A 'one size fits all' approach is not a suitable approach to clinical trials since different trials carry a different level of risk and benefit. Clinical trials can use a wide range of medicines from those that are being developed in people for the first time, to those that have already been used in established clinical practice for many years. Fortunately the European Commission (EC) responded to the criticism of the Directive with the result that the Directive is in the process of being revised as a proposed Clinical Trials Regulation, this has made significant improvements and is currently under consideration.

The length of time required to revise EU legislation highlights the need to get it right first time, this can only be achieved by thorough and effective consultation of relevant stakeholders throughout the development process. While the original Clinical Trials Directive was intended to harmonise requirements, it is widely acknowledged that the Directive was inconsistently implemented across Member States.[1] We have welcomed the publication of the EC's proposal for a Clinical Trials Regulation, on the basis that it provides researchers and clinicians with an effective overall regulatory framework for testing the safety and efficacy of medicinal products, and aims for effective harmonisation across Europe. We envisage this will provide significant benefits for multi-national trials of medicinal products; this will be of particular benefit for rare diseases where the patient population is spread across Europe. Once the Regulation is agreed it will be important for Member States to work together to ensure that it is consistently implemented across the EU, to avoid the mistakes made in the implementation of the Directive.

1. ICREL was a one-year project financed by the European 7th Framework Programme to measure and analyse the direct and indirect impact of the Clinical Trials Directive and was critical of the inconsistent implementation across the EU.

FUTURE OPPORTUNITIES AND CHALLENGES

What could the EU most helpfully do to promote scientific and technological progress and innovation (including in the space sector)?

a. *How could the EU use its existing competence differently to deliver more in your area?*
b. *How might a greater or lesser degree of EU competence deliver more in your area?*
c. *How could improvements to existing EU activities make them more effective and efficient?*

Informed Policy Making

11. Scientific and technological progress and innovation need to be underpinned by effective policy making and informed by the most robust up-to-date scientific evidence. It is also essential to require timely consultation of a cross-section of interested stakeholders and expert groups at the earliest stage possible. There are previously mentioned instances, such as the Clinical Trials Directive and Physical Agents Directive, where this approach could have avoided the negative impact of new legislation.

12. It is essential that new proposals clearly set out their purpose. We also suggest that proposals should be fully assessed with regards to their impact, cost and proportionality through effective impact assessments, including during the development of proposals.

13. We have noted the increasing move towards Regulations away from Directives within EU legislation and the subsequent reduction in flexibility of implementation allowed by member states. Although we recognise the benefits of greater harmonisation across the EU, this further highlights the necessity of fully informed policy making, with an effective consultation of stakeholders.

Transparency

14. To allow full and effective consultation throughout the development process, a culture of transparency and accessibility needs to exist with regard to the content of proposals, including timescales for development and implementation. We accept that, depending on the nature of the proposals, different levels of transparency will need to be applied. In our experience, we have found that finding the correct information on EU proposals at an early stage is sometimes problematic, this is also true of finding the right contact in the EU structure.

15. One potential way of improving the system could be for the EC to adopt the UK parliament communications approach, with an easily navigable web presence that makes it straightforward to identify the progress of a particular piece of legislation. This would also help to facilitate discussions with the relevant UK Government departments on EU legislation, and ensure a more joined up approach.

Responsiveness

16. To ensure the EU retains its competitive advantage, proposals need to be responsive in order to keep pace with a changing research environment.

Where might future EU level action be detrimental to your work in this area?

17. As mentioned previously, the Data Protection Regulation is particularly important in supporting health research that strikes a balance between protecting individual's interests and allowing research for public good. It is essential that Article 83 and associated derogations are maintained as the Regulation moves through the legislative process and are not diluted by Parliamentary amendments. Amendments to clarify and strengthen research provisions would be beneficial to ensure health research is not inhibited. Amendments are also needed to ensure that the use of pseudonymised data in health research is regulated proportionately and to ensure clarity in the scope of the Regulation. We urge the Department of Justice in charge of negotiations to take a firm position on this and would like to highlight the importance of the Department for Business, Innovation and Skills in briefing other departments that are leading negotiations in Brussels.

18. We are currently monitoring the revision of EU legislation on medical devices following the Commission's publication of its proposals for new Regulations on medical devices and *in vitro* diagnostic medical devices. It is essential that legislation is proportionate in regulating patient safety whilst providing an effective legal environment for device companies to operate. We are concerned about recent amendments tabled in committee which expand the scope of the *in vitro* diagnostic medical devices regulation to include products without a direct medical effect. This could significantly increase the regulatory burden on researchers.

19. More broadly, any legislation that affects the operating environment for charities and foundations, including investments and tax, can be detrimental to our ability to achieve our charitable aims. An example of this is the Alternative Investment Fund Managers Directive 2011 which would have limited our ability to maximise our fund raising potential through limiting routes of investment. Fortunately our concerns, and others in the sector, were appropriately considered by the Commission and the Directive was amended.

Where might action at national rather than EU level be more appropriate / effective?

20. Strategic health research priorities for example dementia and mental health, or urgent research initiatives such as responses to a flu pandemic might be more appropriately managed at national level where funding responses can be faster and more targeted to national need.

How could EU and national policies and funding streams interact better?

21. Currently, applications for funding streams can be very resource intensive process, especially when compared to other funding bodies. The process could benefit substantially from removing some of the associated bureaucracy along with more timely provision of information prior to calls, such as Horizon 2020, which has been lacking suitable information thus far. Another common complaint from the research community is the topic specificity of EU funding calls with only certain scientists being suitable to apply, we would welcome more open calls that could encourage more open competition for funding.

What impact would any future enlargement of the EU have on this area of competence?

22. An increasing number of EU Member States will increase the call on EU funds. Whilst it may be important to support research capacity in new Member States, the EU will need to balance this with ensuring that globally competitive research and innovation continues to be funded.

Are there any other points you wish to make which are not captured above?

Embryonic stem cells: The Court of Justice of the European Union decision in *Brüstle v Greenpeace* has called into question the ability to patent embryonic stem cell derived products. There is on-going concern amongst researchers that this decision, which will be revisited in the upcoming case of *International Stem Cell Corporation vs. Comptroller General of Patents* will have an impact on private investment into embryonic stem cell research and translation in Europe. We would urge BIS and other relevant UK Government departments to keep a watching brief on this issue. It is important to note that future UK funding of embryonic stem cell research, through programmes such as Horizon 2020, could be affected by individual Member States willingness to fund embryonic stem cell research.