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The Rt Hon Michael Fallon MP
Department of Business Innovation and Skills
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By email: tacklingeuredtape@bis.gsi.gov.uk

23 August 2013

Dear Mr Fallon,

RE: The government's taskforce on EU regulation

1. EU regulation has a significant influence on the UK life sciences sector. Medical research charities are an integral partner in this sector, supporting the UK's innovative science base on which UK businesses can build and funding research in partnership with industry. We welcome this opportunity to provide evidence to the government's taskforce to help shape a regulatory environment that benefits the UK's life sciences sector.

2. **Key points:**
   - **In the UK life sciences sector, public, private and charity research funders work together to create a unique and innovative research environment that benefits the UK's health and economy.**
   - **EU regulations can have a positive effect on this environment through harmonisation if well designed and implemented. However, it can be highly damaging where this is not achieved, and can be slow and difficult to remedy.**
   - **To ensure the UK remains competitive on the global stage it is important to engage effectively in the policy-making process so that regulation benefits the UK and does not hold the life sciences sector back.**
   - **To improve the effectiveness of regulation the EU should improve its communication and transparency, implement more effective and inclusive consultation, and become more responsive.**
   - **Looking forward, regulation must become more agile to be able to respond to future challenges; this need is especially acute in the rapidly evolving life sciences.**

The UK has a unique medical research environment

3. Public, private and charitable medical research funders work collaboratively in the UK to great benefit for our health and economy; for each pound invested by the taxpayer or charity donor into cardiovascular disease and mental health research, a stream of benefits is produced

equivalent to earning 39 pence and 37 pence respectively each year in perpetuity.[1] Charities partner the biotechnology and pharmaceutical industries to ensure discoveries that they fund are translated into treatments that benefit patients. This makes them key players in the commercialisation process and attracts inwards investment to the UK; a £1 increase in UK government or charity spending on medical research could lead to an increase in private research spending from the pharmaceutical industry of between £2.20 and £5.10.[2] Regulation that affects research funded by charities will therefore also impact the private sector.

4. AMRC represents the leading medical and health charities funding research in the UK and overseas. Our 120 members invested over £1.2 billion into UK medical research in 2012, and approximately £137 million overseas.[3] The proportion of research investment going overseas has increased in recent years, from 6% in 2010 to 10% in 2012, growing on average 15% per year.

Harmonisation

5. Harmonisation of regulations across Europe ensures a level playing field for researchers in the UK (case study 1). And consistent regulation attracts global investors to Europe. Given our world-leading life sciences sector, this significantly enhances the UK's attractiveness as a place to invest. Harmonisation also cuts administrative costs, and promotes collaboration and the sharing of resources to benefit innovation.

6. However, it is critical that all stakeholders are involved in the development of harmonisation initiatives to avoid any unintended negative impacts which will be barriers to research. Early engagement is critical as the relatively slow process of EU legislation can result in long delays before problems can be addressed (case study 2). Some harmonising legislation will unavoidably impact on UK interests and in these instances it is critical the government acts quickly to minimise the damage, including communicating effectively with stakeholders (case studie 3).

7. **CASE STUDY 1:** Directive 2010/63/EU on the protection of animals used for scientific purposes[4] is expected to have a positive impact on UK research by harmonising regulation across Europe. This will bring welfare standards up to the levels in the Animals (Scientific Procedures) Act 1986, which were considered to be among the most robust in the world. This assures investors looking to fund research in EU member states that the research they fund is conducted to a high standard of animal welfare. This also ensures no member state is placed at a competitive disadvantage by variances in regulation. The UK is widely recognised as a world leader in the welfare of animals used in research and was instrumental in the preparation of the EU Directive.

1 Health Economics Research Group (HERG), Brunel University, Office of Health Economics (OHE), RAND Europe, 2008. Medical Research: what's it worth? http://www.wellcome.ac.uk/About-us/Publications/Reports/Biomedical-science/WTX052113.htm

2 Office of Health Economics (OHE), 2009. Forward Together: Complementarity of Public and Charitable Research with Respect to Private Research Spending - http://www.ohe.org/publications/article/forward-together-complementarity-of-public-and-charitable-research-28.cfm

3 2012 AMRC research expenditure database - http://www.amrc.org.uk/our-members_charityfunded-research

4 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF

8. **CASE STUDY 2:** The 2004 European Tissue and Cells Directive[5], as transposed into the Human Tissue Act 2004[6], takes a blanket approach to studies using tissue for human use and does not take in to account the considerable variability that comes with stem cell research studies, which has led to a negative impact on some UK research. A trial of cell transplantation for Parkinson's and Huntington's has experienced severe delays due to inflexible regulation under the Directive. The cell transplantation trial involves collecting foetal tissue from women undergoing abortions. Following informed consent they would undergo a blood test in advance of their procedure to identify any abnormalities. However, the Directive brought in the specification that blood tests had to be carried out on the day of the procedure. This would not allow sufficient time to conduct the appropriate tests and therefore has no safety benefits. Therefore, to comply with the regulation and ensure safety benefits are in place, blood tests would have to be taken in advance (for the purposes of the research) as well as on the day of the procedure (for the purposes of the regulation), causing extra unnecessary stress for the women involved. The Human Tissue Authority has no authority to overcome these issues. This has now caused the study to be halted even further whilst ethical approval is sought to carry out the additional blood test.

9. **CASE STUDY 3:** In 2012 the UK was informed by the European Commission that its exemption for business supplies of research between eligible bodies did not comply with European legislation. The UK accepted the Commission's position and consulted on plans to withdraw the exemption from 1 August 2013.[7] The consultation assumed projects that involved research funds being passed between universities were not for 'true' research and so would be liable to VAT. However, AMRC worked with HMRC to develop their understanding on the nature of collaborative research and issues faced by charities. As a result, HMRC was able to issue guidance[8] to clarify that charity-funded research is still 'out of scope' of VAT and therefore not liable to taxation. HMRC removed the 'VAT exempt' category for business supplies of research services between eligible bodies but as the 'out of scope' category remained, most charity-funded research remained protected. Nonetheless, this change caused a lot of uncertainty and administrative frictions between research suppliers and research funders.

10. Harmonisation can also be achieved outside of legislation, particularly through the collaboration of interested parties or competent bodies of member states, which we welcome and encourage.

Ensuring the UK remains competitive

11. The UK is already a world-leader in the life sciences and it is important that the EU enhances this and does not put us at a disadvantage against global competitors. When considering EU regulation it is important not only to consider how it might affect our ability to compete against other member states but also competitors such as America, Japan and China. Where there are differences in public opinion across Europe it is important the UK engages with the EU to ensure the UK is not held back (case study 4).

5 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF
6 http://www.legislation.gov.uk/ukpga/2004/30/contents
7 https://www.gov.uk/government/consultations/consultation-on-the-withdrawal-of-the-vat-exemption-for-research
8 http://bit.ly/16ztlx5

12. **CASE STUDY 4:** In October 2011, the European Court of Justice (ECJ) ruled in Brüstle vs. Greenpeace[9] that technologies that require the prior-destruction of embryos are not patentable. In the ruling, balls of cells called blastocysts were deemed to be capable of forming a human being and therefore classed as embryos and protected. Many believe that the ruling did not take into full account scientific evidence and also misapplied the Biotechnology Directive.[10] Although this would not outlaw the conduct of stem cell research in the EU, some believe the ruling could disincentivise investment in it. Furthermore, the EU Parliament's legal committee (JURI) recommended, unsuccessfully, that research involving human embryonic stem cells should not be funded through the EU's research funding programme Horizon 2020, referring to the ECJ's prior ruling and calling for policy to be aligned.[11] Regenerative medicine, based partly on this research, has huge therapeutic potential for patients and George Osborne recently named it as one of eight key areas for UK economic growth.[12] Where public attitudes differ between member states it is important that the prerogative of member states to determine ethical issues is upheld and the government ensures UK research is not held back where EU policy is not aligned with that of the UK.

13. The ability of scientists and clinicians to move freely between member states is beneficial to medical research in the UK. As a scientific powerhouse within Europe our research institutions and businesses have considerable pull to attract the brightest minds from across Europe, enhancing our global competitiveness. Such movement also bring other benefits, promoting the sharing of ideas and new techniques and opening doors to further collaborations. The EU and UK government should continue to promote the free movement of such skilled workers.

Improving EU transparency and communication will lead to better regulation

14. Consistent regulation will attract global investors to Europe and the UK's leading life sciences sector makes it a prime destination to base R&D within Europe. Engagement, both by the UK government and life sciences community, is therefore crucial to get EU regulation right. Furthermore, when regulations have a negative impact it is important to engage quickly to address the problems. However, the size, complexity and bureaucracy of the EU can make this very difficult.

15. The UK is recognized for its expertise in many policy areas and therefore has a deserved strong influence on EU policy. It is important that we use this strength, and where others are experts build on their best practice, to ensure that the EU does not prevent the UK from competing on a global stage but opens the doors to enable us to do so.

16. Medical research charities with their unique links to both patient groups and researchers, have valuable insights into unmet need and the actions needed to address health problems. They are keen to work with the UK government and the EU. However, the considerable resources required to engage with EU institutions can act as a barrier to some of those policy will impact on, limiting the EU's ability to identify adverse impacts before implementation. There is a role for umbrella groups such as AMRC and also for the government to facilitate this engagement but there are also a number of steps EU institutions, or national government agencies in some cases, could take to make it easier for stakeholders to engage:

9 http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10
10 http://ec.europa.eu/internal_market/indprop/invent/index_en.htm#maincontentSec2
11 http://www.ft.com/cms/s/0/e3a68410-b624-11e1-a511-00144feabdc0.html#axzz1xn4TRphC
12 http://www.hm-treasury.gov.uk/speech_chx_091112.htm

- **Communication** of policy areas that the Commission intends to look at, and of the purpose of proposals at their outset, will allow charities to be better prepared to respond to consultation, development and implementation.
- **Increased transparency** to make it easier to follow policy-making processes and see where, when and with whom to engage (case study 5). This should include being open to engagement with national organisations.
- **Impact assessment** to identify where legislation in one field may impact on others and ensure that relevant stakeholders are consulted.
- **Realistic consultation timeframes and engagement** to ensure relevant stakeholders are aware and are able to respond.
- **Responsiveness** to address negative impacts and changes in the research environment.

17. CASE STUDY 5: The Clinical Trials Directive 2001/20/EC[13] has created delays in trial setup due to inconsistent implementation of the Directive by member states, increased bureaucracy and inflexible regulation. Cancer Research UK coordinated a joint position across UK, pan-European and other European organisations to demonstrate a common position shared by the medical research community on proposals by the Commission for a new EU Clinical Trials Regulation.[14] The response to this has been positive and so far, helpful. The Commission ran several consultations on plans to revise the 2001 Directive and associated guidance and the draft legislation, published in July 2012, showed they listened to the concerns and viewpoints that were raised in the joint statement.[15] As the legislative process is ongoing, the UK medical research community is continuing to work with the UK government, MEPs, the Commission and counterparts elsewhere in Europe with the aim of ensuring that an effective and proportionate Regulation is agreed. This effective interaction is an example how national organisations can engage effectively with the EU.

Regulation must be agile and able to respond to future challenges

18. **Adaptive licensing**
Medical research is evolving rapidly. The next-generation of treatments poses new challenges to traditional approaches for testing and licensing. In addition, we want to facilitate earlier access to life-saving treatments for patients. The traditional approach of considering a medicine as unsafe before market-authorisation and safe post-authorisation does not reflect the incremental nature of collecting evidence of safety and efficacy. This slows down innovation and patients' access to new medicines. A more adaptive and flexible regulatory environment will help overcome these challenges and catalyse a much needed change in medical research, delivering innovative new treatments to patients sooner and more safely.

19. The UK is already considering these issues at a national level, as are our international competitors in the US and Asia. The EU is currently taking a valuable lead through the European Medicines Agency (EMA), bringing together multiple stakeholders to shape EU policy in this area. If achieved successfully, the UK can become a fertile environment for developing the most innovative treatments, drawing in global investors. As a recognised expert

[13] http://www.eortc.be/services/doc/clinical-eu-directive-04-april-01.pdf
[14] http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_077460.pdf
[15] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0369:FIN:EN:PDF

in this field, the UK can valuably engage with these initial steps though the Medicines and Healthcare products Regulatory Agency (MHRA) to shape future policy and regulation and ensure we are well-placed to compete internationally.

20. **Making patient data available to researchers**
Personal health records are a valuable resource for clinicians and researchers alike. The information contained within them can reveal the most effective ways to care for someone and allow us to better understand the causes and frequency of disease. The Data Protection Regulation currently under debate in Europe[16] will impact on UK researchers who use personal data for research, including those that access NHS patient data. This may also impact on the government's own initiatives; for example, the *Strategy for UK Life Sciences*[17] included a £60 million investment to establish a new secure data service called the Clinical Practice Research Datalink to service the needs of the research and life sciences community. Medical research organisations in the UK have raised concerns at a UK and EU level[18]. UK representation on the Council of Ministers scrutinising this Regulation is being led by the Ministry of Justice. It is important that the full impact on UK medical research and innovation are raised in negotiations in Europe.

21. **Paving the way for personalised medicine**
Stratified medicine holds the potential to revolutionise healthcare and the pharmaceutical industry. This emerging area of medicine promises to treat patients more efficiently by delivering personalised therapies based on the disease risk factors of patients and how they are predicted to respond to certain treatments. These are determined using diagnostic tests or techniques that must be developed and implemented alongside the treatments.

22. Patients and healthcare providers both benefit from more targeted and effective treatments, whereas industry benefits from the potential for more efficient drug development as well as the market expansion for these new treatments. The government has placed stratified medicine at the heart of its *Strategy for UK Life Sciences* and established Genomics England to oversee the implementation of the technology in the NHS.

23. Effective regulation is key to ensuring we capitalize on this new technology. The identification of biomarkers which indicate a patient's suitability for treatment needs large data sets and so, as described above, regulation must allow researchers to handle these safely and securely. We need a regulatory framework that reflects the fact that as treatments become more targeted, sample sizes for trials will be smaller and the current Phase I/II/III model will need adjustment. We will need to be able to conduct trials spread over a wide geographic area to achieve sufficient sample sizes, this will mean collecting and sharing data from many different countries. Furthermore, the close relationship of medicines and diagnostics in stratified medicine means that they must often be developed in parallel. However we currently have a regulatory framework that sees these as quite separate.

24. The UK has a world-leading position in the life sciences. We have demonstrated how the UK benefits from membership of the EU and where there are further challenges in regulation. We have suggested some steps that could be taken to address these and produce better

[16] http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm
[17] BIS OLS *Strategy for UK Life Sciences,* 2011 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf
[18] Joint statement on the draft European Data Protection Regulation http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Personal-information/Data-protection-legislation/index.htm

regulation in the future. A facilitative and agile regulatory framework can ameliorate the considerable risks involved for investors in drug discovery and development. It is important that the UK remains a strong voice in EU policy making to ensure our research is not hampered by EU activity but boosted by the EU's position on the global stage, enabling us to attract inward investment for medical research that will benefit UK health and wealth. We would be happy to expand on any of the points raised in this response.

Yours sincerely,

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