



House of Commons  
Science and Technology  
Committee

---

# EU regulation of the life sciences

---

First Report of Session 2016–17





## Science and Technology Committee

---

# EU regulation of the life sciences

---

### First Report of Session 2016–17

*Report, together with formal minutes  
relating to the report*

*Ordered by the House of Commons to be printed  
7 June 2016*

## Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Government Office for Science and associated public bodies.

### Current membership

[Nicola Blackwood MP](#) (Conservative, Oxford West and Abingdon) (Chair)

[Victoria Borwick MP](#) (Conservative, Kensington)

[Stella Creasy MP](#) (Labour (Co-op), Walthamstow)

[Jim Dowd MP](#) (Labour, Lewisham West and Penge)

[Chris Green MP](#) (Conservative, Bolton West)

[Dr Tania Mathias MP](#) (Conservative, Twickenham)

[Carol Monaghan MP](#) (Scottish National Party, Glasgow North West)

[Graham Stringer MP](#) (Labour, Blackley and Broughton)

[Derek Thomas MP](#) (Conservative, St Ives)

[Valerie Vaz MP](#) (Labour, Walsall South)

[Matt Warman MP](#) (Conservative, Boston and Skegness)

The following member was also a member of the Committee during the inquiry:

[Liz McInnes MP](#) (Labour, Heywood and Middleton)

[Daniel Zeichner MP](#) (Labour, Cambridge)

### Powers

The committee is one of the departmental select committees, the powers of which are set out in House of Commons Standing Orders, principally in SO No 152. These are available on the internet via [www.parliament.uk](http://www.parliament.uk).

### Publication

Committee reports are published on the Committee's website at [www.parliament.uk/science](http://www.parliament.uk/science) and in print by Order of the House.

Evidence relating to this report is published on the [inquiry publications page](#) of the Committee's website.

### Committee staff

The current staff of the Committee are: Simon Fiander (Clerk); Marsha David (Second Clerk); Dr Grahame Danby (Science Clerk); Dr Elizabeth Rough (Committee Specialist); Martin Smith, (Committee Specialist), Phil Raymond (POST Fellow); Darren Hackett (Senior Committee Assistant); Julie Storey (Committee Assistant); and Nick Davies (Media Officer).

### Contacts

All correspondence should be addressed to the Clerk of the Science and Technology Committee, House of Commons, London SW1A 0AA. The telephone number for general enquiries is 020 7219 2793; the Committee's email address is [scitechcom@parliament.uk](mailto:scitechcom@parliament.uk).

# Contents

---

<b>Summary</b>	<b>3</b>
<b>1 Introduction</b>	<b>5</b>
Our inquiry	8
<b>2 Impact of an EU regulatory system</b>	<b>9</b>
Collaboration and market access	9
Application of regulation by states	12
<b>3 The EU regulatory process: the UK's influence on it and scope for improvement</b>	<b>15</b>
UK influence	15
Areas for improvement	18
Complexity and cost	19
Timeliness	21
The precautionary principle and consistency	23
Scientific Advice Mechanism	25
<b>Conclusions and recommendations</b>	<b>28</b>
<b>Formal Minutes</b>	<b>31</b>
<b>Witnesses</b>	<b>32</b>
<b>Published written evidence</b>	<b>33</b>
<b>List of Reports from the Committee during the current Parliament</b>	<b>34</b>



## Summary

The UK life sciences industry has been globally successful. From medical devices, medical diagnostics and pharmaceuticals, through to the synthetic and industrial biotechnology industry, the life science sector is high-tech, research-intensive, diverse and innovative. To stand any realistic hope of tackling challenges like cancer, halting the dementia epidemic and feeding a growing global population, then a strong life sciences sector matters. It currently encompasses almost 5,000 companies employing 200,000 people in the UK, generating an annual turnover of £60 billion.

Research in the life sciences, and the innovation flowing from such research, is subject to an EU-wide system of regulation. In our inquiry we have examined the pros and cons of that regulatory regime and what needs to be done to make improvements irrespective of whether the UK votes on 23 June to remain or to leave the EU. The EU can be an enabler of collaboration among member states, not least in the area of clinical trials: here, robust conclusions require large cohorts which cooperation between member states can provide. This can make a vital difference, particularly for rarer diseases. Our predecessor Committee's inquiries had showed some resistance from the European Commission to evidence-based policy making and science, including the hostility to GM Organisms (along with an arbitrary and unscientific use of the precautionary principle), the dilatory approach to revising the Clinical Trials Directive and the Electromagnetic Field Directive, as well as the sacking of Professor Anne Glover.

The impact of EU-wide regulation of the life sciences can be assessed in terms of the balance between the benefits of harmonised and responsive regulation and the compromises needed to achieve this. By harmonising the procedures under which research is conducted, and intellectual property protected, EU regulation often helps to foster EU-wide cross-border collaborations. Harmonisation in the life science innovations, products, processes and treatments that flow from that research brings with it access to the EU market, and in the process attracts inward investment into UK life sciences. The EU life science regulatory regime may well be more costly for researchers and businesses than individual national systems, but it does at least provide the potential to access a proportionately greater EU-wide market, except in highly politicised sectors like GM.

The UK's Medicines and Healthcare products Regulatory Agency is widely respected, and has been able to exploit its reputation and expertise to positively influence the EU medicines regulatory regime. Failure by some member states to properly implement that regime, however, or the European Commission to enforce it, has reduced its value. We identify areas where the Government needs to work with the EU to secure essential improvements in key aspects of the regulation system—its complexity and cost, its timeliness, its application of the precautionary principle and its consistency. An important start should be made by the Government, in consultation with industry, by drawing up a programme for regulatory simplification in life sciences.

In the event of the UK leaving the EU, some life science researchers and businesses might seek to have many of the EU regulations either replicated or continue to be applied by the UK. Therefore, whatever the outcome of the Referendum, it will be necessary to reduce large areas of unnecessary complexity and overlap in EU regulation. The Government

must energetically follow up on the EU commitment, secured by the Prime Minister, to “regulatory simplification and burden reduction, including through establishing, where feasible, burden reduction targets in key sectors”. One such ‘key sector’ must be the life sciences.

The EU regulatory system for life sciences often imposes protracted regulatory timescales, including when correcting previous bad regulation. The Clinical Trials Directive has been inflexible and inconsistently applied, and a new Regulation coming into force in 2018 represents almost two lost decades. The Government and UK regulators must continue to push for shorter timescales in the EU system, to keep pace with the speed of developments in the sector.

Too often, the precautionary principle has been wilfully misused in the formulation of EU life science policy-making, including and notably for Genetically Modified Organisms. There remains a fundamental need for what the minister called “an enlightened regulatory system on the side of innovation”. A change to a ‘product-based approach’ from the existing unhelpful ‘process-based approach’ would help. The Government should renew its earlier efforts to engender in the EU and other states a far more robust scientific application of the precautionary principle, informed by existing good science evidence.

The recently established EU High Level Group of Scientific Advisers provides an opportunity, following the Commission’s sacking of its Chief Scientific Adviser and its failure to renew the post, to improve EU regulation. The Government should push for the High Level Group to provide a prominent and transparent process for independent scientific advice to the EU institutions, to feed into better European regulation of the life sciences. A defining test of the Group’s influencing capability will come if and when it examines topics like the exploitation of genetic techniques in medicine and agriculture. The regulation of genetic science is an area in which the EU has so far not come close to satisfactorily demonstrating an evidence-based approach to policy making.

Under current arrangements the UK benefits significantly from access to EU science research budgets. If, despite the clear attractiveness of the UK as a research location, EU research funding was withdrawn after the exit negotiations, new funding could come from research collaborations outside the EU and from the Treasury reallocating funds previously sent to the EU. The Government should therefore conduct a risk analysis of the science and innovation funding and collaboration scenarios in the event of Brexit and put in place immediate contingency plans to protect our science and innovation sector from any adverse consequences and to consolidate any benefits.

# 1 Introduction

---

1. The UK science and research community benefits from EU research budgets. More than 50 biotech and pharmaceuticals chief executives recently stated in an open letter that:

The UK is a net recipient of EU funding for its health research, accessing more funding per capita than any other country. Many biotech companies have benefited from ‘Horizon 2020’ and its predecessors, and leaving the EU would leave a significant research funding gap.<sup>1</sup>

The Prime Minister approached the science funding issue from a different starting point when he told the Liaison Committee in May that:

I am setting out the case for why we should stay, and I think for science and research and universities, it is a very good thing. Of course, if we vote to leave, as Prime Minister I will want to ensure that we continue to support science. We would be doing so in a situation where, if our economy took the hit that the forecasts suggest, we could be £36 billion down on our tax receipts and so have less money to put into research, agriculture or anything else.<sup>2</sup>

2. The Prime Minister also referred to support for EU membership among the wider scientific community, stating that “93% of science researchers agreed that EU membership is beneficial to UK science and engineering work”.<sup>3</sup> This appears to have been a reference to a survey by the Engineering Professors’ Council and the Campaign for Science and Engineering.<sup>4</sup> In a recent letter to the *Observer*,<sup>5</sup> the chief executives of the Association of British Pharmaceutical Industries, Glaxo SmithKline, AstraZeneca and the Bioindustry Association were among over 90 signatories who stated that the future success of the UK life sciences sector was underpinned by being part of the EU’s single market and EU regulatory processes. BIS also recently highlighted that the UK life sciences sector is worth more than £60 billion to the UK economy and supports over 220,000 jobs.<sup>6</sup>

3. The House of Lords Science and Technology Committee noted in April 2016 that, during the period 2007–2013, “the UK was a net contributor to the EU overall, but a net receiver of EU funding for research.” Taking the latter into account, the Lords Committee observed that science is a “significant dimension of the UK’s membership of the EU”.<sup>7</sup> BIS has similarly noted that:

Significant amounts of funding to support research and innovation is delivered at the EU level, principally through the EU’s Research Framework Programme, ‘Horizon 2020’. European research funding is, in many ways, an example of how the EU can get it right. Because of the excellence of our research base, it is no surprise that the UK is one of the most successful players in EU research programmes.

---

1 [“UK’s life sciences sector is ambitious for the EU”](#) Financial Times, 23 February 2016

2 Oral evidence taken before the Liaison Committee on [4 May 2016](#), HC (2015–16), Q79

3 Oral evidence taken before the Liaison Committee on [4 May 2016](#), HC (2015–16), Q75

4 [“Role of EU membership in UK science and engineering research”](#), Engineering Professors’ Council and CaSE press release, 16 December 2016

5 [Letters to the Editor](#), The Observer, 8 May 2016

6 [“Life science leaders say UK is better off in a reformed EU”](#), BIS press release, 8 May 2016

7 House of Lords, [EU membership and UK science](#), Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), para 105

Horizon 2020 provides a significant proportion of the EU-level public funding for collaborative and single company innovation projects ... To date, the UK has secured 15.4% of Horizon 2020 funding.

In addition to Horizon 2020 funding, €1.6bn of the UK's allocation of EU Structural and Investment Funds for 2014–2020 will be spent on research and innovation projects. This makes the UK one of the largest beneficiaries of EU research funding.<sup>8</sup>

A report published by the technology company Digital Science noted that, as a result of the UK's current relationship with the EU, "jobs are created, money flows into the country in research contracts and [intellectual property] is monetized globally." It added that the "prospect of Brexit represents a number of very real threats to the UK's prosperity".<sup>9</sup> B IS told us that "UK involvement in the EU allows UK-based organisations to participate in more collaborative programmes, increasing the benefit for UK contributors."<sup>10</sup>

4. The House of Lords Committee described how the science community in Switzerland had to hastily introduce replica science funding programmes at national level when, as a result of sanctions from the EU applied in response to a Swiss vote to curtail freedom of movement, Switzerland was denied access to all Horizon 2020 funding programmes. It is notable that Switzerland is one of the most research intensive countries in Europe. Following lengthy negotiations they were permitted re-entry to Horizon 2020 but on much more restrictive terms.<sup>11</sup> The relevance of the Swiss situation to the UK's Referendum is of course a matter of conjecture given that neither the Government nor the EU have been willing to indicate what form a Brexit agreement between UK and the EU might take. It is clear that under current arrangements, while being a net contributor to other EU spending programmes, the UK benefits significantly from access to EU science research budgets. If, despite the clear attractiveness of the UK as a research location, EU research funding was withdrawn after the exit negotiations, new funding could come from research collaborations outside the EU and from the Treasury reallocating funds previously sent to the EU. ***Therefore, given the cautionary example of the Swiss freedom of movement referendum, we urge the Government to conduct a risk analysis of the science and innovation funding and collaboration scenarios in the event of Brexit and put in place immediate contingency plans to protect our science and innovation sector from any adverse consequences and to consolidate any benefits.***

5. The innovation flowing from science research is subject to the EU's system of regulation. Whether this overall presents a benefit or disbenefit for the UK has been a more contested issue than the balance of funding for research. In this inquiry we have examined the pros and cons of the European regulatory regime in the context of the life sciences.

6. The UK life sciences industry has been one of the most successful globally. Spanning medical devices, medical diagnostics and pharmaceuticals, through to the synthetic and

8 Department for Business, Innovation and Skills (UKL0028) paras 14–16

9 Digital Science, [Examining implications of Brexit for the UK research base](#) (May 2016)

10 Department for Business, Innovation and Skills (UKL0028) para 17

11 House of Lords, [EU membership and UK science](#), Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), para 244

industrial biotechnology industry,<sup>12</sup> the life science sector is high-tech, research-intensive, diverse and innovative. Data from the Bioscience and Health Technology Database shows that in 2014 there were almost 5,000 companies employing 183,000 people in the sector in the UK, generating a turnover of £56 billion in the UK and overseas.<sup>13</sup> According to BIS, this latter figure has now grown to £60.7 billion.<sup>14</sup> In December 2011, the Prime Minister launched the *Strategy for UK life sciences* and this was subsequently incorporated in the Government's Industrial Strategy in 2012.<sup>15</sup> The Strategy stressed that the UK was "Europe's leading destination for inward investment in the sector".<sup>16</sup>

7. EU legislation and regulation of the life sciences is extensive. BIS listed 18 principal regulations and directives,<sup>17</sup> including the Clinical Trials Directive and the Medicinal Products for Human Use Directive which we have examined as case studies in our inquiry. EU regulation holds the potential to facilitate collaboration and innovation across the 28 member states by harmonising the procedures under which research, and the commercialisation of that research, is conducted. It is not currently clear, however, if such benefits are being fully realised or whether other factors, such as prohibitive regulations, or their inconsistent application across the EU, are limiting UK innovation in the life science sector. Prompted by the Government's aim to "renegotiate the United Kingdom's relationship with the European Union and pursue reform of the European Union for the benefit of all member states",<sup>18</sup> as well as to reduce the burden of excessive EU regulation,<sup>19</sup> we decided to examine the impact of EU regulation and policy on the UK life sciences sector. Our predecessor Committee's inquiries had showed some resistance from the European Commission to evidence-based policy making and science, including the hostility to GM Organisms (along with an arbitrary and unscientific use of the precautionary principle), the dilatory approach to revising the Clinical Trials Directive and the Electromagnetic Field Directive, as well as the sacking of Professor Anne Glover (paragraph 69).

**8. We do not prejudge the outcome of the forthcoming Referendum on the UK's membership of the European Union. Nor in this inquiry do we express a view about which outcome would be best for the UK life sciences, less still the UK more generally. Life sciences will clearly not be the determining factor when the British public casts their votes on 23 June. Whatever the result, however, there will need to be action to address a number of concerns about the way the life sciences are regulated in the UK and in the markets it trades with.** The future health of the life sciences sector in the UK is, under either outcome, an important proxy for broader issues around innovation and competitiveness.

12 Association of the British Pharmaceutical Industry ([UKL0029](#)) (Appendix 1 comprises a tabulated summary of some of the key EU legislation, and its UK implementation, that impacts on research in the biopharmaceutical industry alone)

13 Office for Life Sciences, *Bioscience and health technology database: annual report 2014*, 26 March 2015

14 "Life science leaders say UK is better off in a reformed EU", BIS press release, 8 May 2016

15 Office for Life Sciences, *Strategy for UK Life Sciences: one Year On*, 10 December 2012

16 Office for Life Sciences, *Strategy for UK life sciences*, 5 December 2011

17 Department of Business, Innovation and Skills ([UKL0028](#)) para 3

18 Cabinet Office, *Queen's Speech 2015*, 27 May 2015

19 Prime Minister, *EU speech at Bloomberg*, 23 January 2013; Prime Minister, *Letter to Donald Tusk*, 10 November 2015

## Our inquiry

9. We launched our inquiry in January 2016. We examined how EU legislation and regulation can best facilitate, and avoid impeding, collaboration and innovation in the life sciences, and invited submissions on the following issues:

- What are the key EU regulations and frameworks that govern/influence the conduct of research and innovation in the UK life sciences?
- In what ways do these EU regulations affect the UK life sciences? What are their benefits and the drawbacks?
- How transparent, consultative and evidence-based are EU policy-making processes?
- To what extent is the UK able to shape regulatory processes at the EU level that affect the life sciences?
- Is the UK able to depart from the application, standards or timing of such EU regulation?

We received 33 written submissions and took oral evidence from the Shelford Group of hospitals, the Wellcome Trust, businesses and industry representatives, national academies, Cancer Research UK, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Parliamentary Under Secretary of State for Life Sciences, George Freeman MP. We are grateful to them all.<sup>20</sup>

10. In Chapter 2 we discuss the impact of the EU life science regulatory regime, including the effects on collaboration and market access. In Chapter 3 we examine the impact of the EU regulatory process and the UK's ability to influence it, and areas needing Government work to help secure improvement in the system if the UK remains in the EU.

---

<sup>20</sup> The Medicines and Healthcare products Regulatory Agency (MHRA) receives EU money for assessment services contracted by the EU, and the Shelford Group of hospitals and Cancer Research UK indirectly received EU research funding.

## 2 Impact of an EU regulatory system

### Collaboration and market access

11. The Association of Medical Research Charities (AMRC) highlighted that the UK receives the second highest financial contribution from Horizon 2020, after Germany, but also that “the benefits of long-term research funding programmes ... are more than financial ... [by] encouraging collaboration”.<sup>21</sup> Pan-European rules for research programmes have the potential to facilitate collaboration “by harmonising member countries’ approach to research”.<sup>22</sup> The Academy of Medical Sciences concluded 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.”<sup>23</sup> Collaboration in research is also facilitated by existing free movement rules. AMRC told us, for example, that half of the researchers in Cancer Research UK’s Beatson Institute are from other EU countries and a further 28% from non-EU countries.<sup>24</sup>

12. Another driver of research collaboration is the common regime for taking forward the approval and the regulation of the innovations that flow from that research. Some regulatory processes allow individual countries to approve products for EU-wide application (for example medical devices approved by one of 60 ‘Notified Body’ assessment organisations<sup>25</sup>). Importantly, the regulatory regime allows life science products, processes and treatments to have access to an EU-wide market.

13. The Academy of Medical Sciences noted that harmonisation had brought about greater market access, both for the commercialisation of life sciences products, and for attracting inward investment into the life sciences. The Bioindustry Association (BIA) believed that “EU membership and access to the single EU market significantly influences businesses’ decisions to invest and operate in the UK.”<sup>26</sup> The AMRC thought that the single European regulatory framework “plays an important part in the UK’s attractiveness for inward investment and research by the life sciences industry.”<sup>27</sup> The Shelford Group considered that “consistency of regulatory processes and requirements across the 28 member states aids the collaboration and access of new products to EU markets—a product developed in the UK is free to be marketed across the [EEA]<sup>28</sup> without barriers.”<sup>29</sup>

14. The Bioindustry Association’s *UK Life Sciences Manifesto 2015–20* stated:

Europe is the single biggest global market, and access to this market is a key reason for global biopharmaceutical companies deciding to establish their

21 Association of Medical Research Charities (UKL0025) para 1.7

22 Association of Medical Research Charities (UKL0025)

23 Academy of Medical Sciences (UKL0006)

24 Association of Medical Research Charities (UKL0025) para 2.6

25 Department of Business, Innovation and Skills (UKL0028) para 27

26 BioIndustry Association (UKL0022)

27 Association of Medical Research Charities (UKL0025)

28 European Medicines Agency, [Authorisation of medicines](#), accessed 23 May 2016

29 Shelford Group (UKL0010)

European HQ in the UK and invest in R&D activities. It is vital that the UK remains engaged in the EU and takes a leading role in shaping legislative and regulatory policy developments affecting the life sciences sector.<sup>30</sup>

Steve Bates from the BIA told us “You can see the benefits from working in a harmonised scheme that gives you access to a very large market—27% of the global market rather than 3% of the market if it was the UK alone”.<sup>31</sup> In a similar vein, BIS highlighted that:

Retaining membership of a reformed single market, and maintaining our ability to influence its development, will be key to the UK’s future ability to attract investment, develop innovative medicines and technologies, and grow exports in this internationally competitive sector.

Regulatory processes to open up the single market have delivered real benefits, by giving UK-based companies access to the single market and a uniform regulatory system, which can offer certainty and consistency ... In addition, UK companies gain access to wider opportunities in non-EU markets, through comprehensive free trade agreements.<sup>32</sup>

They added that:

EU regulatory processes support the single market and give life science companies investing in the UK access to new opportunities in a wider market for their products. More efficient cross-EU regulatory processes reduce costs for companies, and so increase the attractiveness of the UK as a location for investment. The UK exported £21.4bn of pharmaceuticals in 2014, 54% of which was to the EU—equivalent to £11.5bn of pharmaceuticals or £32m worth of pharmaceuticals each day. This shows how important pharmaceutical European trade is for this sector for the UK, and suggests the importance of efficient European regulations.<sup>33</sup>

15. The EU regulatory system also provides a foundation for access to potentially even wider markets. The Academy of Medical Sciences told us that:

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.<sup>34</sup>

The Transatlantic Trade and Investment Partnership (TTIP), under negotiation between the EU and US for over a year, seeks to boost trade and reduce its cost by harmonising or mutually recognising trade regulations between the two blocs across a large number of sectors, including medicines. The 13th round of negotiations concluded in April 2016.<sup>35</sup>

---

30 Bioindustry Association, *UK Life Sciences Manifesto 2015–20* (October 2014)

31 Q39

32 Department of Business, Innovation and Skills ([UKL0028](#))

33 Department of Business, Innovation and Skills ([UKL0028](#)) para 20

34 Academy of Medical Sciences ([UKL0006](#))

35 European Commission, *Transatlantic Trade and Investment Partnership (TTIP)*, accessed 23 May 2016

There has been some controversy on TTIP on a host of issues.<sup>36</sup> Dr Ian Hudson, chief executive of the Medicines and Healthcare products Regulatory Agency (MHRA), viewed TTIP in a positive light however:

I think it will help our work in a number of areas. Priority areas for us are sharing information between ourselves and our counterpart, the [US Food and Drug Administration], certainly when it comes to inspection. Moving to mutual recognition on inspections would be extremely helpful. At the moment, we inspect in the United States, and the United States sends inspectors over to factories in the UK. To get to a situation where we rely on each other to do that for us would be extremely helpful. It can only help to harmonise requirements.<sup>37</sup>

BIS believed that an agreement with the US would open up “a major market for UK-based companies”.<sup>38</sup> There are conflicting views about whether the UK, in the event of it leaving the EU, could continue to benefit from such EU trade arrangements by inheriting those trade deals.

16. The BIA emphasised the importance of the developments of a proposed new European unitary patent and Unified Patent Court (UPC), expected to open in early 2017. Such intellectual property protections, under a harmonised pan-EU system, would maintain “the lifeblood of the life sciences industry”.<sup>39</sup> They pointed out that the section of the UPC that would deal with chemical and pharmaceutical patents was planned to be based in London.<sup>40</sup> On the other hand, concerns have been raised about the hidden costs of Associated Country status for UK innovation: while the evidence is clear that multi-state research collaborations are essential for the UK to remain internationally competitive, in life science and other fields, and are enabled through EU funding and harmonised regulatory frameworks, researchers and industrial partners in an Associated Country would be unable to exploit research from these collaborations. Professor Sir Leszek Borysiewicz, Chair of the Russell Group’s EU Advisory Group, and Vice-Chancellor, University of Cambridge, explained to the Lords Science & Technology Select Committee:

Associated member status carries with it a huge disadvantage, particularly if we think of the outcomes of that research as they will pertain to the capacity of the UK to exploit them. If you are an Associated Country you have to negotiate that position on intellectual property in a separate way because you do not form part and parcel of those areas. Were we outside the European Union, it is quite likely that we might still be invited because of the quality of research that is undertaken in Europe, but there is no way that any discoveries would then be exploited necessarily in the UK because we would not hold the intellectual property; it would be held by member states. I believe that being there is a huge advantage.<sup>41</sup>

36 Environmental Audit Committee, Ninth Report of Session 2014–15, *Environmental risks of the Trans-Atlantic Trade & Investment Partnership*, HC 857, para 17

37 Q145

38 Department of Business, Innovation and Skills ([UKL0028](#)) para 21

39 Bioindustry Association ([UKL0022](#)), para 14

40 Bioindustry Association ([UKL0022](#)), para 14

41 House of Lords, EU membership and UK science, Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), para 232

17. **The impact of EU-wide regulation of the life sciences can be assessed in terms of the balance between the benefits of harmonised and responsive regulation and the compromises needed to ensure this can be achieved. By harmonising the procedures under which research is conducted, EU regulation can foster cross-border collaborations. These multiple state collaborations are evident at least in the conduct of clinical trials, for example, and setting up such trials through a system where permission needed to be sought country by country would likely introduce even more delay and bureaucracy than the current EU system. Harmonisation in the life science innovations, products, processes and treatments that flow from that research brings with it ready access to the whole EU market, and in the process attracts inward investment into UK life sciences. As we describe below (paragraph 42), the EU life science regulatory regime may be more costly for researchers and businesses, but provides access to a significantly greater EU-wide market.**

18. **We are aware of evidence that under Associated Country status UK researchers and innovators could lose out on opportunities to exploit their research under Associated Country scenarios. The extent to which UK scientists could be able to offset this by pursuing greater global (rather than EU) collaborations remains uncertain. *We urge the Government to investigate this issue.***

### Application of regulation by states

19. The benefits of a regulatory system that provides access to an EU-wide market have to be offset against adverse impacts of the sometimes different ways that regulation is implemented by individual states.

20. Sometimes the scope for flexibility in implementation can be advantageous. BIS highlighted the UK's Early Access to Medicines Scheme, which was:

an example of how the Medicines and Healthcare products Regulatory Agency (MHRA) has used a derogation in EU law that permits national rules on unlicensed medicines to maximise the benefit to the UK sector and patients. This scheme provides a framework for companies to apply to MHRA for a scientific opinion on their product ahead of it being licensed. The company may supply the medicine to the NHS for patients with unmet need who cannot access the medicine in a clinical trial. The [Early Access to Medicines Scheme] encourages early dialogue with other parts of the UK health system to facilitate more rapid uptake of innovations in the UK.<sup>42</sup>

An associated Accelerated Access Review, looking at speeding up access for NHS patients to cost-effective, innovative medicines, diagnostics and medical technologies, was due to report in April 2016<sup>43</sup> but, the Minister told us, had been delayed.<sup>44</sup> He explained that the Review was examining potential “reforms to try to anticipate the way in which technology is changing, the way medical innovation comes to our system, and how we assess, adopt and reimburse.”<sup>45</sup>

42 Department of Business, Innovation and Skills ([UKL0028](#)) para 58

43 House of Commons Science and Technology Committee, [Innovation in, and accelerated access to, healthcare evidence check](#), accessed 23 May 2016

44 Q193

45 Q190

21. Part of the problem of regulation is when it imposes inappropriate standardisation, or leaves scope which allows unwarranted variations in approach, sometimes as a result of ‘gold plating’ of EU regulation by member states, including the UK.<sup>46</sup> The Wellcome Trust told us that:

The UK has encountered problems with its implementation of EU legislation, particularly the concern that this can go further than the legislation requires.<sup>47</sup>

The AMRC echoed such concerns about UK gold plating, “making them more onerous than is needed”. The Minister, George Freeman, assured us that no gold plating had occurred “on his watch”.<sup>48</sup>

22. Another problem area, as the Wellcome Trust told us, is that a failure by member states to properly implement legislation, and failure by the European Commission to enforce it, reduces the value of EU-wide legislation.<sup>49</sup> The Shelford Group (of NHS university teaching and specialist hospitals) believed that the interpretation of EU regulation varied between states, leading to inconsistencies in implementation.<sup>50</sup> The Cell and Gene Therapy Catapult noted that:

How [directives] ... are translated into national law is determined at a member state level. This inevitably leads to differences in implementation between the various member states which can lead to difficulties for developers of medicinal products. Some examples of the differences for [Advanced Therapy Medicinal Product] developers are the translation of the EU Blood Directive (2002/98/EC), EU Tissues and Cells Directive (2003/24/EC) and their commissioning directives.<sup>51</sup>

23. The Shelford Group cited the case of the transposition<sup>52</sup> of the 2001 Clinical Trials Directive. The Wellcome Trust told us that this Directive had been highly criticised for its one-size-fits-all nature, which had led to an “increased burden on academic researchers and a drop in clinical trials conducted in the UK and the EU”.<sup>53</sup> The Academy of Medical Sciences suggested that other countries had taken “a more pragmatic approach” than the UK’s “rigorous implementation” of the Directive.<sup>54</sup> The AMRC believed that the UK’s “stringent” transposition of the Directive had “inhibited how we set up trials [and] as other EU countries went less far, they became a more attractive place to conduct trials, and this dynamic undermined the UK position”.<sup>55</sup> The AMRC explained that “the [Clinical Trials Directive] significantly increased the administrative burden and cost of running academic clinical trials; it also saw a reduction in the number of global trials taking place in Europe.”<sup>56</sup>

---

46 Royal Society of Biology ([UKL0030](#)) para 28

47 Wellcome Trust ([UKL0020](#)) para 31

48 Q191

49 Wellcome Trust ([UKL0020](#)) para 31

50 Shelford Group ([UKL0010](#))

51 Cell and Gene Therapy Catapult ([UKL0018](#))

52 Medicines for Human Use (Clinical Trials) Regulations 2004 ([SI 2004/1031](#))

53 Wellcome Trust ([UKL0020](#)) para 5

54 Wellcome Trust ([UKL0020](#)) para 31

55 Association of Medical Research Charities ([UKL0025](#)) para 5.2

56 Association of Medical Research Charities ([UKL0025](#)) para 2.4

24. AMRC believed that the new Clinical Trials Regulation, expected to come into effect in 2018, is a “considerable improvement” on the Directive, introducing a streamlined approvals process and proportionate approach to the monitoring and safety reporting of clinical trials.<sup>57</sup> The Wellcome Trust acknowledged, similarly, that the European Commission had responded to the criticism of the Directive in framing the revised 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.”<sup>58</sup> The Government reported that it had “been pressing for the EU to introduce a risk-proportionate approach to clinical trial approvals and a mechanism for harmonising applications for multi-state clinical trials”. The Regulation, it said, would “reduce scope for differing interpretations of the legislation across the EU”.<sup>59</sup>

25. Despite the improvement, the amount of variation that could remain in the system was still a concern for the Shelford Group. They worried that adherence to, and assessment against, international quality standards for clinical trials might still differ between EU states. They highlighted too their concern that regulation “can quickly become stale and unsuitable for the pace of the industry” while also be “complex to understand and navigate” for innovators or smaller organisations with limited resources.<sup>60</sup>

**26. While the EU regulatory regime has sought a harmonised approach, a failure by some member states to properly implement legislation, or the European Commission to enforce it, has reduced its value. Variations in the way directives are translated into national law can lead, for example, to difficulties for developers of medicinal products.**

**27. Weaknesses in the 2001 Clinical Trials Directive significantly increased the administrative burden and cost of running academic clinical trials and saw a reduction in trials taking place in Europe. Its replacement Clinical Trials Regulation, expected to come into effect in 2018, appears to be an improvement.** This episode has come at a cost to the sector, however, not least in terms of lost time and opportunity over the last decade or so, as we discuss below (paragraph 52).

---

57 Association of Medical Research Charities ([UKL0025](#)) para 2.4

58 Wellcome Trust ([UKL0020](#)) para 6

59 Office for Life Sciences, *Strategy for UK Life Sciences: one Year On*, 10 December 2012

60 Shelford Group ([UKL0010](#))

### 3 The EU regulatory process: the UK's influence on it and scope for improvement

---

28. A single application to the European Medicines Agency (EMA), based in London, for a marketing authorisation is valid simultaneously in all 28 EU states. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. The EMA's duties in relation to public and animal health span the 28 EU states, as well as the countries of the European Economic Area. Clinical trials must be authorised by the competent authority (the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK) and receive a favourable opinion by an ethics committee.

29. In the UK, the MHRA regulates medicines, medical devices and blood components for transfusion. Its responsibilities include:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure;
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
- supporting innovation and research and development that is beneficial to public health;
- influencing UK, EU and international regulatory frameworks so that they are risk-proportionate and effective at protecting public health.<sup>61</sup>

30. The BIA's assessment of the regulatory system in the context of medicines development was positive overall: "Over a generation, regulators and legislators have built up an effective and integrated European regulatory framework for clinical research and development of new, innovative medicines." They believed that the UK regulator, the MHRA, is "globally respected".<sup>62</sup>

#### UK influence

31. Many of our witnesses highlighted a strong and positive UK influence on EU life science regulation. BIS emphasised that "new proposals for legislation rarely come as a surprise and officials do not wait to see a proposal before deciding whether to exert influence."<sup>63</sup> The House of Lords Science and Technology Committee repeatedly heard

---

61 Medicines & Healthcare products Regulatory Agency, [About us](#), accessed 23 May 2016

62 Bioindustry Association ([UKL0022](#))

63 Department of Business, Innovation and Skills ([UKL0028](#)) para 37

that “UK scientists have considerable influence on EU groupings and decision-making bodies, and therefore played a considerable role in shaping EU policy for science.”<sup>64</sup> The Committee added: “It certainly appears that the UK has a strong voice when it comes to putting a firm UK imprint on EU policy for science.”<sup>65</sup> Professor Dame Anne Glover, until 2014 the EU Chief Scientific Adviser (paragraph 69), told the Lords Committee:

The UK voice is very welcome, very loud, very credible, and it is acted upon [in the EU]. We chair many of the influential committees and, regarding identifying members of the council of the European Research Council, we have members on that council. We help to deliver policy in science funding and where it is spent.<sup>66</sup>

32. BIS gave us several examples of where the UK has influenced the EU regulatory process:

The [Medicines and Healthcare products Regulatory Agency] were heavily involved in the negotiations within the EU Council and with EU Parliament to finalise the new Clinical Trials Regulation and strongly represented UK interests. MHRA were also represented in all of the working groups tasked with implementing the Regulation, including drafting Q&As and guidance as well as influencing the functionality of IT systems that underpin the application of the legislation.

The adaptive pathways pilot launched in 2014 was in large part influenced by UK thought-leaders, and MHRA was influential in developing it. This is a new approach to iterative development that could see a medicine receive an initial licence several years sooner than might otherwise be the case.

MHRA has worked to simplify the regulatory processes’ landscape. The MHRA were also very heavily involved in the negotiations within the EU Council and with the European Parliament to finalise the changes to the Pharmacovigilance legislation, implemented in the UK in August 2012, which led to significant reductions on requirements for industry in terms of reporting for suspected adverse drug reactions and submission of periodic safety update reports.<sup>67</sup>

33. Dr Ian Hudson from the MHRA had a similar message:

The MHRA is one of the bigger agencies across the European Union and puts a lot of resource into the EMA, but having the EMA based in London helps enormously, in that we take a lead in the greatest number of assessment works, whether new assessments, pharma-covigilance or scientific advice. It helps reinforce the UK as a strong place for the pharmaceuticals sector to have a strong national agency, very much open to dialogue, together with the European Medicines Agency based in London as well.<sup>68</sup>

64 House of Lords, EU membership and UK science, Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), paras 62–73

65 House of Lords, EU membership and UK science, Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), para 71

66 House of Lords, EU membership and UK science, Second Report of the Science and Technology Select Committee, Session 2015–16, [HL Paper 127](#), para 64

67 Department of Business, Innovation and Skills ([UKL0028](#)) paras 48, 51, 52

68 Q131

In a similar vein, Steve Bates from the BIA told us:

In a sense, the industry has grown up in a European environment. We are a relatively young sector and most of the legislation has been at European level since the science was developed, so we are at the benefit point of seeing ourselves within our European context. If we look at the UK's influence within that, the MHRA does a third of the files for the EMA in our space. The UK is also lucky to attract about a third of the innovation capital, and it is oversized and overweight compared with the rest of Europe in terms of the biotech sector.<sup>69</sup>

The Bioindustry Association considered that the MHRA had been “able to exploit its reputation, leadership and expertise to positively influence the EU medicines regulatory regime.”<sup>70</sup>

34. There are a number of opportunities for UK organisations to contribute directly to EU policy-making processes. The Wellcome Trust provided a list:

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); and dialogue with the UK Government through the relevant department, the UK's Permanent Representation to the EU and government agencies such as MHRA.<sup>71</sup>

35. The Shelford Group noted that “the NHS European Office has proved to be very effective in flagging up issues, and works closely with professionals on the Medical Device Regulations.”<sup>72</sup> The Academy of Medical Sciences also cited examples of where the development of EU legislation had been significantly influenced by the UK:

During the development of the EU Clinical Trials Regulation the UK was often the leading Member State in pushing for proportionate regulation ... 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.<sup>73</sup>

36. The Shelford Group also praised the UK's influence on clinical trials of investigational medicinal products (CTIMPs):

The UK's MedTech industry, its Competent Authority and its Notified Bodies, are well-regarded and contributing actively to shaping the emergent regulatory processes. The MHRA (UK Regulatory Authority) for CTIMPs and the NHS

---

69 Q39

70 Bioindustry Association ([UKL0022](#))

71 Wellcome Trust ([UKL0020](#)) para 20

72 Shelford Group ([UKL0010](#))

73 Academy of Medical Sciences ([UKL0006](#))

Confederation have been instrumental in review of the new EU Regulations for CTIMPs to ensure that standards arising from the new regulation meet with UK requirements, having consulted UK-wide and taken feedback to Brussels.<sup>74</sup>

The Association of Medical Research Charities reported that “both the UK Government and UK Members of the European Parliament (as well as MEPs from other countries) are keen to hear from the AMRC and its membership and, often, actively seek views.”<sup>75</sup>

37. Dr Ian Hudson from the MHRA outlined the number of ways in which both the MHRA and EMA help businesses, in particular SMEs:

We have established an innovation office, where we are very happy to support maybe academics and SMEs, or it may be bigger companies—those developing novel products who are less familiar with the regulatory pathways—to help them navigate the regulatory pathways. We offer scientific advice to whoever wants it, whether companies, academics or whoever would like to take it, in terms of helping them with their development programme. We have quite a lot of guidance available to help people. We have helplines available—a clinical trials helpline, for example. We do workshops.<sup>76</sup>

38. Brightwake Ltd (a medical technology business) was concerned, however, that the UK’s ability to shape regulatory processes at the EU level—at least for medical devices—was reliant on the impact of the MHRA and that the input that the MHRA received from industry was “limited”. They told us that “although views can be shared within trade bodies like [the Association of British Healthcare Industries], their ability to influence and shape the MHRA’s views have yet to be ably demonstrated.” Until November 2012, the MHRA had published its opinions on new medical device proposals, along with an invitation to comment, but the Government’s migration to ‘gov.uk’ had led to “all links to updates” having been lost. As a result, Brightwake told us, “manufacturers cannot see any updated opinion or calls for evidence” and “industry certainly needs an improved mechanism to discuss with the MHRA concerns, support and evidence which it can use to shape the UK’s position and represent us all at a European level.”<sup>77</sup>

**39. The UK’s Medicines and Healthcare products Regulatory Agency is widely respected, and has been able to exploit its reputation, leadership and expertise to positively influence the EU medicines regulatory regime. The MHRA should reassess its information channels with medical businesses, however, to ensure that all companies and laboratories, including SMEs, are able to seek to influence the regulatory environment.**

## Areas for improvement

40. The Minister for Life Sciences, we were told, signalled some of the challenges to future regulation in the EU to Commissioner Moedas in 2015:

The Minister highlighted the pace of scientific progress in the broad area of the ‘Life Sciences’ (the appliance of science in the key markets of food, medicine, and energy), is creating a clear opportunity for the EU to become forward-

74 Shelford Group ([UKL0010](#))

75 Association of Medical Research Charities ([UKL0025](#)) para 4.1

76 Q157

77 Brightwake Ltd ([UKL0001](#))

looking in terms of the regulation of upcoming technological development. For example, 3D printed medical devices, genome editing, and ‘nutraceuticals’ (the merging together of the traditional ‘food’ and ‘medicines’ categories) all pose challenges to the current regulatory regime which a forward-thinking EU should begin to address.<sup>78</sup>

41. Our inquiry has also identified a need for the EU, with pressure also needed from the Government if the UK stays within the EU, to address particular aspects of the regulation system—its complexity and cost, its timeliness, its application of the precautionary principle and its consistency, as we discuss below.

### **Complexity and cost**

42. The Cell and Gene Therapy Catapult described how the regulatory processes for Advanced Therapy Medicinal Products use EMA’s ‘Centralised Authorisation’ process, and include commercial incentives for developing medicines which meet the needs for example of rare diseases and paediatric care.<sup>79</sup> But the Catapult also pointed to the costs associated with regulatory compliance:

The obligatory Centralised Authorisation process can be an extremely costly (financial and resource) and lengthy process, taking into account a broad range of opinions from different EMA committees and member states and this may act as a deterrent for some smaller developers or those intending to access smaller markets.<sup>80</sup>

Dr Jacqueline Barry from the Catapult explained, however, that while “the cost of a centralised marketing authorisation would be, say, £200,000, [and] a national one would be about £70,000 or £80,000, ... you could argue that that is more cost-effective because it will give you access to 28 member states”.<sup>81</sup> Steve Bates of the BIA put it in context: “The UK is 3% of the global market for pharmaceuticals, and the EU, as at present constituted, is about 27%” (paragraph 14).<sup>82</sup>

43. Professor Ferry from the Shelford Group referred to an “overly complex” amendment to the in-vitro diagnostic medical devices regulation that “does not appreciate how genetic testing is done.”<sup>83</sup> The Wellcome Trust similarly worried about European Parliament amendments which expanded the scope of that particular 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.”<sup>84</sup>

44. Brightwake Ltd told us that fears over particular hip implants and silicone breast implants had led, in their view, to an unjustified increase in scrutiny and therefore cost of regulation.<sup>85</sup> Emma Greenwood of Cancer UK suggested to us that an understandable

78 Department of Business, Innovation and Skills ([UKL0028](#)) para 46

79 Cell and Gene Therapy Catapult ([UKL0018](#))

80 Cell and Gene Therapy Catapult ([UKL0018](#))

81 Q58

82 Q59

83 Qq 16,17

84 Wellcome Trust ([UKL0020](#)) para 15

85 Brightwake Ltd ([UKL0001](#))

desire to avoid legislating unnecessarily meant that opportunities to review and improve legislation might be missed.<sup>86</sup> She cited in particular the need for improvements in the EU regulation governing paediatric drug development,<sup>87</sup> which was a priority for the cancer research sector.<sup>88</sup>

45. Steve Bates of the Bioindustry Association outlined his concerns over the interaction of medicines regulation and chemicals (REACH)<sup>89</sup> regulation:

[REACH] aims to protect from the risks posed by hazardous chemicals. While medicinal products and active pharmaceutical ingredients are exempt from REACH, other substrates ... such as processing solvents used in the manufacture of [active pharmaceutical ingredients] are not exempt, so there is chemical regulation in one part of the field and medical regulation in another part of the field. One of the solvents used for stopping viruses getting into product is being treated under the chemical rules rather than the medicine rules, and we think it would be sensible for them to be treated entirely under the medicine rules.<sup>90</sup>

Darren Budd of BASF acknowledged the need for chemicals regulation, but was critical of the cost of REACH and its complexity.<sup>91</sup>

46. Dr Hudson of the MHRA wanted a shift in emphasis towards exploiting more opportunities in existing legislation “to make sure that the existing things that we know are coming are implemented appropriately and then to support the new initiatives that we have been very heavily involved with, like adaptive pathways, adaptive licensing and PRIME [priority medicines for unmet medical needs].”<sup>92</sup> Criticisms of complexity are by no means confined to the regulation of health sciences. Sense about Science believed that an “expensive and complex regulatory system is a barrier to the conduct of research on GM foods in the UK.”<sup>93</sup>

47. The Bioindustry Association considered that, in the event of the UK leaving the EU:

Many of the EU regulations would either have to be mirrored or accepted from the outside for the UK to remain effective in this sector. In either scenario, the UK would have to follow a system that it cannot influence.<sup>94</sup>

The AMRC emphasised that the UK research sector “envisages that compliance with EU regulation will remain important regardless of changes to the UK’s relationship with the EU, to ensure a harmonised European research sector which is vital for UK and European science.”<sup>95</sup>

---

86 Q100

87 Q115

88 Qq 116–117

89 Registration, Evaluation, Authorisation & restriction of Chemicals

90 Q44

91 Qq 45, 60

92 Q132

93 Sense About Science ([UKL0012](#))

94 BioIndustry Association ([UKL0022](#))

95 Association of Medical Research Charities ([UKL0025](#)) para 5.3

48. BIS pointed to the significance of the Prime Minister’s pre-Referendum commitments from the European Commission and all EU states to:

regulatory simplification and burden reduction, including through establishing, where feasible, burden reduction targets in key sectors. This is the first time the EU has taken such an approach. HM Government is currently undertaking work to assess the areas where we would like the EU to set targets.<sup>96</sup>

49. **It is essential that regulation is proportionate in safeguarding patient safety as well as providing a legal environment for the research and development of effective healthcare interventions. Whatever the outcome of the Referendum, there is considerable scope to avoid areas of unnecessary complexity and overlap in EU regulation and to reduce its burden. The costs of a marketing authorisation under the EU system are greater than a national system, but as we noted above (paragraph 42) it brings wider market access. In the event of the UK leaving the EU, some life science researchers and businesses might seek to have many of the EU regulations either mirrored or continue to be applied by the UK.**

50. *Every effort must be made to avoid adding unnecessary regulatory burdens to already hard-pressed businesses. The Government must energetically follow up on the EU commitment, secured by the Prime Minister, to “regulatory simplification and burden reduction, including through establishing, where feasible, burden reduction targets in key sectors”. One such ‘key sector’ must be the life sciences. We recommend that the Government, in consultation with industry and whatever the Referendum outcome, draws up a programme for regulatory simplification in life sciences.*

### **Timeliness**

51. Brightwake considered that, notwithstanding the increased scrutiny that had been introduced following concerns over some specific implants (paragraph 44), the EU’s regulatory system for medical devices had proved highly successful and was efficient at rapidly bringing the benefits of innovation to people. They claimed that “people in the European Union on average benefit from advances in medical technology 3–5 years earlier than in Japan and 3 years earlier than in the US, without compromising safety”.<sup>97</sup> They argued that, by avoiding excessive delays, the EU system incentivised innovation, while offering the “best balance” between safety and risk.<sup>98</sup> The Wellcome Trust outlined, however, what it saw as sometimes protracted regulatory timescales:

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. ... The European Commission does respond to concerns about individual pieces of legislation but the protracted timescales in addressing problems could be seen as a barrier to competitiveness.<sup>99</sup>

52. A consistent theme in our inquiry was the length of time taken to correct inappropriate regulation. As we noted above, the Clinical Trials Directive has been inflexible and

96 Department of Business, Innovation and Skills ([UKL0028](#)) para 31

97 Brightwake Ltd ([UKL0001](#))

98 Brightwake Ltd ([UKL0001](#))

99 Wellcome Trust ([UKL0020](#))

inconsistently applied (paragraph 23).<sup>100</sup> The European Commission responded with a revised Clinical Trials Regulation which provides less scope for national variations than is possible in transposing directives. While acknowledging the resulting improvements, the Wellcome Trust complained that “it took some time to recognise the concerns and bring forward new regulatory proposals”.<sup>101</sup> By the time the new Regulation comes into force in 2018, there will have been “almost two decades during which EU clinical trials legislation has not been as effective as it could have been”.<sup>102</sup>

53. In another example, the Shelford Group highlighted the consultative processes for the Physical Agents (Electromagnetic Fields) Directive, which our predecessor Committee examined back in 2006.<sup>103</sup> The Group identified a lack of initial consultation which “took 10 years of lobbying and considerable expense by UK and EU authorities and professional bodies to remedy”, which was then followed by a “potentially too consultative” process causing further delay.<sup>104</sup>

54. The Cell and Gene Therapy Catapult welcomed the frequent consultations of EMA’s Committee of Advanced Therapies but noted “long lead times for change”.<sup>105</sup> A tension between the needs of research regulation and of industry investment was illustrated by the ‘hospital exemption’, introduced by the Advanced Therapy Medicinal Products regulation to allow developers to release medicinal products “manufactured on a non-routine basis”. The Catapult noted that some states allowed this even if there was a licensed alternative available. They complained that:

This can act to stifle investment in products that have been developed with clinical trial and safety testing to unequivocally demonstrate safety and efficacy. We suggest that the use of Hospital Exemption is discouraged when there is a licensed alternative, as it is here in the UK.<sup>106</sup>

The Bioindustry Association emphasised that “this should only be allowed on a non-routine basis, in line with the original policy intention”.<sup>107</sup>

55. Professor Berne Ferry from the Shelford Group highlighted the more general problem of the regulatory process trying to anticipate often fast-moving future technology developments:

A general point is that innovation in healthcare and life sciences is moving so fast that the legislation is finding it difficult to keep up. We talk about a lot of it being much more evidence-based, and that scientific input should be in the legislation much earlier than it currently is. One suggestion would be some kind of life science horizon-scanning group here in the UK.<sup>108</sup>

---

100 Wellcome Trust ([UKL0020](#)) para 5

101 Wellcome Trust ([UKL0020](#)) para 6

102 Wellcome Trust ([UKL0020](#)) para 6

103 House of Commons Science and Technology Committee, Fourth Report of Session 2005–06, *Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive*, HC 1030

104 Shelford Group ([UKL0010](#))

105 Cell and Gene Therapy Catapult ([UKL0018](#))

106 Cell and Gene Therapy Catapult ([UKL0018](#))

107 Bioindustry Association ([UKL0022](#)) para 73

108 Q12

Emma Greenwood of Cancer Research UK thought that there was scope for improved horizon-scanning both by the UK Government<sup>109</sup> and the EU institutions.<sup>110</sup> At the moment, such horizon-scanning activities tend to be piecemeal; what Stuart Pritchard of the Wellcome Trust described as an “ad hoc early warning system”.<sup>111</sup> It remains to be seen whether the recent Higher Education white paper<sup>112</sup> proposal that a reformed Council for Science and Technology should have a horizon-scanning function will bring about a step change in capability.

**56. There is limited evidence that patients in the European Union may benefit from advances in medical technology more quickly than those in Japan and the US. On the other hand, the EU regulatory system often imposes protracted regulatory timescales, including when correcting bad regulation. The new Clinical Trials Regulation, replacing an inflexible and inconsistently applied Directive, coming into force in 2018 represents almost two decades of lost time.**

*57. The Government and UK regulators must continue to push for shorter timescales in the EU system, to keep pace with a rapidly developing life sciences sector. In order for UK life sciences to retain our competitive advantage we must support them with the most agile and responsive regulatory environment in the world.*

*58. The Government should explicitly establish a life sciences horizon-scanning group to communicate effectively with universities and businesses about future regulations that could significantly impact on their work. The Group should aim to anticipate technological developments and provide advice to Government and regulators on timely and proportionate legislative and regulatory responses. Such a group could provide a focus for existing horizon-scanning activities in universities, industry and Government. We believe that the EU should also be encouraged to establish more effective horizon-scanning activities across the life sciences.*

### **The precautionary principle and consistency**

59. Our predecessor Committee criticised an overly inhibiting application of the precautionary principle in EU regulation in connection with Genetically Modified Organisms.<sup>113</sup> It noted that the EU regulatory framework was “generally considered to have been heavily informed by the precautionary principle.”<sup>114</sup> While there was no single agreed definition of the principle, the Committee cited one from the UN’s World Commission on the Ethics of Scientific Knowledge and Technology: “When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.”<sup>115</sup>

---

109 Q103

110 Q127

111 Q20

112 BIS, *Success as a Knowledge Economy: Teaching Excellence, Social Mobility & Student Choice*, [Cm 9258](#), May 2016, p 71

113 House of Commons Science and Technology Committee, Fifth Report of Session 2014–15, [Advanced genetic techniques for crop improvement: regulation, risk and precaution](#), HC 328

114 House of Commons Science and Technology Committee, Fifth Report of Session 2014–15, [Advanced genetic techniques for crop improvement: regulation, risk and precaution](#), HC 328, para 51

115 United Nations Educational, Scientific and Cultural Organization, World Commission on the Ethics of Scientific Knowledge and Technology, [The Precautionary Principle](#), March 2005, p 14

60. In our current inquiry, the Bioindustry Association cited a 2000 European Commission communication on the application of the precautionary principle which aimed to “avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism”.<sup>116</sup> The Royal Society noted that the precautionary principle is not applied consistently across EU states. They wanted the implementation of the precautionary principle to include a “reassessment of the need for any restrictions when new evidence becomes available after a reasonable period of time” to remove restrictions that are “no longer scientifically justifiable [... and] so that the evaluation of valuable technologies is not unduly delayed”.<sup>117</sup> They wanted the EU’s application of the precautionary principle to take into account benefits as well as risks, and the consequences of not acting as well as acting.<sup>118</sup>

61. In November 2015 the Life Sciences Minister, George Freeman MP, complained that a blight resistant GM potato had not been commercialised because of a failure by the EU to grant regulatory approval for its commercial use, “despite the absence of any scientific evidence of harm to human health or biodiversity”. The Minister called for a greater focus on growth and enterprise, and “an enlightened regulatory system on the side of innovation”.<sup>119</sup>

62. The Royal Society pointed to the way in which the current EU framework on genetic modification regulates the use of organisms in agriculture depending on how they have been developed (a so-called ‘process-based’ approach) rather than their novel traits. As the Royal Society observed, however, new traits can be introduced into crops through different approaches, some of which are more heavily regulated than others. The result is that “some plants with a particular novel trait [are] captured by the legislation, whilst others are not.” Because technological developments quickly outpace regulations, “process-based regulations fail to capture these new emerging technologies, resulting in a distinction between regulated and unregulated technologies that is difficult to justify from a risk-assessment perspective.” The Royal Society wanted a regulatory system based on the novel trait being introduced, whether by GM, gene-editing or ‘conventional’ genetic improvement techniques—a ‘product-based’ approach.<sup>120</sup> We were told that the European Commission has been reviewing whether to regulate a gene-edited plant that has no foreign DNA as if it were a GMO.<sup>121</sup> More recently, the Royal Society has publicly called for a review of the EU’s blanket prohibition of GM crops.<sup>122</sup> Whether any of this ultimately leads to a sensible approach to GM regulation remains to be seen. Our predecessor Committee saw no cause for optimism in this regard.<sup>123</sup>

63. In the meantime, the Minister recognised the challenge in gaining public acceptance of GM given its historical baggage:

The first generation, if you like ‘GM1.0’, was very crude, particularly the original Monsanto monoculture model: “Spray everything that dies apart from the

<sup>116</sup> European Commission, *Communication from the Commission on the precautionary principle*, February 2000, p 2

<sup>117</sup> Royal Society (UKL0017) para 33

<sup>118</sup> Royal Society (UKL0017)

<sup>119</sup> George Freeman MP, “*Dark Age or Enlightenment? Will Europe lead or legislate against the next Industrial Revolution?*”, 19 November 2015

<sup>120</sup> Royal Society (UKL0017) paras 26-28

<sup>121</sup> Royal Society (UKL0017) para 27

<sup>122</sup> BBC, *Royal Society calls for review of European GM ban*, 24 May 2016

<sup>123</sup> House of Commons Science and Technology Committee, Fifth Report of Session 2014–15, *Advanced genetic techniques for crop improvement: regulation, risk and precaution*, HC 328

thing we have protected.” I do not think anyone thinks that is a particularly progressive way of doing 21st century agriculture, but what we are now seeing is really elegant ‘GM2.0’—the very subtle use of naturally occurring traits. That is incredibly exciting science, and somehow we have to find a way through Parliaments and commissions to explain that to electorates and win their trust in an appropriate regulatory framework.<sup>124</sup>

64. Separately, MRHA are seeking to negotiate new EU Regulations for Medical Devices and in vitro diagnostic devices in a way that preserves “the status of the single market as an innovation-friendly regulatory environment, ... resisting excessively burdensome requirements and pushing for proportionate and risk-based regulation in these negotiations”.<sup>125</sup>

**65. Too often, the precautionary principle has been wilfully misused in the formulation of EU life science policy-making, including perhaps most noticeably in connection with Genetically Modified Organisms. There remains a fundamental need for what the minister called “an enlightened regulatory system on the side of innovation”. In practical terms, an improvement needs to come from a change to a ‘product-based approach’ from the existing unhelpful ‘process-based approach’, and an EU application of the precautionary principle that takes into account the benefits as well as risks and the consequences of not acting as well as acting. *The Government should renew its earlier efforts to engender in the European Commission and other member states a far more robust scientific application of the precautionary principle, informed by existing good science evidence. This will be a prerequisite for meaningful and effective international collaboration in life science research.***

### **Scientific Advice Mechanism**

66. Many of our witnesses identified better-informed regulation and policy-making in the EU and greater transparency as ways of helping to tackle the overly-proscriptive application of the precautionary principle.

67. Charity organisations reported difficulties engaging with EU development of legislation to ensure that scientific evidence is appropriately integrated into the process. The Association of Medical Research Charities told us that “balancing differing cultural and ethical approaches across 28 member states can mean that European legislation can at times result in proposals that do not match the UK’s approach to medical research.”<sup>126</sup> The Wellcome Trust noted that “finding the correct information on EU proposals at an early stage is sometimes problematic”.<sup>127</sup>

68. AMRC found that after initial stakeholder consultations, “it becomes harder to identify how to feed in, who are the key players and where to find updates on the process”.<sup>128</sup> At the same time, the commendable EU focus on ‘European Citizens Initiatives’ which allow for direct public and NGO participation in the development of EU policies can provide an unbalanced evidence base if, as the AMRC observes, these initiatives run counter to scientific evidence. A perhaps more significant barrier to an evidence-based

124 Q179

125 Department of Business, Innovation and Skills ([UKL0028](#)) para 49

126 Association of Medical Research Charities ([UKL0025](#)) para 2.8

127 Wellcome Trust ([UKL0020](#)) para 19

128 Association of Medical Research Charities ([UKL0025](#)) para 3.3

regulatory system is a resistance to science on principle by some. As the Minister told us, “where people are elected on a religious, ethical or cultural ticket of hostility to big science, no amount of briefing notes is going to change their view.”<sup>129</sup>

69. Nevertheless, a prominent and transparent process for providing independent scientific advice to the EU institutions could make an evidence-based approach to regulation more likely. In 2014 the Commission failed to renew the post of Chief Scientific Adviser to the President of the European Commission (held by Professor Anne Glover from 2011 to 2014). It subsequently established a new Scientific Advice Mechanism (SAM).<sup>130</sup> The Life Sciences Minister told us that there are a number of reforms he would like the European Union to look at seriously:

One is a much stronger independent voice for science at the heart of policy making. I was concerned when Anne Glover, the—as it happened—British chief scientific officer was removed. I can accept that a panel of scientific advice could be very powerful, but if Europe is serious about the appliance of science, we need to build scientific advice into the heart of policy making.<sup>131</sup>

70. The SAM aims to support the Commission with “high quality, timely and independent scientific advice for its policy-making activities”.<sup>132</sup> The intention is that a High Level Group of Scientific Advisers, established in October 2015, will draw on a wide range of scientific expertise including that available from national academies. The seven members of the High Level Group were appointed in November. One of its members is Dame Julia Slingo, Chief Scientist at the Met Office. The AMRC worried about what it saw as a lack of life scientist input in the SAM.<sup>133</sup> The initial meetings of the High Level Group have focused on vehicle carbon dioxide emission testing and cyber security.<sup>134</sup>

71. In our inquiry, a common criticism was that the EU policy-making process is, as Brightwake put it, “not transparent or consultative to industry, and therefore is unlikely to be evidence-based”.<sup>135</sup> BIS highlighted the European Commission’s requirement for Impact Assessments for all legislative proposals that have significant economic, social and environmental impacts. BIS told us that as part of the European Commission’s Better Regulation Guidelines, stakeholders should always be consulted when the Commission prepares legislative or policy initiatives, or when performing an evaluation or Fitness Check. The European Commission has also recently launched a public consultation on the Transparency Register to gather input on the current regime for the registration of interests of representatives who seek to influence the work of the EU institutions and on its development into a mandatory Lobby Register. BIS told us that, additionally, it has been advocating the early publication by the EU of draft legislation and Impact Assessments.<sup>136</sup>

72. In the context of medical devices, BIS told us that the European Commission holds quarterly meetings with “a wide range of stakeholders including manufacturers, notified bodies and patient groups, to seek views on significant policy decisions.”<sup>137</sup>

---

129 Q172

130 Royal Society of Chemistry ([UKL0023](#))

131 Q169

132 European Commission, *Scientific Advice Mechanism*, accessed 24 May 2016

133 Association of Medical Research Charities ([UKL0025](#)) para 3.7

134 European Commission, *2nd meeting of the High Level Group of the Scientific Advice Mechanism*, 17 March 2016

135 Brightwake Ltd ([UKL0001](#))

136 Department of Business, Innovation and Skills ([UKL0028](#)) paras 35, 36, 38, 39

137 Department of Business, Innovation and Skills ([UKL0028](#)) para 44

73. The Academy of Medical Sciences noted that the UK's voice at a national level is being complemented by further engagement through EU-wide organisations. For the Academy, this included pan-European networks such as the Federation of European Academies of Medicine. Judging by the minutes of its second meeting in March 2016, there are early signs that the European Commission's new Scientific Advice Mechanism does recognise the importance of such engagement.<sup>138</sup> The Wellcome Trust saw "positive indications that [the SAM] will be supported by resources and infrastructure to draw upon expertise beyond the seven members of the High Level Group, ... utilising national academies of science for example". As the Wellcome Trust noted, a key consideration will be how the SAM evolves and interacts with the other EU institutions. The Wellcome Trust identified a particular need to ensure that the European Parliament and its MEPs have better access to sound independent science advice.<sup>139</sup>

**74. Better-informed input to regulation and policy-making in the EU, along with greater transparency, is needed, not least to tackle instances where the precautionary principle is applied in an overly proscriptive manner. A barrier to an evidence-based regulatory system is a knee-jerk resistance to science by some. The recent establishment of the EU High Level Group of Scientific Advisers, following the Commission's sacking of its Chief Scientific Adviser and its failure to renew the post, could still provide an opportunity to improve EU regulation. The High Level Group is reviewing vehicle carbon dioxide emission testing and cyber security, but a far sterner test of its influencing capability will come in examining the exploitation of genetic techniques in medicine and agriculture. This is an area in which the EU has not come close to satisfactorily demonstrating an evidence-based approach to policy making.**

***75. The Government should push for the EU High Level Group of Scientific Advisers to provide a prominent and transparent process for providing independent scientific advice to the EU institutions, to feed into better European regulation of the life sciences. UK science and scientists have a huge opportunity, not to mention responsibility, to help bring this about. The Government must also encourage the Commission to ensure that all the key stakeholders are kept informed at every stage of policy development.***

---

<sup>138</sup> European Commission, *2nd meeting of the High Level Group of the Scientific Advice Mechanism*, 17 March 2016

<sup>139</sup> Wellcome Trust ([UKL0020](#)) paras 24-25

## Conclusions and recommendations

---

1. *Given the cautionary example of the Swiss freedom of movement referendum, we urge the Government to conduct a risk analysis of the science and innovation funding and collaboration scenarios in the event of Brexit and put in place immediate contingency plans to protect our science and innovation sector from any adverse consequences and to consolidate any benefits.* (Paragraph 4)
2. We do not prejudge the outcome of the forthcoming Referendum on the UK's membership of the European Union. Nor in this inquiry do we express a view about which outcome would be best for the UK life sciences, less still the UK more generally. Life sciences will clearly not be the determining factor when the British public casts their votes on 23 June. Whatever the result, however, there will need to be action to address a number of concerns about the way the life sciences are regulated in the UK and in the markets it trades with. (Paragraph 8)

### Impact of an EU regulatory system

3. The impact of EU-wide regulation of the life sciences can be assessed in terms of the balance between the benefits of harmonised and responsive regulation and the compromises needed to ensure this can be achieved. By harmonising the procedures under which research is conducted, EU regulation can foster cross-border collaborations. These multiple state collaborations are evident at least in the conduct of clinical trials, for example, and setting up such trials through a system where permission needed to be sought country by country would likely introduce even more delay and bureaucracy than the current EU system. Harmonisation in the life science innovations, products, processes and treatments that flow from that research brings with it ready access to the whole EU market, and in the process attracts inward investment into UK life sciences. ... The EU life science regulatory regime may be more costly for researchers and businesses, but provides access to a significantly greater EU-wide market. (Paragraph 17)
4. We are aware of evidence that under Associated Country status UK researchers and innovators could lose out on opportunities to exploit their research under Associated Country scenarios. The extent to which UK scientists could be able to offset this by pursuing greater global (rather than EU) collaborations remains uncertain. *We urge the Government to investigate this issue.* (Paragraph 18)
5. While the EU regulatory regime has sought a harmonised approach, a failure by some member states to properly implement legislation, or the European Commission to enforce it, has reduced its value. Variations in the way directives are translated into national law can lead, for example, to difficulties for developers of medicinal products. (Paragraph 26)
6. Weaknesses in the 2001 Clinical Trials Directive significantly increased the administrative burden and cost of running academic clinical trials and saw a reduction in trials taking place in Europe. Its replacement Clinical Trials Regulation, expected to come into effect in 2018, appears to be an improvement. (Paragraph 27)

## The EU regulatory process: the UK's influence on it and scope for improvement

7. The UK's Medicines and Healthcare products Regulatory Agency is widely respected, and has been able to exploit its reputation, leadership and expertise to positively influence the EU medicines regulatory regime. *The MHRA should reassess its information channels with medical businesses, however, to ensure that all companies and laboratories, including SMEs, are able to seek to influence the regulatory environment.* (Paragraph 39)
8. It is essential that regulation is proportionate in safeguarding patient safety as well as providing a legal environment for the research and development of effective healthcare interventions. Whatever the outcome of the Referendum, there is considerable scope to avoid areas of unnecessary complexity and overlap in EU regulation and to reduce its burden. The costs of a marketing authorisation under the EU system are greater than a national system, but ... it brings wider market access. In the event of the UK leaving the EU, some life science researchers and businesses might seek to have many of the EU regulations either mirrored or continue to be applied by the UK. (Paragraph 49)
9. *Every effort must be made to avoid adding unnecessary regulatory burdens to already hard-pressed businesses. The Government must energetically follow up on the EU commitment, secured by the Prime Minister, to "regulatory simplification and burden reduction, including through establishing, where feasible, burden reduction targets in key sectors". One such 'key sector' must be the life sciences. We recommend that the Government, in consultation with industry and whatever the Referendum outcome, draws up a programme for regulatory simplification in life sciences.* (Paragraph 50)
10. There is limited evidence that patients in the European Union may benefit from advances in medical technology more quickly than those in Japan and the US. On the other hand, the EU regulatory system often imposes protracted regulatory timescales, including when correcting bad regulation. The new Clinical Trials Regulation, replacing an inflexible and inconsistently applied Directive, coming into force in 2018 represents almost two decades of lost time. (Paragraph 56)
11. *The Government and UK regulators must continue to push for shorter timescales in the EU system, to keep pace with a rapidly developing life sciences sector. In order for UK life sciences to retain our competitive advantage we must support them with the most agile and responsive regulatory environment in the world.* (Paragraph 57)
12. *The Government should explicitly establish a life sciences horizon-scanning group to communicate effectively with universities and businesses about future regulations that could significantly impact on their work. The Group should aim to anticipate technological developments and provide advice to Government and regulators on timely and proportionate legislative and regulatory responses. Such a group could provide a focus for existing horizon-scanning activities in universities, industry and Government. We believe that the EU should also be encouraged to establish more effective horizon-scanning activities across the life sciences.* (Paragraph 58)

13. Too often, the precautionary principle has been wilfully misused in the formulation of EU life science policy-making, including perhaps most noticeably in connection with Genetically Modified Organisms. There remains a fundamental need for what the minister called “an enlightened regulatory system on the side of innovation”. In practical terms, an improvement needs to come from a change to a ‘product-based approach’ from the existing unhelpful ‘process-based approach’, and an EU application of the precautionary principle that takes into account the benefits as well as risks and the consequences of not acting as well as acting. *The Government should renew its earlier efforts to engender in the European Commission and other member states a far more robust scientific application of the precautionary principle, informed by existing good science evidence. This will be a prerequisite for meaningful and effective international collaboration in life science research.* (Paragraph 65)
14. Better-informed input to regulation and policy-making in the EU, along with greater transparency, is needed, not least to tackle instances where the precautionary principle is applied in an overly proscriptive manner. A barrier to an evidence-based regulatory system is a knee-jerk resistance to science by some. The recent establishment of the EU High Level Group of Scientific Advisers, following the Commission’s sacking of its Chief Scientific Adviser and its failure to renew the post, could still provide an opportunity to improve EU regulation. The High Level Group is reviewing vehicle carbon dioxide emission testing and cyber security, but a far sterner test of its influencing capability will come in examining the exploitation of genetic techniques in medicine and agriculture. This is an area in which the EU has not come close to satisfactorily demonstrating an evidence-based approach to policy making. (Paragraph 74)
15. *The Government should push for the EU High Level Group of Scientific Advisers to provide a prominent and transparent process for providing independent scientific advice to the EU institutions, to feed into better European regulation of the life sciences. UK science and scientists have a huge opportunity, not to mention responsibility, to help bring this about. The Government must also encourage the Commission to ensure that all the key stakeholders are kept informed at every stage of policy development.* (Paragraph 75)

# Formal Minutes

---

**Tuesday 7 June 2016**

Members present:

Nicola Blackwood, in the Chair

Victoria Borwick

Dr Tania Mathias

Stella Creasy

Carol Monaghan

Jim Dowd

Graham Stringer

Chris Green

Matt Warman

Draft Report (*EU regulation of the life sciences*), proposed by the Chair, brought up and read.

*Ordered*, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 75 read and agreed to.

Summary agreed to.

*Resolved*, That the Report be the First Report of the Committee to the House.

*Ordered*, That the Chair make the Report to the House.

*Ordered*, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 14 June at 9.00 am

## Witnesses

---

The following witnesses gave evidence. Transcripts can be viewed on the [inquiry publications page](#) of the Committee's website.

### Tuesday 22 March 2016

*Question number*

**Stuart Pritchard**, EU Affairs Manager, Wellcome Trust, and **Dr Keith Ison** and **Professor Berne Ferry**, representing the Shelford Group [Q1–30](#)

**Dr Jacqueline Barry**, Director of Regulatory Affairs, Cell and Gene Therapy Catapult, **Paul Browning**, Head of Regulatory Affairs, Brightwake Ltd, **Darren Budd**, Commercial Director UK and Ireland, BASF, and **Steve Bates**, Chief Executive Officer, BioIndustry Association [Q31–68](#)

**Professor Roger Lemon**, representing the Academy of Medical Sciences, and **Sir John Skehel**, Vice-President and Biological Secretary, the Royal Society [Q69–94](#)

### Tuesday 19 April 2016

**Emma Greenwood**, Head of Policy Development, Cancer Research UK [Q95–128](#)

**Dr Ian Hudson**, Chief Executive, **Jonathan Mogford**, Director of Policy, and **John Wilkinson**, Director of Devices, Medicines and Healthcare products Regulatory Agency [Q129–158](#)

**George Freeman MP**, Parliamentary Under-Secretary of State for Life Sciences, Department for Business, Innovation and Skills and the Department of Health [Q159–195](#)

## Published written evidence

---

The following written evidence was received and can be viewed on the [inquiry publications page](#) of the Committee's website.

UKL numbers are generated by the evidence processing system and so may not be complete.

- 1 Academy of Medical Sciences ([UKL0006](#))
- 2 Association of British Healthcare Industries ([UKL0007](#))
- 3 Association of Medical Research Charities ([UKL0025](#))
- 4 BioIndustry Association (BIA) ([UKL0022](#))
- 5 Biosciences for Farming in Africa (B4FA) ([UKL0013](#))
- 6 BIVDA ([UKL0011](#))
- 7 Brightwake Ltd. ([UKL0001](#))
- 8 Brightwake Ltd. ([UKL0031](#))
- 9 Cell and Gene Therapy Catapult ([UKL0018](#))
- 10 Department for Business Innovation & Skills ([UKL0028](#))
- 11 Eli Lilly and Company Ltd ([UKL0003](#))
- 12 Innogen Institute, University of Edinburgh ([UKL0004](#))
- 13 Institute of Biomedical Science ([UKL0009](#))
- 14 Institute of Physics and Engineering in Medicine ([UKL0021](#))
- 15 John Davison ([UKL0008](#))
- 16 Julian Hitchcock ([UKL0024](#))
- 17 Mr Christopher Roy-Toole ([UKL0002](#))
- 18 Mr James Love ([UKL0032](#))
- 19 Parkinson's UK ([UKL0005](#))
- 20 PHG Foundation ([UKL0019](#))
- 21 Professor Alex Faulkner ([UKL0016](#))
- 22 Research Councils UK (RCUK) ([UKL0027](#))
- 23 Royal Society for the Prevention of Cruelty to Animals (RSPCA) ([UKL0014](#))
- 24 Royal Society of Biology ([UKL0030](#))
- 25 Science and Technology Studies Unit (SATSU) ([UKL0015](#))
- 26 Sense About Science ([UKL0012](#))
- 27 Shelford Group Medical Directors' ([UKL0010](#))
- 28 The Association of the British Pharmaceutical Association ([UKL0029](#))
- 29 The Royal Society ([UKL0017](#))
- 30 The Royal Society of Chemistry ([UKL0023](#))
- 31 The Royal Society of Edinburgh ([UKL0026](#))
- 32 Wellcome Trust ([UKL0020](#))
- 33 Wellcome Trust Sanger Institute ([UKL0033](#))

## List of Reports from the Committee during the current Parliament

---

All publications from the Committee are available on the [publications page](#) of the Committee's website.

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

### Session 2016–17

First Report	EU regulation on the UK life sciences	HC 158
Second Report	Digital skills crisis	HC 270

### Session 2015–16

First Report	The science budget	HC 340 (HC 729)
Second Report	Science in emergencies: UK lessons from Ebola	HC 469 (Cm 9236)
Third Report	Investigatory Powers Bill: technology issues	HC 573 (Cm 9219)
Fourth Report	The big data dilemma	HC 468 (HC 992)
First Special Report	Royal Botanic Gardens, Kew: Government Response to the Committee's Seventh Report of Session 2014–15	HC 454
Second Special Report	Current and future uses of biometric data and technologies: Government Response to the Committee's Sixth Report of Session 2014–15	HC 455
Third Special Report	Advanced genetic techniques for crop improvement: regulation, risk and precaution: Government Response to the Committee's Fifth Report of Session 2014–15	HC 519
Fourth Special Report	The science budget: Government Response to the Committee's First Report of Session 2015–16	HC 729
Fifth Special Report	The big data dilemma: Government Response to the Committee's Fourth Report of Session 2015–16	HC 992