Written evidence submitted by the Wellcome Trust (UKL0020)

KEY POINTS

- EU legislation has a significant impact upon life sciences in the UK, both directly and indirectly. This can be positive in simplifying and harmonising regulation but the nature of the legislative process in the EU institutions can cause delay and uncertainty.

- EU policy-making processes are consultative and transparent but are difficult to access. UK organisations are getting better at understanding the policy-making process and the need for timely engagement but this can require significant resource.

- The European Commission does respond to concerns about individual pieces of legislation but the protracted time scales in addressing problems could be seen as a barrier to competitiveness.

- The provision of scientific advice to EU institutions is being improved, but further work is needed to reinforce independent advice to the European Parliament to balance the intense advocacy activity it experiences. In particular, a process for balanced dialogue on ethical issues in the life sciences needs to be considered.

INTRODUCTION

1. The Wellcome Trust is pleased to contribute evidence to the inquiry. The EU has a significant role in shaping regulation of the research and life sciences environment in the UK. Harmonisation of regulatory and legal frameworks within the EU can support international collaboration, offering certainty and consistency. However, EU regulation is not without its problems and can be both bureaucratic and complex.

2. As a global charitable foundation dedicated to improving health, our advocacy work aims to secure the best environment for biomedical research and translation in the UK and EU, which includes securing flexible and proportionate regulation of science and innovation. This is particularly important in light of the increasingly multidisciplinary and international nature of research.

WHAT ARE THE KEY EU REGULATIONS AND FRAMEWORKS THAT GOVERN/INFLUENCE THE CONDUCT OF RESEARCH AND INNOVATION IN THE UK LIFE SCIENCES?

3. There are a large number of directives and regulations governing life sciences, both directly and indirectly. Examples of the key areas of legislation that Wellcome has engaged with are discussed below.

Clinical Trials

4. Effective EU 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.

5. EU legislation has not been particularly successful in this regard. The 2001 Clinical Trials Directive, which was highly criticised for its 'one size fits all' nature, led to an increased burden

[1] Academy of Medical Sciences, *A new pathway for the regulation and governance of health research,* (2011)
[2] 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 were critical of the inconsistent implementation across the EU. http://www.efgcp.be/icrel/

on academic researchers and a drop in clinical trials conducted in the UK and the EU[1]. It is widely acknowledged that the Directive was inconsistently implemented across Member States[2].

6. The European Commission (EC) did respond to the criticism of the Directive with a revised Clinical Trials Regulation. This has made significant improvements that should provide 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. However, it took some time to recognise the concerns and bring forward new regulatory proposals. The new Regulation is expected to come into force in 2018, meaning that there will have been almost two decades during which EU clinical trials legislation has not been as effective as it could have been.

Data Protection

7. The Data Protection Regulation (**DPR**), adopted in the European Parliament in December 2015, is an example of legislation from another area of EU competence that has an impact on life sciences. DPR covers the use of personal data across a wide range of sectors and will have a significant impact on health and social research, affecting how patient data is used in research. Wellcome worked with other stakeholders across the EU to ensure that the DPR creates a clear legal framework that facilitates research while protecting the interests of individuals.

8. We welcomed the outcome of the trilogue process. Strong safeguards and governance structures are already used to ensure that personal information is used safely and securely in research. The final text enshrined the need for such safeguards and rejected amendments from the European Parliament that would have imposed new disproportionate limits on the use of health data in research. The DPR will take effect in 2018, after a two-year implementation period.

9. The DPR is a good illustration of how the life sciences community has learned how to respond to EU legislation: life science organisations identified issues early in the legislative process and pushed for approaches that would support appropriate medical and health research. This was a co-ordinated and constructive campaign sustained over a number of years, requiring significant resource. It should be noted that many life sciences organisations do not have the resources to maintain participation in such protracted campaigns.

Protection of Animals in Scientific Procedures

10. The Protection of Animals in Scientific Procedures Directive, which came into force in 2013, ensured that the UK's strong regulation of the use of animals and high level of welfare in research was not undermined. It also contributed to the spread of best practice in animal welfare, providing a necessary update of EU legislation to reflect changes in science while embedding the 3Rs (Replacement, Reduction and Refinement) principles in legislation.

11. The draft proposal was subject to intense advocacy activity from campaigns in favour of and opposed to the use of animals in scientific research. There were major concerns expressed by many organisations in the life sciences sector that amendments proposed in the European Parliament would substantially restrict research without providing significant benefits for animal welfare. This required significant advocacy effort, sustained over a number of years, to provide evidence that reinforced rather than undermined the UK's existing regulations. Our experience of working on this Directive highlighted the need for early, co-ordinated and sustained engagement with the EU institutions and also demonstrated the need for improvements in the provision of independent and reliable scientific advice to MEPs in particular.

Physical Agents

12. There are many pieces of legislation that are not directly aimed at the life sciences but which can have an impact. An example of this is the Physical Agents (Electromagnetic Fields) Directive which was intended to protect workers in the EU from risks arising from exposure to electromagnetic fields in the workplace. The draft proposal had the unforeseen effect of potentially seriously restricting the use of MRI for research and clinical diagnosis, because the use of MRI would have exceeded the safe limits set out in the Commission's proposal. This was the result of a lack of adequate consultation and engagement with researchers and the medical profession.

13. The Commission was responsive to these concerns when raised by a group of radiologists, research organisations and funders, including the Wellcome Trust, and a revised version of the Directive was adopted containing a derogation for MRI. The development, subsequent withdrawal and revision of the European Physical Agents Directive again illustrates the importance of well-informed, timely and broad consultation and engagement to ensure that any unintended consequences of proposed legislation are identified and a responsive and evidence-based approach is taken when progressing legislative proposals.

Medical Devices and In Vitro Diagnostics

14. A significant proportion of the Wellcome Trust's translational funding portfolio is directed towards the development of medical devices to the point at which they can be successfully taken to market. The EU's regulation of this area is therefore another area of particular interest for us, with implications for the regulatory environment in which we operate, as well as the researchers and companies that receive our funding.

15. We are currently undertaking advocacy on the revision of EU legislation on medical devices and in vitro diagnostic 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 European Parliament amendments which expand the scope of the in vitro diagnostic devices regulation to include products without a direct medical effect. This could lead to researchers being in breach of legislation without realising it and significantly increasing the regulatory burden. The European Parliament is also seeking to mandate genetic counselling for all genetic tests, which we believe is not a proportionate approach.

IN WHAT WAYS DO THESE EU REGULATIONS AFFECT THE UK LIFE SCIENCES? WHAT ARE THEIR BENEFITS AND THE DRAWBACKS?

16. EU regulations have the potential to simplify the regulatory environment for organisations conducting biomedical research in multiple sites across the EU. Where appropriate, an EU regulation can provide a single approach as opposed to 28 different regulatory regimes, simplifying procedures, reducing bureaucracy and timescales for activity such as approval of a clinical trial application and spread of best practice. These benefits help towards accelerating scientific discovery and development.

17. A key challenge with EU regulations is the uncertainty associated with the legislative process. There is an inherent lack of dynamism given the need to build consensus between 28 member states and between the 3 main EU institutions (Commission, Council and Parliament). Legislation can take a long time to progress, for example the Data Protection Regulation took four years to reach the adoption stage in the European Parliament and has yet to be voted upon in plenary. Although timescales like this are not unique to the EU, this prolonged duration could be argued to reduce the competitiveness of the life sciences sector by creating uncertainty and delaying decision-making, for example when research organisations (in the public or private sector) decide where to locate research activity.

18. A further concern is the efficiency of the European Parliament. As with any national parliament it is subject to significant advocacy activity from interested parties. However, the scale of this activity can lead to substantial burdens on the legislative process. The Data Protection Regulation, a complex technical proposal, received over 5,000 amendments. This level of amendment adds further delay into an already long process, requiring extended discussion and voting time. Improvements to better focus consideration of legislation while maintaining proper scrutiny would be a challenge but highly positive to address the concerns on protracted process.

HOW TRANSPARENT, CONSULTATIVE AND EVIDENCE-BASED ARE EU POLICY-MAKING PROCESSES?

19. There is often criticism of the lack of transparency and consultation in EU decision-making[3]. 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, particularly in the European Commission.

20. There are a number of opportunities for UK organisations to contribute to EU policy-making processes. These include: direct interaction with the European Commission through expert groups and contributions to consultations; contact with UK MEPs and relevant MEPs from other member states (for example, parliamentary committee chairs and rapporteurs – the MEPs who steer a particular piece of legislation through the parliament); and dialogue with the UK Government through the relevant department, the UK's Permanent Representation to the EU (UKREP) and government agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA).

21. The legislative process, as with national parliaments, relies upon the ability of organisations to develop robust evidence-based contributions while having the knowledge of parliamentary procedure and the resources and capacity to sustain advocacy. This can be a significant challenge for many organisations. Anecdotal evidence suggests that some UK organisations do not always recognise or prioritise the importance or value of interaction with the EU institutions, possibly because they consider that policy issues can be addressed by the UK Government or in the Houses of Parliament, or due to resource constraints. Strengthening links between the Houses of Parliament and UK MEPs could provide further opportunities for UK organisations to contribute to European Parliamentary deliberations.

22. In the Trust's experience the UK is in a strong position on life sciences with a number of UK organisations taking part in policy dialogue in Brussels to an increasing extent and being more effective. This does create a potential source of tension if UK organisations are seen to promote a UK position that does not acknowledge the need for consensus or the different attitudes and approaches of other EU member states.

Trilogue Approach

23. The lack of transparency of informal 'trilogues' is of concern. This 'single reading agreement' approach, which foregoes the traditional legislative process, is intended to reduce the time needed to reach final agreement between the three EU institutions. Trilogue meetings are usually held in private and attended by a limited number of representatives from each institution. The content of the discussions is generally not made public, although the Parliament does provide some feedback to the relevant committees as negotiations continue. Full transparency would enable interested parties to follow and understand the reasoning for decisions and enable better-informed external scrutiny and challenge.

[3] HM Government, *Review of the Balance of Competences between the UK and the EU: Health* (2014)

Scientific Evidence

24. The development of a new Scientific Advice Mechanism (SAM) to inform decision making within the European Commission is a welco development. In particular there are positive indications that it will be supported by resources and infrastructure to draw upon expertise beyond the seven members of the High Level Group of experts that forms the core of the SAM, utilising national academies of science for example.

25. A key consideration is how the SAM evolves and interacts with the other EU institutions. Although the European Council can utilise expertise from national governments, science advice within the Parliament could be strengthened to balance the substantial amount of often conflicting information MEPs receive on legislation from external organisations. The European Parliament can utilise its own Directorate General for Parliamentary Research Services and the Science and Technology Options Assessment (STOA) Panel, the latter of which is similar to the UK's Parliamentary Office of Science and Technology. These existing resources should be strengthened and co-ordinated (where appropriate) with the SAM to ensure that MEPs have greater access to independent scientific advice.

TO WHAT EXTENT IS THE UK ABLE TO SHAPE REGULATORY PROCESSES AT THE EU LEVEL THAT AFFECT THE LIFE SCIENCES?

26. The UK has, in theory, the same opportunity as any other member state. It has a well-respected permanent representation to the EU that is effective in representing UK concerns in Council discussions, liaises well with UK MEPs and supports UK organisations to understand the legislative process and how to contribute to it effectively. Research by the London School of Economics[4] suggests that the UK Government is particularly effective in Council negotiations. The UK is also fortunate to have a strong science and research base from which it can draw expertise and evidence o support policy formulation at EU level.

27. Our experience is that engagement with the three EU institutions is relatively straightforward. Interaction with the European Parliament relies to some extent on the effectiveness and engagement of UK MEPs in a particular piece of legislation, which can vary widely. Research by the London School of Economics[5] does suggest that the UK is in a weak position in the European Parliament as most British MEPs do not sit in the groups that dominate discussion. However, there are a number of examples where UK MEPs have been well-placed to influence legislation, for example as rapporteurs on a number of life sciences proposals such as the current medical devices legislation.

28. UK organisations are increasingly active in dialogue with the EU institutions. There have been a number of policy areas, referred to elsewhere in this submission, where the implications of legislation were not identified early enough and UK organisations were unable to provide timely input. The experience with these pieces of legislation has encouraged UK life science organisations to collaborate and co-ordinate their work more effectively. For example, the UK life sciences sector now regularly seeks a consensus position (with other EU organisations) to support advocacy work in Brussels, as happened with the Data Protection Regulation.

29. An area of particular interest for life sciences policy is that of ethics. A number of issues within the life sciences are controversial and have potential challenges in reaching a consensus at EU level. This is an inherent risk in a union of 28 member states with many different cultural attitudes

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[4] Europe Datablog, 2 Nov 2015, http://www.theguardian.com/world/datablog/2015/nov/02/is-uk-winner-or-loser-european-council, accessed 29 February 2016

[5] Europe Datablog, 17 Dec 2015, http://www.theguardian.com/news/datablog/2015/dec/17/how-often-do-uk-meps-get-their-way, accessed 29 February 2016

to the life sciences. Harmonisation shouldn't necessarily be the goal in these circumstances and many ethical issues are delegated to national authorities to deal with. This needs to be supported by a system at EU level that can provide a suitable dialogue process for difficult issues to be debated in a balanced and timely manner.

IS THE UK ABLE TO DEPART FROM THE APPLICATION, STANDARDS OR TIMING OF SUCH EU REGULATION?

30. Derogations are possible to allow for differing national circumstances. Directives also permit member states some leeway, within agreed parameters, to adapt the legislation to best fit their national situations. However, substantive variation from legislative text agreed by the EU nstitutions is inappropriate and leads to significant challenges.

31. One issue that the EU does need to focus energy upon is implementation. A failure by member states to properly implement legislation and failure by the European Commission to enforce does reduce the value of EU wide legislation. The UK has encountered problems with its implementation of EU legislation, particularly the concern that this can go further than the legislation requires. For example, a review by the Academy of Medical Sciences suggested that other Member States took a more pragmatic approach than the UK's rigorous implementation of the Clinical Trials Directive[6].

March 2016

[6] Academy of Medical Sciences, *A new pathway for the regulation and governance of health research,* (2011)