
Summary

- We believe that the introduction of EU legislation and regulation across the 28 Member States can help to foster cross-border collaborations by harmonising the procedures under which research is conducted, as long as these laws are carefully designed so as not to be unnecessarily prohibitive for research.¹
- The Academy has engaged substantially with a number of recent EU legislative developments, including the General Data Protection Regulation, Regulation on Clinical Trials on Medicinal Products for Human Use, and Directive on Animals Used for Scientific Purposes. We worked alongside partners to raise concerns and inform debate, and have broadly seen outcomes which align with our positions.
- Harmonisation across the EU, derived from such regulations, has eased the exchange of samples, tissues and data for researchers, opened markets for commercialised research products, and made the UK more attractive to industrial investors.
- Development of these regulations has required ongoing monitoring and input from the community, and overall the UK remains highly engaged. A number of our Fellows feel it is valuable to engage with these processes, and that this 'seat at the table' has typically delivered the desired results for legislation in our sector.
- The provision of science advice within the EU is a developing area, and one which the Academy continues to monitor and contribute towards. We continue to engage through our European network, the Federation of European Academies of Medicine.
- The UK benefits from the enhanced influence generated through the placement of key pan-EU agencies within our borders, including the European Medicines Agency based in London, supporting closer ties with our national, counterpart agencies.

However, as noted in our submission to the Balance of Competencies review: 'In some instances, Regulation and Directives that become UK law can occasionally impose unnecessary constraints on the conduct of research. These situations illustrate the need for Government and UK stakeholder groups to maximise their engagement with all the European Institutions to ensure that new legislation delivers favourable outcomes with minimal risk of unforeseen dependencies'.

Introduction

The Academy of Medical Sciences promotes advances in medical science, and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes experts drawn from a broad and diverse range of research areas.

We welcome the opportunity to respond to the House of Commons Science and Technology Committee inquiry into EU regulation of the life sciences.² We are not

¹ Joint National Academies, Submission to BIS Review of the Balance of Competences between the United Kingdom and the European Union, 2013.

² www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2015/inquiry/

advocating any position with respect to UK's continued membership of the EU, but take this opportunity to present views on the current situation regarding relevant regulation. Our written evidence has been informed by engagement with our Fellows, from across the disciplines and sectors we represent. The Academy has been involved extensively in some of the areas discussed within this submission and we would be pleased to provide further evidence, and our previous relevant outputs, if helpful.

Q1. What are the key EU regulations and frameworks that govern/influence the conduct of research and innovation in the UK life sciences?

As a member country, the UK is able to engage from the outset to influence legislation that impact the pan-EU research environment. The Academy has engaged with a number of EU legislative processes pertinent to medical research in the UK – we have outlined below those with which our involvement has been greatest.

EU General Data Protection Regulation

Triologue negotiations around this Regulation were completed in December. It is the legal framework on the protection of personal data which aims to strengthen and unify data protection for individuals within the EU. The Academy has welcomed this opportunity to set out provisions that support health research by striking an appropriate balance between the safe and secure use of personal data in research and the rights and interests of individuals.³ However, during legislative development a series of amendments were proposed by the European Parliament that put established uses of research data at risk (e.g. biobanks and disease registries).

Alongside partners including the Wellcome Trust and our European network – the Federation of European Academies of Medicine (FEAM) – we warned of the potential damage to several research areas.⁴ In a joint 2014 statement, we specifically cited the European Prospective Investigation into Cancer and Nutrition (EPIC), the European Medical Information Framework, and the Human Brain Project as European investments in genetics which would be put at risk. Ultimately, triologue negotiations between the Parliament, Commission and Council of Ministers led to a final draft which addressed our concerns. We remain aware of the importance for continued engagement as the UK's data laws are updated to take into account these changes, as raised in this Committee's recent 'Big Data' report.⁵

EU Regulation on Clinical Trials on Medicinal Products for Human Use

This Regulation aims to create a favourable environment for conducting clinical trials, with the highest standards of patient safety, for all Member States. The renewal of this legislation provided an opportunity to improve on the preceding law, which had several weaknesses and complexities that had concerned the medical research community.^{6,7,8}

³ www.acmedsci.ac.uk/policy/policy-projects/european-data-protection-regulation/

⁴ www.datasaveslives.eu/

⁵ <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2015/big-data/>

⁶ Academy of Medical Sciences, Response to the European Commission consultation on the assessment of the functioning of the "Clinical Trials Directive 2001/20/EC (2010)

⁷ Response to Consultation on Functioning of the Clinical Trials Directive (2010) FEAM

⁸ www.acmedsci.ac.uk/policy/policy-projects/a-new-pathway-for-the-regulation-and-governance-of-health-research/

These included a lack of uniformity across Member States and a non-proportionate approach to assessing risk, which contributed to escalating costs and delays. The Academy worked alongside UK and EU partners to inform the new Regulation, which was drafted in a way which addressed our concerns around streamlining approval for multi-centre trials and minimising administration, while maintaining patient safety.⁹

EU Directive on Animals Used for Scientific Purposes

This Directive aims to harmonise animal research standards across the EU, and received a broadly positive reception following efforts across the sector to inform its development and transposition into UK law. In 2014 the Academy noted the impact of the legislation in enhancing animal welfare standards and introducing the concept of 'refinement, replacement and reduction' across the EU.¹⁰ There are concerns within the community that the routine review of this Directive, scheduled for 2017, may introduce fresh instability in this area, and in August 2015 the Academy joined other organisations in supporting the current legislation, and we will engage further as necessary.¹¹

Broader regulatory influences

There are also a broad range of other regulatory influences relevant to the medical research sector which the Committee may wish to seek further information on, including:

- **European Citizens Initiatives** – popular petitions to raise EU Parliamentary debates. Two such petitions to which we have responded are the 'One of Us' initiative which called for the withdrawal of EU funding for research involving human embryos, and the 'Stop Vivisection' initiative which called for the phasing out of animal testing within the EU.^{12,13} The Academy and wider UK community contributed to both debates, and the final stance adopted by the EU Parliament largely aligned with our stance on both occasions.¹⁴
- **Intellectual Property** – the UK is currently a signatory of the European Patents Convention, which sits outside the EU. However, a new Unified Patent Court (UPC) is being established within the EU to provide a single Member State patent system, and the life sciences division of the UPC is to be based in London. This has been broadly welcomed by industry stakeholders, who see great value in the proximity of the patent process to their business.¹⁵
- **European Court of Justice** – judicial outputs from the ECJ cases, such as the *Brustle vs. Greenpeace* ruling, which recommended that certain innovations relating to human embryonic stem cells should not be patentable.¹⁶ We note that concerns were raised by industry representatives at a recent Parliamentary Committee hearing that intellectual property arrangements attached to Horizon 2020 funding were one factor dissuading UK businesses from engaging further with this source of funds.¹⁷
- **EU Physical Agents Directive (2004/40/EC)** – which could have seriously restricted the use of MRI for research and diagnosing patients, an outcome which was averted through engagement from the community.¹⁸

⁹ www.acmedsci.ac.uk/policy/policy-projects/test-clinical-trials-regulation/

¹⁰ Statement supporting European Directive 2010/63/EU on the protection of animals used for scientific purposes (2014) Academy of Medical Sciences

¹¹ www.acmedsci.ac.uk/policy/major-policy-strands/using-animals-in-research/

¹² europa.eu/rapid/press-release_IP-14-608_en.htm

¹³ europa.eu/rapid/press-release_IP-15-5094_en.htm

¹⁴ www.acmedsci.ac.uk/policy/policy-projects/the-stop-vivisection-european-citizens-initiative/

¹⁵ BioIndustry Association, UK Life Sciences Manifesto 2015-20 (2014)

¹⁶ curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10

¹⁷ House of Lord's Science and Technology Committee, oral evidence session, 26 January 2016

¹⁸ A survey of the potential impact of the European Union Physical Agents Directive (EU PAD) on electromagnetic fields on MRI research practice in the UK. Perrin and Morris (2008) J Magn Reson Imaging.

- ***In Vitro* Diagnostic Medical Devices Regulation (2012/0267)** – the development of this legislation poses significant restrictions to access to genetic testing, and has been the subject of a joint statement by several stakeholders across the sector.¹⁹

Q2. In what ways do these EU regulations affect the UK life sciences? What are their benefits and the drawbacks?

The principles of harmonisation which underpin many EU regulations have been extremely beneficial to the UK life sciences. At the level of individual researchers, some Fellows highlighted examples from within their own discipline where harmonised EU regulatory frameworks had significantly eased the exchange of samples, tissues and data. Instances of particular research benefits include for rare diseases and ‘orphaned medicines’, where individual Member States may not have sufficient data to reach meaningful conclusions or offer commercially-attractive markets for new products.²⁰

Harmonisation has brought about greater market access, both for the commercialisation of life sciences products, and for attracting inward investment into the life sciences. This provides a greater degree of stability for firms operating across international boundaries and has supported trade settlements which open up new markets for UK research outputs. EU trade deals have provided UK business with greater access to over 50 foreign markets, including a recent EU-South Korea Free Trade Agreement, which has led to significantly increased levels of trade.²¹

The benefits of harmonisation also extend to industrial stakeholders with the Chief Executive of GlaxoSmithKline, Sir Andrew Witty, recently stating that ‘Europe has gone from 27 fragmented, independent, not-talking-to-each-other regulatory authorities in the healthcare space to one. That’s a big deal.’²² More broadly, industry representatives have noted that the EU and associated harmonisation are ‘a key reason for global biopharmaceutical companies deciding to establish their European HQ in the UK and invest in R&D activities’.²³

However, as noted in our submission to the Balance of Competencies review: ‘In some instances, Regulation and Directives that become UK law can occasionally impose unnecessary constraints on the conduct of research. These situations illustrate the need for Government and UK stakeholder groups to maximise their engagement with all the European Institutions to ensure that new legislation delivers favourable outcomes with minimal risk of unforeseen dependencies’. At present, the UK remains highly engaged with EU processes and this ‘seat at the table’ has broadly delivered the desired results for legislation affecting the medical research sector.

¹⁹ www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/resources/wtp059075.pdf

²⁰ www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000034.jsp

²¹ CBI, Choosing our Future, October 2015

²² Pharma chief says Brexit would seriously disrupt UK (Jan 2016) Research Fortnight

²³ BioIndustry Association, UK Life Sciences Manifesto 2015-20 (2014)

Q3. How transparent, consultative and evidence-based are EU policy-making processes?

A number of our Fellows broadly felt it was valuable to engage with the EU policy-making processes to ensure that the final outcomes were appropriate, and many were highly engaged in regulatory issues attached to their own field. Greater transparency throughout the process would be welcomed, but Fellows largely feel able to channel their voice via institutions including the National Academies, learned societies and charities, which form part of a highly-engaged UK community.

The provision of science advice within the EU is a developing area, and one which the Academy continues to monitor and contribute towards. The appointment of a Chief Scientific Adviser by the previous President of the European Commission was welcomed by the research community as a way of improving the status of evidence-based advice within European policy-making. However, the new Commission President did not retain this post and concerns were expressed by the community, including through a joint letter from the European Academy networks, which noted the value of the role in providing independent, high-quality and transparent advice.²⁴

The post is to be replaced by a Scientific Advice Mechanism (SAM) based around input from a High Level Group (HLG) of experts, alongside the networked Academies from Member States. This mechanism remains at an early stage of development, and the Academy continues to engage, particularly through our network FEAM, to ensure the final structure is able to operate effectively to inform policy-making. Establishing a broadly supported mechanism for advice across diverse Member States presents a challenge, but several Fellows welcomed the transparency of the SAM development process, including the publication of the proposed model and the invitation for the community to nominate HLG members.

Q4. To what extent is the UK able to shape regulatory processes at the EU level that affect the life sciences?

A number of Fellows cited examples where the development of EU legislation had been significantly influenced by UK concerns, including those previously discussed. During the development of the EU Clinical Trials Regulation the UK was often the leading Member State in pushing for proportionate regulation, an outcome which is broadly considered to have been achieved. Elsewhere, in relation to the EU Directive on Animals Used for Scientific Purposes, UK regulations were seen as a driving force for increased welfare standards established across the entire EU, and saw the concept of the '3Rs' (refinement, replacement and reduction) embedded in the pan-EU framework. This harmonised research which would otherwise most likely continue under national legislation in Member States, possibly with lower standards.

The UK's voice at a national level is complemented by further engagement via EU-wide organisations. For the Academy, this included pan-European Academy networks such as the Federation of European Academies of Medicine (FEAM), of which we are a member. Our counterpart UK Academies are active members within their own, comparable networks, which seek to coordinate and promote activities across critical research policy

²⁴ www.acmedsci.ac.uk/download.php?f=file&i=29923

issues. Collaboration with Academies across the EU on issues of common interest (such as the regulation of health research) has ensured that activities aimed at informing and influencing policy account for a range of country-specific issues – thereby increasing their impact with EU decision-making bodies.

The UK also benefits from the enhanced influence generated through the placement of key pan-EU agencies within our borders. The location of organisations such as the European Medicines Agency (EMA) in London is valued by industry and the academic community as an opportunity for greater input into regulatory development, and for access to the support provided by such institutions.²⁵ The location of the EMA supports stronger ties with the UK's own Medicines and Healthcare products Regulatory Agency, creating a foundation for greater synergy between the two bodies.

Q5. Is the UK able to depart from the application, standards or timing of such EU regulation?

As set out in Protocol No. 25 on Shared Competence within the Treaty on European Union and the Treaty on the Functioning of the European Union, the existence of EU policies on research does not constrain the freedom of national research policies.²⁶

We would draw the Committee's attention to the distinction between EU Directives versus Regulations – the former of which require transposition into UK law, while the latter are directly applicable to all Member States without further legislation. The transposition of EU Directives into UK law continues to offer opportunities for national priorities to shape the final legislation, and the Academy and other members of the life sciences community engage with this part of the process.

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²⁵ BioIndustry Association, UK Life Sciences Manifesto 2015-20 (2014)

²⁶ eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT